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EXAMINING REFORMS TO IMPROVE THE MEDICARE PART B DRUG PROGRAM FOR
SENIORS

FRIDAY, JUNE 28, 2013

House of Representatives,
Subcommittee on Health,
Committee on Energy and Commerce,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Burgess, Whitfield, Lance, Cassidy, Griffith, Bilirakis, Ellmers, Engel, Capps, Green, Barrow, Caster, and Waxman (ex officio).

Staff Present: Clay Alspach, Chief Counsel, Health; Gary

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Andres, Staff Director; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Julie Goon, Health Policy Advisor; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Monica Popp, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Heidi Stirrup, Health Policy Coordinator; Brian Cohen, Staff Director, Oversight and Investigations, Minority Senior Policy Advisor; Alli Corr, Minority Policy Analyst; Elizabeth Letter, Minority Assistant Press Secretary; Karen Lightfoot, Minority Professional Staff Member; and Stephen Salisbury, Minority Special Assistant.

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Mr. Pitts. The time of 10:00 o'clock having arrived, the subcommittee will come to order. The chair will recognize himself for an opening statement.

Today's hearing is an opportunity for us to examine Medicare's part B drug benefit and to assess how well it is working for both seniors and providers. While most prescription drugs are covered under Medicare part D, certain outpatient prescription drugs and biologics are covered under part B. Covered part B drugs are usually those administered in a physician's office or hospital outpatient setting, including injectable and infused drugs, drugs used in conjunction with durable medical equipment, oral drugs for cancer or end stage renal disease, and some self-administered drugs in the hospital outpatient setting. As a result of the 2003 Medicare Modernization Act, MMA, Medicare reimburses providers for the cost of part B drugs and their administration at what is known as the average sales price, ASP, plus 6 percent, with Medicare paying 80 percent of that amount and beneficiaries paying the remaining 20 percent. I would like to commend members on both sides of the aisle for their work on the part B drug benefit. And I will highlight a few pieces of legislation.

H.R. 800 by Congressmen Whitfield and Green, which seeks to exclude prompt pay discounts from manufacturers to wholesalers from the calculation of ASP; H.R. 1416 by Congresswoman Ellmers, which would terminate application of sequestration to certain

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physician-administered part B drugs; and H.R. 1428 by Dr. Burgess and Representative Kind which seeks to provide coverage for immunosuppressive drugs for kidney transplant recipients.

And there are other issues as well. For example, reimbursement rates have caused a shift of some patient populations, such as those with primary immune deficiency diseases and other rare diseases, from treatment in the physician's office, treatment in the hospital outpatient department, arguably the worst setting for someone with a compromised immune system. We should also examine the variation in reimbursement rates for the same drugs and services across various settings to ensure that patients are being treated at the most clinically appropriate and cost effective site. While some drugs and biologics must be administered in the hospital outpatient setting, it is also the most expensive site of care for the Medicare program itself and for the beneficiary, who pays a 20 percent copayment.

I would like to welcome our witnesses today. They represent perspectives from the Federal Government, providers, and patients. And I look forward to their testimony. Thank you.

I yield the remainder of my time to Dr. Burgess.

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[The prepared statement of Mr. Pitts follows:]

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Dr. Burgess. I thank the chairman for the recognition.

So there is no question the part B drug coverage has improved the lives of patients. But Federal regulations can really stand in the way of compassionate patient care and common sense. After the Medicare Modernization Act, now nearly 10 years ago, we saw dramatic consolidations in the oncology space such that now the purchase and storage of drugs is regarded as physician service for the purposes of sequestration. Well, this ruling does not serve patients well. In fact, it is contrary to the statute itself, I believe. It is contrary certainly to any flexibility the agencies are supposed to have. And it is contrary to basic math.

Mr. Chairman, thank you for working with myself and others on both sides of the dais here to pursue answers from the Centers for Medicare & Medicaid Services on this important issue.

The math is also problematic and doesn't add up in how we pay for patient care after kidney transplantation. Medicare pays for 50,000 kidney transplants each year at a cost per patient of well over \$125,000. So do the math on that, and it is over \$60 billion a year. Kidney transplantation offered end stage renal disease patients an alternative to a lifetime of costly, time consuming, and sometimes painfully dialysis treatment. However, the government's protection of its investment arbitrarily ceases after 36 months, when Medicare suddenly refuses to pay for the life-sustaining immunosuppressant drug

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coverage needed to keep a transplanted kidney alive and functioning. So oddly, it is Federal policy -- not the disease itself -- that is the greatest threat to these patients. So instead of ensuring the investment, the government would rather lose patients or rather patients lose their graft, lose their kidney, return to dialysis, and get back in line for another transplant, taking another organ out of circulation for someone else. Instead of protecting the transplant, we further limited supply of donors' organs, and we burden the Federal budget while jeopardizing patient lives.

I challenge every member on this committee to support the bipartisan H.R. 1428 to correct this irrational and arbitrary policy. Our patients are waiting. I think they have waited long enough. It is time for us to put common sense in front of arcane policy.

Thank you, Mr. Chairman. I yield back.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Dr. Burgess follows:]

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Mr. Pitts. Now filling in for the ranking member of the subcommittee Mr. Pallone, we have Mr. Green from Texas, who is recognized for 5 minutes for an opening statement.

Mr. Green. Thank you, Chairman Pitts, for holding this important hearing. And thank you to the witnesses for taking the time to be with us, particularly Dr. Brooks and Dr. Melton. And we have so many Texans on here, you will hear we are from the great State of Texas many times, although sometimes that is redundant.

The part B drug program, which helps pay for chemotherapy and other services, is an important piece of Medicare. I have had a long interest in preserving seniors' access to quality care by ensuring Medicare pay at a rate that will retain a robust network of providers. This is what we are trying to do with the SGR reform. And I think part B rates are part of this larger discussion.

Today we are discussing at least three bills. The first, a bipartisan bill offered by my colleague from Texas Dr. Burgess, will provide Medicare coverage for immunosuppressive drugs for kidney transplant recipients. This bill has earned support from both sides of this committee. And it is my hope we can act on it and move to the full House for a vote.

The next bill offered by Mrs. Ellmers has earned support from both sides of this committee. Also it is imperative that we examine the impact of sequestration on cancer patients. And I am pleased this bill

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has been introduced because it highlights the shortcomings of using sequestration as a tool to accomplish our much needed goal of balancing the Federal budget. I am proud to lead the letter to CMS with my colleague from Texas, Congressman Pete Sessions, that was signed by 124 Members of Congress expressing concerns that cuts resulting from sequestration to critical cancer medications are forcing oncologists to turn cancer patients away. We asked CMS to do something about this problem with their existing authority but haven't gotten the answer we wanted. I should point out that I do not believe Mrs. Ellmers' bill goes far enough as part of the discussion around restoring the reimbursement rates. It must also be restoring funding for after-school lunches, medical research, education funding, Corps of Engineers, and other critical funding.

Finally, H.R. 800 is also known as the prompt pay bill that is being discussed today. I am proud to have introduced this bill in past sessions of Congress. I am pleased my colleague and friend Chairman Whitfield decided to introduce it most recently. We have worked together over the years to move this issue forward. The bill simply excludes the prompt pay discounts offered by manufacturers to wholesalers for the average sales price for drugs and biologics covered under Medicare part B. This became an issue when the Medicare Modernization Act was enacted. It reduces the amount doctors are reimbursed, sometimes below the amount they actually pay for

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administering cancer treatment and the result is fewer doctors participating in Medicare. Reducing the number of options for cancer patients reduces access, and that is just bad policy.

While some of my colleagues have pointed out that sequestration has also done this -- and they are right -- this is a separate issue. The prompt pay discount has negatively affected cancer patients for many years before sequestration. Whether we adopt legislation, repealing it, replacing it or otherwise altering sequestration, without adopting H.R. 800, the underlying issue will still exist. H.R. 800 is noncontroversial and has been supported by virtually every member of this committee. In fact it was adopted by this committee during the consideration of the Affordable Care Act by a voice vote, only to be unfortunately left out in the bicameral negotiations. The prompt pay bill deserves this committee's support. And I ask that Chairman Pitts move forward by marking up this legislation in the near future. Moving this bill or including it in a larger package makes sense.

And now, Mr. Chairman, I would like to yield my remaining time to my colleague, Congressman Engel.

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[The prepared statement of Mr. Green follows:]

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Mr. Engel. Thank you. Thank you very much. I appreciate it.

As Wednesday's hearing highlighted, the current Medicare benefit structure is very complicated. It is particularly true with the drug benefit, where some drugs are covered if infused by an infusion pump under the part B benefit while others are covered under the part D benefit. Unfortunately, the part D benefit does not cover the supplies, equipment, and professional services necessary to deliver infusion drugs safely in the house. The nursing component for infusion therapy can only be performed under part A through a certified home health agency if the patient meets the definition of "homebound." As a result of this fractured benefit, many beneficiaries that could safely receive treatment at home are relegated to being served in a skilled nursing facility or hospital which adds unnecessary costs to the health care system and exposes patients to hospital-acquired infections. Unfortunately, Medicare stands virtually alone in denying coverage for home infusion even though the private sector has proven for decades that infusion in the home can be cost effective as well as done in a setting that best meets the patient's wishes. While Medicaid covers the drugs used in home infusion therapy and while that payment is important, we cannot continue to look only at the silo of drug payment without also looking at the need for full coverage of the associated equipment, supplies, and services for infusion therapy provided in the home or other alternate site settings. In the past,

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I have included legislation to make sure that the least costly clinically appropriate environment for infusion services is covered rather than forcing individuals to obtain these services in the hospital or nursing homes. And it is my hope that the committee and Congress work with me in that effort.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Engel follows:]

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Mr. Pitts. We are voting on the floor. We have 11 minutes left. We will try to finish the opening statements of members at this time.

The chair yields to Mr. Whitfield for 5 minutes.

