

PROMOTING DISEASE MANAGEMENT IN MEDICARE

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES
ONE HUNDRED SEVENTH CONGRESS
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**PROMOTING DISEASE MANAGEMENT IN
MEDICARE**

TUESDAY, APRIL 16, 2002

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

The Subcommittee met, pursuant to notice, at 3:16 p.m., in room 1100 Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory and revised advisory follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
March 28, 2002
No. HL-15

CONTACT: (202) 225-3943

Johnson Announces Hearing on Promoting Disease Management in Medicare

Congresswoman Nancy L. Johnson (R-CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on promoting disease management in the Medicare program. **The hearing will take place on Tuesday, April 9, 2002, B-318 Rayburn House Office Building, beginning at 3:00 p.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include academics, practitioners, and health plans with expertise in disease management. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Approximately 12 percent of all Medicare enrollees accounted for three-quarters of all Medicare fee-for-service program costs. Many of these beneficiaries have chronic health conditions, such as diabetes, hypertension, asthma and congestive heart failure that require repeated and costly hospitalizations. Medicare's costs could be curtailed if the program is designed to better manage health care for these beneficiaries.

Disease management programs assist both the physician and patient with a plan of care that helps evaluate and prevent complications and improve outcomes through evidence-based practice guidelines and patient empowerment strategies. Typically this is used to improve health outcomes and reduce the costs of chronic diseases.

Some fee-for-service providers have incorporated disease management programs, but only to a limited extent. But in general, health care for those in Medicare fee-for-service with chronic illnesses has been poorly coordinated across sites of care and is often fragmented, although many providers have expressed greater interest in using management techniques to improve care.

Conversely, Medicare+Choice plans widely use disease management programs and have found preventative care and case management may ultimately save money by avoiding costly hospital stays. According to the 2000 Survey of Disease Management Practices, "virtually all" plans have at least one disease management program. The average plan has four disease management programs in place, and 95 percent of plans have a diabetes disease management program. Finally, at least 75 percent of plans have asthma and congestive heart failure disease management programs and almost 50 percent of plans have a disease management plan for coronary artery disease.

On February 22, 2002, the Centers for Medicare and Medicaid Services issued a request for proposals to conduct demonstration disease management programs in the fee-for-service program as required by the Benefits Improvement and Protection Act. The demonstration programs are for congestive heart failure, diabetes, or coronary heart disease. The proposal recognizes the value of expanding disease management to additional beneficiaries.

In announcing the hearing, Chairman Johnson stated, "As Congress modernizes and strengthens Medicare, we must recognize the significant role disease management can play in improving seniors' lives. Unfortunately, this is yet another area in which Medicare significantly lags behind the private market. By encouraging widespread incorporation of disease management programs in Medicare, we will help improve patient outcomes while reducing health costs."

FOCUS OF THE HEARING:

Tuesday's hearing will focus on promoting disease management programs in traditional and managed Medicare.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please note: Due to the change in House mail policy, any person or organization wishing to submit a written statement for the printed record of the hearing should send it electronically to hearingclerks.waysandmeans@mail.house.gov, along with a fax copy to (202) 225-2610, by the close of business, Tuesday, April 23, 2002. Those filing written statements who wish to have their statements distributed to the press and interested public at the hearing should deliver their 200 copies to the Subcommittee on Health in room 1136 Longworth House Office Building, in an open and searchable package 48 hours before the hearing. The U.S. Capitol Police will refuse sealed-packaged deliveries to all House Office Buildings. **Failure to do so may result in the witness being denied the opportunity to testify in person.**

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. Due to the change in House mail policy, all statements and any accompanying exhibits for printing must be submitted electronically to hearingclerks.waysandmeans@mail.house.gov, along with a fax copy to (202) 225-2610, in Word Perfect or MS Word format and MUST NOT exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

Note: All Committee advisories and news releases are available on the World Wide Web at <http://waysandmeans.house.gov/>.

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

* * * NOTICE—HEARING RESCHEDULED * * *

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
April 2, 2002
No. HL-15-Revised

CONTACT: (202) 225-3943

Rescheduled Hearing on Promoting Disease Management in Medicare Tuesday, April 16, 2002

Congresswoman Nancy L. Johnson, (R-CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee hearing on Promoting Disease Management in Medicare, previously scheduled for Tuesday, April 9, 2002, **will now be held on Tuesday, April 16, 2002, at 3:00 p.m., in the main Committee hearing room, 1100 Longworth House Office Building.**

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please note: Due to the change in House mail policy, any person or organization wishing to submit a written statement for the printed record of the hearing should send it electronically to hearingclerks.waysandmeans@mail.house.gov, along with a fax copy to (202) 225-2610, by the close of business, Tuesday, April 30, 2002. Those filing written statements who wish to have their statements distributed to the press and interested public at the hearing should deliver their 200 copies to the Subcommittee on Health in room 1136 Longworth House Office Building, in an open and searchable package 48 hours before the hearing. The U.S. Capitol Police will refuse sealed-packaged deliveries to all House Office Buildings.

All other details for the hearing remain the same. (See Subcommittee Advisory No. HL-15, dated March 28, 2002.)

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

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2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. Any statements must include a list of all clients, persons, or organizations on whose behalf the witness appears. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers of each witness.

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226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman JOHNSON. Good afternoon. The hearing will come to order. Mr. Stark is near at hand, we hope, and so I would like to start. I consider this one of the most important hearings the Subcommittee has had.

Seniors in traditional Medicare are literally held hostage to an outdated benefit package that denies them the state-of-the-art care that is possible under programs like disease management (DM). Programs designed to assist both the physician and patient to develop a plan of care can help defray rising costs while at the same time improving the quality of health outcomes and tremendously improving the quality of life of our seniors. Unless we transform Medicare from a sick and acute care program, the costs we face as the baby boomers age will be staggering, but the health needs of the rising number of seniors suffering from multiple chronic illnesses will not be met.

So, as we start this hearing, I believe it lies at the heart of improving both the quality of Medicare and managing its costs. I would have to say that as I have gone through doctors' offices where these protocols are being used, medical organizations, all kinds of providers, honestly, I have never seen such enthusiasm, such excitement by both patients and providers for the quality of life disease management is making possible for seniors with very serious and chronic illnesses, as well as the respect for the costs that can be avoided and the long-term cost control that is possible through this approach that dramatically improves quality.

A small portion of Medicare beneficiaries, 12 percent, account for 75 percent of all Medicare fee-for-service payments. Typically, it is these beneficiaries who suffer from chronic illnesses such as diabetes, asthma, or coronary heart disease. In many cases these high costs come from repeated hospitalizations due to poor medication compliance, lack of adherence to a prescribed treatment plan, and lack of patient self-management skills.

In addition, there are also provider-related problems that undermine efforts to coordinate and better manage patient care: poor communication, and narrowly focused payment systems that result in inadequate and fragmented monitoring of patients. Yet, as the baby-boom generation retires, the number of chronically ill beneficiaries is expected to increase, causing Medicare costs to escalate.

Disease management programs, designed to assist both physician and patient to develop a plan of care using evidence-based practice guidelines, more consistently manage illness, and will better involve the patient in their own health care. This will defray some of the costs while improving the health care of our senior citizens.

While some providers have attempted to implement disease management programs in Medicare fee-for-service, health care for beneficiaries with chronic illness remains typically fragmented and poorly coordinated. Conversely, many managed care entities have developed a wide array of cost control programs that combine ad-

herence to evidence-based medical practices with better coordination of care across providers.

Medicare+Choice (M+C) plans have found preventive care and case management saves money and avoids costly hospital stays. According to the 2000 Survey of Disease Management Practices, the average M+C plan has four disease management programs, with 95 percent of plans having diabetes disease management.

Netcare, a diabetes management program covering 7,000 diabetics in 7 managed care organizations, actually decreased hospital admissions by 18 percent, resulting in a 12 percent savings. Think of the impact on people's lives.

There has been some movement toward implementing disease management programs in fee-for-service. A coordinated care demonstration authorized by the Balanced Budget Act (BBA) resulted in approval of 15 programs. In addition, on February 22, Centers for Medicare and Medicaid Services (CMS) issued a Request for Proposal to conduct demonstration disease management programs targeted specifically toward congestive heart failure (CHF), diabetes, and coronary heart disease. The demonstration projects will operate for up to 3 years, after which a formal evaluation will be conducted by CMS.

These proposals hold the hope that we can achieve the twin goals of improving care and saving money, long recognized as central tenets of managed care. I am pleased to welcome Ruben King-Shaw from the Centers for Medicare and Medicaid Services, who will comment on these exciting new opportunities.

I will also welcome other experts: Dr. Wennberg from Dartmouth University will discuss regional variations in quality-of-care. Dr. Hillman from the Marshfield Clinic will explore their exciting work in incorporating disease management into fee-for-service Medicare. Dr. Henschke from Cornell University will present her firsthand efforts in managing lung cancer patients. Dr. Lord from Humana, and the President of the Disease Management Association of America, will discuss Humana's work in M+C. Finally, Dr. Anderson of Johns Hopkins University will discuss his work in this field.

I look forward to your testimony, and I specifically welcome Ruben King-Shaw for your first appearance before this Committee, but I hope not your last. As the testimony you will offer us today is testimony that speaks more to the future needs of our seniors and to the future evolution of Medicare than frankly any testimony we have had to date. So welcome to you, Mr. King-Shaw, and when Mr. Stark joins us, if he would like to make an opening statement, I will make room for that, and meanwhile I would like to recognize my colleague from Florida, Congresswoman Thurman.

[The opening statements of Chairman Johnson and Mr. Foley follow:]

Opening Statement of the Hon. Nancy L. Johnson, a Representative in Congress from the State of Connecticut, and Chairman, Subcommittee on Health

Good morning. Today's hearing will focus on the important subject of disease management and its application to the Medicare program. Disease management has significant potential to improve health outcomes and the quality of patients' lives, and may reduce health costs.

A small number of Medicare beneficiaries—12 percent—accounted for 75 percent of all Medicare fee-for-service payments. Typically, these beneficiaries suffer from

chronic illnesses, such as diabetes, asthma or coronary heart disease. In many cases, these high costs are from repeated hospitalizations as a result of poor medication compliance, lack of adherence to a prescribed treatment plan, and lack of patient self-management skills.

In addition, there are also provider related problems, such as poor communication and coordination between providers, and inadequate and fragmented monitoring of patients that undermines patient care.

As the baby boom generation retires, the number of chronically ill beneficiaries is expected to increase, causing Medicare costs to escalate. Disease management programs—programs designed to assist both the physician and patient to develop a plan of care, using evidence-based practice guidelines—should help defray some of these costs and improve health care outcomes.

While there have been some attempts by providers to implement disease management programs in fee-for-service, health care for beneficiaries with chronic illness is typically fragmented and poorly coordinated. These shortcomings are due to multiple health care providers and multiple sites of care.

Conversely, many managed care entities have developed a wide array of cost-control programs that combine adherence to evidence-based medical practices with better coordination of care across providers. Medicare+Choice plans have found preventative care and case management saves money and avoids costly hospital stays. According to the 2000 Survey of Disease Management Practices, the average Medicare+Choice plan has four disease management programs, with 95 percent of plans having a diabetes disease management program.

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These proposals hold the hope that we can achieve the twin goals of improving care and saving money—long recognized as a central tenet of managed care.

We are pleased to welcome Ruben King-Shaw from the Centers for Medicare and Medicaid Services who will comment on these exciting new opportunities.

I would like to welcome our other experts. Dr. Wennberg from Dartmouth College will discuss regional variation in quality of care. Dr. Hillman from Marshfield Clinic will explore their exciting work in incorporating disease management in fee-for-service. Dr. Henschke from Cornell University will present her first hand efforts in managing lung cancer. Dr. Lord, from Humana and the President of the Disease Management Association of America will discuss Humana's work in Medicare+Choice. Finally, Dr. Anderson of Johns Hopkins University will discuss his work in this field. I look forward to your testimony.

Opening Statement of the Hon. Mark Foley, a Representative in Congress from the State of Florida

Madam Chairman, I want to thank you for holding this very important hearing today on disease management programs in Medicare. As you know, Congress created Medicare in 1965 for the purpose of providing a basic health insurance package for our elderly—who, in many cases, cannot make ends meet. In its current form, Medicare is a reactive program that generally pays only when the beneficiary gets ill.

However, with health care costs rising between eight and ten percent each year we need to reexamine the entire health system in order to save it. Medicare must move from a reactive pay-as-you go system to a pro-active “wellness care” model. This shift will save the American people billions of dollars while increasing the quality of life of our elderly. The notion is simple—if we can get a patient to the doctor soon enough, then the overall cost of taking care of that person dramatically decreases. That is why Congressman Sander Levin and I introduced H.R. 2058, the Medicare Wellness Act. Our bill would be a major step in providing necessary preventive care benefits to our elderly. Specifically, the bill would establish a Healthy Seniors Promotion Program; expands coverage of preventive services; establishes a national fall prevention campaign; sets up a clinical depression screening demonstration project; and, requires a study of elderly disease prevention.

Again, Madam Chairman, I commend your actions today in bringing this very important issue to our committee. I hope that as you and your committee begin work on a larger Medicare bill this year that you will give strong consideration to incorporating some of the provisions in our bill.

Thank you.

Mrs. THURMAN. Thank you, Madam Chairman, and I just also want to thank Mr. Shaw for being here today, and for the benefit of the Members of this Committee, to let them know that Mr. Shaw came from Florida, was a very able Administrator, and was one who strengthened, I think, in many ways the health programs in the State of Florida through his time, and then certainly coming into the Federal Government, in which he helped us attain some very valuable waivers that he had been pushing before he left Florida. So, we certainly are pleased to have him before us today and for the work that he has done on behalf of the United States, but also on behalf of our citizens in Florida. Welcome.

Chairman JOHNSON. Thank you, Congresswoman Thurman. I was aware of his service in Florida. I am glad you were here to make some comment. I would like to recognize now my colleague and Ranking Member, Congressman Stark, for his comments.

Mr. STARK. Well, thank you. I apologize for being late, Madam Chair, and I want to thank you for this hearing. We are going to hear about Medicare beneficiaries, who are more likely to have chronic illnesses and perhaps even more than one of them. I hope that we can be careful not to focus on the short-term costs of covering and caring for these individuals. Without budget rules and scoring rules, it is tempting to do that. In the short term, it might be in Medicare's interests to curtail the costs by curtailing care, and that is not I think what the Chair has in mind, certainly not what this Ranking Member has in mind.

There isn't an incentive that I can determine, in the managed care industry as we know it, for plans to invest in the long-term health of their enrollees. If they keep getting adjusted each year, it is hard to see how they will recover major costs.

So, I think this is a topic that is long past due, and I think that you are brave to venture into a complex area where I am sure you are going to get a lot of opinions of what is wrong with every way that people suggest how to do it. I hope we can get at it, and maybe in a couple of years we will be able to see this become a standard part of Medicare, and I thank you for your interest in it.

Chairman JOHNSON. Thank you, Mr. Stark. Mr. King-Shaw?

STATEMENT OF RUBEN KING-SHAW, JR., DEPUTY ADMINISTRATOR AND CHIEF OPERATING OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. KING-SHAW. Well, Madam Chairwoman, thank you very much for the opportunity to talk about something so important and so meaningful and so much a part of what I have been focused on for a number of years. To Congressman Stark, again, thank you, and Congresswoman Thurman, always good to see you again.

It is very, very appropriate that I take time to thank all the Subcommittee Members for being here and for the great leadership you have shown in this area. Clearly, disease management has enormous potential for Medicare, and has proven its ability to provide

great results outside of Medicare for a number of years. In fact, there are really millions of individual seniors included who benefit from the power of disease management programs in the Medicaid and commercial sectors.

We in Medicare have been demonstrating various technologies—I will share them with you in a moment—but truly have some ways to go in harnessing the power of these disease management methodologies for the benefit of the people we serve and the mission that we have chosen, which is to care for poor people and old people and those who need public assistance for their daily health care needs. I think it is important, though you have my written statement that goes into great detail of the specifics of what we are doing at CMS, I think it is important to take a moment in just this first opening discussion about what do we mean when we say “disease management” in Medicare.

I think disease management is best described as a continuum, if you will, that can be both very robust on one end and particularly light on another. So, as I walk through some of the common elements of a robust disease management program, I think we get a sense of what a full, comprehensive disease management program would look like.

It would have elements of a clinically driven best practice or evidence-based clinical strategy. That is where it begins, with strong clinical leadership based on proven, effective clinical strategies. It would then include the integration of administrative, particularly data, and financial resources to support the patient-physician relationship.

This truly is a patient-centered strategy for improving health care outcome, treatment, and wellness. There is an important element of patient education in disease management, and as patients understand the pathology of their condition, they become full participants in the help and healing process. As you can see, they actually become a partner and take ownership of the health care itself.

A significant part of provider education is attributed to disease management, and there is the important discipline of risk assessment, truly knowing the population. You will hear a term, “population management,” and an important part of population management is stratifying the population according to levels of risk or understanding of disease or degree of severity in these types of things.

There is an important part of disease management that focuses on outcomes and outcome measures. All successful disease management programs truly do have ways of identifying the objective, the clinical, the social, the cultural even, outcomes that are the target of performance. So, here are some quite rigorous, very effective ways of measuring those outcomes. Then clearly there are cost savings, and then the provision of comprehensive, integrated, but coordinated care across the delivery system.

So, these are the elements of what I would describe as a very robust disease management program, and I will share with you some examples that we are focusing on at CMS in a moment. There are elements of disease management, as I have just outlined, that can appear in isolation. You can have two or three of these deployed

very effectively, and those would end up on the lighter scale of disease management. It is within that continuum of sources, of resources, of approaches, that you will find most disease management programs.

It is also a good question to ask, well, where is disease management most effective? I think Chairwoman Johnson has addressed those, and they are in the chronic conditions. They are most commonly found in asthma, congestive heart failure, coronary heart disease, Alzheimer's, cardiovascular, and so forth, diabetes, depression, hypertension, and increasingly substance abuse and chemical dependency, as well as lung disease and mental health such as depression conditions.

So, where you have in the Medicare program an increasing number of beneficiaries who are suffering from chronic diseases, it would be a natural progression, a natural advancement of the Medicare program, to begin to harness more effectively disease management methodologies. Where have these methodologies been proven to be most successful? It truly has been in the managed care or coordinated care or integrated care world.

Whether that has been in Medicaid or the commercial environment, or managed indemnity before that, it has truly been in the managed care arena where we have developed the most promising models for disease management. Why would that be the case? Why would managed care be the place where the expertise has grown up in such abundance around disease management?

Well, for one thing, these private plans have the flexibility to reconfigure resources around the patient-physician relationship. These private plans also have the ability to achieve greater returns on the continuity of care. They are more free to respond to the needs of the population. They can be more agile in financial models or contracting or partnerships. They can build coalitions with clinical and academic and pharmacological and community-based resources around the needs of a population or a patient, and they have the ability to maintain a platform that is conducive to further disease management operations.

So, it is within the context of a delivery system which is flexible and agile and patient-centered that we have seen the most effective deployment of disease management programs. So, if we are looking at one of the ways that Medicare can preserve the benefits of disease management, it would clearly be to shore up the M+C program itself, in that the provision of an actuarially sound methodology of financing M+C programs will preserve for seniors in those programs the benefits of disease management that they currently enjoy.

Clearly there is an application of disease management programs outside of M+C, and so the next few comments that I will share with you will give you some sense of what we are doing outside of the M+C environment. In addition to what you may have already read about is our preferred provider organization (PPO) demonstration solicitation that we have just announced.

We are looking at doing some things around congestive heart failure that will identify clinical outcomes among congestive heart failure patients, either in M+C organizations or outside in the fee-for-service world, that would give us the ability to direct resources,

data, information, coordinated care for a better outcome in revised incentive payments, if you will, as a result of good clinical outcomes.

Similar efforts are underway with the ESRD, end-stage renal disease patients, and here is an important part of disease management which is often missed. These are often extremely effective methodologies for addressing disparities in health care, disparities among men and women and among ethnic and racial groups.

So ESRD, which is disproportionately a condition where African Americans suffer, effective disease management programs are among the ways to address that disparity by truly integrating care and all of the other things that I listed up front. Similar types of interventions can address disparities in other ways, between rural and urban areas, between male and female.

There are a number of things that we are doing in coordinated care, like demonstrations. You heard Madam Chairwoman refer to those. There are some very interesting implications for direct contracting with provider sponsored organizations.

I mentioned early on that part of disease management is building teams, communities of care, if you will, and so where you have community-based organizations, be they medical or cultural or social or community support, that you can build a delivery system around, then you can be quite effective with those. So provider sponsored organizations, case rate methodologies, where you truly are able to build a financial model around a continuum of care based on a diagnosis, these are areas that we are beginning to do some work now.

None of this will substitute for a financially sound delivery system as whole, be it M+C or the Medicare program itself, but there are ways that we can begin to do a better job.

Just a couple of other examples that kind of will lay out the landscape of some of the power of disease management, and I will go around the country a little bit. Up in Boston there is a very effective diabetes program that truly focuses on the provision of annual retinal eye exams, an important part of diabetes management, as well as monitoring hemoglobin and cholesterol levels.

Down in Florida, that great Sunshine State, there is quite an effective program that is looking at cancer through disease management, and the measurement there has been acute care hospital days which have gone down 15 percent over a 2-year period through effective use of disease management, and also looking for admissions as a result of complications from cancers, which is already down 10 percent.

Then I'll stop in New York, because there is an application of a more interesting, perhaps, disease management program around the issues of mental health.

I am very pleased to be able to share with you this opening. I would love to be a part of whatever question and answer or further discussions you would like to have. I have had the privilege of being a part of disease management both at private and State and now Federal level. I am happy to be a part of this great hearing, and I can spend whatever time you would like, just respond to your questions, continue the dialog.

Thank you again, Madam Chairwoman.

[The prepared statement of Mr. King-Shaw follows:]

Statement of Ruben King-Shaw, Jr., Deputy Administrator and Chief Operating Officer, Centers for Medicare and Medicaid Services

Chairman Johnson, Congressman Stark, distinguished Subcommittee members—first, thank you for inviting me to discuss the significant role that disease management can play in improving people’s lives. Also, I want to express my appreciation to you, Chairman Johnson and other Subcommittee members for your leadership on this issue. Analysis of disease management is an integral part of the Centers for Medicare & Medicaid Services’ (CMS) efforts to improve and strengthen Medicare and improve the health care services provided to all Medicare beneficiaries. As the delivery of health care has matured, we all know that individual health care providers routinely plan and coordinate services within the realm of their own specialties or types of services. However, rarely does one particular provider have the resources or the ability to meet all of the needs of a chronically ill patient. Ideally, as part of a disease management program, a provider or disease management organization is dedicated to coordinating all health care services to meet a patient’s needs fully and in the most cost-effective manner. I want to discuss with you in greater detail the challenges and opportunities in integrating disease management into Medicare. The demonstration projects we are developing can help achieve the President’s principles to improve and strengthen Medicare while ensuring that America’s seniors and disabled beneficiaries receive high quality care efficiently.

As you may know, last July, the President proposed a framework for strengthening and improving the Medicare program that builds on many ideas developed in this Committee and by other Members of Congress. That framework contains eight principles to guide our efforts:

- All seniors should have the option of a subsidized prescription drug benefit as part of modernized Medicare.
- Modernized Medicare should provide better coverage for preventive care and serious illness.
- Today’s beneficiaries and those approaching retirement should have the option of keeping the traditional plan with no changes.
- Medicare should make available better health insurance options, like those available to all Federal employees.
- Medicare legislation should strengthen the program’s long-term financial security.
- The management of the government Medicare plan should be strengthened to improve care for seniors.
- Medicare’s regulations and administrative procedures should be updated and streamlined, while instances of fraud and abuse should be reduced.
- Medicare should encourage high-quality health care for all seniors.
- The President, the Secretary, the Administrator and I are determined to work constructively with Congress to achieve these principles. We believe disease management is a critical element for meeting these goals. We are currently undertaking a series of disease management demonstration projects to explore a variety of ways to improve beneficiary care in the traditional Medicare plan. These demonstrations provide beneficiaries with greater choices, enhance the quality of their care, and offer better value for the dollars spent on health care. The almost complete absence of disease management services in the traditional Medicare plan is another striking indication of how outdated Medicare’s benefit package has become. We appreciate this committee’s efforts to improve and strengthen the traditional Medicare plan, and we are pleased to be working with you on legislation that will make disease management services more widely available.

Disease management is also one of the principal reasons why the President and Secretary Thompson have advocated immediate action to give seniors reliable private plan options in Medicare, and to prevent further pullouts of private plans from the Medicare program. Disease management services have been available to millions of seniors through private plans, yet inadequate and unfair payments are threatening those benefits. The most important step that Congress could take right now to allow seniors who depend on disease management to keep these valuable services, and to provide rapid access to such services to many more seniors who need them, is to fix the problems with the payment system for private plans.

BACKGROUND

A relatively small number of beneficiaries with certain chronic diseases account for a disproportionate share of Medicare expenditures. These chronic conditions include but are not limited to: asthma, diabetes, congestive heart failure and related cardiac conditions, hypertension, coronary artery disease, cardiovascular and cerebrovascular conditions, and chronic lung disease. Moreover, patients with these conditions typically receive fragmented health care from providers and multiple sites of care. We need to find better ways to improve and coordinate care for these patients and to do so more efficiently. Such disjointed care is confusing and can present difficulties for patients, including an increased risk of medical errors. Additionally, the repeated hospitalizations that frequently accompany such care are extremely costly, and are often an inefficient way to provide quality care. As the nation's population ages, the number of chronically ill Medicare beneficiaries is expected to grow dramatically, with serious implications for Medicare program costs. In the private sector, managed care entities such as health maintenance organizations, as well as private insurers, commercial firms, and academic medical centers, have developed a wide array of cost-control programs that combine adherence to evidence-based medical practices with better coordination of care across providers.

Several studies have suggested that case management and disease management programs can improve medical treatment plans, reduce avoidable hospital admissions, and promote other desirable outcomes. Coordination of care has the potential to improve the health status and quality of life for beneficiaries with chronic illnesses. Although there is a distinction between the two models, the case management approach is generally used to coordinate care to a patient with multiple chronic conditions, while the disease management approach tends to focus primarily on the patient and one chronic condition, such as congestive heart failure. In the largest sense, both disease management and case management organizations provide services aimed at reaching one or more of the following goals:

- Improving access to services, including prevention services and necessary prescription drugs.
- Improving communication and coordination of services between patient, physician, disease management organization, and other providers.
- Improving physician performance through feedback and/or reports on the patient's progress in compliance with protocols.
- Improving patient self-care through such means as patient education, monitoring, and communication.

These goals echo the President's principles of improving the Medicare program through better care for serious illness, delivering higher quality health care, and protecting Medicare's financial security.

PROVIDING RELIABLE COVERAGE OPTIONS THAT INCLUDE DISEASE MANAGEMENT

We are already taking advantage of private sector expertise in disease management to give Medicare beneficiaries more services for their premiums, often with lower cost sharing and more benefits than are available under traditional Medicare. For example, Medicare+Choice plans provide many benefits that are valuable to seniors with serious and chronic health conditions, such as:

- *A Medicare+Choice plan in Boston that has a comprehensive disease management program for its enrollees with diabetes. This has resulted in significant increases in the share of enrollees who received annual retinal eye exams and are monitored for diabetic nephropathy and substantial improvements in the management of their Hemoglobin and cholesterol levels.*
- *A Medicare+Choice plan in Florida that has a comprehensive disease management program to monitor, facilitate, and coordinate care for enrollees with cancer. As a result, the number of acute hospital days per cancer case dropped by about 15% over two years and the share of inpatient admissions for complications with cancer has declined by 10 percent.*
- *A Medicare+Choice plan in New York that has a case management program for those hospitalized for mental health disorders and nearly doubled the share of its enrollees who received follow-up care within 7 days of their hospital discharge. This is consistent with research that has shown that individuals who receive after-care following hospital stays for mental illness are more likely to be compliant with their treatment regimens and less likely to be readmitted to the hospital.*

We are also undertaking several demonstration programs improve the disease management options available to seniors in private plans. The projects represent a wide range of programs and approaches, and they address a number of chronic conditions. First, we just announced yesterday a demonstration project to expand health plan options in Medicare+Choice. Preferred Provider Organizations (PPOs) have been successful in non-Medicare markets in providing disease management services and other valuable benefits for patients with chronic illnesses, yet they are almost nonexistent in Medicare. CMS is conducting the demonstration to test ways to provide more health plan options to people with Medicare. We hope to award demonstrations later this year in up to 12 geographic areas that will be available to enroll beneficiaries during the Fall open enrollment period and begin to serve enrollees next January. This demonstration program will test changes in methods of payment for Medicare services that may be more efficient and cost effective while improving the quality of services available to beneficiaries. The demonstration plans will be considered Medicare+Choice plans and must offer all of Medicare's required benefits, but will also have the flexibility to offer greater access to drug benefits. Second, we are giving Medicare+Choice organizations that meet specific quality indicators extra payments recognizing the costs of successful outpatient management of congestive heart failure (CHF).

DEMONSTRATION PROGRAMS IN FEE-FOR-SERVICE MEDICARE

The outdated benefit package in fee-for-service Medicare does not include disease management, and so beneficiaries in fee-for-service have not had access to these valuable services. To identify innovative ways to include coordinated disease management services in an inherently uncoordinated fee-for-service system, we have a number of demonstrations both underway and in development. This includes demonstrations that are being implemented under legislation developed with bipartisan support in this committee. In one fee-for-service project at Lovelace Health Systems in New Mexico, we are testing whether intensive case management services for CHF and diabetes mellitus can be a cost-effective means of improving the clinical outcomes, quality of life, and satisfaction with services for high-risk patients with these conditions. As part of the evaluation, we will be looking at mortality, hospitalization rates, emergency room use, satisfaction with care, and changes in health status and functioning.

We also have implemented an End Stage Renal Disease (ESRD) Managed Care Demonstration project that began in September 1996. Among other things, the demonstration was designed to test whether: integrated acute and chronic care services, and case management for ESRD patients improve health outcomes; and whether additional benefits are cost-effective. Services were provided for 3 years at each site—**Kaiser Permanente in Southern California and Advanced Renal Options in Southern Florida**. We measured outcomes such as: survival, hospitalizations, patient satisfaction, transplantation, vascular access, hematocrit and adequacy of dialysis. In general, enrollees in the demonstration exhibited comparable or better outcomes when compared to those in fee-for-service. This demonstration provided us with valuable information as we consider new ways to better serve ESRD beneficiaries, including the possibility of developing a new ESRD demonstration.

In another demonstration, we have selected 15 sites to provide case management and disease management services to certain Medicare fee-for-service beneficiaries with complex chronic conditions. These conditions include congestive heart failure, heart, liver and lung diseases, diabetes, psychiatric disorders, major depressive disorders, drug or alcohol dependence, Alzheimer's disease or other dementia, cancer, and HIV/AIDS. This demonstration was authorized by the Balanced Budget Act of 1997 to examine whether private sector case management tools adopted by health maintenance organizations, insurers, and academic medical centers to promote the use of evidence-based medical practices could be applied to fee-for-service beneficiaries. This program was designed to address important implications for the future of the Medicare program as the beneficiary population ages, and the number of beneficiaries with chronic illnesses increases. We are testing whether coordinated care programs can improve medical treatment plans, reduce avoidable hospital admissions, and promote other desirable outcomes among Medicare beneficiaries with chronic diseases. The projects have just begun enrolling patients. The statute that authorizes these projects allows for the effective projects to be continued and the number of projects to be expanded based on positive evaluation results—if the projects are found to be cost-effective and that quality of care and satisfaction are improved. In addition, the components of the effective projects that are beneficial to the Medicare program may be made a permanent part of the Medicare program. These initial projects are varied in their scope and include both provider organizations as well as commercial companies, utilize both case and disease management

approaches, are located in urban and rural areas, and provide a range of services from conventional case management to high-tech patient monitoring. For example:

- **CorSolutions Medical, Inc. of Buffalo Grove, Illinois** will implement an urban disease management program targeting beneficiaries in Texas and Indiana with high-risk CHF. The program will offer an extensive array of interventions including an in-home assessment, patient education, and physician reports.
- **Carle Foundation Hospital of Urbana, Illinois** will implement a rural case management program targeting beneficiaries in eastern Illinois with various chronic conditions. Interventions include health assessments, patient and physician education, medication review, and supportive services.
- **Health Quality Partners of Allentown, Pennsylvania** will implement an urban and rural disease management program targeting beneficiaries in eastern Pennsylvania with various chronic conditions. This integrated delivery system will provide disease-specific education, and coordination and arrangement of medical care and social services.
- **Quality Oncology, Inc. of McLean, Virginia** will implement an urban disease management program targeting beneficiaries in Broward County, Florida with cancer. This commercial vendor will match the plan of care written by the patient's own oncologist with its guidelines based on the type, location and stage of the patient's cancer. The program's medical director will contact the patient's oncologist to discuss any differences between the care plan and the guidelines. A care manager will provide patient education and counseling, care coordination, and service arrangement.
- **Washington University of St. Louis, Missouri and StatusOne Health of Hopkinton, Massachusetts** will implement an urban case management program targeting beneficiaries in St. Louis with various chronic conditions. In this joint venture, patients will receive health and self-care education, personal goal setting and health and social services.
- **QMED, Inc. of Laurence Harbor, New Jersey** will implement an urban disease management program targeting beneficiaries in Northern California with coronary artery disease. This commercial vendor will combine data from a cardiac monitoring device with its system knowledge database to assist physicians in assessing the patient's condition and formulating treatment recommendations. In addition, cardiac medications will be provided to participants in financial need.

BUILDING FOR THE FUTURE

We are also developing future demonstration projects that will expand options for Medicare beneficiaries in the Medicare+Choice program and the traditional Medicare program. Recently, we announced a new and innovative demonstration, as required by the Benefits Improvement and Protection Act of 2000 (BIPA), that will test the combination of providing disease management services and offering outpatient prescription drugs to Medicare beneficiaries with advanced-stage congestive heart failure, diabetes, or coronary heart disease. The goal is to coordinate care and assist beneficiaries in managing their doctors' orders and monitoring their medication, which in turn will lead to better, healthier and fuller lives. Under this demonstration, disease management organizations may be paid a monthly premium for coordinating the care of patients in the studies and for the cost of prescription drugs. We will require each organization participating in the program to measure improvements in health outcomes and reduce Medicare program expenditures. In fact, participating organizations must post a bond guaranteeing savings for the program. Also, as mandated by BIPA, we are developing a physician group practice demonstration encouraging coordination of Part A and Part B services, rewarding physicians for improving beneficiary health outcomes, and promoting efficiency.

In addition to stabilizing the existing Medicare+Choice program, and providing more health plan options, like our PPO initiative, we want to develop specific health plan options for those beneficiaries with chronic illness. We are investigating disease management projects that would work with a diverse group of organizations, including Provider Sponsored Organizations (PSOs), integrated healthcare systems, disease management organizations, and Medicare+Choice plans. We want to enhance the clinical management of care to better serve the patients, provide for more effective coordination of services, and improve beneficiaries' health clinical outcomes and reduce costs to the Medicare program.

For example, we are considering demonstrations to test capitated payment arrangements with qualified organizations that will use the case management techniques to treat chronic diseases such as congestive heart failure, diabetes, and

chronic obstructive pulmonary disease. This would allow a plan to specifically target treatment and coordination for chronic diseases. The payment models are intended to improve the coordination and quality of care for Medicare beneficiaries and to reduce costs to the Medicare program. The targeted populations could include beneficiaries eligible for both Medicare and Medicaid, as well as the frail elderly.

Similar to the current BIPA demonstration project, we also are interested in applying the private sector contracting techniques that health plans use in the Medicare+Choice program with disease management for fee-for-service populations. In addition, as I mentioned, we are considering building on the positive aspects of our current ESRD demonstration to further explore using integrated care management systems for beneficiaries with ESRD. We want to test the effectiveness of disease management models in increasing quality of care for ESRD patients while ensuring that this care is provided both more effectively and efficiently.

Our evaluations of all of these projects will inform our future efforts. We are evaluating health outcomes and beneficiary satisfaction, the cost-effectiveness of the projects for the Medicare program, provider satisfaction, and other quality and outcomes measures. We anticipate that better outpatient care and monitoring through the case management model will reduce avoidable hospitalizations, avoid unnecessary services, and improve outcomes. The Agency also is exploring various payment options, including case-rated methodologies for treating particular conditions, such as stroke, that may lend themselves to this type of payment system. We recognize, however, that costs for some individual cases, particularly those in which appropriate medical services were previously underutilized, could increase with coordination of services. Nevertheless, we expect that in the aggregate, the costs to Medicare will be the same or lower through the efficiencies that will result in providing appropriate care and this will more than offset the added expenses.

While these new demonstration programs hold promise, they are not yet fully tested and they are no substitute for the comprehensive coverage that many beneficiaries prefer through private plans. The most important step for helping Medicare build for the future, in terms of providing integrated benefits that keep patients healthy, is to create a stable and fair payment system for Medicare+Choice plans.

CONCLUSION

Disease management is a critical element for improving the nation's health care delivery system. Yet seniors are far less likely than other Americans with reliable access to modern, integrated health care plans to have access to disease management services. Through changes in Medicare's unfair payment system for private plans, we are working to give seniors the same access to modern disease management services that other Americans enjoy. We also are working to address the difficulties of providing effective disease management services in the fee-for-service plan. Our goal is to make disease management services widely available, enabling beneficiaries to enhance their quality of care and get better value for the dollars they spend on health care. We look forward to continuing to work cooperatively with you Chairman Johnson, this Subcommittee, and the Congress to find innovative and flexible ways to improve and strengthen the Medicare program while making sure that beneficiaries, particularly those with chronic conditions, have access to the care they deserve. I thank you for the opportunity to discuss this important topic today, and I am happy to answer your questions.

Chairman JOHNSON. Thank you very much, Mr. King-Shaw, for your testimony. I did have a chance to read through it, and it offers us a lot of very good information.

I want to focus for just a minute—and I have several questions, so I want to just hit on these things lightly—but you stress in your testimony that the M+C programs and eventually the PPO programs are the only access Medicare has right now for patient-centered systems of care, and I think that is true. You talk about in the fee-for-service area building teams of care, but that team approach is only sort of automatically available to us through the more integrated care plans.

It has struck me, as I have worked in this area, that as important as any one factor in the ability of those plans to offer disease management is their information management technology. They ac-

tually can follow their patients more easily. They can communicate among their providers more easily. They can track and incentivize their patients to participate in their own care in a way that fee-for-service Medicare from Washington can't do.

Do you want to comment a little further on the information technology aspect of an integrated care system and, how that means that we really have to look at alternatives to fee-for-service medicine if we are going to accomplish these goals in the near term?

Mr. KING-SHAW. Well, that is clearly, clearly a powerful point, and one of the advantages that private plans and M+C organizations bring is that they typically have front end pieces that they can attach to their claims system to integrate all types of claims, and increasingly the types of interactions or encounters that happen outside of the regular claims operation.

So, as we do a better job at collecting lab results and lab values, not just the financial but the actual values, as these organizations have access to other types of qualitative data, they can array it and display that to identify progress, to measure the effectiveness of the interventions, to actually look at the risk. I mean, in every disease management program you have got those that have a condition and know it, those who have it and don't know it, those who don't have it but are about to get it or are at risk for getting it.

This kind of data that M+C organizations can integrate throughout the continuum of care makes them particularly qualified to maintain that kind of risk and outcome and performance data. It also enables them to do something with reimbursement and contracting and pricing of those relationships.

On the fee-for-service side, we have a long way to go. There are ways to do it. We have several people who pay claims in the Medicare program, A and B and DMERC, Durable Medical Equipment Regional Carrier, and all of that. So, integrating the data will be a challenge on the fee-for-service side, but there are organizations, disease management organizations, that bring that expertise. There are system integrators that would like to be able to bring that value to us on the fee-for-service side. There are some contractors that do have large pieces of the care continuum that can bring us that value, or team up with other organizations to integrate that data.

So, it does present challenges on the fee-for-service side, but it is without question where 84 percent of the population is, where we can do the most work.

Chairman JOHNSON. All right, thank you. In my opening statement I mentioned that 12 percent of our Medicare beneficiaries account for 75 percent of the spending, and in his testimony later on Dr. Wennberg will suggest a disease management approach to some of the end-of-life use issues. He notes the enormous variation across the country in the number of seniors that pass away in intensive care units (ICUs) in some areas and very uncommonly in ICUs in other areas; the disparate use in physician visits. You know, is that going to be a focus of one of your demonstrations, to really look at the management of end-of-life illness and the efficacy of one approach versus another?

Mr. KING-SHAW. It certainly could be, and I think it should be. When we issue solicitations or invitations, either in writing

through the official means or through the conversations that Tom Scully, the Administrator, the Secretary, and I have around the country, we are always interested in ideas that people bring us, initiatives that we can support and work through.

This is one area that makes a lot of sense. The closest we have come—I mean, actually it's not commonly thought of as a disease management program, but in many ways it is—is the Program of All-Inclusive Care for the Elderly (PACE program) itself. Our PACE program is, you know, an all-inclusive program for frail elders, and in there is a great deal of knowledge and value and opportunity to strengthen disease management technologies and methodologies around people late in life.

So, the answer would be yes. How we do it, where we do it, would be a function of someone bringing to us that expertise that we can connect with and support and develop.

Chairman JOHNSON. We have known for such a long time that so much of our money is spent in the waning months of one's life, I do hope that we will think about how much the private sector does know in this area. I think they know less than they know in the area of diabetes and some other areas, so I appreciate that, but I think this does need to be a focus of our thinking as we develop approaches to managing the costs of care and improving the quality of life.

Lastly, let me just ask you if you—I noticed with your comments about the end-stage renal disease management care demonstration project that began in September 1999, you comment that it did improve outcomes. You don't comment on whether it cost money or saved money. You don't comment on why, with this project completed now and under our belts, we aren't thinking about rolling this out through Medicare across all of our ESRD providers, when clearly it did improve at least quality-of-care. So, if you would, comment on the cost aspect and why we aren't ready to move that out.

I would ask the same question in terms of diabetes. I have stood in doctors' offices. I have seen what fantastic, simple programs we have available that can help physicians monitor patients much more easily, can get patients involved in their care ever much more easily. When you look at what it would do to prevent blindness and all kinds of complications as people age, it does seem to me that there are areas in here where we might even use the national coverage process to change the way we—you know, what care it is we are willing to pay for.

Mr. KING-SHAW. Thank you very much for that, Madam Chairman. Actually, we are working on at least two different ESRD disease management initiatives. There is one in the variety of looking at a true capitated model that would enable, at a fixed rate per enrollee, ESRD providers to provide the basket of services that patients need. We are also looking at some more of the disease management coordinated, noncapitated models. We are looking at different ways, as I mentioned, you know, case rate methodology.

So, there are a number of different initiatives that we have underway, organized toward ESRD, so you will be hearing about them more. We are engaged with partners and interested parties to help us do that. So, as they cook a little bit more and become

more structured, there will be ways for us to present those to you and anybody else who is interested.

There is actually quite a lot of work we are doing in the area of diabetes, both in the 15 BBA-sponsored diabetes—I am sorry—disease management programs, there is work being done in diabetes, and of course the Beneficiary Improvement Protection Act (BIPA) provided an opportunity for types of disease management. In that second group, we are actually including the cost of prescription drug coverage—

Should I wait?

Chairman JOHNSON. Go ahead.

Mr. KING-SHAW. The cost of prescription drug coverage.

As far as the cost goes, in these past examples, they have proved to be at least cost-neutral. There is some spike in cost as you bring services to people who have under-utilized the system, and there is an investment cost, so you will very commonly see a spike early on in the treatment process. That levels out and actually reduces over time as you stabilize and provide all the basket of services, so it is our view that they actually are quite cost-effective, and over the life of the program actually at least a break-even, most likely even as a small benefit to the Medicare program.

Chairman JOHNSON. Thank you very much. Mr. Stark?

Mr. STARK. Thank you, Mr. King-Shaw, for your testimony. Is there any reason now that providers shouldn't be required to put in place practice guidelines and patient safety plans as a condition of participating in Medicare?

Mr. KING-SHAW. Well, we actually have a new policy forthcoming, a new regulation forthcoming on conditions of participation. There are several guidelines that are sponsored by the various medical societies, and those best practices and guideline are freely available to physicians.

The Medicare program has traditionally not prescribed a way of practicing, or at least tries not to do that, and so by identifying any particular protocol or guideline or best practice, we would be stepping way outside of where the traditional role of Medicare has been, though we can work in a consultive way with quality organizations to identify best practices and be a part of research in evidence-based methodologies and that kind of thing.

Now, our carriers do have local medical guidelines that are developed in a very consultive way or consultative way with physician groups, and there is a Carrier Advisory Committee of medical professionals who help them do that. So there is considered effort going on at the carrier level, regional level, to embrace best practices and good medical decision making.

Now, the actual issue of proscribing them and mandating them, that is a different issue than Medicare has dealt with before from a clinical, physician point of view.

Mr. STARK. It is fair to say that—I believe at this point you basically completed one ESRD demonstration, and you have 17 other demonstrations currently working. If that is all you have got, does CMS really have enough information to make a determination as to whether disease management and case management has value for Medicare beneficiaries, either in terms of quality or in cost sav-

ings to the taxpayers? Do you know enough now to make that decision?

Mr. KING-SHAW. Yes, I believe that we have enough experience to know that there is great value in disease management methodologies when done well and when done in partnership with organizations who do it well. I believe like anything else a poorly designed, poorly supported effort, be it a study or a protocol or a project, is not going to derive the kind of results that a well thought out, well financed, well put together, clinically led program is.

So, I think what we have learned is that there are some best practices in disease management that we have imported from other organizations, that we have learned in partnering with other organizations, and there are some not so best practices. So, I think that that is sound and that is credible.

As we move forward, I think the objective would be to take from demonstration to operation, to mainstream, if you will, those models, those best practices that have worked well, while not shutting the door to the ever-evolving methodologies that are being generated in the private sector, that Medicare can be a part of. So, I think we have enough information to move forward appropriately, cautiously, with the right kind of responsible decision making, but we clearly, clearly can see greater benefit from disease management than what we are seeing today.

Mr. STARK. Well, we don't have any today. Is that correct?

Mr. KING-SHAW. We have some. What I have described in the testimony are some disease management initiatives that have been launched. There are 15 of them that are being launched now as a result of BBA. There were others that preceded it in ESRD and a few other areas that have given us meaningful results. Even if we want to do it differently going forward, the results were meaningful in helping us guide that decision.

We have a number of others that are under development right now, and there actually are a number of disease management organizations that are operating within the M+C world that continue to bring good value to Medicare beneficiaries in M+C environments.

Mr. STARK. When you say "good value," do you suggest then that the M+C plans save money by using disease management?

Mr. KING-SHAW. When effective, yes. I mean, having spent some time outside of the Federal government, I can tell you that yes, when effectively done, again with all the elements that I identified in my oral comments, they clearly produce cost savings to the program, both the insurer itself and the program that they operate under, either Medicaid or Medicare or commercial. They also can do a great deal in terms of reduced costs on the part of the beneficiary, of the patient, by better managing their condition or their disease.