Mr. Whitfield. Well, Chairman Pitts, thanks very much. And I really appreciate the witnesses being with us today as we discuss these important topics. I certainly want to thank Gene Green and others who have been involved in our efforts to resolve the so-called prompt pay issue. As many of you know, manufacturers give discounts to distributors that help offset costs of shipping, handling, and reflects time valued money and risk incurred in the distribution process. But when Medicare calculates how much a physician will be reimbursed for drugs under the part B program, it includes them in the sales price. And doing this artificially reduces the reimbursement to the physician, the oncologist, which places even more stress on these practices. In cancer, for instance, we know that four out of five patients that are treated are treated outside of a hospital, within a physician's practice. And over the past few years, there has been a trend of closings and consolidation of these practices. And any time I meet with an oncologist today -- it makes no difference where they are from -- they all cite reimbursement as one of the primary reasons for this consolidation and closing. But it is ultimately the patient that suffers the consequence of this problem, as clinics close or consolidate, access to care for the treatment of cancer is diminished,

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and patients are shifted into the hospital which we all know is the most expensive type of treatment. So I hope that as we work on this physician payment reform that we also take a serious look and solve the so-called prompt pay issue.

So I look forward to working with you, Mr. Chairman, and others as we try to resolve this very serious problem. And at this time, I would like to yield whatever time she may consume to Mrs. Ellmers of North Carolina.

[The prepared statement of Mr. Whitfield follows:]

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Mrs. Ellmers. Thank you to my colleague and thank you, Mr. Chairman, for holding this subcommittee hearing on these very important pieces of legislation. I have sponsored H.R. 1416, which is the Cancer Patient Protection Act. This benefit to our seniors, our Medicare recipients, is essential. We all know sequester went into effect. We needed those funding cuts at the Federal level. However, I believe wholeheartedly that as an unintended consequence of this, we have now harmed one of our most vulnerable populations, Medicare patients who have now received the diagnosis of cancer. You know we have wonderful cancer treatment centers in our communities. And I would like to point out also that it isn't just about cancer patients. It is also about patients with rheumatoid arthritis, osteoporosis, lupus, any autoimmune disease that medication has to be given under the direction of a physician.

We have to restore this sequester cut because it is the drugs that have been cut. And these drugs are very, very expensive. The physicians have received their 2 percent cut in reimbursement. But we have to restore that drug cut because we will not be able to continue to provide that benefit to them within their communities.

I can't imagine a family in crisis finding out about cancer to their loved one and then knowing that they are going to have to travel 20 miles outside of their community to go to a hospital. Many of these individuals are on fixed incomes. They are low income. They will not

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have the ability to be transported to those facilities where the cost actually increases which, as we all know, defeats the purpose of the sequester to begin with.

So I feel very strongly we need to pass this piece of legislation. We have a bipartisan list of cosponsors. I am very proud of that. And we will continue in this effort, again, to protect those seniors in this way. It is very important.

And I yield back the remainder of my time.

Mr. Pitts. The chair thanks the gentlelady.

[The prepared statement of Mrs. Ellmers follows:]

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Mr. Pitts. We have a little over 6 minutes left. At this time, the chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes.

Mr. Waxman. Thank you, Mr. Chairman. I want to thank our witnesses for coming here today. And I want to thank you for holding this hearing. It is our first time in quite a while that we have looked at the Medicare part B drugs. And this is a worthwhile focus because we spend, according to the GAO, almost \$20 billion for these drugs each year, including some of the most expensive drugs on the market. We should be looking carefully at where the money goes.

We will be hearing about several pieces of legislation. We have already heard about them. And I know for several years oncologists and other providers have raised concerns about whether payments under the part B program are adequate. Their focus has been on legislation that would increase the Medicare average sales price and part B reimbursements by excluding prompt pay discounts. The Obama administration has a different view. Its budget proposes cuts in reimbursement rates. And I hope our witnesses can give us some insight on both the adequacy of part B drug reimbursement rates and whether there are opportunities to save money for taxpayers by modifying these rates.

We have already heard a little bit about Congresswoman Ellmers' bill. It would exempt part B drug reimbursement from the effects of

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the sequester. As part of the broad sequestered Medicare payments, part B drug reimbursement rates were reduced by 2 percent. We are going to hear from other witnesses today that will say that this cut will have a disproportionate impact on administrative reimbursements. Cancer clinics have reported that due to these payment cuts, they will have to turn patients away. Well, that would be a terrible outcome. These drugs are essential to cancer patients, and the arbitrary payment cuts undermine patient health and the entire Medicare program. This illustrates once again why an arbitrary and automatic sequester is such a bad policy.

My concern with Mrs. Ellmers' bill is that it only addresses one problem. We need a comprehensive and balanced sequester fix, not a piecemeal fix that increases payments for cancer drugs and ignores cuts to Head Start or Pell Grants or physician reimbursements or vaccines for children or vital defense programs. Sequestration was supposed to never happen. It was supposed to be so ridiculous that we were to avoid it. And now it is in place, and we ought to correct it.

Mr. Chairman, we shouldn't pretend the consequences of the part B payment cuts are an isolated example. They highlight the broader reality. When you take the hatchet to the Federal budget, there are going to be serious consequences. This is not an unintended, unforeseeable consequence. I also hope we can learn about other ways to cut part B drug spending. As I said earlier, part B drugs pay for

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\$20 billion worth of drugs annually, including many expensive biological and specialty drugs. In some cases, these drugs can cost tens and even hundreds of thousands of dollars per patient per year. The Medicare program is the primary purchaser of these expensive drugs. Drugs save lives. We need these drugs, and we need to keep developing new ones. But we should also make sure that Medicare is getting a good deal.

I supported legislation in the past that ends the pay for delay abuses and brings generic biologics to market faster. My legislation, requiring part D drug manufacturing rebates, would save over \$140 billion in the next decade, and we should be looking to see if there are other ways, like negotiations or rebates, that would help make sure taxpayers are getting their money's worth on part B drugs.

Let me give an example: For those people who are on Medicare and Medicaid, the dual eligibles, we used to pay for their drugs under Medicaid and we got a rebate. When the prescription drug part D bill was adopted, they said, let's take them out of Medicaid and put them under Medicare. Suddenly we are paying a higher rate for the same drugs, often for the same people. The drug companies love it. But why should we be spending that extra money when we can be using that for worthwhile purposes by making sure that the cancer drugs and the physicians who deal with those cancer drugs get adequately reimbursed. It is very frustrating to see people wanting to protect the drug

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companies' profits, wanting to protect every special interest group until they find one that they are sympathetic to. And we all are sympathetic to this issue because it deals with the most vulnerable people who have cancer.

I look forward to the hearing and am looking for some solutions.

[The prepared statement of Mr. Waxman follows:]

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Mr. Pitts. The chairman thanks members. That concludes the members' opening statements.

For information of the members, I am looking at the screen here, we have 1-1/2 minutes left in the first vote but still 314 Members haven't voted. So we will have time to get over. We have a series of votes. We will reconvene after the last vote, which should be around 11:00. So at this point, the subcommittee stands in recess.

[Recess.]

Mr. Pitts. The recess having expired, we will reconvene.

On our panel today, we have five witnesses. Mr. Cliff Binder, Health Care Financing Analyst, Congressional Research Service; Dr. Barry Brooks, Partner at Texas Oncology on behalf of the U.S. Oncology Network; Ms. Nancy Davenport-Ennis, President and CEO of the National Patient Advocate Foundation; Dr. Larry Melton, Medical Director of Kidney/Pancreas Transplantation from Baylor Medical Center; James Cosgrove, Director of the Government Accountability Office.

Thank you for coming. Thank you for your patience as we were interrupted by votes on the floor.

Your written testimony will be entered into the record. You will each be given 5 minutes to summarize your testimony. And so at this time the chair recognizes Mr. Binder for 5 minutes for his opening statement.

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**STATEMENTS OF CLIFF BINDER, HEALTH CARE FINANCING ANALYST,
CONGRESSIONAL RESEARCH SERVICE; BARRY BROOKS, M.D., PARTNER, TEXAS
ONCOLOGY, ON BEHALF OF THE U.S. ONCOLOGY NETWORK; LARRY B. MELTON, M.D.,
PH.D., FACP, MEDICAL DIRECTOR, KIDNEY/PANCREAS TRANSPLANTATION,
BAYLOR MEDICAL CENTER; NANCY DAVENPORT-ENNIS, CEO AND PRESIDENT,
NATIONAL PATIENT ADVOCATE FOUNDATION; AND JAMES COSGROVE, DIRECTOR,
GOVERNMENT ACCOUNTABILITY OFFICE**

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STATEMENT OF CLIFF BINDER

Mr. Binder. Chairman Pitts, Congressman Green, and distinguished subcommittee members, I appreciate the opportunity to be here today. My name is Cliff Binder. I am a Health Care Financing Analyst at the Congressional Research Service. I was asked to provide an overview --

Mr. Pitts. Pull the mic a little closer, if you could.

Mr. Binder. I was asked to provide an overview of Medicare part B prescription drug payments. In 2010, Medicare spent about \$81 billion on most prescription drugs; and about a quarter of these expenditures, \$19 billion, were for part B drugs. There are two broad principles that determine if a drug is covered under part B. The drug is furnished incident to physician services, and it is usually not self-administered. Most part B drugs are administered to patients by injection or infusion, but there are exceptions. Cancer drugs account for a large portion of part B drug expenditures. Providers -- mostly physicians -- but also hospital outpatient departments, clinics, and durable medical clinic suppliers buy part B drugs, then bill Medicare when they administer the drugs to patients. Physicians and other providers receive two payments from Medicare for part B drugs, one payment for administering the drug and the second payment for

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purchasing and supplying the drug. The Balanced Budget Act of 1997, BBA, set the payment rate for Medicare part B drugs at 95 percent of the average wholesale price, AWP. In spite of BBA changes, however, Medicare drug payments increased rapidly between 1999 and 2003, rising nearly 25 percent a year. In response to the part B drug price escalation, Congress modified the payment methodology in the Medicare Prescription Drug Modernization Act, MMA. MMA changed part B reimbursement in two ways. It increased the amount physicians received for part B drug administration and it decreased the amount physicians were paid for supplying part B drugs. Beginning in 2005, Medicare began paying for the majority of part B drugs based on a formula of 106 percent of the drug's average sales price, ASP. ASP includes most price concessions, such as volume and prompt pay discounts and rebates. When manufacturers factor price concessions into ASP data, the effect is to lower a drug's ASP. Drug manufacturers are required to submit data to CMS on ASP and the companion price used mostly for Medicaid rebates average manufacturer price, AMP. CMS sets the part B drug prices for each quarter based on sales data submitted by drug manufacturers from two previous quarters. If drug manufacturers raised prices in the two quarters after they submitted their ASP data, providers might be unable to purchase drugs below what Medicare pays. When prices decline after manufacturers submitted their ASP data, such as when generic products are introduced, providers often are able to