Just as an example, to the extent that there is any out-of-pocket cost sharing on the commercial side—I come from hospital admissions—effectively reducing hospital admissions is a cost saver to the patient's out-of-pocket expense. To the extent that there is not a prescription drug benefit in the Medicare program outside of M+C, disease management that brings prescription drug coverage,

as this new BIPA package would, or by helping people manage their diseases and manage their medications, so that they are not over utilizing or having contraindications or drug-to-drug interactions that would lead to other types of complications, there is cost saving on the part of the patient there, as well as the program overall.

So, I would say yes, most definitely, when effectively done, disease management is a cost saver to the program, to the patient, with quite, quite substantial benefits in clinical outcome, satisfaction, and performance. It has to be done well. You can't do a bad job with it and expect those kinds of results.

Mr. STARK. Thank you.

Mr. KING-SHAW. Thank you, sir.

Chairman JOHNSON. Mr. McDermott?

Mr. McDERMOTT. No questions.

Chairman JOHNSON. Mrs. Thurman? I am going to recognize him after you, but since you are on the Subcommittee.

Mrs. THURMAN. Thank you, Madam Chairman.

Mr. Shaw, I guess the problem—and I don't disagree with disease management at all. You and I know of a very good health plan that—AvMed, which is all over the State of Florida, but even in our Fifth District, we know what they have done with the congestive heart failure program, and what they have saved and what they have done.

Quite frankly, we talk about the fact that the M+C programs have had an excellent way of handling this, but all indications are, M+C programs are leaving. It would seem to me that it would be nice to think in a real true world, and everything was great, that that would happen.

My concern is that we are not seeing that happen, but it also seems to me that the M+C programs are no different than Medicare fee-for-service in many ways. They are both with doctors. They both have an insurer. From what I can gather with M+C, the insurer is the one somewhat that makes some of these decisions to and for the patient, and that drives what doctors might do.

So, why is this so hard, or why do we think this is going to be so hard to implement under fee-for-service Medicare? What are the components that we are missing in Medicare that would make this transition happen?

Mr. KING-SHAW. One of the elements of success in the fee-for-service world, where it has been successful—I am not going to represent to you that all M+C programs or all managed care programs do a great job at disease management and save a lot of money. There is, as I say, there are robust, there are all right, there are best practices, and less than best practices, but where they have been successful, wherever they have been applied, they have had some common elements.

One is an organized delivery system where you truly have a community of care, where there are a number of primary care physicians and specialists who truly have organized their efforts around the effective treatment of a disease, who know the population. They know the other Members of the community of care. There are conversations, there is information sharing, there are feedback reports that give the providers and the care givers and the patient and ev-

everybody else around that community, if you will, information about the patient's progress. The M+C organizations have that platform established, and many of them actually have networks that are especially carved out because they are effective at diabetes or hypertension or congestive heart failure.

So, in the fee-for-service world our delivery system is not so well organized. It is quite a disparate system, and so you need to have an organizer, you need to have a partnership with a disease management entity, which doesn't have to be M+C—it could be somebody else—and the patient, to assemble that community of care around the needs of the individual. It is not a given. Then to integrate data which is actually captured in many different parts of the system, to bring them together. That can be identified by diagnosis or by patient or by substance or by the DM community.

All are doable. I mean, there is technology. There are people who know how to do it. You know, there are resources to do those things. It is all doable. It is just not a ready-made platform, the way it is outside of the fee-for-service sector.

Mrs. THURMAN. In Medicare, it sounds to me like there needs to be some kind of a benefit payment structure within our Medicare fee-for-service to provide for that. Is that what we are kind of saying? I know we talked about primary care, talked about the gatekeeper. Those were kind of some of the buzz words at the time.

Is there anything in our Medicare payment services now that would allow us to do that? For example, we have struggled with the issue of whether or not we should pay for every year an exam. Right now I can't remember if Medicare—I don't think we ever offered that once-a-year exam, so that at the beginning, the person comes in at the beginning of the year, you have an opportunity—what are some benefit issues that we could be doing under Medicare fee-for-service, that would help in fact organize as you are suggesting?

If we can find out and we can put them in the right direction, we are in better shape, and then you have somebody that also can organize this to some—are we doing anything in the benefit plan to help to do that?

Mr. KING-SHAW. Excellent question. The principal piece on the benefit side is preventive care services, and that is by no coincidence a part of the President's principles for reforming and strengthening and modernizing Medicare. It is with that preventive piece, the screening piece, that you do a lot of your risk measurement up front and your monitoring that is such an important part of disease management.

So, for example, we have very specific screening tests that are covered under Medicare but they are specific. General health care screening is not included. That would be one.

Clearly, prescription drugs. When you have many of these conditions, the prescription drug cost for wellness and prevention and maintenance is an integral, important part. I think that the power, the potential power of the new round of BIPA demonstrations does include prescription drugs in the community of care, if you will. Without a prescription drug benefit on the fee-for-service side or any clinical trial as something to attach to, you have left a huge hole out there.

Then the last piece, again, is you have to have an integrator, a care manager, somebody who is truly organizing all of this on behalf of the patient-physician relationship. There we are testing methodologies that would have physicians actually empowered through primary care case management type of things and financial resources brought to bear, to enable him or her to perform that integrating function.

Mrs. THURMAN. In the M+C programs we actually provide them those incentives to do that through the payment structure and/or whatever, so—

Mr. KING-SHAW. Yes, yes.

Mrs. THURMAN. Okay. Thank you very much.

Mr. KING-SHAW. Thank you.

Chairman JOHNSON. Mr. Houghton?

Mr. HOUGHTON. Madam Chairman, first of all, thank you very much for letting an alumnus come back to this Subcommittee, an outsider, and I really applaud you for having this hearing. It is just under so many things that we need to talk about and discuss.

Mr. King-Shaw, thank you so much. We are honored to have you here, and you are doing just a wonderful job. I would like to ask you a question. You mentioned in your testimony the disease management for lung cancer, and I know Dr. Henschke is going to be talking about this a little later, but in terms of just the human part here, cancer, lung cancer kills so many people and is often so expensive to treat, particularly in the final stages. How can your agency really take steps to help those patients get good care, but care that won't break the bank? That is really the only question I have.

Mr. KING-SHAW. Well, again I would say it begins with the screening piece. I am familiar with some of the work being done up at my alma mater, Cornell University, around this area, and in fact the kind of screening, that computerized tomography (CT) scanner screening for lung cancer, is a proven, effective way of risk assessment which is a part of the overall package. So not having the ability to do that for lung cancer specifically is an issue, and so we would look to be able to do a better job at screening as a part of disease management, in order to be more successful at it. That is one.

I would also say that as we partner with community-based organizations, again, one of my comments was, partnering with academic medical institutions, community-based care providers and those types of things, there are folks out there who know very well how to manage and treat this condition. It is expensive, and so when we talk about making things less so or moving the care earlier in the development of the condition, so that your interventions can be more effective and the downstream costs can be minimized, but there is a certain amount of financial commitment that, you are going to have to make to effectively manage or treat lung cancer patients.

So, I think the short answer is, we would partner with those folks who know how to do this, again until we can build more infrastructure inside. We would have to look at our ability to provide some of the important screening up front, the capabilities, and you

know there is the case that, as I said, Medicare law does not specifically allow us to do this.

There is always the opportunity to look at our overall benefit structure it and modify it, in this case for lung cancer but I would suggest for many other conditions as well, through the national coverage decision process. Where we have a need to look at technology or methodologies and go through evidence-based review of its potential to contribute to life and wellness in the Medicare program, we have a mechanism to do that. We need to have a law that says it is covered, first, but once we have that, there is a process that we have already established that can help us bring to the Medicare program technologies and strategies such as this one, for lung cancer patients or for anybody else.

Mr. HOUGHTON. Just to follow up on that just a bit, since it is not quite a third but almost a third of all the cancer deaths really are from lung cancer, this is such an important area, break down a little bit what you mean by partnering.

Mr. KING-SHAW. Well, for example, if we were to do a provider sponsored, in this case demonstration for disease management around lung cancer, one of the places I would look to is Cornell, who is doing this. There are other types of academic or provider organizations that are doing this.

So to partner, it would mean bringing them in as either a care manager, or we would develop a patient population we would place under their management. They would develop a proposal that would look at what resources they would have to bring, educators, care managers, and so forth; a system for providing some of the related care needs of lung cancer patients.

We would work out a financial mechanism, whether that would be a case rate or a capitation, or that would be some type of bundled rate or fee-for-service or some administrative reimbursement that covers the cost of integrating these things. There is no risk involved. There are many different financial relationships you can build.

Mr. HOUGHTON. These are things that could be done, not are being done now. Is that right?

Mr. KING-SHAW. Yes, that is correct. These are things that could be done. We are doing them, applying those technologies, those methods, to things other than lung cancer. A lot of what I have talked about in diabetes or hypertension and congestive heart failure are those very same types of applications. We are not doing it currently for lung cancer. We could.

Mr. HOUGHTON. Thank you. Thank you, Madam Chairman.

Mr. KING-SHAW. Well, thank you.

Chairman JOHNSON. Thank you, Mr. King-Shaw. I just did want to ask one final question. I know you have got a proposal out there for a number of disease management demonstration projects. I wondered if you could just give us a quick run-down of how many Medicare beneficiaries you are going to target for each demonstration, whether they will be distributed across the regions of the country, across minority populations, urban/rural, and what incentive will there be for physicians to participate?

Mr. KING-SHAW. I can maybe give you some sense by picking a few at a time. The PPO demonstrations, we anticipate there

being 12 geographic markets spread throughout the country, because every market has a different nuance. Twelve geographic areas, twelve markets should give us, I think, a well-rounded comprehensive, and we would look at large and small towns and big cities. There are some rural methodologies out there that people would want to bring, so I would hope to have some rural participation as well in those 12.

A number of the, it is the BBA, what is currently the 15 demonstrations, have been everywhere from—we have some in Virginia, you have some in the Midwest and in New England, you have got those down—we understand that there is about, I think, 6,700 Medicare beneficiaries that we would anticipate being a part of those.

Under the new BIPA ones, there is a cap of 30,000 beneficiaries. I can get you all of this information in writing with a much more detailed spreadsheet that would give you the number of lives and markets and locations once the contracts are awarded, sometime after July.

In the testimony, if you don't have it, I can provide it, too, there is a grid that gives you the geographic location and the disease class of the current 15 BBA demonstrations. I can also give you some more of the history of the lives that were involved in some of the past demonstrations.

[The information follows:]

Medicare Coordinated Care Demonstration

Project Site	Rural/ Urban	Beneficiary Location	Pro- jected Benefi- ciaries To Be Served	Targeted Diseases
Avera McKennan Hospital Sioux Falls, SD	Rural	SD, IA, MN	634	Congestive heart fail- ure and related car- diac diseases
Carle Foundation Hospital Urbana, IL	Rural	Eastern IL	1,518	Various chronic condi- tions
CenVaNet Rich- mond, VA	Urban	Richmond	614	Various chronic condi- tions
CorSolutions, Med- ical, Inc. Buffalo Grove, IL	Urban	Houston	1,963	High-risk congestive heart failure
Erickson Retire- ment Commu- nities Baltimore, MD	Urban	Baltimore County, MD	396	Various chronic condi- tions
Georgetown U. Medical Center Washington, DC	Urban	DC, MD suburbs	1,025	Congestive heart fail- ure

Medicare Coordinated Care Demonstration—Continued

Project Site	Rural/ Urban	Beneficiary Location	Pro- jected Bene- ficiaries To Be Served	Targeted Diseases
Health Quality Partners Plumsteadville, PA	Both	Eastern PA	1,070	Various chronic conditions
Hospice of the Valley Phoenix, AZ	Urban	Maricopa County, AZ	1,092	Various chronic conditions [Note: Demo not limited to end-of-life care]
Jewish Home and Hospital New York, NY	Urban	New York City	365	Various chronic conditions
Mercy Medical Center Mason City, IA	Rural	Northern IA	607	Various chronic conditions
Medical Care Developments Augusta, ME	Rural	ME	1,218	Congestive heart failure or post-acute myocardial infarction
Quality Oncology, Inc. McLean, VA	Urban	Broward County, FL	1,426	Cancer
QMED, Inc. Lawrence Harbor, NJ	Urban	Northern CA	571	Coronary artery disease
University of Maryland Baltimore, MD	Urban	Baltimore, MD	339	Congestive heart failure
Washington University St. Louis, MO/StatusOne Health Hopkinton, MA	Urban	St. Louis, MO	5,422	Various chronic conditions

Chairman JOHNSON. Well, thank you very much. You did mention in response to my colleague from Florida's comment, that under the fee-for-service system there would have to be some compensation for this management capability that the managed care systems are able to provide. I assume in your demonstration project, you will get a better handle on what it will require for physicians to add the extra time it takes to spend on patient education and to coordinate care, or a non-physician assistant. So, I think those costs that are currently being absorbed by the Choice plans will be isolated in these demos and will get a better handle on that.

Mr. KING-SHAW. Yes. In fact, in some of these demos there is an administrative fee which is a part of the demonstration to the best of our understanding right now to cover those costs. You are absolutely correct, as these demonstrations unfold, we will get a much better handle of what the financial resources that are re-

quired on the part of physicians and other clinicians to be effective disease managers. We can then build a model that would incorporate that.

Mr. MCDERMOTT. Madam Chairman, may I ask a question?

Chairman JOHNSON. Yes.

Mr. MCDERMOTT. We had sporadic reports recently in Seattle of patients having difficulty finding physicians who would take payment for Medicare. What I am interested in understanding is, do you think that in the face of our attempt to cut reimbursement in this session of the Congress that we can expect that there will in fact be more patients who have access to the kind of health care you are trying to deliver? Do you think you are going to get more doctors involved in that kind of chronic management if we cut our rates by 5¼ percent?

Mr. KING-SHAW. Well, I mean, the sustainable growth rate that Congress gives us to work with resulted in those negative updates, the physician fee schedule that you are referring to. Absent a change in that formula or corrective action then that's what we have to live with. So, I think that we need to recognize that there is a threat to the integrity of a provider network in Medicare with the financing and the financial pressures under—on top of the system right now. So, should we be concerned about that threat? Yes. One of the things that we are doing at CMS through our 10 regional offices and out of the outreach, is we are seeking to obtain very quantifiable specific data about participation rates in Medicare, either as a result of the current numbers or as anticipation of more oblique numbers going forward. As we collect that very specific about those who are just saying they are going to leave, but actually leave, actually disenroll, we can provide that information to leadership for consideration.

Beyond just looking at the number of physicians who leave Medicare or not is the important question of is there a restriction of panels? Do you see physicians reserving less and less time in their weekly schedules for Medicare patients? Are they closing their practices to any additional Medicare patients? The conversation seems to have remained at, are we going to lose doctors through Medicare? Perhaps we may not lose a doctor through Medicare—from Medicare. We may have that very same physician restrict the ability of Medicare patients to get their attention, and that is as much of a concern to us.

Is that a threat? Absolutely. Are we going to try to articulate that in clearer objective ways? Absolutely.

Mr. MCDERMOTT. What is the administration's proposal to deal with the 5.4-percent reduction?

Mr. KING-SHAW. Work with Congress to figure it out.

Mr. MCDERMOTT. Thank you for that clarifying answer.

[Laughter.]

Mr. MCDERMOTT. Thank you, Madam Chairman.

Chairman JOHNSON. Thank you very much for your testimony. I did discuss before the hearing started, the things that the Virginia hospitals are doing, and I will look forward to hearing from you as to how that fits in, and the other reports that are coming out now, the one from Ernst & Young and Cap Gemini on disease management and fee-for-service beneficiaries. So, we look forward

to working with you on these issues in the months to come, and hopefully making some significant progress. Thank you very much for your testimony this morning.

Mr. KING-SHAW. Thank you, Madam Chair.

Chairman JOHNSON. I would invite the final panel up, Dr. John Wennberg, the Director of the Center for Evaluative Clinical Sciences, Dartmouth University; Mike Hillman, Dr. Hillman, the Medical Director of the Business and Community Health, Marshfield Clinic, Marshfield, Wisconsin; Dr. Claudia Henschke, Professor of Radiology, Director of the Division of Chest Imaging, and Director of the Division of Health Policy and Technology Assessment at Cornell University; Dr. Gerard Anderson, Professor of Health Policy and Management, International Health, Johns Hopkins University; and Dr. Jonathan Lord, Senior Vice President and Chief Clinical Strategy and Innovation Officer of Humana.

We welcome you all to this important hearing and look forward to your comments. We will move right through. We have that roughly 5-minute rule, and then we will follow that by questions.

Dr. Wennberg, welcome.

**STATEMENT OF JOHN E. WENNBURG, M.D., M.P.H., DIRECTOR,
CENTER FOR THE EVALUATIVE CLINICAL SCIENCES, DART-
MOUTH COLLEGE, HANOVER, NEW HAMPSHIRE**

Dr. WENNBURG. Thank you, Chairman Johnson, Congressman Stark. I am glad to be here today. I have been asked to comment on geographic variations in traditional Medicare and their implications for the design of chronic disease management programs.

In my written testimony, I document extensive unwarranted regional variations in the patterns of practice. The amount of care patients receive depends as much on where they live as it does on the disease they have.

First, there is extensive under use of effective care. That is, care that works and all patients should get. Second, there is extensive misuse of discretionary care such as elective surgery, care that should depend on what patients want, but seems to depend too much on what providers prescribe. Third, there is extensive over use of physician visits, testing, imaging, hospitalizations, and stays in intensive care. The frequency of use in a given region has to basis in medical science and is determined by the supply of resources rather than medical need.

Finally, Medicare spending varies extensively. In 1996, per capita spending in Miami was nearly 2½ times that of Minneapolis, but greater spending does not buy higher quality-of-care. These regions score equally poorly on such measures of quality as the percent of diabetics who get needed eye exams or heart patients who get needed drugs. Greater spending is not associated with greater rates of elective surgery. Rates are about the same in high-cost regions such as Orange County, California, as in low-cost regions such as Portland, Oregon.

What then does greater spending buy? It buys more visits, more tests, more stays in hospitals, and more stays in intensive care. In some regions Medicare enrollees average more than 20 visits to medical specialists during the last 6 months of their lives. In other regions the average is less than three. In some regions nearly 30

percent of Medicare deaths occur in ICUs; in others, fewer than 7 percent do. This all adds up to a lot of money. If the pattern of conservative practice observed in regions with low spending were the norm for the Nation, we have estimated a savings of over \$40 billion in 1996. The implications seem quite clear. If disease management programs in traditional Medicare are to have system-wide impact on overall quality and costs, they will need to provide remedy for each category of unwarranted variation.

The causes and remedies for variation are different according to the category. Disease management programs organized by health maintenance organizations (HMOs) have been quite successful in reducing under service of such things as diabetic eye exams and beta blockers. They should well work in traditional Medicare, particularly if the claims data can be mobilized and patient registries can be mobilized to assist in that process. Variations in discretionary surgery and other preference sensitive treatments pose a greater problem. In some regions virtually no patients with breast cancer receive a lumpectomy, while another region's almost have to. Such variation occurs because patients aren't involved in a meaningful way in the choice of treatment. Patients need to understand their options.

A basic problem is that Medicare fee structure rewards procedures, not counseling. Disease management demonstration projects should be given flexibility to deal with these flaws that perversely interfere with informed patient choice.

The principal cause of geographic variation in visits, testing, and hospitalizations of the chronically ill is variations in the supply of resources relative to the size of the population served. More physicians means more frequent visits. More hospital beds means more hospitalizations. Greater use of care means more Medicare spending. We interpret these patterns as evidence for inefficiency in the use of resources, not health care rationing. Medical science provides no guidelines regarding appropriate use and studies conducted at the population level show no gains in life expectancy associated with a twofold variation in spending across the United States for Medicare. For these reasons, we believe there is widespread overuse of such services.

Dealing with the overuse of what we call supply sensitive services poses a great challenge. The problem is finding the appropriate level of resources. Only staff model HMOs have dealt effectively with this problem. Staff model HMOs practice what Alan Enthoven has called "private sector health planning." That is, they regulate the capacity of their organizations. Since their benchmarks for resource inputs are consistently lower than the prevailing rates in their regions, the cost of their care has been correspondingly lower than fee-for-service medicine. For the Nation to achieve such efficiency, health care organizations serving fee-for-service populations would need to become accountable for their own capacity.

While the task of comprehensive reform of the management of chronic disease is formidable, we need to get on with it. I applaud the Subcommittee's willingness to address the complexity of this task. I applaud the efforts by CMS to invite chronic disease management companies to undertake demonstration projects in fee-for-service Medicare. We need to learn how well the network model

can improve the quality-of-care in each category of service, but the complexity of the task warrants additional demonstration projects carried out by provider organizations serving traditional Medicare populations. In my written testimony, my colleagues and I have recommended that such a demonstration project be undertaken.

I want to thank you for the opportunity to testify, and also to thank you personally for the kind comment that you made on our paper in health affairs.

[The prepared statement of Dr. Wennberg follows:]

Statement of John E. Wennberg, M.D., M.P.H., Director, Center for the Evaluative Clinical Sciences, Dartmouth College, Hanover, New Hampshire

My name is John Wennberg. I am a member of the faculty of Dartmouth Medical School. I have been asked to comment on variations in Medicare spending and quality, and on the implications of these variations for the design of chronic disease management programs. It is now well known that spending for traditional, fee-for-service, Medicare varies extensively. For example, in 1996, age, sex and race adjusted spending for non-HMO Medicare services in the Miami hospital referral region was nearly two and a half times higher than in the Minneapolis hospital referral region. In a recent *Health Affairs* article (attached), my colleagues and I described some of the variations in quality of care among hospital referral regions, as well as the association between quality and spending. We looked at three categories of medical services: "effective care," "preference-sensitive care" and "supply-sensitive care."

It is important to make distinctions among effective care, preference-sensitive care and supply-sensitive care because the causes of the variation and the remedies are different for each category. Moreover, variation in per capita Medicare spending is associated with only one of these categories—supply-sensitive care. If disease management programs are to have an important impact on the overall quality and cost of care for the chronically ill, the programs will have to address variations in each category.

I will summarize very briefly what we mean by the terms effective, preference-sensitive, and supply-sensitive care. Each of these categories of care raises a different challenge to the design and implementation of disease management programs.

Effective care is evidence-based care—care that we know works and we know all eligible patients should get. Our studies show *extensive underuse of effective care* among fee-for-service Medicare enrollees in virtually every part of the country. For example, in some regions of the United States, less than 20% of post-heart attack patients who were classified as "ideal" candidates for a particular medication actually received the medication. There are similar patterns of underuse of effective treatments for Medicare enrollees with diabetes, and evidence that there is poor compliance with guidelines for cancer screening and immunizations. The principal cause of variation in the delivery of effective care is a lack of infrastructure—systems that make sure that appropriate care is provided in a timely way.

Correcting the underuse of effective care will demand improvement in the infrastructure of the everyday practice of medicine. Staff model HMOs provide exemplary models of how this can be done and a number of network HMOs (and their disease management company subcontractors) have had success in promoting provider compliance. Health insurance claims provide the information databases that can identify patients who need services, so that both patients and providers can be reminded to seek and administer appropriate care in a timely way. The processes of care can be monitored with these claims databases, at the level of individual practitioners or physician groups. We have shown that this monitoring is possible using the Medicare claims data; and many health systems already have the information available, but have not put it to use.

Underuse of effective care can be reduced by collecting and monitoring the processes of care at the hospital and physician group levels. Medicare claims data can serve as the basis for establishing disease management registries to identify patients in need and document health care quality. Medicare claims should be made available in "real time" for

use in disease management demonstration projects in traditional Medicare.

Preference-sensitive care pertains to conditions where at least two valid treatment strategies are available, each with its own risks and benefits. Since the choice of treatment involves tradeoffs that ought to depend on patients' preferences—such as the choice between surgical or pharmaceutical treatment—the patient's choice of treatment should determine what is done. There are wide variations in the use of discretionary surgery and other preference-sensitive treatments. For example, the rates of lumpectomy for breast cancer and prostatectomy for prostate cancer vary by a factor of five among hospital referral regions in the United States. In some cases, the principal cause of variation is that there is substantial uncertainty about the risks and benefits of the treatment options because there have been no clinical trials to determine the facts. The fundamental problem, however, is the failure to involve the patient *in a meaningful way* in the choice of treatment. Decisions should belong to the patient, but provider opinion tends to dominate. For this reason, we believe there is **widespread misuse of preference-sensitive care**.

Dealing with the misuse of preference-sensitive care requires that patients become actively involved in the choice of treatment in those clinical situations where options exist. Shared decision making or “informed patient choice” is gaining recognition as the remedy for unwarranted variations in this category, but implementation is just beginning. Staff model HMOs and a few IPA HMOs provide examples of implementation, but the results are spotty. A basic problem facing IPA and traditional Medicare is that the fee structure doesn't reward providers who implement shared decision making; in other words, reimbursements reward activity, rather than careful consideration of all the options. The most important goal of this effort should be to make sure that people with chronic illnesses know what the options are (including costs, risks, and benefits). The current system does not reward or encourage physicians to engage in this effort. It should, because it is the right thing to do. It could also save money. Several studies have shown that informed patients tend to want less surgery than surgeons are inclined to recommend under the current system of rewarding procedures rather than counseling.

Misuse of discretionary surgery and other forms of preference-sensitive care can be reduced by actively involving patients in the choice of care. We must make sure that chronically ill patients understand their options and are aware of the benefits and risks of treatment. Disease management demonstration projects should be given flexibility to deal with the current flaws in the traditional Medicare fee structure that perversely interfere with informed patient choice.

Supply-sensitive services are those in which the frequency of use is not determined by well-articulated medical theory, much less by scientific evidence. Supply-sensitive services include physician visits, diagnostic tests, hospitalizations, and admissions to intensive care among patients with chronic illnesses. The variations are particularly striking among the most seriously ill Medicare enrollees. In some regions, Medicare enrollees average more than 20 visits to medical specialists during the last six months of their lives; in other regions, the average number of such visits is fewer than three. In some regions, nearly 30% of Medicare deaths occur in ICUs; in other regions, fewer than 7% do.

The principal cause of variation in utilization of services is the regional and local variation in resources. More hospital beds per capita mean more hospitalizations per capita among those who have chronic diseases such as congestive heart failure, diabetes and chronic pulmonary disease. More cardiologists per capita mean more visits with cardiologists per person with heart disease. Yet there is little medical theory—and no evidence—about the appropriate frequency of such services—that is, what rate of physician visits, for example, results in the best health outcomes. Moreover, studies conducted at the population level have demonstrated that there are no gains in life expectancy associated with higher frequency of intervention. For these reasons, we believe there is **widespread overuse of supply-sensitive services**.

Dealing with the overuse of supply-sensitive services poses the greatest challenge to the implementation of a comprehensive program in disease management. Most of the care given to patients with chronic disease belongs in this category. Those who live in areas with more resources are likely to have more visits with doctors, more tests, and more admissions to hospitals and to intensive care, particularly at the end of life. This is the category of care that “explains” higher per capita spending, but it is not associated with better quality of care or extension of life expectancy. Medicare enrollees living in regions where per capita spending is higher than average don't receive more effective care—and the differences in spending are also

not explained by higher rates of major (non-elective) surgery. (See Exhibit 2 in the attached article.)

The role of supply-sensitive services in both spending and outcomes has received little attention from academic researchers. The topic barely makes it onto the research agenda, and there are few studies that could provide a basis for constructing guidelines that might tell us how many physicians are actually needed in a given region, what rate of visits to physicians results in the best outcomes for those with chronic diseases, or whether the use of expensive diagnostic technology actually improves accurate diagnosis, health, or survival. Recent research on the redesign of clinical practice to introduce group visits and open appointment schedules is encouraging because it breaks the cycle of supplier-induced demand and could serve as the basis for redesign of chronic disease management.

Except for staff-model HMOs, insurers and providers have not responded to the challenge of determining what works and how much is enough. Much of the intellectual leadership in the research on redesign of clinical practice comes from these organizations, which are able to control their own per capita resources (eg. doctors hired, hospital beds constructed or contracted for, patterns of practice). But the efficiency of staff-model HMOs in the use of supply-sensitive care is probably more a byproduct of a corporate strategy of remaining competitive with fee-for-service medicine than a conscious attempt to manage chronic disease. As Alain Enthoven has pointed out, such HMOs practice "private sector health planning." That is, they regulate the capacity of their organizations. Since the staff-model HMO standards for resources are consistently lower than the prevailing rates of resources in the regions where they compete, the cost of HMO care has been correspondingly lower than the cost of fee-for-service medicine. For the nation to achieve HMO-like reductions in spending, health care organizations would need to become accountable for capacity. This is a formidable task and one that in the absence of reform of payment systems is probably impossible.

Addressing the overuse of supply-sensitive care is made even more challenging by the cultural assumption that more health care is better. There might be hope in the growing public awareness that for many patients with advanced chronic illness, high-technology interventions such as admissions to intensive care are both futile and unpleasant, degrading the quality of life in its closing months and years. The chronic disease management movement might find natural allies among the growing numbers of Americans who are trying to reform of end of life care.

Reducing the overuse of hospitals, intensive care, physician visits and testing among chronically ill Americans should be a national priority. This must be done if we want to reduce unwarranted Medicare spending and improve health care quality. Disease management programs must address this priority. However, the scientific basis for defining optimal care is weak and, with the exception of staff model HMOs, the tools available for dealing with the causes of variation are also weak. Demonstration projects are needed to establish benchmarks for effective clinical practice for supply-sensitive care and to identify "best practice" models for efficient care.

While the task of comprehensive reform of the management of chronic disease is a formidable challenge, we have a moral obligation to take it on. I applaud the committee's willingness to address the complexity of the task and confront the difficulty of finding workable solutions. Progress often begins with debate, which I hope these hearings will spark. I also applaud the efforts by CMS to invite chronic disease management companies to implement experimental chronic disease management in fee-for-service Medicare. We need to learn how well the IPA model can improve the quality of care in each category of service. The complexity of the task, however, warrants additional demonstration projects, and some should be carried out by provider organizations serving traditional Medicare populations. In our Health Affairs article, my colleagues and I recommend a demonstration project that could prove that the federal government and responsible health care organizations can establish a partnership to fruitfully address each category of unwarranted variation. The results could, I believe, improve the quality and efficiency of services provided for all fee-for-service Medicare beneficiaries. And it is only the first step in improving the quality of care for all chronically ill Americans while we demonstrate that doing medicine right does not mean doing it the most expensive way.

Chairman JOHNSON. Thank you. Dr. Lord.

STATEMENT OF JONATHAN T. LORD, M.D., CHIEF CLINICAL STRATEGY AND INNOVATION OFFICER, HUMANA INC., LOUISVILLE, KENTUCKY, AND PRESIDENT, DISEASE MANAGEMENT ASSOCIATION OF AMERICA

Dr. LORD. Good afternoon. My name is Jack Lord, and I am the Chief Innovation Officer for Humana. I am also the President of Disease Management Association of America.

Health benefits companies like Humana have turned toward disease management programs to help Members get appropriate and effective care. Humana, like many other health plans, has changed its approach to medical management after years of understanding that the real needs that people have is to have supported self management. That approach emphasizes Members' control of their own care and help to make better decisions.

Dr. Wennberg and I have collaborated for the last decade at the American Hospital Association and an organization called Health Dialog to produce tools that help people make better decisions.

Disease management programs also provide for personalized support for the people who are sick so they can get more effective care, and certainly self-care opportunities for the well. The availability of technology, e-health and the Web make those systems far more effective.

Disease management was evolved to help deal with some of the symptoms of a systemless world. Fragmentation, variation, lack of adherence to clinically proven practices, lack of patient involvement and the absence of predictive tools, where we had to rely on data from our rear view mirror as opposed to looking forward, characterized the way health care has been practiced in this country in many regions.

Disease management does support self management of individuals, focuses on what Dr. Wennberg calls effective care, uses evidence-based treatment protocols to provide information to both patients and practitioners, emphasizes the coordination of care, and uses advanced sciences to help track patients and look at outcomes. That science could be used to help predict future needs of people.

The impacts of disease management programs include better care planning, both at the individual level as well as at a population level, healthier behaviors on the parts of individuals and their families, better clinical outcomes, physical function and quality of life, better access in care coordination, and ultimately lower cost, reduced hospitalizations, surgery and invasive procedures.

Research shows that disease management is effective. Humana has been an industry leader in this effort, and we have put our effort and resource behind that. Whether it is in specialized diabetic care for Hispanics in San Antonio or in the under served areas of this country in terms of rural health care, we have seen results. Diabetes programs show that patients who are managed through disease management programs have increased frequency of hemoglobin A1c testing, foot exams, eye exams, and cholesterol exams, and demonstrate reduced hospitalization. Congestive heart failure programs show significant reductions in inpatient stays, admissions, emergency room visits, as well as the reduction of disease-specific claims and co-morbidities. These are outlined in our written testimony.

Humana's own experience reflects the research. Congestive heart failure, 90 percent of patients show improvements or stabilization of their disease, and a 60-percent reduction in hospitalization. Coronary artery disease patients show significant reductions in cholesterol levels, and patients who have chronic renal disease show greater percentages achieving dialysis targets when people are in disease management programs than outside of those programs.

The bottom line is, what is right for patients and what is right for you and me? People are more engaged in their own care. They get effective care. That is, care that has been proven to be right. They avoid unnecessary or harmful care, and they have an opportunity to have improved compliance both in their drug regimens as well as the medical regimens that are prescribed by their physicians. The net result is improvement in self-reported health and real functional status for individuals.

We have outlined some stories in the written testimony, stories that reflect our sensitivity around the privacy of our Members, but also give you a glimpse of the kinds of care and the kinds of outcomes that are achievable.

One quick example. Mrs. V. We have an example here of a patient who had successful behavior modification when enrolled in a disease management program for congestive heart failure.

The key to success is targeting the right patients and being sure they are connected to the right care. The M+C programs have had advantages because of the data and the integration of services. We can use claims to target that information, and we can use outreach programs like our Personal Nurse program, where we provide essentially a concierge for those people who have complex significant chronic disease.

The bottom line to all of this is disease management has demonstrated advantages for the chronically ill Medicare beneficiary. Most M+C programs have offered some form of disease management programs, and those efforts should be continued. There is a tremendous opportunity to extend disease management programs beyond the M+C program to a fee-for-service program, and have an impact on getting the right care to people and lowering the cost of the care that is provided to Medicare beneficiaries across the country.

Thank you, Madam Chair.

[The prepared statement of Dr. Lord follows:]

Statement of Jonathan T. Lord, M.D., Chief Clinical Strategy and Innovation Officer, Humana Inc., Louisville, Kentucky, and President, Disease Management Association of America

Good Afternoon. My name is Jack Lord, and I am Chief Clinical Strategy and Innovation Officer for Humana Inc., one of the nation's largest health benefits companies. Humana provides health benefits to nearly 6 million commercial, military, and Medicare beneficiaries. I have also spent time as Director of Quality for the Naval Medical Command, Executive Vice-President for a large health system in Maryland, as Chief Operating Officer of the American Hospital Association, and as President of Health Dialog, a company providing tools and services to enhance consumer medical decision making. Additionally, I am president of the Disease Management Association of America. I am pleased to be here to tell you about how health benefits companies like Humana have turned to disease management programs to help our members—especially those members most in need of care—to obtain appropriate and effective care.

Over the past six or seven years, the offering of health benefits has significantly changed to address what consumers want. Many of those changes are already bearing fruit. So not only do we have a great chance to exceed the expectations of our customers—they couldn't be lower—but by the time everybody becomes aware of the great changes that have taken place in our business practices, we will already have results to prove that the new approaches work—not just for us and for employers but for patients, too. I'm happy to be here to share some of these results and, more importantly, some of these success stories, with you today.

First, I'd like to tell you a little bit about how health plans have begun to focus on disease management as a core strategy for addressing medical management. Then, I'll share with you some information about disease management programs—what they are, how effective they are, and what we do at Humana, as a health plan, to better target, recruit, and triage our members, and to provide better continuity and integration of care. Finally, I'd like to talk a little bit about how disease management can be extended to all Medicare beneficiaries, and note some practical obstacles that may stand in the way.

New Approaches to Medical Management

Consumers in the market place have made health plans to look in the mirror and rethink how they approach medical management. Humana, like many other plans, has made extensive changes in its approach. We are trying to focus our effort on providing personalized support to the sick so they can get appropriate care and provide opportunity for the healthy to manage their own health with the help of advanced information technology. We take seriously our relationship with our members and our responsibility to help them get more control and make better decisions about their health and their care.

Our data show that a relatively small percentage of members consume the health care services that account for 90 percent of health care costs each year. Medicare knows this phenomenon well. In the Medicare population these tend to be very sick people with chronic conditions that require ongoing attention if they are not going to enter a cycle of costly acute episodes, or beneficiaries at the end of their lives.

Think, for a moment, about the people you know with serious chronic diseases—people with diabetes, heart disease, or kidney disease. These people need to receive routine care for their conditions, adhere to treatment protocols, comply with medication regimens. And if they do, their conditions can be maintained and their health functioning significantly improved. For many of the most common and costly conditions, programs have been developed to operationalize the clinical knowledge that will keep these chronically ill people feeling relatively healthy, keep them out of the hospital and reduce their health care needs and costs.

These sorts of programs are increasingly prevalent in health plans. A survey last year by the American Association of Health Plans found that the average plan had at least five disease management programs, usually focusing on diabetes, coronary artery disease, congestive heart failure, asthma, high risk pregnancy, and depression.

What is disease management?

Disease management provides disciplined, evidence-based, expert-approved support for individuals with chronic conditions to help them become more aware of their condition and of their treatment choices, to change their behavior to reduce their health risk, and to bridge their relationships with their physicians. They do this by educating the patient and encouraging adherence to a personalized treatment plan based on the body of clinical expertise we call "evidence-based medicine."

Disease management evolved over the last twenty years out of the recognition that our health care system does not behave like a system at all. DM is an approach to patient care that is designed to compensate for the fragmentation in service delivery, the unwanted variation in care, the lack of adherence to clinically proven practices, the lack of adequate patient education and decision support, and the inadequate involvement of patients in making decisions about their care.

Disease management is a multi-disciplinary set of services that generally involves identifying the population at risk and eligible for disease management services, and matching interventions with need; educating patients for self-management, including primary prevention, behavior modification, and support for compliance with the treatment plan; ongoing, structured assessment and the use of evidence-based practice guidelines to establish personalized treatment goals and to standardize treatment plans; ongoing communication with the patient and her family, with routine reporting and feedback to her physicians and support-service providers; measuring, evaluating, and managing outcomes; and periodic reassessment and feedback to cap-

ture problems as early as possible and to make adjustments to treatment goals and care plans before the problems become more severe.

For many patients the need for health care is ongoing and the required patient effort is significant. Intensifying the support provided to those patients and their practitioners can improve the process and outcomes of care. Disease management supports the patient's self-management and uses evidence-based treatment information as a basis for coaching the patient and providing timely information to the practitioner. Since most physicians practice alone or in small, single-specialty groups without an infrastructure or team to support the systematic management of patients with chronic disease, DM programs emphasize the coordination of services between the treating physician and nurse case managers, educators, pharmacists and other health care professionals. Because of the need for daily monitoring of measures of health or adequacy of medication, such as blood sugar in diabetes or body weight in congestive heart failure, patients with chronic illness need to take an active role in the management of their disease. Advanced information technology is frequently used to monitor patients, such as Interactive Voice Response (IVR) systems that allow patients to make daily reports of their vital signs and symptoms using a touch-tone telephone, facilitating regular reporting of process and outcome indicators.

By maximizing patient adherence to prescribed treatments and to health-promoting behaviors, patients with chronic diseases should experience better clinical outcomes, better functional capacity and quality of life, better access to care, better coordinated care, and lower health care costs through a reduction in hospitalization, surgery or other invasive care.

Effectiveness of Disease Management

So what does the research say? How effective are these programs?

A study of a diabetes program implemented in several plans concluded that the program generated substantial cost savings and resulted in substantial improvement in all clinical measures. According to the study, "members were more likely to receive HbA1c tests, foot exams, eye exams, and cholesterol screenings while enrolled in the program . . . [and h]ospital utilization decreased dramatically for each plan's diabetic population."¹ Another study that followed a group of patients with congestive heart failure showed significant improvements a year after enrollment, including a 48 percent reduction in inpatient (acute) days, a 36 percent reduction in inpatient admissions, a 31 percent decrease in ER visits, and a 20 percent decline of average length of stay, yielding an average reduction in disease-specific claims of 54 percent and total claims of 42 percent.² Health status improved, too—surveys revealed a 16 percent improvement in functional status and quality of life, as reported by patients themselves.

Our own experience mirrors these results. We have found significant savings related to the investment in time and support to help the sickest of our members. But more importantly, we have seen significantly improved health results for the members. Ninety percent of participants in our CHF program show stabilized or improved disease status, with a 60 percent reduction in hospitalization. Participants in our coronary artery disease program show improved cholesterol control. And a recently published study of our End Stage Renal Disease program, comparing its results against the U.S. Renal Data System, a national registry of 300,000 ESRD patients coordinated by CMS, found significantly higher percentages of Humana members met their dialysis adequacy targets than the national average. Hospital bed days were 45 percent lower than the USRD average and ER visits dropped 75 percent over the two year study period. Mortality for the Humana population was 80 percent of the expected mortality compared to the USRD standard.

Of course, financial results tell only a small part of the tale. The financial results improve because patients become more engaged in managing their own health care, take better care of themselves, get care that experts say they should be getting, avoid care that does them little good, improve their compliance with drug regimens, and generally experience improved health and functional status. Let me tell you a few of these stories.

Mrs. V. is an obese diabetic female enrolled in the CHF program. At the time of admission, she exhibited moderate fatigue and shortness of breath with exertion. Her treatment plan focused on weight control, exercise, and maintenance of a low-sodium diet. Mrs. V. eventually came to exercise four times a day at 45 minutes

¹Robert J. Rubin et al., *Clinical and Economic Impact of Implementing a Comprehensive Diabetes Management Program in Managed Care*, 83 *J. Clin. Endocrinol. and Metab.* 2635, 2640 (1998) (Attachment B).

²Am Heart J 1999;138: 633–40.

per day, moderated her salt intake, and lost 60 lbs. She is very satisfied with the program and looks forward to the regularly scheduled calls. Mrs. B is a woman with coronary artery disease enrolled after an angioplasty. She required consistent reinforcement with routine exercise and stress management. At enrollment, she couldn't walk a one block without complaining of fatigue, but after one month she is able to walk a mile without fatigue, feels less stress and is more motivated to manage her health.

One of the keys to a successful program is targeting the interventions to the right patients so that services are matched to needs. At Humana, we use our extensive claims information, including daily feeds of pharmacy data, to identify and link members with relevant information and services. To improve enrollment in our DM programs, we used pharmacy and claims data to identify those members who were likely to have a diagnosis of a chronic disease for which we had an established disease management program. We were then able to compare program enrollment with disease incidence so we could improve the targeting of our efforts to recruit people into the programs. We subsequently broadened our eligibility criteria and initiated new procedures for the identification and recruitment of individuals who would most benefit from DM services.

In addition, Humana has implemented a "Personal Nurse" program that reaches out to members during acute episodes of illness. The personal nurse provides pre- and post-hospital care coordination, coaching and navigational support to help members make their treatment choices, referral into appropriate disease management programs, consultations with a pharmacist for drug-related issues, and access to interactive, on-line personal health tools.

In this regard, the Medicare+Choice plans have capabilities that Medicare simply does not have. We have procedures that enable us to identify members as soon as they enter a hospital, which, in Humana's case, triggers an outbound contact from a Personal Nurse who can assess the member's suitability for a disease management program and recruit the member directly into an appropriate program. In addition, the freshness of our pharmacy reports provide a rich source of information about the member's condition, compliance, complications, and comorbidities, which we can use to identify members for intervention, track guideline compliance, and enable our pharmacy consultants to evaluate possible drug treatment problems.

Extending Disease Management to the FFS Population

At the moment, these great advantages for the care planning and support for chronically ill beneficiaries are available only to Medicare+Choice members. However, these represent a relatively small percentage of Medicare beneficiaries. Most beneficiaries continue to receive their care in the fragmented, uncoordinated fee-for-service world. We continue to believe that the "system-ness" offered through Medicare+Choice plans creates distinct advantages for the prompt identification and recruitment of beneficiaries into appropriate disease management programs.

However, we commend the efforts of the Medicare program to experiment with the use of disease management and care management programs in the FFS environment and encourage further demonstrations of its effectiveness. With appropriate targeting and recruitment, free-standing disease management programs can produce savings for the Medicare program and, through the systematization, care coordination, and access to best-practice medicine that is at the core of DM programs, improve the care experience of Medicare beneficiaries. CMS Administrator Sculley has signaled his intention to conduct more demonstration projects to use private disease management services to bring some of the benefits of managed care to the fee-for-service beneficiaries still struggling to navigate the fragmented, uncoordinated health care "system." We think these demonstrations are worth expanding. In the coming years, with the advancing age of the baby boomers and the increased ability of our health system to keep them alive with chronic illnesses, the number of Medicare beneficiaries having to manage chronic health conditions is likely to rise. There are clearly some obstacles to the implementation of DM in the Medicare FFS population that will require some creative solutions. The most important of these is the identification and recruitment of the most suitable beneficiaries during their moments of acute need—mechanisms that exist within M+C plans to identify people when they are first entering an episode of acute illness do not currently exist. In addition, Medicare cannot rely on claims information for the identification of eligible beneficiaries unless it is very timely. These problems are not insurmountable, but they do need to be addressed.

Conclusion

Disease Management offers significant advantages for the chronically ill Medicare beneficiary. Most Medicare+Choice plans will offer DM services and should be sup-

ported for doing so. But for the many beneficiaries who are not able to obtain coverage in a M+C plan, further extending the demonstrations to make private sector DM services available would be very desirable.

Chairman JOHNSON. Thank you very much, Dr. Lord. Dr. Hillman.

STATEMENT OF MICHAEL HILLMAN, M.D., MBA, MEDICAL DIRECTOR, BUSINESS AND COMMUNITY HEALTH SERVICES, MARSHFIELD CLINIC, MARSHFIELD, WISCONSIN

Dr. HILLMAN. Representative Johnson, Mr. Stark, on behalf of Marshfield Clinic, thank you for conducting this hearing. My name is Mike Hillman. I am the Medical Director for Business and Community Health Services at Marshfield Clinic.

The hallmark of the Medicare population is age. In our society, an almost constant companion to age is chronic disease. Our current health care system, largely shaped by the health care reimbursement market, is not designed to prevent or meet the needs of those who are chronically ill. It is a fundamentally reactive system. It emphasizes response to acute problems instead of prevention, diagnosis of disease instead of early screening, symptom relief instead of health behavior change.

The behavior of our health care system as a whole is exactly the behavior that the CMS reimbursement system rewards, and not just for the Medicare population. Make no mistake about it, CMS reimbursement policy is mirrored by most commercial insurance carriers.