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purchase these drugs for prices significantly below Medicare's payment rate. Medicare part B drug payments have increased at a slower pace since 2004, posting average increases of less than 5 percent a year. MMA also required the Inspector General to conduct drug price monitoring to determine if ASP is more than 5 percent higher than AMP. If Medicare part B drug payments exceed ASP by 5 percent or more, the Secretary has authority to substitute a different payment methodology that would reduce Medicare drug reimbursement. OIG has reported that there was at least a 5 percent difference between ASP and AMP for some part B drugs. There has been concern that part B drug reimbursement may be inadequate for some providers. Provider groups contend that discounts manufacturers give drug wholesalers have the effect of reducing ASP, making it difficult for these providers to cover the cost of purchasing some drugs. In addition, some in Congress and other groups have questioned whether drug shortages have been complicated by the part B drug pricing methodology and whether these, along with manufacturers' production problems, speculation, industry consolidation, and other factors have contributed to drug shortages, particularly for sterile injectable drugs, a part B drug category. Moreover, questions have been raised whether the two-quarter lag between the time when manufacturers report ASP and the time when CMS releases Medicare part B drug prices make it difficult for some providers to purchase drugs at competitive prices. Most recently,

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some providers have raised concerns that the effect of applying the mandatory Budget Control Act of 2011, BCA, reductions to Medicare part B drug reimbursement will further reduce payments to providers, potentially reducing Medicare beneficiaries' access to services.

In general, sequestration is the permanent cancelation of budgetary resources by a uniform percentage, but certain programs and activities are exempt from sequestration, and special rules may be applied to programs such as Medicare.

Even though there are special Medicare rules that would limit a reduction in program benefit spending to 4 percent, BCA limits the Medicare program benefits reduction to 2 percent; thus beginning April 1, 2013, Medicare payments for covered services, including physician services and part B drug payments, are subject to 2 percent reductions. According to CMS, the 2 percent reduction applicable to Medicare only applies to Medicare's provider payments. Beneficiary cost sharing amounts and amounts paid by other health insurance are not reduced.

This concludes my statement. I would be happy to answer questions.

Mr. Pitts. The chair thanks the gentleman.

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[The prepared statement of Binder follows:]

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Mr. Pitts. I now recognize Dr. Brooks for 5 minutes for an opening statement.

STATEMENT OF BARRY BROOKS, M.D.

Dr. Brooks. Chairman Pitts, Congressman Green, members of the committee, thank you for the opportunity to testify on behalf of the U.S. Oncology Network and community oncology in general on the Medicare part B drug program.

I am Barry Brooks. For 31 years, I have been taking care of cancer patients. Being an oncologist is intellectually and emotionally challenging, but I think it is the best job in the world, and I love it. As a community oncologist, I feel I am part of a dying breed. Our way of life and practice is being squeezed out of existence. We are struggling to make ends meet and continue to care for our beloved cancer patients in the private practice setting. But the way red ink is spreading over our ledgers, there won't be many of us left in a few years. Instead, we will all be employed in arrangements we don't like in institutions where doing the right thing requires executive approval. But I am not here to complain about my job prospects. I am here to talk about demographics and math.

Medicare covers over 60 percent of cancer patients and the Medicare population is growing every day. And worse, the expensive

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care these patients need are shifting from my low cost realm into higher cost arenas. You all know the problem, cancer care costs more in the hospital outpatient department. And hospital-based care is growing by leaps and bounds. The root of the problem has two parts. One, Medicare doesn't adequately cover the cost of community oncology practice care; and, two, Medicare payments and rules are tilted in favor of the hospital. Since 2005, community oncologists have been slowly bleeding to death. After MMA, Medicare pays us for cancer patients an average sales price plus a 6 percent service payment for the costs and risks associated with purchasing, storing, mixing, administering, disposing these drugs. The 6 percent is the only Medicare payment for the significant work to prepare chemotherapy for administration. And even if the drugs are ready for infusion on arrival to our practice, paying acquisition costs would not reflect the cost of inventory and the systems needed to manage it.

Even prior to sequestration, Medicare drug reimbursement did not cover our costs. Due to technical flaws in the ASP formula plus six in theory does not equal plus six in reality. Wholesaler prompt pay discounts reduce ASP values that are not extended to our clinics. ASP values always take 6 to 8 months to be reflected in our price. We cannot collect the entire copay allowable and Medicare does not reimburse us for uncollectible beneficiary coinsurance.

These issues are not new. As far back as 2007, MedPAC reported

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the reimbursement for some drugs was below market price. This means that we have to give away our services for free or, worse, we have to pay for seniors' cancer drugs out of our own pockets. Since April 1, we are living under ASP plus 4.3 percent. While controlling deficit spending is important, the administration's decision to apply the sequester both to our 6 percent payment services part and to the entire drug costs has effectively cut our services payment by 28 percent. It forces us to subsidize Medicare patients or send them elsewhere for care.

Oncologists around the country are making these difficult decisions, and I respect each practice's choice. But one thing is certain, operating at a loss on more than half your patients is not a sustainable model. While tweaks to the Medicare reimbursement rates would go a long way towards shoring up community cancer care, variations in reimbursement for the same services in different outpatient services tilt the competitive landscape in favor of the hospital and encourage inefficiency. One-third of U.S. hospitals purchase chemotherapy drugs through the 340(b) program and enjoy margins of over 30 percent on their Medicare cancer drugs. It is no wonder drug spending in hospitals is increasing so rapidly and patients and oncologists alike are migrating to these settings. Pushing patients with expensive to treat conditions into more expensive settings to get the same care and the same result makes as much sense as adding a trap door to a canoe.

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The patients get lost in this setting. The hospitals get lower drug costs. They get higher reimbursements. The patients have to travel further. They have to wait longer. They have to pay more out of pocket. This is just not right, and it is not necessary.

I know I am preaching to the choir here. Members of this committee have introduced and supported legislation like that from Congressmen Green and Whitfield to help with prompt pay; Congresswoman Ellmers' H.R. 1416; 30 members of the committee have signed a letter questioning how the administration handles sequester cuts on Medicare part B for oncology; and others have just signed a recent leadership letter to the so-called Lance-Pascrell. We also want to thank Congressman Rogers and others working with him to implement site-neutral payment, as recommended recently by MedPAC. The world's best cancer care delivery system is struggling to take care of our patients. We and they need your help.

Thank you for letting me talk today.

Mr. Pitts. The chair thanks the gentleman.

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[The prepared statement of Dr. Brooks follows:]

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Mr. Pitts. I now recognize Ms. Davenport-Ennis for 5 minutes for an opening statement.

STATEMENT OF NANCY DAVENPORT-ENNIS

Ms. Davenport-Ennis. Thank you, Chairman Pitts, and thank you, Congressman Green, and thank you also, members of the committee. I have submitted previously written testimony to the testimony. And so what I would like to do now is to simply have a conversation with you and share with you what we see happening to the Medicare patients in the United States that we have been taking care of for the past 17 years.

To date, we have closed over 750,000 cases dealing with Medicare and Medicaid patients in the United States. And what we see is that since the passage of MMA, when we stripped away the reimbursement between the drug margin and the services with the commitment that there would be additional codes put in place in 2004 to bring the reimbursement for physicians up to where they had been so they can maintain their practices, we have seen a waterfall of changes and reductions to reimbursement to physicians. And why do our patients care? Why is that our battle? It is our battle because the number one asset we have in winning our individual war on cancer or any other chronic disease is a physician who is there to treat us. What I can say to you is that we look at the destabilization of the workforce today

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as a result of things like a prompt pay discount which loses a 2 percent or the imposition of sequestration which is a 2 percent cost cut across both the drug and the service. We look at the continued threat of ASP reduction. So there is no stability when a practice is trying to plan for the future. And the result to the patients that we serve is really simple. They are now facing a reduction in actual practices available in their community to see them. And when we lose a practice in the community, not only does the senior or the disabled lose it, so does every man, woman, and child living in that community. We are seeing patients being shifted to hospitals for site of care. It may mean longer distances for them to travel. It may mean longer wait times for them. We have had it documented that it means an additional cost of \$6,000 to the system for each patient that is shifted to the hospital outpatient setting for care. And because the patient is responsible for a 10 percent copayment, it means \$600 to \$650 for the patient.

We have seen the formularies change within Medicare part B and we have seen many of our newer drugs that our patients need are now being put out on a specialty tier. And at that level when we did an analysis of 996 of our Medicare patients, what we found is that they were paying on average out of pocket for specialty tier drugs through Medicare \$684 per prescription that represented 50.2 percent of the cost of the drug.

Let me describe to you the Medicare patients that we handle.

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Traditionally, their household incomes are under \$23,000. They are very proud people, many of whom have worked their entire lives to save and to live independently throughout the final years of their lives. The seniors that we treat come to their diagnosis and seek support through copay even though for them to do that it is such a transgression against their independent living. We had \$447.6 million donated to nine copay programs in the United States of America over the past year, and it was not sufficient to meet the demands. As your committee has looked at remedies for the prompt pay issue and you are looking at remedies to solve many of the Medicare part B reimbursement issues, I want to thank you on behalf of the Medicare patients that we represent. And I want to also commit to you that our foundations are here to work by your side to see that these bills that have been introduced through your committee are passed.

I am pleased to answer in great detail what is happening with our patients going through shifts in site of care. But as my closing remark, I would like to you note that since April 1, we have started tracking the number of patients being shifted from a community practice to a hospital outpatient setting. In 90 days, we have had 10 States that have reported shifting patients from the community practice setting into the hospital setting. So I would urge the committee to do what you do best, and that is to look at how do we minimize financial devastation for Medicare part B beneficiaries?

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I thank you for the opportunity to answer questions.