In addition, leveraging Medicare resources by selectively denying medical services or reducing reimbursement along faulty geographical assumptions is unfair and does not work. Dr. Wennberg has elegantly debunked the faulty logic behind these assumptions.

However, an even greater problem is the Resource Based Relative Value Scale, RBRVS fee schedule, which is based on a model of medical practice centered on traditional patient/physician encounters, instead of the value of care that is actually provided. This model is terribly outdated.

When you think about it, physicians are the second most expensive resource in a patient's health care team. The patient is the most expensive. Therefore, the use of patient/physician encounters as the primary vehicle for delivering health care is shamefully wasteful.

The Anticoagulation Service described in my testimony, illustrates a population health intervention that is 100-percent telephonic, yet delivers superior quality with dramatic savings to CMS. Patients with chronic conditions are best served by a systematic multi-disciplinary approach in which the patient plays an active role. This approach requires a large front-end investment in information systems and process change: process change that defines roles and expectations of patients, physicians, nurses, and others in accordance with what each is most qualified to do in the most value-added way.

I have submitted testimony to you that describes some of the information and population health tools and strategies used at Marshfield Clinic, including a detailed account of our

Anticoagulation Program, a program that has dramatic and positive effects on both health care quality and cost. I detailed this program for three reasons.

First, if we look at disease management separate from population health management, we would never have chosen to engage in this effort. Anticoagulation is not a disease. The process of managing anticoagulation has a profound quality-of-care and cost-benefit effect that extends across the boundaries of many diseases. Isolated disease management interventions are not optimal. However, disease- or condition-specific population health interventions, when provided in a coordinated manner, make a lot of sense.

Second, the effectiveness of any population health intervention is synergistically enhanced if it is part of an integrated and coordinated system of care, the record of which should be immediately available electronically and can be accessed 24–7–365 by an “actionably” qualified health care provider; that is, someone who can understand the information and act on it, such as a registered nurse.

Third, it is essential to measure the value, the quality, and quantity per unit cost of a population health intervention. Cost should be a part of any quality or process improvement platform. It certainly is in other industries, but in other industries there is a market that rewards companies for providing services or products of superior value. That is not the case with the current CMS reimbursement policies.

One final thought. I believe that a reimbursement system that stakes its financial solvency on the currency of patient provider encounters is at risk. At the same time, a care system that devalues the currency of patient provider relationships is at perilous risk.

Thank you. It is truly an honor and privilege to be here.

[The prepared statement of Dr. Hillman follows:]

Statement of Michael Hillman, M.D., MBA, Medical Director, Business and Community Health Services, Marshfield Clinic, Marshfield, Wisconsin

On behalf of the physicians and staff of Marshfield Clinic, I want to thank you for conducting this hearing and for the opportunity to comment on Disease State Management in the Medicare program.

This document will summarize the following: (1) why it is important to view ‘disease management’ as a carve-out of ‘population health management’; (2) Marshfield Clinic’s approach to disease management, particularly as it relates to the Medicare population; (3) how the current reimbursement system influences (or may influence) population health strategies to reduce the cost of health care, while improving the health, of the Medicare population.

Marshfield Clinic is the largest private group medical practice in Wisconsin and one of the largest in the United States, with 678 physicians, 5158 additional staff, and 1.6 million annual patient encounters. The Marshfield Clinic system includes a major diagnostic treatment center, a research facility, a reference laboratory and 39 regional centers located in northern, central and western Wisconsin. The largest concentration of physicians is in the city of Marshfield (population ~19,000). The facility houses almost half of the physicians at the Clinic. The facility is attached to a 534-bed hospital, St. Josephs, which is owned by a separate company, Ministry Health Care. Marshfield Clinic serves a disproportionately large socio-economically challenged population. As a 501(c)(3) non-profit organization, Marshfield Clinic is a public trust, and thus obligated to serve all who seek care, regardless of their ability to pay. The Clinic serves several federally designated Health Provider Shortage Areas (HPSAs). These communities are typically geographically remote, older, and educationally-challenged. Logging, mining, and agriculture are the economic mainstays. The Clinic also provides services in partnership with a federally funded Community Health Center at 13 locations in Wisconsin providing comprehensive inte-

grated care to un- and under-insured residents of the community with incomes at or below 200% of the federal poverty level. Security Health Plan of Wisconsin, a tax-exempt health maintenance organization, is a wholly owned subsidiary of Marshfield Clinic and provides financing for health care services for almost 120,000 members throughout northern, central and western Wisconsin.

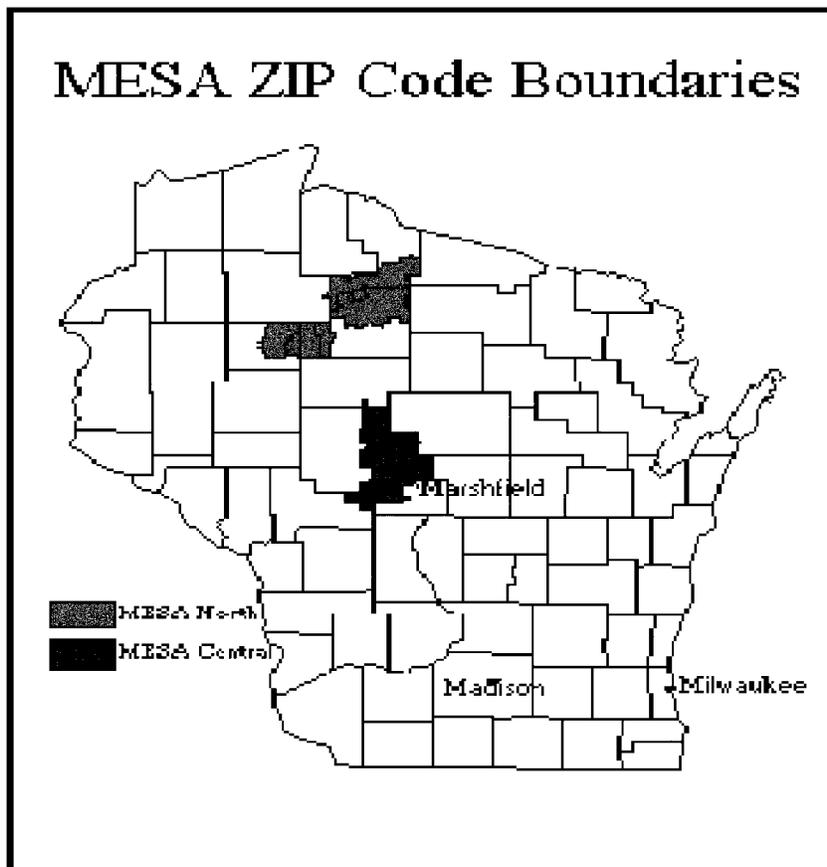
Marshfield Clinic has developed and acquired sophisticated tools, technology, and other resources that complement and support the population health management strategy of the Clinic. These include an electronic medical record, a data warehouse, an immunization registry, and an epidemiological database that enable enhanced definitions of disease states, diagnoses or conditions, and activity-based cost analysis of CPT level interventions. These tools have enormous scientific, clinical and social policy potential that has only been partially tapped.

During the last three decades, Marshfield Clinic funded and installed, and fully implemented a sophisticated electronic medical record (EMR) which now contains years of historical data, including diagnoses, procedures, test results, medications, immunizations, alert events, outcome measurements, and demographics. Marshfield Clinic's 39 regional centers are linked by common information systems. The EMR provides instant portability across our system facilitating communication between providers in different departments and at different centers. For instance, easy access to previous diagnostic test results avoids duplicate ordering of lab and radiology tests. We presently put 2.5% of revenue into the operation and maintenance of the Clinic's information system, a cost for FY 2001 that amounted to \$22,073 per physician.

Marshfield Enhanced Charting & Code Acquisition (MECCA) is an integral part of the EMR. It allows us to collect high quality data for health care, research and education. It is a point-of-care application, acting as an electronic medical assistant that requires providers to document and/or review data from lists of items, such as visit types, providers, vital signs, diagnoses, procedures, medications, and alerts. MECCA plays an important role in patient safety because it tracks drug allergies and other diagnoses including past medical history, family history, food alerts, latex allergies, and allergic reactions. Because MECCA is required for all scheduled patient encounters in Marshfield Clinic (including ambulatory surgery, unscheduled encounters, and hospital procedures), it helps us track the resources needed for medical care and is the foundation of an order-entry system for providers. MECCA will also be used to capture data from Hospital Discharge Summaries. Patient identifying information is only available to providers who have previously taken care of the patient.

Marshfield Clinic has developed innovative preventative health care measures such as an immunization registry (Regional Early Childhood Immunization Network or "RECIN"). RECIN is a computer program that allows the sharing of immunization information between and among providers and public health departments. RECIN allows providers to have electronic access to a child's immunization history, including any alerts or reactions to immunizations. Such access minimizes the possibility of over-immunization and potentially severe allergic reactions. Equally important, access to this information allows public health personnel to target children who have not been immunized. As a consequence of this program, Marshfield Clinic and concerned public agencies have been able to increase childhood immunization rates from 67% to 92% in Wood County alone. The RECIN platform can be applied to many other population health care problems affecting Medicare. Examples include anticoagulation, lipid, and diabetes management, as well as preventive services including flu and pneumovax vaccinations for vulnerable populations.

Marshfield Clinic has also developed a very unique resource known as MESA (Marshfield Epidemiologic Study Area) for clinical research in population health management.



MESA.—In the 24 zip code areas shown in map of Wisconsin, virtually all of the 88,000 residents get almost all of their medical care from a Marshfield Clinic facility. This population is very stable. The Clinic has medical records of this population dating back to the early 1900s.

MESA captures nearly all the health care information of those residing in the 24 zip codes above. Consequently, population-based health research can be done that includes all of the populations that comprise these geographic communities. Unlike most other research facilities, MESA researchers can monitor the residency of individuals on a daily basis by using updates of births, deaths, new patients, and name and address changes to Clinic databases. This allows researchers to monitor the health of a community over time by linking this residency information with the extensive health care information available in Clinic databases and medical records.¹

The research opportunities afforded by MESA contrast starkly to the studies performed by payers (HMOs and other insurers). Payer research is largely based on claims data and is restricted to narrow populations circumscribed by a common disease from multiple communities, receiving their healthcare from multiple provider organizations. Likewise, MESA affords a very important perspective not provided by the research of traditional academic medical centers. Typical academic medical research is accomplished through randomized clinical trials. In these studies populations are studied across multiple sites in very disparate geographic communities. Typically, the populations are medically homogenous except for the single hypothetical factor that is being tested. This type of research has limited value because

¹DeStefano F, Eaker ED, Broste SK, Nordstrom DL, Peissig PL, Vierkant RA, Konitzer KA, Gruber RL, Layde PM. (1996). *Epidemiologic Research in an Integrated Regional Medical Care System: The Marshfield Epidemiologic Study Area*. *J Clin Epidemiol*; 49: 643–652.

it is so severely restricted. It is widely accepted that multiple, often un-anticipated variables, are important determinants to individual's and populations' health. Yet, there are very few tools to study multiple variables simultaneously. MESA is a platform that enables analysis of multiple variables simultaneously.

'DISEASE MANAGEMENT' AS A PART OF 'POPULATION HEALTH MANAGEMENT'

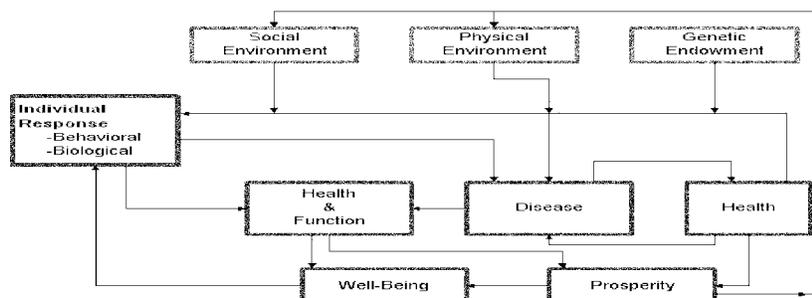
Medicare is defined by a predominantly aged population, many members of which have chronic diseases or conditions. Hence, the need for 'disease management'. Patients with chronic conditions typically enter a health care delivery system seeking acute care services traditionally covered under insurance, but they also may need services related to counseling and behavior change, support groups, communication between visits, continuous coordination with other health professionals, and medical supplies. Unfortunately, traditional fee-for-service payment approaches offer a chronically ill patient face-to-face office visits as the primary mechanism for receiving care and rarely encompass the range of services needed across the continuum of care. There is a misalignment among what the patient needs, how the services are provided, and how needed services are reimbursed.

The explosive growth in the size of the Medicare population is one of three drivers that will completely transform health care in the next 10–15 years. The other two drivers are human genomics and a revolution in healthcare consumerism. It is essential to consider these drivers, as well as the health factors that drive chronic disease, so that we minimize the possibility that changes in the Medicare health system cause unintended, more expensive, consequences.

People use physicians primarily when they are, or perceive they are, ill. Their use of physicians is defined primarily by encounters. Most traditional fee-for-service reimbursement occurs on a 'per encounter' basis. Therefore, physicians compete with each other for per-encounter business. They compete more vigorously for those encounters that reimburse at higher rates. The corollary is also true. It is not in the best business interest of physicians to compete for those patient encounters that are reimbursed at lower rates (i.e. Medicare). This situation poses a significant access problem for the Medicare population. Especially, when because of their age and chronic diseases, they require so much non-reimbursed care (care that does not have to be physician-encounter-driven). Therefore, it becomes in our enlightened self-interest to manage patients in the most cost-effective manner possible. Hence, our strategy to use population health management principles.

Population health management. The sine qua non of population healthcare management is the improvement of the health status of a selected population by focusing on the needs of that population. There are multiple determinants of the healthcare needs of any population.

Multiple determinants of health model.ⁱⁱ



In the context of the multiple determinants of health model, population health management can be defined as “the technical field of endeavor which utilizes a variety of individual, organizational and cultural interventions to help improve the morbidity patterns (i.e., the illness and injury burden) and the health care use behavior of defined populations.”ⁱⁱⁱ

ⁱⁱ Evans, R., M. Barer, and T. Marmor. (1994) *Why are Some People Healthy and Others Not? The Determinants of Health of Populations*. Aldine de Gruyter. New York.

ⁱⁱⁱ Chapman, LS. (1997). *HEALTH MANAGEMENT: Optimal Approaches for Managing the Health of Defined Populations*. Summex Corporation. Seattle, WA.

The generally accepted objectives for population health management include: (1) reduction in volume of services utilized, (2) shift of utilization to lower cost settings, (3) achievement of clinical improvement by focusing on the health status of the population, (4) integration of health care services, (5) organization of providers into networks, and (6) evaluation and documentation of quality.^{iv} Within each of these objectives, there is great number of considerations from both philosophical and operational perspectives, especially as they relate to the *performance* of the access system for a horizontally integrated health system like Marshfield Clinic.

To simultaneously accomplish the first 3 goals of population health, mechanisms must be in place to *assist patients in becoming active, empowered participants in their own health care decisions*, while reducing the need and use of unnecessary or ineffective medical services—enhancing the overall health status of a defined population.^v

The increase in patient responsibility inevitably results in a fundamental change in the patient-physician relationship. Patients, and the information with which they make decisions, are no longer solely dependent on their physicians. Patients, in the above model, are partners. They are customers. They are consumers. The consumerism that has already reshaped other large parts of the American economy (retail, information, automotive, and manufacturing) is carrying over to healthcare.^{vi} Much of this consumerism is driven by the increased information available on the Internet.

Physicians at Marshfield Clinic are not unique in their resistance to the demands of a changing healthcare delivery system. The value of specialty practice culturally persists at the Clinic today. The desire to develop this core competency of specialty care drove the formation of the Clinic. Implicit in subspecialty training is the emphasis on “sickness-care”. Specialists are not needed to prevent illness. They are needed to perform extraordinarily technical deeds to stave off mortality and reduce morbidity. However, even the most ardent advocates of specialty practice will now admit that it is not efficient use, for example, of a heart surgeon’s time to manage a post-operative valve replacement patient’s anticoagulation medicine. It is also not good patient care, because it not something that heart surgeons are expert at doing.

Likewise, it is not the best use of a cardiologist’s time to manage Type II diabetes in patients that have a stable myocardial status. Again, it is also not good patient care. It is not something that cardiologists are expert at doing. Then, whose job is it to manage these patients with these problems? At Marshfield Clinic, like many physician-oriented multi-specialty clinics, it falls to the primary care physicians—internists and family practitioners, and their physician extenders (Nurse Practitioners and Physician Assistants). For the last 6 years, the Marshfield Clinic has purposefully re-directed patients under the care of procedural specialists to the primary care departments.

We believe that the business case to be made for this approach is sound, even considering the internal conflict attendant Medicare fee-for-service reimbursement. Primary care is the entry point from which subspecialty care demand is generated. Dysfunctional access to primary care limits the growth of subspecialty care. Dysfunctional access to primary care makes it virtually impossible to develop a consistent, system-wide collaborative effort to maximize customer satisfaction and consumer health outcomes at the lowest cost per life.

To further improve access to primary care, we are redefining the scope of practice for the different members of the health care team. For example: primary care physicians see new patients, provide hospital care, do complex follow-up exams, and perform procedures. Nurse Practitioners and Physician Assistants do most follow-up care and screening (as opposed to diagnostic) exams. Registered Nurses triage acute patient symptoms, provide case management, educate, and coach behavioral change—all integral elements of disease management.

Disease Management. Disease Management is a further refinement and application of population health principles that we now utilize in the Marshfield Clinic. There are four basic steps.^{vii} One, define the population. Two, determine what care processes will most effectively and efficiently meet the needs of that population. Three, measure the effectiveness of those care processes. Four, improve the care processes further. The vision for Marshfield Clinic using population health as a core

^{iv} Fos, PJ, DJ Fine, and PJ Foss. (2000). *Designing Health Care for Population: Applied Epidemiology in Health Care Administration*. Jossey-Bass. San Francisco

^v Montrose, G. (1995). *The Art & Science of Demand Management*. Group Health Association of America

^{vi} Herzlinger, R. (1997). *Market-Driven Health Care*. Perseus Books, New York.

^{vii} Runde, D. (1999). *Weaving Disease Management Into the Fabric of Patient Care*. Health Care Horizons Institute for the Future. Menlo Park, CA

strategy is to develop consistent, continually improving, system-wide collaboration to maximize customer satisfaction and consumer health outcomes at the lowest cost per life, and as a result, deliver care that is of superior value and liking to the members of its communities.

DISEASE/POPULATION HEALTH MANAGEMENT AT MARSHFIELD CLINIC

In 1995, Marshfield Clinic performed an “outside-in” assessment of its primary care system. From the patient-as-a-customer perspective, we found that our system could improve greatly by addressing the following needs: providing symptom-based advice with respect to whether patients needed to see a provider; if they don’t, how they can self-manage their symptoms; if they do, when do they need to be seen, and with what type of provider.

The needs of the providers-as-a-customer were different. Our providers wanted to provide continuity of care 24–7–365 (although they were not willing/able to work 24–7–365) and increase their access (by reducing unnecessary patient encounters).

Marshfield Clinic found that the respective needs of the patients and the providers could be met, and exceeded, by a 24–7–365 Registered Nurse (RN) call center that systematically answered patients symptom-based concerns, and, using Marshfield Clinic’s electronic medical record in combination with the physicians on-call, provide true continuity of care. Strictly speaking, we developed a population health management/disease management intervention on healthcare resource utilization.

This RN call center department was named ProActive Health. This department provided these interventions on behalf of both Marshfield Clinic and Security Health Plan (the Clinic’s wholly owned insurance product). The interventions that this department developed in collaboration with its customers include the following: symptom-based triage, prenatal health, asthma, secondary cardiac prevention, diabetes, and anticoagulation management. The basic principles underlying all of these interventions are as follows:

- Patients are selected. In the case of RN “triage” and pregnancy, they are self-selected. In other cases they are identified through the use of Health Risk Appraisals or utilization data.
- A condition/symptom-specific assessment is performed telephonically. This assessment includes reviewing the patient’s electronic medical record. And for those patients with a chronic condition, particular attention is paid to the providers’ care plan.
- Marshfield Clinic has developed an extensive intranet repository of clinical practice guidelines that were/are modified from national guidelines. Provider care plans are checked against those guidelines (particularly for asthma, diabetes, and secondary heart prevention). Our QI department, which organizes the development of these guidelines, is now examining interventions directed towards compliance with these guidelines.
- For acute symptom-based advice, the RNs consult more than 500 guidelines, many of which were specifically modified by Marshfield Clinic physicians to enhance their effectiveness. These guidelines help the RN advise the patient if they need to be seen, in what time frame, and by what type of provider. In addition, the RN helps the patients to develop a self-care plan. For the condition-specific (i.e. “Disease Management”) interventions, the patients and RNs customize a curriculum of educational messages and behavioral coaching based on the patients’ current knowledge base, and the degree to which that individual is at risk for acute decompensation.
- For several of these programs, active RN case management is integrated with the education and behavior coaching. Case management is the heart of population health management. Simply stated, it is a collaborative multi-disciplinary process to assess, monitor, and intervene. Physicians are part of the team, but the actual case managers are non-physicians, often nurses. The overall mission is to provide care efficiently, minimizing unneeded office visits, maximizing usefulness. Most of the services can be provided by telephone. In these programs, the RN assumes responsibility for a group of patients. These patients require particularly close monitoring and medication management towards a specific clinical or laboratory indicator. After specialized training, using protocols developed by our physicians, in compliance with the legislatively defined scope of an RN’s practice, our Disease Management Nurses help patients adjust their medications (without having to see their physician).

Marshfield Clinic has a number of disease management programs in various states of maturity. These programs include: Diabetes, Prenatal Health, Congestive Heart Failure, Asthma, Lifestyle Management, Secondary Cardiac Prevention, and Anticoagulation Management. In addition, a number of programs are on the “drawing board”. Those programs include Hypertension, Hyperlipidemia, Obesity, Prenatal care, and Low Back Pain. Many members of the Medicare population suffer from several of these conditions concurrently. To give you a more complete picture of how a mature disease management program should work, we will describe our Anticoagulation Service Disease Management program in more depth.

The Anticoagulation Service is particularly germane for the following reasons. One, it demonstrates how all the essential components of a disease management program work together. Two, it is the program of ours that is most fully developed with respect to clinical and economic outcomes measurement. Three, it demonstrates the power of connecting a disease management program directly to physician practices.

Anticoagulation is the process of making the blood less likely to clot (form a scab) inside the body. When a clot forms inside the body (within the blood vessels), it causes either a stroke or heart attack. There are a number of very common conditions in the Medicare problem that predispose the formation of these internal clots. These conditions include atrial fibrillation (2–3% of the population over 65 years of age), congestive heart failure, deep vein thrombosis (especially after orthopedic procedures and during cancer chemotherapy), and mechanical heart valve replacement. Almost all of these conditions are caused by age and chronic disease.

The most common outpatient drug used for anticoagulation is warfarin. While the risk/benefit ratio of using warfarin in this patient population is indisputable, the window of therapeutic benefit is narrow. That is, under-anticoagulation with this drug doesn't prevent stroke and heart attack. Over-anticoagulation can cause dangerous internal bleeding. Furthermore, the metabolism of this drug (the way that it is broken down by the body) is very sensitive to changes in diet, exercise, and many other common medications taken by this population (e.g. antibiotics). Therefore, the administration of this drug has to be done very carefully. A monthly blood test is required to adequately monitor the effects of this medication.

When this drug is administered in the standard way, the incidence of hospitalizations or death is 7–10% per year (the risk of stroke or heart attack without this drug is substantially higher). However, with our disease management approach to patients taking this medication, that risk is reduced to less than 2% per year.