Mr. Pitts. The chair thanks the gentlelady.

[The prepared statement of Ms. Davenport-Ennis follows:]

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Mr. Pitts. And now recognizes Dr. Melton for 5 minutes for an opening statement.

STATEMENT OF LARRY B. MELTON, M.D., PH.D., FACP

Dr. Melton. Thank you, Chairman Pitts, Congressman Green, and Congressman Burgess, for this opportunity to briefly address the Energy and Commerce Committee as it examines reforms to improve the Medicare part B drug program. I applaud this committee for its leadership and ongoing commitment to strengthening our Nation's health care system. I am Dr. Larry Melton, Medical Director of Kidney and Pancreas Transplantation at Baylor University Medical Center. In my many years of practice and work at Dallas, Texas, I have become familiar with a variety of Medicare program challenges and policy imperfections that could be improved to save both lives and Federal resources. Within my field of organ transplantation, the most obvious and flawed Medicare policy is the program's arbitrary 36-month coverage restriction for patients' immunosuppressive drugs post-transplantation. As you may know, organ transplant recipients must take immunosuppressive medications for the lifetime of the transplanted organ. If immunosuppressive medications are discontinued, rejection and loss of the transplanted organ are almost certain to occur.

Since 1972, Medicare has covered people with end stage renal

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disease without regard to age or SSDI status. There is no Medicare coverage limit for a dialysis patient. By contrast, kidney transplant recipients lose Medicare coverage at an arbitrary 36 months after transplant. In 1972, it was estimated that the ESRD program would cost \$250 million. Today the program costs in excess of \$250 billion. These figures are staggering, and there is no question that a functioning transplant with immunosuppressive drug coverage is vastly less expensive than the cost of dialysis. When renal transplants fail, patients again require dialysis, and may even be candidates for retransplantation, both of which would be covered by Medicare. Extending immunosuppressive coverage beyond the 36-month limit would decrease the risk of organ failure due to patients not taking their immunosuppression.

The New England Journal of Medicine highlighted a survey conducted by the American Society of Transplantation that found 70 percent of U.S. kidney transplantation programs reported that their patients had an extremely serious or very serious problem paying for immunosuppressive medications and 68 percent reported deaths and graft losses attributable to cost-related nonadherence. The study further found that since patients with kidney failure need either long-term dialysis or a functioning renal transplant to survive, failing to pay for ongoing immunosuppression ensures that Medicare's initial investment in kidney transplantation is squandered, that patients die

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prematurely, and the U.S. taxpayers pay for more expensive but inferior therapy after some transplants fail unnecessarily. At present, Medicare spends approximately \$70,000 to \$80,000 per year on a dialysis patient, which Medicare covers indefinitely. However, Medicare on average spends less than a quarter of that amount for a kidney transplant recipient after a year of the transplant. For more than a decade now, members of this committee have introduced and supported legislation, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act, to address Medicare's deficiencies in this area. Most recently, Congressman Michael Burgess and Ron Kind have led the bipartisan and bicameral effort to secure passage of this reform.

I strongly encourage everyone on this committee to cosponsor, support, and pass H.R. 1428 during the 113th Congress. The legislation saves lives, preserves life-saving donor kidneys, and reduces the cost burden to the Federal Government, a win-win for patients and the U.S. Treasury. The bill would allow individuals who are eligible for immunosuppressive drugs whose insurance benefits under part B have ended due to their 36 months running out to remain in the program only for the purpose of receiving immunosuppressive drugs. If they have group health insurance, they would not qualify for coverage beyond the 36 months. The legislation is intended to be a coverage backstop only for those who otherwise have no coverage. The

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legislation ensures that Medicare would remain the payer of last resort and would not usurp coverage offered by private insurers. It is not sound public policy or cost effective for Medicare to cover the initial costs of a kidney transplant and then stop immunosuppressive drug coverage after 36 months. It is unfair to living donors and to those families who have donated organs of the deceased loved one for the Federal Government not to do everything possible to maintain the transplanted kidney and the gift of life that they have provided.

On behalf of kidney patients, families, physicians, surgeons and all involved in the transplant process, I ask that this committee make the 113th session of Congress the last Congress in which many patients will lose Medicare coverage after only 36 months. The Burgess-Kind legislation simply corrects a costly policy inequity. It covers transplant anti-rejection medicines only.

I thank you for the opportunity to focus a few minutes on what we in the organ transplant community view as the necessary reform to the Medicare drug program. Thank you.

Mr. Pitts. The chair thanks the gentleman and now recognizes Mr. Cosgrove for 5 minutes for his opening statements.

[The prepared statement of Dr. Melton follows:]

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STATEMENT OF JAMES COSGROVE

Mr. Cosgrove. Chairman Pitts, Congressman Green, and members --

Mr. Pitts. Did you push the button? Is the light on?

Mr. Cosgrove. It is on.

I am pleased to be here today as you discussed Medicare's payment for part B drugs and potential reforms. As you have heard, part B drugs are often an important part of treatment for cancer, autoimmune disorders, chronic kidney disease, and other serious conditions. In 2010, Medicare spent nearly \$20 billion for part B drugs in all settings, including physician offices and hospital outpatient departments. That was about 9 percent of all part B expenditures that year. Last October, we issued a report that examined spending and utilization data for high expenditure part B drugs. Specifically, we analyzed the 55 drugs with the highest Medicare expenditures in 2010. We also examined spending and utilization trends from 2008 to 2010 for the same drugs. And then finally we estimated national spending for the total U.S. insured population for these drugs and calculated the share attributed to Medicare. So in my statement today, I would like to highlight several findings from our October report.

First, we found that Medicare expenditures were highly concentrated among relatively few drugs. In 2010, the 55 highest

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expenditure drugs represented about 85 percent of all Medicare spending on part B drugs, or about \$16.9 billion. Ten of those drugs accounted for approximately 45 percent of all part B drug spending. Most of the 55 drugs are under patent and can be purchased from only one manufacturer. At the time of our report, none of the 10 highest expenditure drugs and only nine of the 55 drugs we analyzed had a generic drug alternative. Of the 55 drugs in our analysis, 23 were used to treat cancer and its side effects. Others were used to treat various conditions, such as immune system disorders, cardiovascular disease, chronic kidney disease, and asthma or, as you have just heard, to prevent organ transplant rejection.

Second, the number of Medicare beneficiaries who used each drug as well as the average cost per beneficiary varied widely. Some of the drugs were associated with high Medicare expenditures either because many beneficiaries used the drug or because the drug had a very high price. For example, Medicare spent about \$193 million on influenza vaccines in 2010. The cost per beneficiary was only about \$13. But more than 15 million beneficiaries were vaccinated. Medicare spent about \$143 million on Factor VIII recombinant used to treat hemophilia A. In contrast to the influenza vaccines, Factor VIII recombinant was only used by 660 beneficiaries but it cost nearly \$217,000 per beneficiary. Among the 10 drugs with the highest cost per beneficiary, four cost more than \$50,000 and five more than \$20,000.

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Third, spending, utilization, and prices generally increased in the 2 years. Medicare expenditures increased for 42 of the 55 drugs. The drugs with the greatest increases in expenditures also had the greatest increases in utilization. In particular, the four drugs with the largest increases were new drugs that had been recently approved by the FDA. Expenditures for one of these drugs Lexiscan, a stress agent for beneficiaries who cannot take a stress test, grew by approximately 10,000 percent over the 2-year period because the utilization grew by 11,000 percent. Prices for most drugs increased between 2008 and 2010, although the price changes were not as dramatic as utilization changes. The price of Ventavis, a drug used to treat pulmonary arterial hypertension, increased by 52 percent, which was the largest price increase we observed. Because utilization of Ventavis also increased, expenditures for the drug rose by nearly 94 percent over the period. The price of the vaccine used to prevent pneumonia increased by 36 percent. Some drugs did decrease in price. The largest decline was 38 percent, and yet still remained among the highest expenditure part B drugs.

Finally, our findings show that Medicare is an important part of the national market for many of these high expenditure drugs. Specifically, we found that Medicare spending accounted for the majority of estimated total national spending on 35 of the 55 highest expenditure part B drugs. Almost \$17 billion Medicare spent for the

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highest expenditure part B drugs, \$11 billion, or 65 percent, was spent on drugs for which Medicare beneficiaries accounted for the majority of total U.S. spending. For 17 of the drugs, Medicare spending represented two-thirds or more of total spending. And for six part B drugs, Medicare's share of national spending exceeded 85 percent.

This concludes my prepared remarks. I am certainly happy to respond to any questions.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Cosgrove follows:]

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Mr. Pitts. That concludes the opening statements. We will now go to questioning. I will begin the questioning and recognize myself for 5 minutes for that purpose.

Dr. Brooks, explain a little bit more what impact would removing the prompt pay discount from the Medicare formula have on patients and our overall health care system, if you would.

Dr. Brooks. Well, sir, obviously the weight of the sequester would not be removed just by removing prompt pay but it would help us a great deal. Prompt pay diminishes ASP for our offices by approximately 1 to 2 percent. It is a floating number. It is not consistent. But it decreases our reimbursement by about 1 to 2 percent. As I like to tell my colleagues, my income in 2012 was 102 percent from commercial insurance. And what that means is that we lost 2 percent on our Medicare patients in our office. So if we were to get rid of the prompt pay discount, that would restore us to baseline if the weight of sequester were also treated more uniformly in our space.

Mr. Pitts. Now the President has proposed a 3 percent cut to the SP formula. What would happen to your practice if that were to go into effect?

Dr. Brooks. Well, sir, I don't know whether to answer you seriously or with some humor. But we did not include in any of my remarks anything about disruption or drama or threats or anything of

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that sort. But I can assure you that if ASP plus 3 percent were to ever be enacted, that disruption and drama would occur. We would not be able to take care of our Medicare patients at that rate. We would immediately have to discontinue that because the losses would be enormous. The hospital outpatient departments that are currently taking our patients do not have the capacity to overnight take those patients in. And there would be an enormous access problem.

Mr. Pitts. All right. Mr. Cosgrove, page 2 of your testimony states that "Medicare expenditures for part B drugs in 2010 were concentrated among relatively few drugs."

Is it fair to conclude then that the majority of drug expenditures under part B should not be considered high expenditure drugs?

Mr. Cosgrove. Under part B, Medicare covers hundreds of drugs. So yes. I think the problem is just complex and it may not be a one-size-fits-all because you have some drugs that either because a lot of people use them or few people use them and they are very expensive or some combination are very expensive. And that is probably where the attention should be focused.

Mr. Pitts. Ms. Davenport-Ennis, in reviewing the GAO testimony, I noticed that a number of the high expenditure drugs on the list under part B are drugs used to treat cancer and various autoimmune diseases. And I am reminded of the new lupus drug that was recently released, representing the first new treatment for patients with this disease

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in over 50 years. How important is it for patients with diseases like cancer to have access to new and ground-breaking treatments in your opinion?

Ms. Davenport-Ennis. Thank you for the question.

So from a patient's point of view, often the traditional drugs that are in the marketplace are not going to continue to work for cancer patients that have been in therapies for years and years. If there is a cancer patient that has a very advanced cancer, often you have to move them to the newer drugs in the marketplace that will stop that disease where it is. And whether it is cancer or whether it is another chronic debilitating or life-threatening condition, the new drugs hold the promise of independent living. They hold the promise that people can stay at work. They hold the promise that they can maintain their role as a parent, as a spouse, and as a member of society. So each time we create a regulatory hurdle that puts that new drug further away from the patient, the more likely we are to see earlier debilitation due to disease and less independent living and, therefore, additional cost to the system and other places.

Mr. Pitts. Dr. Brooks, please describe for us some of the differences patients experience between being treated in a community-based oncology practice and receiving cancer treatment in a hospital outpatient department.

Dr. Brooks. Well, I briefly described the differences in

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convenience and financial commitments in my testimony. But just to review, patients often have to travel a bit further to get to a hospital outpatient department. They often have to wait a bit longer. And CMS' costs in a hospital outpatient department are higher by at least 50 percent. Those are the superficial aspects of the problem. But, in fact, they are greater. I told my colleagues about a husband and wife pair that I used to take care of years ago and I ran into recently. And they told me about their follow-up care in another State. The husband goes to a private practice for his follow-up and he goes in for his appointment at 10:00 o'clock in the morning. He gets to the laboratory, sees his physician, and he is home by 11:00 o'clock. His wife chooses to go to a nearby tertiary hospital outpatient department. And it is a very well run and well respected institution. She has an appointment for a laboratory at 10:00 o'clock and an appointment for an x-ray at 11:00 o'clock, an appointment for a physician at 1:00 o'clock and outpatient counseling at 3:00 o'clock. And she is home by 4:00 o'clock. And she gets basically the same services as her husband does in a local community oncology office.

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DCMN HERZFELD

[12 p.m.]

Dr. Brooks. Those are just -- that is just an anecdote for you to understand that while they give good care in hospital outpatient departments, and we never say otherwise, it is just different.

Mr. Pitts. Did you want to add anything, Ms. Davenport-Ennis?

Ms. Davenport-Ennis. I would. I would like to add the human element to that. So when we have a Medicare patient that contacts us and says, I am now being moved from the community setting with my doctor, and I am going to need to travel 28 miles to get to the hospital, I am going to be in an infusion chair, and I may be there for an hour, I may be there for 6 or 8 hours, the journey when you leave that chair to return to home is indescribable. So if I may be personal with this body, I would like to.

My husband is a stage 4 cancer survivor. We had to move him from a local oncologist, and we had him in a hospital setting. The simple 28-mile journey resulted in such acute emesis that we had to be rescued by an ambulance roadside. We are not a rare exception. The side effects for cancer treatment are serious, and they are not simply managed, and so when we move you to a community hospital setting, you may indeed be able to handle that transfer no problem whatsoever, but

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we have many cases that document otherwise.

We think that the hospital cost is something that is important to us. We have worked for 17 years to try to work with patients to handle the cost of care in a financially sound manner, and to exert the full limits of their insurance benefits, and to encourage them to get Medigap policies so that, indeed, they are protected as they move forward, and even though they play by the rules, the system is failing them.

Mr. Pitts. The chair thanks the gentlelady.

I now recognize the gentleman from Texas Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Ms. Davenport-Ennis, can you expand on Dr. Brooks' testimony and share the patient's point of view how the prompt pay discount would affect access to Medicare beneficiaries?

Ms. Davenport-Ennis. So as we have talked to many of the patients who have had their sites of care shifted, and as we have worked with the doctors that are handling them, what we know is that many of the practices started operating on reduced margins in 2004 because we never got the codes back up to where they needed to be, and ASP has been unstable at best. So if we could, indeed, restore a 2 percent prompt pay discount to many of these practices, it would be the difference between adding back another oncology nurse case manager or not having

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one. It would be the difference between being able to have after-hours support for the patient and sending them to the hospital phone line for after-hours support.

So there are many services that we think could be restored, and you could maintain practices. And for the record, I would like to report that to this point we have had 1,200 practices in the United States that have either closed completely or compressed their services into hospital settings in which we lost capacity because the number of chairs available for chemo at the hospital were not commensurate with what they had before the compression and equal to the practice as well.

Mr. Green. Okay. Dr. Brooks, can you walk through the importance of that 6 percent additional service fee and what has it accounted for? And I know cancer-treating drugs can be very expensive. For example, if it was a \$100,000 treatment, that would be \$6,000 that would be part of the service fee. Can you walk us through that?

Dr. Brooks. I would be delighted to, Congressman.

Obviously, the sequester has definitely removed any incentive we have for prescribing expensive drugs, because a small percent on a large number cuts both ways. But the prompt pay discount takes that 6 percent of ASP and attenuates it by 1 to 2 percent, in our opinion. We have to have working capital for inventory, administration, storage, inventory management, systems for transport, pharmacy costs, clean

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room, equipment, waste disposal. We have to deal with the problem of inadequate copay collection from Medicare beneficiaries -- that runs about 5 percent in most of our practices -- drug denials. And then there is the problem of price increases which are not reflected in ASP for about 6 months.

This results in pretty much taking away our 6 percent service margin that we previously had, but with sequester we have attenuated that ASP by an additional 1.7 percent, or 28 percent of our services payment that we have gotten before. So now we are, as we say, breathing through a straw because we are under water.

Mr. Green. Okay. With prompt pay, now sequestration, what is the effective percentage? It is lower than the 6 percent?

Dr. Brooks. I am not sure I understand your question, but, yes, sir, if we were to restore both of those, we would be back to very close to break even on our cancer -- Medicare cancer part B drugs, and we would be able to go back to life as we had it in 2012. Not great, it was a lot of migration into the hospitals, but it would be much better than we currently have.

Mr. Green. And I know Ms. Davenport-Ennis talked about the impact on patients. In your practice have you seen the same situation that she talked about?

Dr. Brooks. Yes, sir. I thought that she was very eloquent describing the patient problems of the frail cancer patient having to

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travel great distances to a site of care. We see that a lot in our State of Texas, where people have to travel. When community practices close, my Texas oncology, if we were to lose our ability to take care of Medicare patients in rural, small-town, and in medium-sized Texas, cancer patients, Medicare beneficiaries would be traveling, 100, 200 miles each day for site of care that would take --

Mr. Green. I only have about 20 seconds.

Mr. Binder, obviously Congressman Whitfield and I have introduced legislation on the prompt pay discount and the calculation. Isn't it true that this was fixed within the Medicaid program, the prompt pay issue?

Mr. Binder. I am sorry, could you repeat that?

Mr. Green. Was the prompt pay issue fixed within the Medicaid program?

Mr. Binder. The prompt pay --

Mr. Green. Is your mike on?

Mr. Binder. It doesn't -- to my knowledge, the prompt pay discount that is proposed in the legislation wouldn't impact the Medicaid program directly. Medicaid prices, the Medicaid rebate is determined off of average manufacturer price, and that price excludes all discounts already.

Mr. Green. Okay. Okay. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

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Now recognize the vice chairman of the subcommittee Dr. Burgess,
5 minutes for questions.

Dr. Burgess. Thank you, Mr. Chairman. Before I get to questions, I would like to submit for the record a few things. The article from the New England Journal of Medicine from, I think, February of last year that Dr. Melton referenced on the impact of coverage limits on immunosuppression. I also have statements from the National Kidney Foundation, the American Society of Nephrology, and the American Society of Transplant Surgeons, and I would like to make those all part of our proceedings today.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

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Dr. Burgess. Dr. Melton, frequently here on this committee we hear people talk about, you know, we only want sound science; we want to make our decisions based on sound science. So tell me, is there a good scientific rationale for the 36-month interval for covering immunosuppression after a renal transplant and then stopping that activity?

Dr. Melton. There is no rationale that that is based on at all that I am aware of. The patients that we transplant are required to take immunosuppressant medications for the life of the transplant. And it is true that many times they require more medications early on in their transplant course, and those can be reduced later on, but the need to take those medications continues to exist forever.

Dr. Burgess. So there is not some point at which a patient's immune system just kind of accepts life as it is with this new graft that is sitting in the body, and the immune system just kind of turns off its recognition of this as a foreign object? That doesn't happen, does it?

Dr. Melton. No, sir, that doesn't happen.

Dr. Burgess. So since it doesn't happen, then what happens to the graft when you run out of the immunosuppressive activity?

Dr. Melton. The body begins reacting against the graft, the immune system begins to reject that graft, and over a period of time the patient will lose the kidney transplant and will return to dialysis

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therapy.

Dr. Burgess. So you as a physician would see what, that the ability -- the filtration rate of that grafted kidney would begin to diminish, so tests that you do or blood work that you do would begin to reflect a lower functionality of that transplanted kidney?

Dr. Melton. Yes, sir, that is correct.

Dr. Burgess. So what is the patient going to experience during that time?

Dr. Melton. The patient begins to develop symptoms of kidney failure: tiredness, loss of appetite, inability to concentrate. They will begin to have some pain over and around the kidney transplant itself, indicating that there is an inflammatory rejection process going on there, and many times that results in us having to remove that kidney transplant because of the discomfort and pain that the patient is developing.

Dr. Burgess. So it is not a silent activity as far as the patient is concerned; they are aware that there is a problem?

Dr. Melton. Yes, sir, they are.