All five of the 'ProActive Health' dot points described above were used in this program. The patients are introduced to the program by their physicians (to reassure the patient that it is an extension of their physician's practice) or are referred immediately upon discharge from the hospital. The patients are entered into a special tracking database that prevents them from falling through the 'cracks' due to the complicated monitoring schedule and telephonic follow-up routine. Our nurses case manage the patients through guidelines developed by Marshfield Clinic. They adjust the patients' warfarin doses according to protocol. They educate and coach the patients about recognizing on their own the many pitfalls that influence anticoagulation (diet, activity, other medications, other illness). The RN case managers have access to the Medical Director of the program and the patient's personal physician for the 5–10% of time when the protocols don't cover a patient's situation. All of the interactions are documented in both database and the Clinic's electronic medical record. The RN's EMR note is signed by the patient's personal physician (so they always know what is going on with their patient). In addition to the RN case manager, the patients have access to the 24–7–365 RN ProActive Health Nurseline for acute symptom-based advice. This entire program is done telephonically without any reimbursement from CMS.

We recently conducted a study that was funded by the Agency for Healthcare Research and Quality under its new Integrated Delivery System Research Network initiative. It assessed the impact of Marshfield Clinic's Anticoagulation Service on health care utilization measures, including urgent care, emergency department and inpatient events. In the study, we compared these measures in two study groups of individuals receiving warfarin therapy. One group consisted of individuals that were enrolled and managed in the Anticoagulation Service; the other group consisted of individuals who received standard care for their warfarin management needs. All study subjects were under the care of Marshfield Clinic cardiologists for at least some of their health conditions. The study included a total of 408 study subjects and 359 years of study observation time.

In the course of providing this intervention, we noted that two-thirds of the phone calls were not directly related to warfarin dosing. Rather, they resulted from the patients calling in about other health concerns that they correctly thought would influ-

ence their state of anticoagulation. Therefore, in the study funded by AHRQ, we looked at all hospital events, not just the events directly related to warfarin. Hospital events occurred at a much lower rate in the Anticoagulation Service group compared to the standard care group. Based on our analyses, the expected difference in hospitalizations per 100 person years was approximately 28.7 hospitalizations. This difference was not only large but also statistically significant ($P < .014$).

For the 86% of the study population that are Medicare beneficiaries, total Medicare costs avoided per hospital event were estimated at \$9,443 in constant year (2000) dollars. Hospital facility costs represented about 76% of these costs. Non-hospital costs, primarily physician and laboratory costs for both inpatient and outpatient care, represented the remaining 24% of costs. Estimated avoided CMS costs were \$8,221 per hospitalization. The difference between total Medicare costs per hospitalization and CMS avoided costs, which was \$1,222 per hospitalization, is represented by expected Medicare beneficiary co-payments and deductible: \$446 per hospitalization and annual Part B deductible of \$776.

Total avoided Medicare hospitalization-related costs per 100 person years of Anticoagulation Service enrollment compared to standard care was estimated at approximately \$271,014 based on a differential hospitalization rate of 28.7 events and an average total Medicare-related cost of \$9,443 per hospitalization. CMS total avoided costs per 100 person years were estimated at \$235,943. Reduced Medicare beneficiary co-payments and deductibles were estimated at \$35,071. In developing estimates of avoided costs, a conservative approach was utilized; it is believed a greater savings are likely available than those estimated.

Using the Marshfield Enhanced Charting & Code Acquisition (MECCA), we know that our system has 12,477 unique patients on warfarin anticoagulation. 95% of those patients are Medicare-eligible. If we generalized the Anticoagulation Service to the entire population receiving warfarin under the care of Marshfield Clinic, CMS would avoid over \$28,000,000. It will cost Marshfield Clinic about \$3,000,000 to do so, none of which is currently reimbursed.

We are certain that near-equally compelling savings can be achieved with our congestive heart failure, diabetes, and other population health initiatives. The anticoagulation example provides clear evidence that better health can be achieved at significantly less cost. These results can be greatly expedited if Medicare reimbursement policy influences the healthcare market to rely less on patient-physician encounters, and more on integrated systems of care that extend the benefits of patient-physician relationships.

THE RELATIONSHIP OF MEDICARE REIMBURSEMENT TO THE HEALTHCARE MARKETPLACE AND POPULATION HEALTH MANAGEMENT

The health care system that we presently live with is not well designed to meet the needs of the chronically ill. The current delivery system responds primarily to acute and urgent health problems emphasizing diagnosis, ruling out serious conditions, and relieving symptoms. Patients with chronic conditions are better served by a systematic approach that emphasizes self-management, care planning with a multidisciplinary team, and ongoing assessment and follow-up. This systematic approach requires a large front-end investment in information systems and process change. Marshfield Clinic is making that investment. Yet the health care marketplace, largely shaped by CMS reimbursement policy, works against developing this type of approach.

Even without any financial incentive or reimbursement for this front-end investment required for population health, clinics like Marshfield in the Wisconsin Medicare payment locality, are already under-reimbursed by CMS. Marshfield Clinic recently conducted an internal analysis to determine to what extent the Medicare program covers the cost of providing services to Medicare beneficiaries. Our analysis demonstrates that the Clinic presently recovers only about 70% of its costs in providing Medicare Part B services. We do not believe that we are unique, but suspect that the shortfalls in Medicare revenue are common for physicians providing Medicare Part B services. We urge you to take steps to remedy this inequity as soon as possible.

To calculate the percent of its Medicare allowed costs for which Medicare reimbursement is received, Marshfield accountants eliminated all expenses and revenues received that might potentially be questioned by the Medicare program. Our methodology for FY 2000 follows principles applied in our annual FQHC cost report that was audited by external auditors and submitted to the state. (Marshfield Clinic in conjunction with Family Health Center Inc. functions as a federally qualified health center (FQHC) under the Medicaid Program.) For the purposes of this analysis, all expenses and revenues from activities such as the outreach lab, veterinary lab, re-

search and education, rental property and optical and cosmetic surgery departments were removed. Our accountants also removed all non-Medicare "Allowed" costs related to our bad debt, interest expenses, marketing programs, government affairs activities, National Advisory Council, goodwill amortization and other miscellaneous costs.

For FY 2000, Marshfield Clinic's Medicare revenue was 71.52% of costs for fee-for-service Medicare. For FY 2001 Medicare revenue (un-audited) as a percent of costs goes down to 70.59%. For FY 2002 we project that Medicare revenue will decrease as a percent of costs to approximately 68.5%.

Reimbursement shortfalls of this magnitude interfere with the Clinic's capacity to further implement disease management programs in the many departments where we believe efficiencies can be captured. The declines in Medicare reimbursement that Marshfield Clinic experienced in FY 2000 and 2001, and has projected for FY 2002 are due in part due to payment updates lowered by CMS in anticipation of volume offsets. CMS has assumed that increasing volume in response to tightening reimbursement takes place uniformly across the country. We believe that this simplistic point of view and the pursuant regulatory response by CMS are a constant source of frustration and a major obstacle to the coordination of care for beneficiaries by organizations whose mission is to provide better patient care.

Marshfield Clinic has demonstrated that by reducing both the volume and intensity of services provided to Medicare beneficiaries, savings are accruing to Medicare Part A, Medicare Part B, and the beneficiaries we serve. Unfortunately, from the point of view of promoting the financial viability, disease management activities that serve the welfare of beneficiaries and the interest of the Medicare program can be potentially self-defeating if not reimbursed. It will be difficult to promote the long-term view that disease management strategies are a rational response to the current economic incentives of the Medicare fee-for-service program.

Organizations that stake their future to the currency of patient-physician encounters as the basic unit of medical care value are at risk in the present fee-for-service reimbursement environment. At the same time, we believe that patients who stake their future to the healthcare system that devalues the benefit of patient-physician relationships are equally at risk.

CONCLUSIONS

In summary, we believe that there are significant quality-of-care concerns as well as the business case to be made that population/disease management holds significant promise for the Medicare program. However, Congress must take several steps to address the misalignment of incentives in the Medicare reimbursement market.

The Institute of Medicine suggests that fee-for-service payment can be adapted to provide incentives for quality improvement by encouraging cooperation and providing reimbursement for care outside of the traditional office visit, which is not always optimal for meeting patients' needs. This approach involves developing relative values for the elements of work performed over time by physicians and other health professionals.^{viii}

That may be a reasonable suggestion, but probably not realistic. It still relies on encounters (although not face-to-face), rather than care as the unit of value from which reimbursement occurs. And that is the reason that capitation, as it has been thus far administered, also doesn't work. It also relies on encounters. Although in a capitated system, encounters have negative value instead of a positive value.

We need to develop a reimbursement system that is somewhere in between: a system that reimburses for continually improving *value* (quality + quantity, unit cost) in care. Marshfield Clinic looks forward to the opportunity to work with you on this.

Thank you for considering our views.

Chairman JOHNSON. Dr. Anderson?

^{viii}Institute of Medicine (U.S.). Committee on Quality of Health Care in America. (2001). *Crossing the Quality Chasm: A new Health System for the 21st Century*. Washington, D.C. National Academy Press.

STATEMENT OF GERARD ANDERSON, PH.D., PROFESSOR, PUBLIC HEALTH AND MEDICINE, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MARYLAND, AND DIRECTOR, PARTNERSHIP FOR SOLUTIONS, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MARYLAND

Dr. ANDERSON. Chairwoman Johnson, Ranking Member Stark, Members of the Subcommittee, thank you for inviting me to testify this afternoon.

I am Gerard Anderson, a Professor at Johns Hopkins University and Director of the Robert Wood Johnson National Program Partnership for Solutions: Better Lives for People with Chronic Conditions.

In my testimony this afternoon, I want to focus your attention on the large number of Medicare beneficiaries with multiple chronic conditions and how this creates challenges and opportunities for disease management. Our analysis suggests that 63 percent of Medicare beneficiaries have two or more chronic conditions, and this is in contrast to only 5 percent of children and 20 percent of adults with multiple chronic conditions.

So, when we think of disease management in the Medicare program, we need to be considering the complex, multiple conditions of a disabled and aged population. This is probably the most critical differences between disease management programs in the private sector and in the Medicare program. It is much easier to design a disease management program for a patient with a single chronic disease, such as diabetes, arthritis, or congestive heart failure than it is to design a disease management program for a patient with diabetes, arthritis, and congestive heart failure.

If Medicare is going to pursue a disease management program strategy, then these programs must be able to demonstrate they are equipped to handle Medicare beneficiaries with multiple chronic conditions. In the working age population, multiple chronic conditions are the exception. In the Medicare population, they are the norm.

Caring for Medicare beneficiaries requires that disease management programs make certain modifications. For example, and as we have heard today, many disease management programs rely on self-management as a backbone to their success. However, many Medicare beneficiaries are unable to self-manage because of their dementia or their problems with multiple chronic conditions.

Medicare beneficiaries are very likely to see many physicians. For example, 1 in 5 Medicare beneficiaries sees 14 or more doctors during the year. Therefore, all disease management programs should have the information capability to allow physicians to know what other physicians are doing when they treat a patient in common.

Now we know that doctors recognize the need for better care coordination. We, ourselves, conducted a national Survey of Physicians, surveying physicians who provide more than 20 hours of patient care per week. These physicians told us they were having difficulty coordinating care with other doctors and other health professionals. Two-thirds of them told us they were not well-trained in care coordination. The payoff to the Medicare program of better co-

ordination is fewer unnecessary hospitalizations, fewer nursing home placements, and fewer drug-drug interactions.

In our survey of physicians, 44 percent of them told us that poor care coordination results in adverse drug reactions; 36 percent said that it resulted in unnecessary hospitalizations; and 24 percent of them said it leads to unnecessary nursing home placements.

Lack of care coordination is also a problem expressed by people with chronic conditions. We did a survey of Americans, and we found that about 16 million Americans go to the pharmacist every year only to be told of a drug-drug interaction.

Now, think of the Medicare beneficiary going to the pharmacist, those fortunate enough to have drug coverage, they go to the drug store only to be told that their drug can't be filled because another medication, probably ordered by a different doctor, is going to give them a potential problem. So what do they do? Do they fill it anyway? Do they ask the pharmacist? Do they call the doctor who ordered the prescription? Do they call their primary care physician? Do they phone a friend? What do they do? Disease management programs must be able to help this Medicare beneficiary standing at the pharmacy counter.

An alternative to disease management programs for fee-for-service Medicare is to pay explicitly for care coordination. For example, our data suggests that cost utilization and poor outcomes really started about four or more different chronic conditions. So perhaps an enhanced payment, a monthly management fee, for example, would be appropriate for physicians who are willing to take on the clinical and possibly other service coordination activities for this group of complex patients. These physicians would have to meet certain criteria in order to be able to be eligible for payment; for example, having appropriate office staffing, information and communication systems.

I would like to leave you with a fact and a concept. The fact is that two-thirds of Medicare spending is for Medicare beneficiaries with five or more chronic conditions, two-thirds of Medicare spending. The concept is that Medicare is a program for people with chronic conditions. It just doesn't know it.

[The prepared statement of Dr. Anderson follows:]

Statement of Gerard Anderson, Ph.D., Professor, Public Health and Medicine, Johns Hopkins University, Baltimore, Maryland, and Director, Partnership for Solutions, Johns Hopkins University, Baltimore, Maryland

Good morning and thank you for inviting me to testify on the important topic of disease management in Medicare. I am Dr. Gerard Anderson, Professor of Public Health and Medicine at Johns Hopkins University, and Director of a Robert Wood Johnson Foundation project, Partnership for Solutions: Better Lives for People with Chronic Conditions.

My role today is to provide this Committee with information about chronic conditions in the Medicare population and talk about some aspects of disease management that are particularly important to consider for Medicare.

Chronic Conditions in Medicare

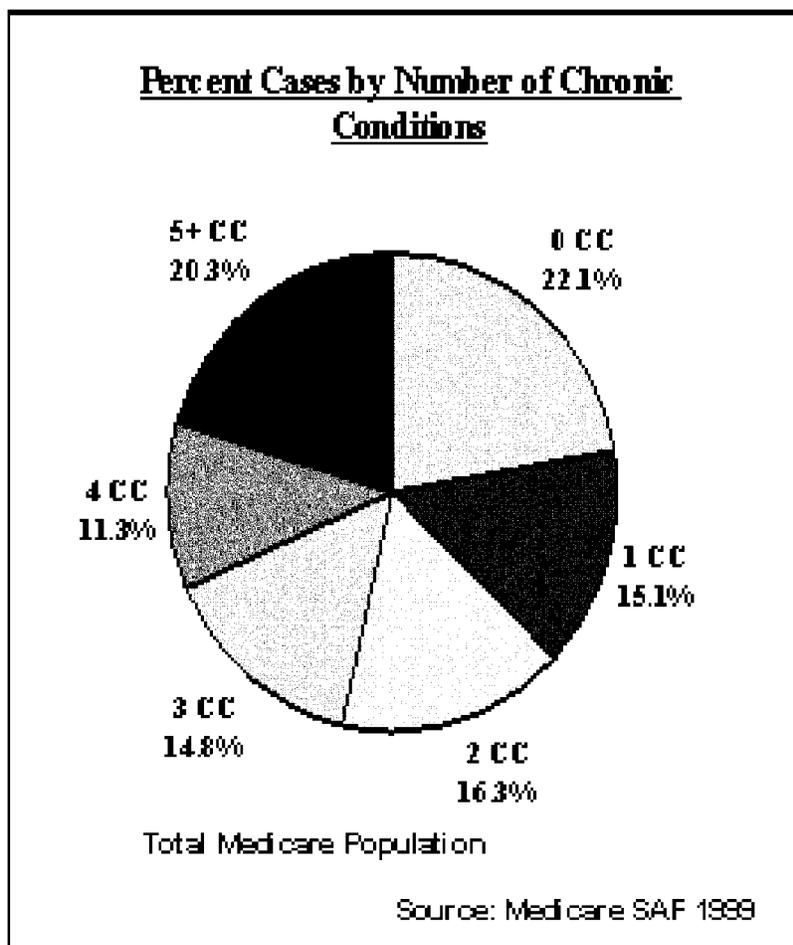
The top five chronic conditions in the Medicare population overall are: hypertension, diseases of the heart, diseases of the lipid metabolism, eye disorders, and diabetes.¹ There is not a great deal of variability by age or eligibility status in the top disease rankings although there is some variation by age and eligibility status.

- Senility and organic mental disorders are most prevalent in the 85 years and older population. They begin appearing among the top 15 conditions in the 75–79 year old group.
- Affective disorders are the fifth most prevalent group of conditions for the disabled population but rank 13th for the general Medicare population. Other conditions related to mental health appear more prevalent in the disabled population than in the aged Medicare population.
- Asthma is one of the top 15 most common conditions among disabled Medicare beneficiaries but asthma is not otherwise very prevalent in the Medicare population.

¹The top 15 most common chronic conditions in Medicare are: hypertension; diseases of the heart (including coronary arteriosclerosis and congestive heart failure, cardiac dysrhythmia, among others); disorders of the lipid metabolism (including hyperlipidemia and pure hypercholesterolemia among others); eye disorders (including senile nuclear sclerosis, senile cataract, glaucoma among others); diabetes mellitus; non-traumatic joint disorders (including osteoarthritis and rheumatoid arthritis among others); thyroid disorders (including hypothyroidism and thyrotoxicosis among others); COPD and bronchiectasis (including chronic airway obstruction and chronic bronchitis among others); diseases of the male genital organs; diseases of arteries, arterioles, and capillaries (including peripheral vascular disease, arteriosclerosis of extremities or aorta, among others); senility and organic mental disorders (including Alzheimer's and senile dementia among others); spondylosis, intervertebral disc disorders, and other back problems; affective disorders (including neurotic depression, major depressive disorder among others); osteoporosis; diseases of the urinary system; viral infection (chronic); chronic ulcer of the skin; other connective tissue disease; other nutritional, endocrine, and metabolic disorders; other endocrine disorders; nutritional deficiencies; anemia, schizophrenia and related disorders; anxiety, somatoform, dissociative, and personality disorders; other nervous system disorders; cerebrovascular disease (including cerebral arteriosclerosis among others); asthma.

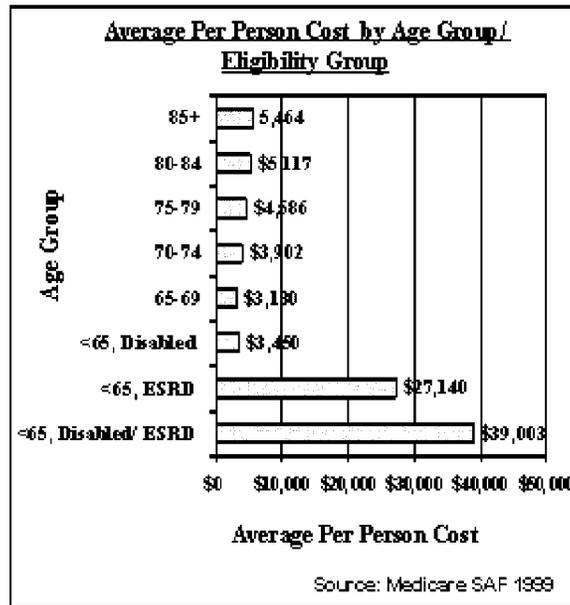
General Prevalence and Cost

About 78% of the Medicare population has at least one chronic condition while almost 63% have two or more. Of this group with two or more conditions, almost one-third (20% of the total Medicare population) has five or more chronic conditions, or co-morbidities.

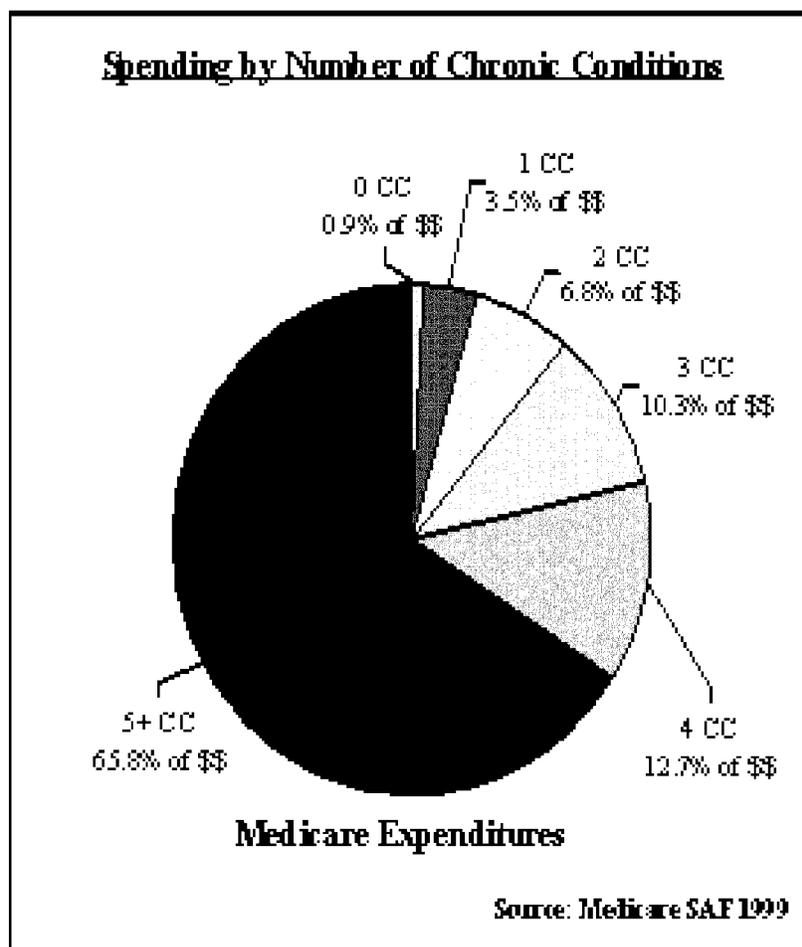


In general, the prevalence of chronic conditions increases with age—74% of the 65 to 69 year old group have a least one chronic condition, while 86% of the 85 years and older group have at least one chronic condition. Similarly, just 14% of the 65–69 year olds have five or more chronic conditions, but 28% of the 85 years and older group have five or more. Fourteen percent of the people with disability-related eligibility have five or more chronic conditions but 46% of the ESRD patients have five or more.

Average per beneficiary spending increases gradually with age but the variation in average costs related to number of chronic conditions is more significant. In 1999, the average per person costs for people with no chronic conditions was \$160 (including the under 65 entitled), while the average per person cost jumps to \$13,700 for people with five or more chronic conditions. The average per beneficiary spending across all ages and eligibility groups is \$4,200. Per beneficiary spending increases more than 2½ times between two and four chronic conditions, and nearly triples again from four to five chronic conditions.



People with one chronic condition are 15% of the Medicare population but only 3.5% of the spending. People with 3 chronic conditions are also 15% of the population but 10% of the spending. People with 5 chronic conditions are 20% of the population but 66% of program spending.