Dr. Burgess. Well, let me ask you this: Okay, 36 months go by, we stop immunosuppressive drugs because we think that is good Federal policy. The patient begins to reject their kidney. You do the right thing, which is bring that patient back in to the dialysis clinic or refer them back to the dialysis clinic. Does that take care of the

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problem?

Dr. Melton. Well, that keeps them alive. It doesn't keep them healthy as they were, and it certainly doesn't correct the problem of losing the drug coverage after 36 months.

Dr. Burgess. So what about the quality of life for that individual, does it get affected at that point?

Dr. Melton. Oh, absolutely. Quality of life on dialysis is nothing compared to transplantation. Transplantation essentially makes someone a normal individual, if you will; they are able to work, they are able to travel, they are able to participate in sports activities, they can have families. Many patients who are on dialysis are, frankly, beat up by the procedure and are unable to hold a job, and they suffer a lot of complications from kidney failure and dialysis therapy that shortens their life span.

Dr. Burgess. Well, as I seem to recall, this is back in the 1970s, so it is probably much more frequent now that a patient could even successfully carry a pregnancy who has gone through a transplant.

Dr. Melton. Oh, absolutely. We have -- at our institution we have about 40 patients now, 40 women, who have successfully had pregnancies with their transplants, most recent -- well, not most recently, but recently a young woman with a combined kidney and pancreas transplant that delivered twins successfully.

Dr. Burgess. That is a remarkable story.

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So what about the -- immunosuppressive drugs have been around for a while, cyclosporine, I guess. Is that still the main one?

Dr. Melton. Cyclosporine has been around since the mid-1980s. There are several others that have come into play since that time.

Dr. Burgess. So do we have generic -- the availability of generics for those?

Dr. Melton. We do have generics for some of the drugs, not for all of them.

Dr. Burgess. Does the ability of generics reduce the overall price tag for providing immunosuppressant drugs?

Dr. Melton. Some of the generic drugs are less expensive, particularly if they are covered through some insurance plans. I had our social workers actually run a pro forma on that for me about a year ago, and surprisingly -- cyclosporine was one of the drugs that you mentioned, and surprisingly the generic forms of cyclosporine came in only about a third less than the brand-name drug. So there was not a substantial -- well, a third is a substantial reduction, but it was still a pricey drug for the patients.

Dr. Burgess. I guess the point would be the last time -- you know, we have got to do stuff that the Congressional Budget Office tells us we can afford to do, so the last time the Congressional Budget Office scored this particular piece of legislation, they gave it a dollar score. Would it be fair to say that rescoring this with this

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information about the use of generic medications might result in a lower score?

Dr. Melton. I don't know how they go about their scoring process.

Dr. Burgess. I don't, either.

Dr. Melton. It is a mystery to me. The only comment I can make about that is it is -- certainly relooking at these drug costs would be of benefit, I think, to our patients.

Dr. Burgess. It would also be a benefit if we could look longer than a 10-year window, because if you add the cost of dialysis in perpetuity to a patient who lost their graft after 3 or 4 years, clearly it is going to come down on the right side of the cost curve.

Thank you, Mr. Chairman. I am going to yield back my time. If we have time for a second round, I will be willing to participate.

Mr. Pitts. The chair thanks the gentleman.

Now recognize the gentlelady from Florida Ms. Castor, 5 minutes for questions.

Ms. Castor. Well, Mr. Chairman, I appreciate you holding today's hearing and all of the very insightful testimony from our witnesses. Thank you very much for being here.

I want to talk about one fixable issue, the two-quarter price lag on the part B price calculations.

Mr. Binder, one issue you discuss in your testimony is that two-quarter lag in part B price calculations for provider

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reimbursement. Can you elaborate on the issue? How does this come into play?

Mr. Binder. Well, manufacturers report their data, their ASP prices, to CMS, and then CMS has a period of time to process the information and apply it to the prices they are going to pay for those drugs. And it is done on a billing-code basis, so there is -- for some billing codes there is a number of drugs included, and for some there is just one drug when it is a sole-source drug. But that process takes some time, and there is analysis involved, and so it is 6 months before the prices --

Ms. Castor. Six months?

Mr. Binder. -- are applied.

Ms. Castor. What are some of the impacts of that 6-month lag?

Mr. Binder. Well, it varies. You know, if the drug price goes up, and, you know, certain buyers, say, for instance, buyers who don't buy in very large volume, are more likely to be affected by this than large-volume buyers or purchasers, they could, you know, have to pay more for the drug than they can get from Medicare in payment. If the price goes down, purchasers, providers are more likely to have it -- to buy it at a lower price than they are getting.

Ms. Castor. Dr. Brooks, you discussed this in your testimony. Give us the real -- what is happening in the real world with a 6-month lag?

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Dr. Brooks. Well, the 6-month lag is a problem. There are a lot of the pharmaceutical and biologic firms that have a business model whereby they raise prices about once a year, and they put us under water for 6 months. And then before we quit prescribing their drugs, they allow 6 months where we can more or less hold when ASP comes back to respectability, and then they have another price increase again the next year.

This is what we see, this up-and-down price sequences where we have 6 months under water, then 6 months to try to catch up, and then 6 months down again. It is a relentless process, and a more rapid reconciliation of those price increases that we have to pay with what we are actually reimbursed would be most helpful to our ability to deliver cancer care to our Medicare patients.

Ms. Castor. That is consistent with what I am hearing from doctors back in Florida. And I know it seems like an arcane detail, but I think it is having big impacts. And sometimes in Congress we hear about problems that are difficult to solve, and sometimes we hear about problems that are easier to solve, and it seems like one that, Mr. Chairman, would fall into the easier category. In this day and age, when you can communicate with anybody anywhere in the world in seconds, and we can pull up any piece of data on our iPads that we have here or our iPhones, it certainly seems to me like we should be able to determine accurate Medicare drug prices without a 6-month lag in

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time.

The two-quarter lag is written into Medicare law, so this is a problem for Congress to solve. And, Mr. Chairman, I hope we can work together to find a solution on this.

I would also like to talk about the impact of the sequester. It has been in place for several months now, but it is no longer front-page news, but that doesn't mean that it is not causing real harm. One area where it has hit hard is in reimbursements for Medicare providers, including the part B drug providers.

The sequester required a 2 percent cut in reimbursements. Earlier this year The Washington Post had quite an article on it identifying one cancer clinic that said that due to the sequester, they would have to stop treating as many as one-third of their 16,000 patients. And this is consistent with the testimony here this morning.

Dr. Brooks, can you tell us what -- put us in the real world here. What is this 2 percent cut having -- what impact is it having on patients that you see?

Dr. Brooks. Well, Congresswoman, thank you for the question. I only alluded to it briefly, but it is not a 2 percent cut for Medicare part B drugs in oncology. CMS has interpreted the rule perversely, in our view. They have cut not only our 6 percent services payment, but also the entire 100 percent drug acquisition costs that we do for CMS. So they cut us on all of Medicare's expenditure so that it results

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in a 28 percent reduction in our services payment, and this has put us under water and has cost those of us --

Ms. Castor. It is so irrational. I mean, it really highlights the irrationality of the sequester, just across-the-board cuts that are not based on the real needs of the American people. And it is not just Medicare part B, it is cuts to NIH, and medical research funding, Head Start, Meals on Wheels. And I think the solution -- I know that legislation has been filed particularly on this point, but the real solution are both sides of the aisle coming together to replace the sequester.

Now, yesterday the -- my side of the aisle, the Democrats, we appointed budget conferees. We are ready to go negotiate, and I would ask my friends on the other side of the aisle to please do not be afraid to come together and negotiate. We are seeing a real-world impact of the sequester.

Thank you, Mr. Chairman.

Mr. Pitts. The gentlelady's time has expired.

The chair recognizes the gentleman from Louisiana Dr. Cassidy, 5 minutes for questions.

Dr. Cassidy. Dr. Brooks, Ms. Davenport-Ennis, I am struck, it seems like we have a trifecta of bad things driven by government policy. One, 340B program or something else is, among other things, driving community oncologists to go into a hospital outpatient network, that

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that hospital outpatient network charges Medicare more, that the patient pays more, and that they are less convenient.

For folks who don't know what emesis is, Ms. Davenport, vomiting. Your husband was so sick, he was vomiting on the way back that he dehydrated in a half-hour drive and had to get an ambulance. This is like a quadrifecta of bad things. Did I hear that right, or am I misstating what the two of you said?

Ms. Davenport-Ennis. So from my point of view, you have heard it exactly right. And I would like to comment, if I may, on 340B.

Dr. Cassidy. Okay. You may want to elaborate what the program is for those who may not be familiar.

Ms. Davenport-Ennis. So when we look at 340B, the intention of the program was well intended. We were phasing out Hill-Burton hospitals that were supplying support to the at-risk populations. We introduced 340B concept so that hospitals serving at-risk populations could buy drugs at a reduced price, could bill them at a standard price; the margin could therefore be used for that hospital to make certain they could continue to serve the at-risk populations.

Initially the intent was to have 600 to 900 hospitals in the country as part of 340B. Today we have over 6,000 hospitals in the 340B program, and the margins are not necessarily consistently offering support to the at-risk population. The margins are being used to recruit community oncologists to come into that hospital setting.

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Dr. Cassidy. Now, is that allegedly, or do you have evidence of that?

Ms. Davenport-Ennis. No, we have evidence of that, in talking with a number of the practices. We work with oncologists in 50 States in the United States who work with us in case management services and in our copay relief services, and so it is not alleged, it is documented, and we -- I would like to ask --

Dr. Cassidy. So just to be sure, I am sorry to interrupt, but the program that supposedly is the subsidized care for the uninsured and for the Medicaid and Medicare patient to bring a set of services that otherwise they would not be able to have, you are saying that there is evidence that it is not being used for that, but rather to subsidize the purchase of community practices, bringing them into the hospital outpatient department, and in the meantime increasing costs to Medicare, to the patient, and decreasing convenience. Is that what you are saying?

Ms. Davenport-Ennis. Yes. What I am saying is that indeed the 340B hospital structure now allows it to offer very attractive packages to oncologists for them to leave their practices and associate or to bring their entire practices to the hospital setting, yes, sir.

Dr. Cassidy. Now, I will say that I work and I still see patients in the Louisiana public hospital system, and that there are some hospitals I will declare that are still doing the correct mission with

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the 340B program.

Ms. Davenport-Ennis. You are exactly right.

Dr. Cassidy. Yeah. A lot of my patients would not have drugs otherwise.

Mr. Cosgrove, I have been struck anecdotally there is evidence that the drug shortages, for whatever the etiology of the drug shortage is, is leading to the need to substitute more expensive drugs for much less expensive generic drugs; that the shortage of sterile injectables in the oncologic space, for example, is requiring the use of more expensive drugs. Now, that is anecdotes. I read it in the paper. Did you find evidence for that influencing utilization and cost?

Mr. Cosgrove. We did not. We did not look at that specific --

Dr. Cassidy. Did you look at that? Microphone, please. Did you specifically look at that, or you just -- you looked at it and didn't find it?

Mr. Cosgrove. We did not look at that. GAO has a report it issued in November of 2011, I believe, looking at shortages and their causes. There is follow-up work going on right now. It is a mandated study to try to get behind what is exactly causing those shortages and what the trends are.

Dr. Cassidy. Okay. Dr. Brooks, anecdotally are you seeing evidence for that or -- because, again, I read about it in the paper, so that is why I am --

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Dr. Brooks. Well, sir, it is not anecdotal. We in US Oncology are -- and with the help of our corporate partner, McKesson, we monitor the space extremely tightly, and I am actually involved in that monitoring. And your comment about steroids is spot on. We sent out an alert recently that methylprednisolone is in short supply. It costs pennies, but it is in very short supply because of the pressure of manufacturers.

ASP plus 6, I believe -- and I don't know that the office of MMA -- but I believe it was designed to curtail expenditures around expensive products. They never understood that they were going to create a race to the bottom in generic market so that our generic oncology drugs get lower and lower and lower prices, and then eventually it becomes not worthwhile to make these drugs. It costs only 2 or \$3. They are expensive, they are hard to store and all this other stuff. It just -- the economic incentive vanishes.

Dr. Cassidy. We are out of time, but if I may say, so Mr. Waxman at the outset saying that we are saving money by price controls, it may be that we are saving money in the short run, but long term penny wise, pound foolish, because we are having to substitute far more expensive drugs.

I yield back. Thank you for your indulgence.

Mr. Pitts. The chair thanks the gentleman.

Now recognize the gentlelady from California Mrs. Capps, 5

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minutes for questions.

Mrs. Capps. Thank you, Mr. Chairman. I am very pleased we can come together for another bipartisan hearing to address some commonsense improvements to Medicare, including two important provisions that I have cosponsored.

Medicare beneficiaries are a medically vulnerable population, and we have a responsibility to ensure that they have access to high-quality, community-based care and are not facing unreasonable financial burden. Unfortunately this isn't always the case, but I am pleased to see we have a lot of good bills from this committee to help address some of these shortcomings.

I have heard a lot from my constituents about challenges with continuity of care, access to providers, and the prohibitive costs of treatments for cancer and other chronic conditions. Cuts as a result of sequestration are taking a real toll on providers and have serious implications for access. For one oncologist in my district who sees a patient base that is over 90 percent Medicare beneficiaries, this has meant letting staff go, the sequestration, making serious pay cuts, and taking out a home equity loan just to keep the doors open, because if she doesn't do this, patients will have to travel more than 30 miles to the next closest provider.

While I do have serious concerns about piecemeal approach of easing the impact of only one part of sequestration, that doesn't mean

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that this issue isn't an incredibly important one and does deserve our attention. I hope we can find a solution that minimizes the harm to patients and providers, especially in the context of an overall sequestration fix. I know it is not going to be easy, but I believe we can do this if the House majority will let us.

I also wanted to highlight that there are other improvements to Medicare part B that do not involve drug benefit, but are also critical to address gaps in care that many patients face. Navigating complicated treatment options for yourself or a loved one, especially with a cancer diagnosis, this can be a full-time job and more, and without a plan it can be really overwhelming. And that is why this week my colleague from the Ways and Means Committee Mr. Boustany and I introduced H.R. 2477, the Planning Actively for Cancer Treatment Act, or the PACT Act. This bill would improve the health of Medicare beneficiaries with a cancer diagnosis while reducing inefficiencies in the Medicare system.

The Medicare program spends over \$55 billion each year to treat patients diagnosed with cancer, and too many of those patients do not receive a written care plan that explains the diagnosis, the prognosis, the treatment, and the expected symptoms. This leads to poor coordination among providers, reduced adherence rates, and increased stress or pain for the patient and their family.

However, a strong body of research shows that care planning

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coordinates care between numerous providers, and it also encourages shared decisionmaking between doctors and patients about how to best move forward based on both medical evidence and patient wishes. It addresses both the cancer treatment, but also the side effects from treatment, while addressing the patient's needs, and this can be done in a holistic way. Research has confirmed that this kind of coordinated care really does improve patient outcomes, increases patient satisfaction, reduces unnecessary utilization of healthcare resources.

Ms. Davenport-Ennis, as someone who is very familiar with the challenges patients face -- I know all of you are, but there is not much time -- would you share how this bill could help patients as they navigate cancer care, something I have been advocating for for a very long time?

Ms. Davenport-Ennis. You have, and on behalf of the cancer patients in the country, thank you for the work that you continue to do.

What this would do is provide a road map to survival, and it would show them what the stops are going to be along the way, and it would identify to them what to do when you have reversals. It would also allow them to manage their resources and to plan accordingly. It would also allow us to have an opportunity for end-of-life discussions when we need to have end-of-life discussions as part of planning for the

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full continuum.

It is, indeed, the beacon for the future, and it is something we have lobbied for in this city for more than 10 years, and we are very hopeful that you are going to make it happen this time.

Mrs. Capps. Well, I am going to need a lot of help, as you know, and maybe -- Mr. Chairman, this is a request. I have another whole topic to bring up on restraining excessive cost sharing, the Patients' Access to Treatment Act, another bill that I have introduced with Mr. McKinley. I will just submit it for the record, and perhaps some of you may wish to comment on it.

[The information follows:]

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Mrs. Capps. But I kind of wanted to get just a nod from the rest of you about this kind of coordinated care plan that we are advocating to see if it fits your needs, yes or no, quickly. Thumbs up? Is that the verdict?

I mean, it is kind of one of those no-brainers, isn't it, that we should just set ourselves around to doing, and I appreciate very much this opportunity to discuss it.

I yield back.

Mr. Pitts. Without objection that will be entered into the record, and I would also like to ask unanimous consent that the following documents be submitted for the record: a letter from the California Health Institute, a letter from the American Society of Clinical Oncology. Without objection, so ordered.

[The information follows:]

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Mrs. Capps. Mr. Chairman, I was just informed by staff that I should ask, because we had a lot of nods, and I don't think the recorder can --

Mr. Pitts. All right. The witnesses will please respond verbally to --

Mrs. Capps. Just really quickly yes or no.

Dr. Brooks. It would be a great asset, and as long as it wasn't sort of an unfunded mandate, we would cherish it.

Mrs. Capps. The question is whether there is agreement about the need for a coordinated care plan, a plan, a written plan.

I guess one strong affirmative. We will note that.

Dr. Melton. In support of my oncology colleagues, absolutely.

Ms. Davenport-Ennis. And in support of the patients that we serve in the United States, absolutely.

Mrs. Capps. Thank you.

Ms. Davenport-Ennis. Yes.

Mrs. Capps. Thank you.

Mr. Pitts. All right. That concludes the first round. We will have one follow-up. We will go on each side. Dr. Burgess for follow-up.

Dr. Burgess. Thank you, Mr. Chairman.

You know, I know people watching these hearings sometimes get confused. We have got a representative from the Congressional

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Research Service here. We appreciate him being here. We also talk about the Congressional Budget Office, which does the scoring of legislation that is introduced in Congress. There is another budgetary body down at the White House called Office of Management and Budget. Certainly Center for Medicare and Medicaid Services makes its own determinations to some degree.

But one of the main things, one of the main foci of today, has been the inclusion in the category of physician services the acquisition and storage of very expensive drugs. And I think, Mr. Binder -- I don't want to put you on the spot, but I think even CRS would agree that you have a family practitioner who diagnoses pneumonia, writes a scrip, tears it off, hands it to the patient, says go down to the pharmacy and buy these penicillin tablets and take them, and you will get better. If you were -- it would be wrong to say we are going to include that cost in the physician's service and then subtract 2 percent from that total bill and get that money back to the government. It just wouldn't make good sense.

So the acquisition -- and this was part of my opening statement, that the math function doesn't compute here. This is my beef with the Centers for Medicaid and Medicare Services. We sent them a letter signed by a lot of members of this committee; we got a nonresponsive response. Sorry, not good enough. We sent a follow-up letter to them that you really have to delineate to us how in the world that acquisition

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and storage requires a medical degree and a State license in order to do that, because otherwise it just opens the door for all other sorts of mischief. So I hope that we are able -- Dr. Brooks, I hope that we are going to be able to get some sensibility surrounding that.

More difficult aspect to undo the sequester. I mean, the sequester, after all, was bipartisan legislation, much more bipartisan than the Affordable Care Act; was signed by the President. Same President who signed the Affordable Care Act signed the sequester. So we are often told on this committee when we complain about the Affordable Care Act, hey, it is the law of the land, get over it. Well, the same statement could be made about the sequester: It is the law of the land.

But we do need to be certain that it is administered properly, and in this case, I think Dr. Brooks is exactly on target, it is not being administered properly. And you may even want to address -- you get some -- I mean, your practice margin is pretty narrow, and there is lots of things that put pressure on your business model, but everyone on this dais would say it is a good business model. We want you to be focusing on what you do best, which is taking care of the cancer patient. A patient gets cancer, they want to go to a clinic where that is all they take care of. They don't want to go to a clinic where they are also delivering babies and treating kids with runny noses. They want a cancer specialist, and I don't blame them, and that is what you

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provide.

But you are also, if I recall correctly, under State law and under our Texas law, with the franchise tax. This is something you also have to deal with with the acquisition and storage costs that also erodes your ability to take care of patients.