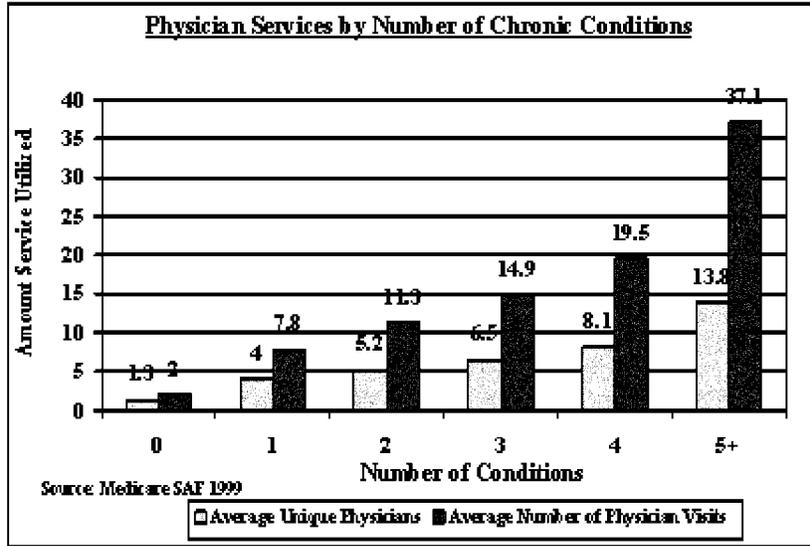


Key Utilization

There is strong pattern of increasing utilization as the number of conditions increase. Fifty-five percent of beneficiaries with five or more conditions experienced an inpatient hospital stay compared to 5% for those with one condition or 9% for those with two conditions. 19% of Medicare beneficiaries have an inpatient stay. Inpatient days per thousand beneficiaries jumps from 335 days for those with one condition to over 7000 days per thousand among those with 5 or more conditions. The average days per thousand across all beneficiaries was 1944.

In terms of physician visits, the average beneficiary has just over 15 physician visits annually and sees 6.4 unique physicians in a year.² There is almost a four-fold increase in visits by people with five chronic conditions compared to visits by people with one chronic condition. The number of unique physicians seen increases almost two and half times for people with five or more chronic conditions relative to those with just one chronic condition.

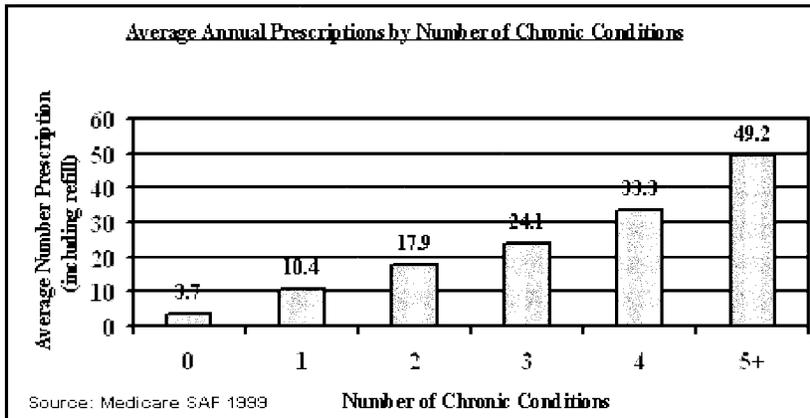
²This number of unique physician visits is 6.7 when people who died are included and is 4.6 when only outpatient settings among the age-entitled are included in the analysis.



The average Medicare beneficiary fills almost 20 prescriptions. Within this average, the under 65 year old population fills on average 26.3 prescriptions and those 65 years and older fill 19.1 on average. We found that beneficiaries with no chronic conditions fill an average of 3.7 prescriptions per year while those with any chronic conditions fill an average of 22.7.

There is a strong trend in utilization of prescriptions when examined by number of chronic conditions.

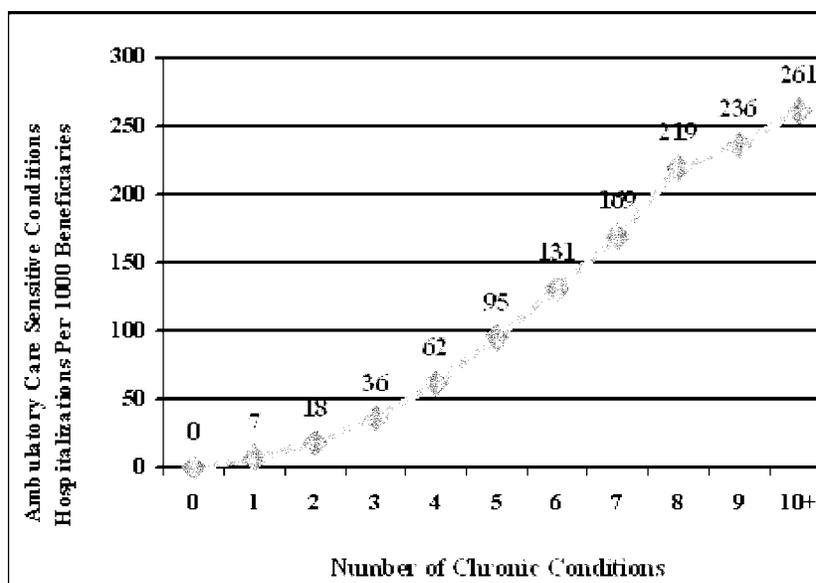
- Average annual prescriptions filled jumps from 3.7 for all people studied with no chronic condition to 49.2 for people with five or more chronic conditions.
- Growth in usage between those with no chronic conditions and those with one chronic condition is over 180 percent—from 3.7 to 10.4 prescriptions filled.
- Usage grows 72% between one and two chronic conditions, from 10.4 to 17.9 prescriptions filled.
- There is a 48% growth in average annual usage between four and five chronic conditions (33.3 to 49.2).



Implications

So what does all this information mean for beneficiaries, the providers that serve them and the program overall. There are indications in the data that there is a lot of care provided to beneficiaries with chronic conditions—particularly those with multiple chronic conditions. There are also indications that the care may not be well-coordinated and that for beneficiaries with multiple chronic conditions there are adverse outcomes.

For instance, we have found that as the number of chronic conditions increase, so too do the number of inappropriate hospitalizations for illnesses that could have received effective outpatient treatment (Ambulatory Care Sensitive Conditions). Per 1,000 beneficiaries, these hospitalizations increase from seven for people with one chronic condition to 95 for beneficiaries with five chronic conditions, and jumps again to 261 for people with 10 or more chronic conditions.³



These poor outcomes are likely a result of poor care coordination among the many services used and providers seen. It may be that different providers are recommending conflicting treatments that result in poor outcomes including adverse drug events. It could be that one condition is receiving treatment, while other chronic conditions go unattended and then become acute episodes.

There is other information to support this theory. In our surveys of people with chronic conditions and people with serious chronic conditions, we know that care coordination is a problem.

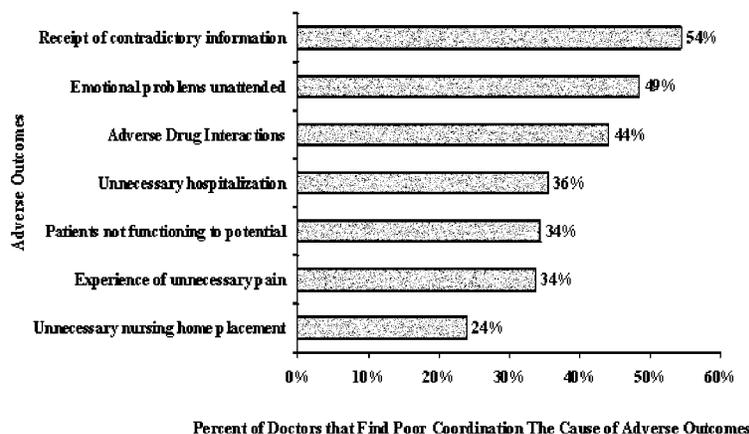
We hired Gallup to conduct a national survey people with serious chronic conditions:

- 26 percent report receiving contradictory advice from different doctors in the past year
- 20 percent report they were often or sometimes sent for unnecessary or duplicate tests or procedures
- 23 percent report that they often or sometimes received conflicting information from different health care providers
- 25 percent report that they were often or sometimes diagnosed with different medical problems for the same set of symptoms from different providers

Our work at Partnership for Solutions shows that physician think that care coordination is both important and difficult to do. We conducted a national survey of physicians who provide more than 20 hours of direct patient care during the week.

³This analysis includes only age-eligible beneficiaries.

Almost two-thirds of these physicians reported that their medical education training was not adequate to the task of caring for people with chronic conditions and 17 percent reported that they had problems coordinating care with other physicians. Most importantly, physicians in our survey think that poor care coordination leads to poor outcomes.



What Can Be Done to Change the Situation?

I believe policymakers, payors, and providers are increasingly attentive to the issue of chronic conditions. The Centers for Medicare and Medicaid Services (CMS), for example, is becoming more actively engaged in the issues of chronic care in Medicare, in part thanks to the efforts of Congress in the Balanced Budget Act of 1997 and more recent legislation.

As you know, CMS is implementing a 15-site Medicare Coordinated Care Demonstration that will provide case management and disease management services to different Medicare populations. An important aspect of these demonstrations is coordination with community-based services. There is also a more recent CMS call for proposals for a demonstration testing disease management strategies and the benefit of prescription drugs for beneficiaries with specific diseases (congestive heart failure, diabetes, and coronary heart disease).

These demonstrations are important and will test the idea of integration and coordination in larger health care settings. I think there are issues in traditional disease management that need to be explored and addressed in order for them to be successful in the Medicare population whether these programs are applied only in demonstration or directly into the larger program.

Disease management programs in Medicare must be able to demonstrate that they are equipped to handle Medicare beneficiaries with multiple chronic conditions. In the working age population, multiple chronic conditions are the exception, in the Medicare population they are the norm. Unlike the working age population, it is more common in Medicare to have patients who cannot adequately self-manage their care because of dementia or other problems. Many disease management programs rely on improving self-management. Any disease management program should have the information capacity to allow physicians to know what other physicians are doing to treat a shared patient, which can be particularly challenging in a program where the average beneficiary sees slightly more than six unique doctors in a year. Finally, disease management programs need to have protocols for handling people with multiple, complex chronic conditions.

Beyond disease management, there are other options worth exploring that will improve care for Medicare beneficiaries with multiple chronic conditions. These options would be interim, modest steps in for Medicare program. We know a great deal about Medicare beneficiaries and their conditions, as well as the lack of coordination within the system that affects them.

Unlike the traditional method of disease management, which targets enrollees with particularly high cost conditions, it may be useful to look at some of the people who are having the most difficult time with multiple medical conditions (whatever those conditions may be). We should focus on people with four or five chronic condi-

tions who, for whatever reason, have difficulty self-managing one or more of their conditions. These are people who typically see many physicians, who fill a large number of prescriptions, who need an array of health care services, and who are at risk of poor outcomes if the clinical care and other care is not well-coordinated.

For this group of target beneficiaries, there could conceivably be a physician payment adjustment that compensates physicians for the additional visit and other office time necessary to work with these patients. This type of adjustment could be available to all physicians treating any Medicare patient who meets the criteria.

Unlike a broad-based payment available to all physicians, a more targeted approach could also be considered. Again, the target beneficiary population would be those with four or five conditions who have difficulty self-managing one of their conditions. This approach is modeled roughly on Medicaid Primary Care Case Management programs and would reimburse certain providers for complex clinical care management and coordination. In this model, a treating physician accepts added responsibility to coordinate the clinical care provided by all treating physicians. Beneficiary enrollment would be voluntary.

Physicians could participate to the extent that they agreed to follow certain administrative procedures to track and monitor all aspects of a beneficiary's care, act as a referral, receive and coordinate clinical reports from others involved in the patient's care, maintain a comprehensive medical record and be available to provide greater consultation time surrounding a qualified beneficiary's care.

There are a number of payment options that could apply to this clinical care management model, two of which are used in Medicaid. One would be a monthly per patient management fee which is separate and apart from billing for specific services rendered. Another option is a monthly capitation to the physician for a range of primary care services and the care coordination activities.

There are a number of design issues that would have to be considered in applying a PCCM-type approach to Medicare. Under either payment structure, the model would require some sort of provider designation such that participants would have to meet certain standards for care, quality, and administrative capabilities. Because only one provider can be paid for the clinical care management of a particular patient, more administrative capabilities may be required of the carriers.

Another possible modest step for Medicare would be to develop a modified home visit benefit. The current home health benefit is for people in need of extended home nursing and personal care services and who meet a technical definition of "homebound."⁹ The current 60-day episode of care payment reflects the extended nature of the benefit. There seems to be need, however, for another type of benefit that is not as extensive or intensive as the current home health benefit.

Although current rules require direct physician supervision of staff seeing Medicare patients, direct supervision is not always practical. Physicians have said it would be helpful to clinical care if they could authorize their office nurses or physician assistants to periodically conduct home visits to check on patients. This benefit would be limited in scope to infrequent medical monitoring when a patient is not able to come to the office due to temporary or otherwise acute health conditions but allows the physician more direct knowledge of health status and functioning than a service delivered through a separate agency.

There could be limits built into the design of any new benefit such as limiting the number of visits per beneficiary per year, defining the qualifications of practitioners who might make such home visits, restricting services within the benefit, and having the visits related to patient-specific events such as acute exacerbations of chronic conditions, or times when a patient's treatments have been altered due to a change in health status.

One other option, that is not mutually exclusive with anything else discussed here has to do with physician training and physician ability to care appropriately for people with chronic conditions. I note that the Medicare program is providing almost \$8 billion in direct and indirect medical education support in 2002. For this money Medicare could ask the training programs to emphasize care coordination as part of their curriculum. The Medicare program could encourage analysis of the appropriate treatments for people with multiple chronic conditions, given that most Medicare beneficiaries have multiple chronic problems, this should be a priority.

Summary

Chronic care in Medicare is an important issue although a difficult one. Chronic conditions affect both program beneficiaries and program financing in significant and growing ways.

It is important for the program to begin to take steps to address the growing disparity between what the program is currently designed to do and the changing needs of its beneficiaries.

I have proposed some ideas today that we are working on at Partnership for Solutions. Indeed, there are many other ideas as well that need to be debated and refined. In general, I would ask Members to think about solutions to the current problems keeping in mind a few key principles or goals.

- Care coordination for people with multiple chronic conditions should be a top priority.
- Any new benefit or service should address the common problems of beneficiaries with multiple chronic conditions rather than address similar needs disease by disease.
- Any new benefit or service should be accessible to all beneficiaries and not be designed such that it only can be provided in special settings or by providers who are not widely available to beneficiaries.

I thank you for this opportunity and will be happy to answer any of your questions.

Chairman JOHNSON. Dr. Henschke?

STATEMENT OF CLAUDIA I. HENSCHKE, M.D., PH.D., PROFESSOR OF RADIOLOGY, WEILL MEDICAL COLLEGE, CORNELL UNIVERSITY, NEW YORK, NEW YORK

Dr. HENSCHKE. Madam Chairman, thank you very much for having this important hearing and for including me. For the record, I am Claudia Henschke, Professor of Radiology of Weill Medical College of Cornell University.

Each year, approximately 160,000 Americans die of lung cancer. That is more than 50 times the number of people who died in the attack on New York City in Washington on September 11. The overall cure rate of lung cancer is dismal, somewhere around 10 percent.

About 85 percent of the lung cancers found in our usual care today are of late stage, and their cure rate is essentially zero. None of the other major cancers—that is colon, breast, prostate—for which screening is provided has such a poor outcome.

The prognosis of patients found with early stage lung cancer is much brighter. It is well accepted that early stage, Stage I, non small-cell lung cancer has a 5-year survival rate of over 70 percent. Thus, early detection is compelling as the probability of cure is significantly increased.

However, today's usual care results in less than 15 percent of the non small-cell lung cancer being found in early stage. Low-dose CT screening, on the other hand, finds about 80 percent of cancers in this early stage, and this high percentage has been well documented in studies in the United States, Japan, and Europe. This improvement is due to the many more detailed images obtained by the CT Scan, currently about 300 images per person and, thus, lung cancers can be found as small as a grain of rice, as compared to being recognized when they are the size of a grapefruit. This resulting dramatic shift from finding 15 percent of cancers in the early stage to over 80 percent, suggests a concomitant improvement in the cure rate. However, further follow up is still needed of the currently ongoing studies to confirm the exact amount of this improvement.

Analysis of Medicare cost data has shown that the cost associated with treatment of late-stage lung cancer is at least twice the cost of treatment of early stage lung cancer. Thus, there is consid-

erable financial incentive for early detection as well. The charge of a low-dose screening CT is currently set at \$300 at our institution, although in some places it is lower and in other places higher. This test is painless, the images are acquired in a single breath hold in less than 20 seconds, and this equipment is already available in private practice offices, community hospitals, as well as major medical centers throughout the country.

In my opinion, the most realistic scenario suggests that the cost is less than \$3,000 per life year saved, much less than the benchmark value of \$50,000 for renal dialysis, and the worst-case scenario is still less than that benchmark amount.

Today, under usual care, thoracic surgery is performed on many individuals with no cancer at all. By following the recommended management plan of nodules, either incidentally detected by chest X-ray or CT, many unnecessary biopsies and surgeries may be avoided by assessment of nodule growth on subsequent CT scan one or several months later. A rational lung cancer management plan of screening and standardized workup, in terms of actual nodule growth, provides the benefit of early diagnosis and early treatment and thus could save many lives.

Current cost of care of the 170,000 annually diagnosed patients with lung cancer averages at least \$50,000 per case, totaling more than \$8.5 billion a year. The majority of these dollars are spent on late-stage treatment, with a very poor outcome. This does not include the work of many benign nodules, which often undergo surgery as well.

We are most concerned about the currently planned National Cancer Institute (NCI) randomized trial for assessment of CT screening for lung cancer. It will be the most expensive screening trial ever planned, well over \$200 million, and it will take at least 10 years to complete. It is, however, unlikely to provide an answer, as it has the same design flaws that recently caused the firestorm about mammography screening. Our published article points out these fundamental flaws, and this article was widely endorsed.

Even the front page article in the New York Times noted that our article caused the NCI to continue to endorse mammography. It is simply not rational for the NCI to embrace the design considerations when it comes to mammography and yet ignore these same considerations when it comes to lung cancer. Now is an opportune time to intervene before the planned trial starts, so as to avoid the misleading results and resulting confusion seen in mammography screening.

However, despite numerous attempts for open discussion of the currently planned trial or design alternatives that are less costly and more efficient, we have been ignored. Such alternative designs allow for assessment of the effectiveness of CT screening as a part of a practice management plan. These designs provide the benefit of CT screening to all participants and allow for careful assessment of the improvement in the lung cancer cure rate and the associated costs.

These alternative studies will lead to more definitive answers in much less time than the contemplated NCI trial. It is important to recognize that our group in New York has been doing lung cancer screening over 10 years. We have found that the costs to perform

the trial being contemplated by the NCI to be at least six times the cost per patient as other alternatives.

We think this is a very important topic for the Subcommittee to address and appreciate the opportunity to present our views. A thoughtful approach to the careful evaluation of the benefit and cost of CT screening now has the potential to save more lives than all of the other treatments developed for cancer to date. Such a benefit should not be delayed for years by a very expensive and probably inclusive trial.

I suggest to the Subcommittee that the issue of cancer screening and how such screening is evaluated is the most important health care issue of our time. With our rapidly changing technology, we need to make rapid and accurate decisions regarding the scientific application of these potential screening tests.

The prevailing methodology has overwhelming design flaws and an open scientific debate is essential. The confusion about mammography screening for breast cancer, despite seven large trials involving more than \$500,000 women over 30 years make this point abundantly clear.

Thank you.

[The prepared statement of Dr. Henschke follows:]

Statement of Claudia I. Henschke, M.D., Ph.D., Professor of Radiology, Weill Medical College, Cornell University, New York, New York

Each year, approximately 160,000 Americans die of lung cancer, that is more than 50 times the number of people who died in the attack of September 11, 2001. The overall cure rate of lung cancer is dismal, somewhere around 10%.

About 85% of the lung cancers found by our 'usual' care are late-stage, and their cure is essentially zero. None of the other major cancers (e.g., colon, breast and prostate) has such a poor outcome.

The prognosis of patients found with early stage lung cancer is much brighter. It is well accepted that early stage (Stage I) non-small-cell lung cancer has a 5-year survival rate exceeding 70%. Thus, the emphasis on early detection is compelling, with the probability of cure significantly increased.

Today's 'usual' care results in less than 15% of non-small-cell lung cancer being found in Stage I. Chest x-ray screening alone resulted in less than 30% of cancers being found in this early stage. Low-dose CT screening, on the other hand, finds about 80% in this early stage and this high percentage has been well documented by studies in the United States, Japan, and Europe (1-6). This diagnostic improvement of the CT is due to the many more detailed images it produces of the lungs (currently over 300/person) as compared to the single chest x-ray image. The resulting dramatic shift in early stage cancers from 15% to over 80% suggests a concomitant improvement in the cure rate. However, further follow-up is still needed of the currently on-going studies to confirm the exact amount of this improvement.

Analysis of Medicare cost data has shown that the cost associated with treatment of late stage lung cancer is at least twice the cost of treatment of early stage lung cancer. Thus, there is also considerable financial incentive for early detection. The charge of a low-dose screening CT scan currently set at \$300 at our institution, although it may be as low as \$200, although considerably more is charged in some settings. The test is painless, the images are acquired in less than a single breath-hold, that is in less than 20 seconds and this equipment is already available in private practice offices, community hospitals as well as major medical centers throughout the country (7-9). In my opinion, the most realistic scenario suggest that the cost is less than \$3,000 per life-year saved, the worst-case is less than \$40,000 per life-year saved.

Today, under 'usual' care, thoracic surgery is performed on many individuals with no cancer at all. By following the recommended management plan for nodules either incidentally detected on chest x-ray or CT, many unnecessary biopsies and surgeries may be avoided by assessment of nodule growth on a subsequent CT scan one or several months later. A rational lung cancer management plan of screening and standardized work-up in terms of actual nodule growth provides the benefit of early diagnosis and early treatment to over 80% of the individuals diagnosed with lung

cancer as compared to that less than 15% as currently found and thus save lives now.

Current cost of care of the 170,000 annually diagnosed with lung cancer averages at least \$50,000/case, totally more than \$8.5 billion. This does not include the work-up of many benign nodules, which often undergo surgery as well. The majority of these dollars are spent on late-stage treatment, with a very poor outcome.

We are most concerned about the currently planned National Cancer Institute randomized trial (RCT) for assessment of CT screening for lung cancer. It will be the most expensive screening trial ever planned (well over \$300 million currently estimated) and it will take at least 10 years to complete. It is, however, unlikely to provide an answer as it has the same design flaws that recently caused the firestorm about mammography screening (10). Our published article pointed out fundamental flaws of the design and this article was widely endorsed (11–13). Even the front-page article in the *Los Angeles Times* noted that our article in part caused the NCI to continue to endorse mammography. It is simply not rational for NCI to embrace the design considerations when it comes to mammography yet ignore these same considerations when it comes to lung cancer. It is an opportune time to intervene before the planned trial starts so as to avoid the misleading results that occurred with mammography.

However, despite numerous attempts for open discussion of the currently planned trial, or design alternatives that are less costly and more efficient, we have been ignored. Such alternative designs allow for the assessment of the effectiveness of CT screening as part of the practice management plan; these designs provide the benefit of CT screening to all participants and allow for careful assessment of the improvement in the cure rate and associated costs. These alternative studies will yield more definitive answers in much less time than the traditional trial being contemplated. It is also important to recognize that our group in New York has been doing lung cancer screening for over 10 years and we have found that the cost to perform the trial being contemplated by the NCI is at least 6 times the cost per patient as other alternatives. In addition, it will take more than 10 years to have an answer, which will most likely be misleading.

We think this is a very important topic for the Committee and appreciate the opportunity to present. A thoughtful approach to careful evaluation of the benefit and cost of CT screening now has the potential to save more lives than all of the treatments developed for cancer to date. Such a benefit should not be delayed for years by a very expensive but probably inconclusive trial. I suggest to this committee that the issue of cancer screening and how such screening is evaluated is the most important healthcare issue of our time. With our rapidly changing technology, we need to make rapid and accurate decisions regarding the scientific application of these potential screening tests. The prevailing methodology has overwhelming design flaws and an open scientific debate is essential. Just looking at the confusion we have in regards to mammography where there have been no fewer than 7 large trials involving more than 500,000 women over 30 years makes this point abundantly clear.