But the big thing you brought up, and what I really want to perhaps ask you to comment on, you said 102 percent of your business is required to pay for all of your business, because the government doesn't carry its fair share. Did I understand you correctly when you made that statement?

Dr. Brooks. Yes, sir. Those were numbers for 2012. That is our calculation. Our professional medical oncology payment for my salary is 102 percent from commercial payers, meaning that the Medicare and Medicaid are minus 2 percent. So we actually paid for the privilege of taking care of those patients, and that sounds like horrible or something, but we were okay with that. I mean, I hate to say it. Our mission is to take care of patients, and we are okay with a small loss to continue doing what we believe we should do.

Now under sequester our incomes are falling like a stone, and I don't -- I can't give you a number for how bad it is, but there is a multiplier effect going on here, and it is much worse than we -- our accountants projected for us, the actual dollars coming in. And we are anticipating that the -- everybody says, oh, there is no drama,

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nobody is losing access. We anticipate that there will be a two-stage approach here. The smaller practices that are not taking adjustments will begin to have to turn out their lights for the last time in August or September, in our calculations, and our complicated larger practices are working quietly behind the scenes to arrange for transfer of these patients to other venues because we will not be able to continue to subsidize our Medicare beneficiaries.

Dr. Burgess. But I would just project that the entire -- we also heard some discussion about consolidation of practices. Certainly cardiologists saw that with the consolidation of their practices moving to the hospital. The Affordable Care Act is going to put some pressure on practices of all sorts to consolidate. I mean, in fact, Zeke Emanuel, one of the principal architects of the Affordable Care Act over at the White House, said that he wanted doctors to work for a hospital or a health plan or the government; that was a better way, in fact, to practice; that you and I are dinosaurs in private practice.

I do -- we do need to keep a focus on this, because your comment that part of your practice pays for the other part, it is the government part that is not carrying its weight. As that level is expanded, and it will be, make no mistake about it, January 1st of this next year, by a year from now we will be seeing that in a big way, we won't be crying about just the sequester, we will be crying about what a significant negative impact that has had on your practice.

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I want you to know we are prepared -- we are trying to prepare for that, we are trying to make sure we are on top of that, but it is, indeed, a difficult question. But both sides need to be involved in this discussion.

I will yield back, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

Now recognizes the gentlelady Mrs. Capps, 5 minutes for follow-up.

Mrs. Capps. Mr. Cosgrove, your testimony provides us a broad overview of key part B drug spending facts. If I could briefly go over some of these facts with you?

First, about how much does Medicare part B pay for drugs each year?

Mr. Cosgrove. In 2010, it was almost \$20 billion, \$19.5 billion.

Mrs. Capps. Your testimony indicates that many of these part B drugs can be particularly expensive, costing tens of thousands of dollars or more. Why is this? I know patients want to know.

Mr. Cosgrove. Well, the price -- I mean, Medicare is -- working through physicians is accepting market prices, which are set by manufacturers.

Mrs. Capps. Okay. Am I correct, Mr. Cosgrove, that for many of these drugs, Medicare part B is the largest single -- single largest purchaser?

Mr. Cosgrove. Yes, that is absolutely true. For 35 of the 55

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drugs that we looked at, Medicare was the majority purchaser, and there were a handful of drugs for which Medicare paid more than 90 percent of the share of the total market.

Mrs. Capps. And just to be clear here, we need to do all we can to keep the drug pipeline flowing. These new drugs are expensive, but they do save lives. And a thriving drug industry is important for Medicare and for patients, that goes without saying, but we also need to make sure that we are spending taxpayer dollars wisely, and we are spending so much on these part B drugs that I wonder if we are able to get the best deals possible.

Do you have any thoughts here, Mr. Cosgrove? Does Medicare part B program have all the necessary tools that it needs to help reduce drug costs for taxpayers and beneficiaries?

Mr. Cosgrove. Well, I think this is a lot of money when you are talking about \$20 billion.

Mrs. Capps. Yes.

Mr. Cosgrove. And you are also talking about drugs that can be incredibly valuable on a wide variety of things, but that can be true for lots of parts of Medicare as well. And so I think that it is the responsibility of this committee and the rest of Congress to make sure that we are always getting the best deal, to make sure that providers are paid appropriately, and that beneficiaries have access to quality care, but that Medicare is not overpaying, and that would include making

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sure that we pay the right price and we set the right incentives for providers to do the right thing.

Mrs. Capps. Mr. Binder, do you have any thoughts on this?

Mr. Binder. Well, I agree with what Mr. Cosgrove said. The drug-pricing methodologies are complicated, and in this case you are talking about overlaying a methodology on the market mechanism as well, the manufacturers price their drugs. So you are overlaying this methodology, this payment methodology, and that becomes complicated, and you add sequester on that, it becomes even more complicated.

But there have been a number of proposals, including in the President's budget and other places, for other fixes or adjustments to either the ASP plus 6 or other approaches that could potentially help alleviate some of these issues.

Mrs. Capps. Thank you.

I will just bring up again the second bill, H.R. 460, the Patients' Access to Treatments Act, that I have introduced with Mr. McKinley, because it does address restraining the excessive cost sharing for specialty drugs, bringing medically necessary treatment within reach for average Americans.

While this bill only addresses the private insurance, the problem isn't unique to the commercial market. Under part B patients who face a serious diagnosis or are living with a chronic health condition are subject to significant financial burdens. Unlike the protection that

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many of us have with private plans, seniors who can't afford supplemental coverage and have traditional Medicare part B plans have no out-of-pocket max. That means that they continue to pay 20 percent out of pocket for every part B service, as you know. And for patients undergoing cancer treatments or requiring ongoing doctor-administered therapies, this cost can be prohibitive, especially when you realize that half of Medicare beneficiaries have incomes below \$22,000 a year.

I mean, this is a set-up for failure. Health expenses constitute almost 15 percent of household budgets for individuals who are on Medicare, nearly three times the spending of non-Medicare households. I sound like I am on a soapbox, but maybe I will ask just in conclusion, 15 seconds, Ms. Davenport-Ennis to comment.

Ms. Davenport-Ennis. Certainly the Medicare beneficiary is not in a position to pay what is required in a 20 percent copayment into perpetuity in part B Medicare.

Mrs. Capps. Thank you.

Yield back.

Mr. Pitts. The chair thanks the gentlelady.

We are going to go to one more round on each side, one more follow-up on each side. So the chair recognizes Mrs. Ellmers from North Carolina, 5 minutes for questions.

Mrs. Ellmers. Thank you, Mr. Chairman, and I apologize for coming in so late to this so important subcommittee hearing.

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I do have a couple of questions, and I would like to ask Ms. Davenport-Ennis and Dr. Barry Brooks this question. Earlier I made an opening statement regarding the Medicare part D and the effect that sequester has on those cancer drugs or chemotherapy agents. Given my discussion with the community oncologists and the numerous media reports that are going on now over the past few months, you know, we are now entering into about the third month of this affecting chemotherapy drugs. Basically patients are being forced out of their local community clinics to the more expensive hospital setting. What impact do you believe my bill would have in stopping this harmful trend?

Ms. Davenport-Ennis. I believe that it will at least stop some of the hemorrhaging of what is happening now. I think ultimately the committee is going to need to look at a comprehensive approach to what can be done to stabilize reimbursement to the practices, but your bill is certainly going to take a significant step forward in resolving this.

Mrs. Ellmers. Thank you.

Dr. Brooks?

Dr. Brooks. I agree that your bill would slow our hemorrhage and allow us to return to some semblance of stability. One-third of the market of community oncology has migrated to the hospital in the last 7 years, and that has been accelerated in the last 3 months under the weight of the sequester burden, and were we to relieve that, hopefully access could be maintained, and community oncology could continue to

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be practiced the way it has for the last two decades.

Mrs. Ellmers. Thank you.

I would also like to pose another question to the entire panel. Basically, as you know, the whole point of sequester is to reduce the spending at the Federal level; however, treating people in the hospital is actually more expensive than providing the same service in a physician's office or clinic setting. In fact, studies show that providing chemotherapy costs Medicare and the taxpayers \$6,500 more per patient per year in the hospital setting and \$650 out of the patient's own pocket.

Basically also, and I will just add this, just last night I saw attacks from doctor -- a doctor from Tulsa, Oklahoma, that read, quote, We have sent 50 percent of our chemo to hospitals in the past week, even patients with good insurance, because drugs are unaffordable for us at this point.

Given that the application of sequester by CMS is actually costing taxpayers money instead of saving it, shouldn't Congress be doing everything in our power to reverse this and make a change where we see a need? And I will just ask a basically yes or no answer from the entire panel.

Mr. Binder. I am sorry, could you repeat that?

Mrs. Ellmers. Basically -- I caught you off guard. Basically my point is as a result of more patients going to the hospitals and

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being treated in the hospital setting, it actually costs Medicare and the hard-working taxpayers of America \$6,500 more per patient per year, but then also, and this is the truly, you know, shameful part, another \$650 out of pocket for that patient. In your opinion, shouldn't we be doing everything we can to fix that?

Mr. Binder. Yes.

Mrs. Ellmers. Okay. Perfect.

Dr. Brooks?

Dr. Brooks. Absolutely.

Ms. Davenport-Ennis. Completely.

Dr. Melton. I would agree.

Mr. Cosgrove. Medicare needs to save money.

Mrs. Ellmers. Thank you. I appreciate that from all of you.

And, Mr. Chairman, I would like to submit for the record a statement from the American College of Rheumatology. It is actually a publication examining reforms to improve the Medicare part D drug program for seniors.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

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Mrs. Ellmers. Thank you, Mr. Chairman, and I yield back the remainder of my time.

Mr. Pitts. The chair thanks the gentlelady.

That concludes the questioning from the Members. The Members may have additional questions that we will submit to you in writing. We ask the witnesses to please respond promptly to the questions that we send you. I remind Members that they have 10 business days to submit questions for the record, and Members should submit those questions by the close of business on Tuesday, July 16th.

[The information follows:]

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Mr. Pitts. Very informative hearing. Thank you very much for your patience as we had to delay due to floor votes. Without objection, the subcommittee is adjourned.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned.]