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Chairman JOHNSON. Thank you very much, Dr. Henschke, and thank you all for your testimony.

Dr. Wennberg, I have been interested in your work documenting the really tremendous variations across the Nation in patterns of practice and the lack of any evidence of parallel variations in quality. Yet, solutions to this irrational and costly variations have been difficult to develop.

Do you think that disease management, because the protocols are developed through professional experience based on outcomes research and best practices, could help us not only establish a more uniform approach to core illnesses nationwide, but reduce the costs in some regions without compromising quality?

Dr. WENNBERG. That is quite a question. I believe that the evidence seems to be pretty clear that when we have scientific consensus that something should be done based on clinical trial evidence, as the best quality of evidence, and that particular intervention does not involve tradeoffs that imply preferences, that disease management programs have definitely shown themselves capable of getting the beta blockers out, getting the A1C hemoglobin done, and so I think that we can count on a quality improvement along those dimensions.

The cost issues are more complicated. First of all, the costs that we see that are associated with the variations in regional costs have nothing to do with beta blockers, failures to do them, and so forth. It has to do with the intensity with which chronically ill people are treated across the board. I have always been aware that there is a balloon effect in health care, namely, if you improve the way that a certain subgroup of the population is treated, the rest of the population is likely to get the spillover effects of the supply side problem.

For example, we have observed in some of our studies that patients have engaged in decision support systems for shared decision making will become more conservative in their treatment choices, but the overall workload of surgery in the region continues at the same level. In other words, other patients that aren't involved in the study are getting it. So, I am concerned that, for example, a successful disease management program may be apparently working, in terms of reducing overall cost, but unless the control group is carefully defined, namely, as those others at risk of receiving the

care that is in that region that isn't being used by that population, you can get a very different opinion on that.

I think that, and I said in my testimony, that I think ultimately the cost issues are going to have to come back to an open debate about what is an efficient capacity of the system, and some of our systems have just twice as many resources in them as others do. Until we come to terms with that, we will continue to see regional variations.

As we continue to increase the capacity of the system by training more physicians and building more technologies, we can count on the costs going up, and the reason is because this kind of care is not driven by science. It is not driven by well-articulated medical theories about intervention. It is done basically by the simple hypothesis or the simple fact that if you have twice as many physicians in a region, you have twice as many office hours to offer, and you therefore have twice as many visits, and visits associated with all sorts of other kinds of activities.

Chairman JOHNSON. I appreciate what you are saying, and the significance of your response. On the other hand, as Dr. Anderson says, Medicare is increasingly going to be about managing chronic illness and is—

Dr. WENNERBERG. Right.

Chairman JOHNSON. A chronic disease management program, though we don't have chronic disease management capability. As we get that capability in place, and we begin to manage those chronic illnesses, and then if we do, as you suggest in your article, which is a little different than any disease management demonstration I am aware of, look at end-of-life illness management from the same point of view, then I think we are going to, at a very profound level, change the way we practice.

Now that brings me to my second question. Disease management does depend on patient participation. A number of you had really marvelous, pithy ways of describing this. Dr. Lord, you said supported self-management in a systemless world and the supported self-management, and then you did point out that somebody with Alzheimer's can't self-manage. This issue of self-management, outside of Medicare you can create systems in which the right of physician to educate a patient about self-management can be absolute, and it is no surprise that it is outside of the fee-for-service reimbursement system of Medicare that this capability for physicians to act differently in order to get patients to act differently has developed.

All of you know perfectly well our coding process, all of the experts we have involved in coding, all of the complexities of coding, we can't even—and I see my colleague, Mr. McDermott isn't here, but we were on the phone when we asked experts who have been in the Medicare program for 10 years what the difference between a comprehensive physical is and a detailed physical, and they can't tell you till this moment.

I spent a year and a half trying to get my intermediary to figure out what partial hospitalization is versus outpatient mental health for seniors, and we can hardly do that.

Now, the idea that Medicare could define, and one of you mentioned a management fee, could define a management fee or could

define a physician visit education component in a fee-for-service system that whether it is in government or in the private sector focuses on encounters is, in my mind, simply not possible or else we cannot wait for it. If we did, it would be so complicated that there would be mostly war over whether this was or was not eligible for a management reimbursement.

That is one of the reasons why I am so focused on systems. I brought systems out in terms of technology, and some of you talked about the need for that, but this issue of patient involvement goes very directly to physician activity. If reimbursements don't encompass that activity, you will never get management education. In the disease protocols that I am familiar with, that management education function moves from the physician to the disease management company, who then educates the patient in the guidelines of the doctor.

So, I don't know that you can do this through fee-for-service. I don't really see any opportunity to do that because while you can, a system can contract management or can develop management within its capability, I don't see how Washington can develop the definition of management, and how the complexity of our coding system for a moment will enable us to reimburse for this in a way that the Inspector General won't destroy in the course of events.

So, I would like for you to comment on that issue of physician involvement and the degree to which disease management does require a different attitude toward physician education of the patient.

Dr. WENNBERG. Me?

Chairman JOHNSON. Yes, and anyone else who wants to comment as well.

Dr. WENNBERG. Well, let me say that I am not here defending the current fee-for-service system. The questions about how that payment system is organized is really what a lot of this debate is all about, and I would think some way of paying for the management of chronically ill people, where we have organizations that are responsible for that, can work in many ways. For example, at least several of the organizations that are represented around this table have fully salaried physicians and have health care organizations that are already serving defined populations. The question is how do we modify the current payment systems to make it work.

Capitation is one strategy, but capitation has always been presented as a competitive model, and many parts of the country there simply is only one system, and we have got to figure out somehow how to make that system work. Clearly, the kind of models we are talking about, patient education, group visits, is a wonderful idea, and it works, but you can't bill for it. In fact, it is very efficient, and it breaks this kind of supplier-induced demand problem between the doctor supply and that because they are suddenly no longer being paid just for doing piecework. That is where we need to get to.

So, the question is how can we get there? In our proposal that we put in the Health Affairs article, we basically wanted to allow certain health care organizations that are intimately involved now in chronic disease management, in fee-for-service environments, to see if they could not come up with some suggestions for modifica-

tions in the fee structure that would support the fundamental reforms which, Madam Chairman, I hear you asking for.

Chairman JOHNSON. Thank you. Dr. Lord?

Dr. LORD. Several comments. First, with respect to self-management, I think one of the things that we have been focused on, in terms of program design, and an area that Jack and I have collaborated on for the last several years, is trying to level the ball field so that people have a fair shake in the health care system, understanding their disease and understanding their choices.

I think if anybody on the panel holds up a hand-mirror about their experiences in the system or their family's experience, it is confusing. It is very confusing when you are sick. It is even more confusing and scary when you are facing a fateful decision. How can we help people at that time of absolute need just deal with the confusion and the lack of "systemless," the combination of fragmentation of care, coupled with what was described by Dr. Anderson as multiple co-morbidities? It creates real problems and challenges for folks.

Now the world has changed. The world has changed from a technology perspective, the world has changed from access-to-information perspectives, the world has changed in a number of ways that we can work with, collectively and individually, with people who are facing significant illness. I think there are opportunities within the Medicare structure to create a fee-for-service model that would pay for someone to serve as a concierge or coordinator or adviser to people who have chronic illness. It may be another function that hasn't been defined yet in the health care system, but it is something that if you think about people's experience, they really need. It may be unreasonable to expect that is only a physician's role out into the future, and I believe, through some of the demonstration projects that CMS is presenting, we have an opportunity to try some different approaches that really help deal with a very common and a very human issue that all of us have touched or faced somewhere in our family's lives.

Chairman JOHNSON. Dr. Anderson?

Dr. ANDERSON. In the long run, I agree with you that we have got to change the payment system, but in the short run, we have to deal with the existing fee-for-service system. So, what I would take a look at is the Medicaid program, which has been running primary care case management programs quite successfully for a number of years, and has dealt with the payment issues with this, has dealt with the coding issues in the primary care case management program. So there is a model for Medicare to take a look at to do many of these functions.

The way I would set it up in the Medicare program is to take a look at people that had four or five different chronic conditions, different chronic conditions. These people see an average of 10 to 12 doctors in the course of the year. They need their care coordinated desperately.

The care that is actually being provided to them is not very good, as my example about the prescription drugs illustrated, but I could also give you examples about unnecessary hospitalizations or unnecessary nursing home patients. There would be savings from care coordination if we could figure out a way to get these 10 doc-

tors to talk to each other. Part of it is information system, but we need a primary care physician to be responsible for saying, "What is the endocrinologist doing, what is the cardiologist doing for my patient?" To get that to happen, I think you need to pay them.

Chairman JOHNSON. Those are very interesting comments. I think they underestimate the problem of getting the information from all of the people involved when you have got a lot of chronic illnesses, and I think they completely ignore the liability concerns. If you have Medicaid, you are sheltered from liability. I don't know who would want to take the liability on their shoulders of coordinating the care, when you have multiple chronic illnesses, and possibly disagreeing with one of the doctors so that you can better integrate the care.

So, I think this is a pretty big and difficult issue. It is one that systems are solving themselves. So, right now we can reimburse the system, and the system can do it. In the long run, of course, we have to have a way for the whole system to do it, but I feel real urgency about pressing ahead and encouraging systems that can take on this responsibility to move rapidly because this is—I agree with you—this is already a chronic care program.

Dr. Hillman?

Dr. HILLMAN. Yes, I agree completely with you. I think to rely on physicians, first of all, to educate patients is a misuse of health care resources. Physicians have no training in patient education, patient behavior paradigms, that type of thing. It is just not part of physician training.

Likewise, to ask physicians to be coordinators of care is also probably a misuse of their capabilities. I think that there are other types of health care providers that can provide these functions as long as they have coordination in terms of having an electronic medical record. For example, that is portable from site-to-site or physician to physician. Those information systems allow a case manager, such as a registered nurse, well within their scope of practice, to perform these functions.

I don't think that it is going to be beneficial to put an individual in a role where they are going to be adversarially questioning other people's judgments. If the system keeps the care in mind itself, as opposed to the encounters in mind, is what our current reimbursement system does, I think we will do a lot better.

Chairman JOHNSON. Mr. Stark?

Mr. STARK. Well, I thank you all for taking the time.

One of the things that troubles me—the Chair asked if I would yield to—

Chairman JOHNSON. Let me recognize Mr. Houghton, since he has to leave and has taken a very, very great interest in the issue of lung cancer detection. Congressman Houghton.

Mr. HOUGHTON. Thank you very much.

Listen, I am sorry to do this, Pete. Thank you very much for your letting me—I have just got to get out of here—

[Laughter.]

Mr. HOUGHTON. It is not because I want to, but because of something else.

Dr. Henschke, if I understand it, you have got two points; one, get it early, and then don't go into these expensive trials which are

going to push off the inevitable. I would like to ask you really two questions. The first is this.

We talk about lung cancer, and then obviously you get into the idea of smoking. Smoking inevitably enters the discussion, and don't smoke, and you won't get cancer. Do you agree with this? Also, why should we put money into research on early screening detection, when perhaps it would be better spent on prevention, and cessation programs and things like that?

Dr. HENSCHKE. Well, I certainly agree that we should put a lot of effort in smoking cessation programs particularly in those of younger individuals. However, there are 50 million currently smoking individuals in this country and some 50 million former smokers. Even if we stop smoking today, if no one smoked, we would have lung cancer deaths for a considerable time, 20 or 30 years in the future, and we should do something for these individuals, and we can save many of those lives.

So, we think that screening should go hand-in-hand with smoking cessation, that actually you can give them a lot of information, and people who come to screening programs also are interested in stopping. So, these two should go hand-in-hand.

Mr. HOUGHTON. The second question, and I will be brief, there was a report presented to the National Cancer Institute in August last year that presents really a very pessimistic picture. It talks about lack of progress in research, and high-death rate, and unenthusiastic attitude of doctors, and researchers, and other health care providers, and also total lack of communication and cooperation among those involved in treating and managing the disease that you might want to comment on that.

Dr. HENSCHKE. Well, I was a participant of that program project review for lung cancer, and, yes, lung cancer has, there has been a pessimistic attitude in these past years, but now with screening really making its changed the attitudes. At that meeting, there was emphasis on collaborative efforts, there were a whole set of priorities that were detailed that are very good priorities. The problem is that funding for lung cancer has been much less than funding for the other cancers, even though, for example, it kills more than seven times as many cancers—it causes seven times as many deaths as breast cancer, it gets about a tenth of the funding or so.

So, the pessimism is more due to the lack of funding, and we do have now a lot of information that we could obtain about the biology and the innovative treatments that could be used in view of these new techniques. So, there is a lot of excitement, there has to be funding, and there has to be implementation of those priorities that were set by that report.

Mr. HOUGHTON. Thank you very much. Thank you, Madam Chairman.

Chairman JOHNSON. Thank you for being with us today, Congressman Houghton. Congressman Stark?

Mr. STARK. Well, thank you again, as I said. I am glad to see that the Marshfield Clinic, it used to be the Doege Clinic?

Dr. HILLMAN. It used to be the Dayton Clinic?

Mr. STARK. Dr. Doege?

Dr. HILLMAN. Doege, yes.

Mr. STARK. I grew up next door to him in the summers, a long time ago. He is no longer—Marshfield is easier to spell.

I am troubled, and I want to say at the outset that Dr. Lord had nothing to do with this, but what was absent in his testimony and what can happen in case management as a result, I suppose, of clinical strategy and innovation, was the Chipps case that Humana was involved with, where they terminated 100 critically ill children to save \$78.5 million for the Humana program. Fortunately, the court decided to whack them with punitive damages for \$78.5 million, but that was overturned. My question is of concern of might this be used, and I would be more concerned in the for-profit part of medical delivery than I would in the not-for-profit because the incentives would not be so high there is how do we prevent mischief?

If you begin to identify people with chronic diseases, as I presume you would in the workplace before they mature into Medicare, do we run the risk of tremendous selectivity, companies like Humana or Aetna, Marshfield Clinic, Johns Hopkins saying we don't want you or finding whatever ways they can to discourage these people? Are we all going to have the red mark of "C" on our foreheads saying we are chronic and therefore become the great unwashed of the people running around hat in hand looking for health care.

Now, this is a panel of physicians, and I am far more comfortable with your training and approach to taking care of me than I am your company treasurer or whomever may make these decisions at some point to, say, terminate or design recruiting or advertising programs to subtly select. There is a new health care gang out, Sterling, I guess it is, who does a fee-for-service Managed Care Plus Choice. They have got some cute tricks—50-percent co-pay for durable medical equipment. What does that tell you? Nobody in a wheelchair or walker should apply or 50-percent deductible, as many have for mental illness procedures.

I guess I am worried that this could turn on us if we are not careful, and that is my question, how do we prevent and, Dr. Lord, I impugned your company here by sort of indirection, and I will let you respond, but I am concerned that we not begin, and the privacy issues come up this morning. I don't think that is as bad for a Democrat that is probably blasphemy, but I really think that we have got to sacrifice some privacy to get the kind of research that I would like to see in outcomes research done.

How can we assure that this won't just kind of categorize the people we end up getting back to the Hansen's disease farms and sort of putting all of these Medicare critical people off in one corner, and then we will have trouble getting them into the best of the plans?

I am sorry, Dr. Lord, go ahead. You were not there. I want to stipulate, you did not come aboard until this case was behind you.

Dr. LORD. First of all, the Chipps case really has nothing to do with today's testimony, but beyond that, I think in terms of the disease management programs that we provide, we provide to all beneficiaries, regardless of plan design and regardless of program—government, commercial, TriCare, programs that are provided, as my 20-year-old daughter would say "disregardless" of how people

have shown up at our doorstep and provide a set of services that really are intended to try to get rid of waste that exist in the system.

I think the theme-line, from Jack through all of the panelists here, is that there is waste and inefficiency in the system because it does not act like a system. The more that we can do a few things, one, help provide information, coordinate services, allow people to be sovereign in terms of making some choices that are right for them, which in many cases people have been disenfranchised of choice, how can we do that and how can we make that work on a systematic base?

I believe that it is the incentives that exist for, for-profit enterprises, nonprofit enterprises, but most importantly people, that we somehow rationalize the kinds of care that we provide and allow the fact that we live in a world with a lot of abundance and don't live in the paradox of abundance that creates waste and get rid of the waste that exists in the system today.

Dr. ANDERSON. I think it is not that most Medicare beneficiaries have one "C" on their forehead, Mr. Stark, but it is probably two or three or four "C's." We have essentially got to deal with the issue of multiple chronic conditions, not just the single "C," and we have got to deal with it in two different ways. In fee-for-service Medicare, I think we do have to pay for coordination of care. If we don't pay for it, we make the person or their care giver the de facto care coordinator. I think in many cases self-care coordination is fine, but I would like to have the advice and really the guidance of a physician in many cases, and I think I, unfortunately, need to pay for those types of activities.

Mr. STARK. I would like that. I mean, as a patient, I would rather talk to one of you guys than I would some kind of social worker who has been trained to tell me the kind of stuff I can find on the Internet. I am not very comfortable or I wasn't before I went to see Dr. Walsh reading about it on the Internet, and he is not the most charming, bedside manner guy in your institution, I might add, but, nonetheless—

Dr. ANDERSON. Technically, very good.

Mr. STARK. Yes, thank God, but nonetheless, what I am suggesting is that we patients would just as soon talk with the guy that has got the knife, what is going to happen, Doc? Don't send me over there to somebody who is going to just give me the stuff I can read. I want to know what are you going to do relative to me.

Dr. ANDERSON. I am taking into account your specific circumstances, because your collection of chronic conditions that you have, which is different from the next person, and you have got—

Mr. STARK. Does Marshfield still—Dr. Hillman wants to say something—does Marshfield deal with fee-for-service? Do you take fee-for-service patients?

Dr. HILLMAN. Yes.

Mr. STARK. I guess what I want to ask, and then you can say whatever you want, is would Dr. Anderson's idea of having a fee, a physician whose job it would be to be a coordinator work in your system, for example?

Dr. HILLMAN. Most definitely. Just to reinforce that, I forgot which management guru said that you can't manage what you

don't measure. I can tell you 100 percent that what you don't reimburse, you certainly aren't going to measure, and you are certainly not going to manage, and we have to do that.

Marshfield Clinic is a 501(c)(3) clinic, and as a public trust, we see everybody. One of the things that you had asked a question before of Mr. King-Shaw was why couldn't physicians be required, for example, to follow clinical practice guidelines and provide care plans in order to participate in Medicare? I can tell you that, for example, in our area, which is one of the under reimbursed areas in the country, that our competitors would welcome that because they would say, "Hey, look. We are no longer qualified to take care of Medicare patients. Ship them to Marshfield," which is what they do right now anyway.

That is why we have had to develop the systems that we have, and that is why we have made the investment to develop an electronic medical record, to develop the epidemiological database that we have, basically, so that we can take care of people in a more effective manner.

I would also point out one other thing. You may feel better right now, and I agree that if you were going to have a surgery or a specific care intervention that is dangerous to you, you would feel more comfortable talking to a physician, but the majority situations that arise in chronic care aren't related to that. They are related to behavioral changes, to monitoring the effectiveness of dosage changes in the medications, and those things don't need to be done by a physician. We are wasting a huge amount of health care resource by not employing the right type of provider to provide those services. As the Anticoagulation program that I detailed in my testimony showed, those things can be done by nurse case managers, and the patients like it a lot better. It is done on a 24-hour basis, it is done when it is convenient for the patient. It is backed up by another nurse call center that has access to the patient's medical records so that people know what is going on, not just from their physician at Marshfield, but among any of the other 38 regional centers that Marshfield Clinic provides care at, many of which are in disproportionately socioeconomic-challenged populations.

Mr. STARK. I grew up there.

[Laughter.]

Dr. HILLMAN. Well, you made it out.

[Laughter.]

Mr. STARK. I miss it. I am sorry. Thank you, Madam Chair.

Chairman JOHNSON. Thank you. That was very interesting. Congresswoman Thurman?

Mrs. THURMAN. Thank you.

Dr. Anderson, in reviewing and looking over the testimony by Ruben King-Shaw, it struck me that many of the demonstration programs that they are embarking on in fee-for-service seemed to concentrate on maybe one specific illness, as versus what you are suggesting is I think, which I actually think is a very good idea, it seemed to me that where you would want to start is where those are four or five so that you could have a real idea of how you were managing.

I think, for the most part, a doctor that deals with somebody with CHF for whatever, I mean, pretty much manages that patient.

So, the real management of disease is when you are talking about many kinds of disease that would be a problem. So, I would hope that maybe one of the messages this Subcommittee could carry back in a demonstration issue is to maybe look at a demonstration where you are looking at a patient with several chronic conditions, as versus one. That does concern me a little bit. I think that is a very good idea.

The liability issue, and, of course, we have all been through this Patient's Bill of Rights, and this issue and that issue, but, Dr. Lord, because you do this now, that is what your company does is supposedly manages for managed care, and how do you work through this? I mean, doctors, maybe you as an individual or as Humana can't be held liable, but the fact of the matter is your doctors and others could. So, I am not sure that I understand this liability issue when it comes to a managed or when you are trying to manage different disease management. I kind of got lost in that argument there. Can you help me a little bit here?

Dr. LORD. Sure. The disease management function is to support the care between practitioner and patient, and it is to provide access to resource, in terms of information for both groups as they enter what Dr. Anderson described as a very complex world. Very few people have just a single disease to contend with. They have multiple pieces of challenges going on clinically, as well as in their family life, as well as economically, that all make a full picture. The only person who could be making the kinds of decisions that are right for that individual are, first, the individual and, second, with the advice of their practitioner, whether that is a physician or another type of practitioner.

What we have tried to do is get out of the management business and be in a position to provide best-in-class information to both the patient, as well as to the practitioner, to provide information that helps reinforce things that the patient should be doing.

For instance, if a patient is receiving a drug after a heart attack, they need to take that drug on a regular basis. We can send out an automated reminder that lets them know they haven't gotten the refill. Why can we do that? In our commercial programs, our pharmacy benefits manager lets us know within about 24 hours every time we fill the position. We can go ahead and use automated systems and use some logic around our electronic data warehouses to provide that information to people.

Now, we are not prescribing the drug, we are reminding the individual about their care. Health plans are not care providers. They are not hospitals, they are not doctors, but what we can do is a much better job, and what we are trying to do is a much better job of getting information back to people. We are the hub and spoke of a lot of the transactions that take place in the health care system. We know and we have insights about what works for people and what are best practices, and we can serve that up in ways that both practitioners can take advantage of, as well as patients. I think that really is the focal point for our business as we go forward, and clearly it is the insight that we want to try to give to people who face the complex problems that Dr. Anderson described.

Mrs. THURMAN. It is not insurmountable to believe that Medicare fee-for-service could do very similar. I think that Dr. Anderson

mentioned that. Dr. Hillman, you seem like you want to just jump right in here. Did you have something you wanted to add to this?

Dr. HILLMAN. Yes, and I will be a little bit careful because I am going to be a little bit provocative.

Mrs. THURMAN. We love it.

Dr. HILLMAN. I think that information is very helpful, but, quite frankly, information is of limited use. For example, I don't know how many people know how many teeth they have in their mouth. You don't need that information to know that you have to brush them twice a day.

When you have multiple chronic diseases, and you have multiple facets of information about complex systems and drugs, and a lot of these people that are seeing 5 and 10 physicians are taking 15 and 20 medications and that type of thing. There is only so much information that you are going to be able to pass on to something that they are going to be able to act responsibly with before they become overwhelmed, dejected, and decide to forget the whole thing. That is why I think that case management is a very critical part of this.

The other thing that I think has been ignored by it—

Mrs. THURMAN. Earlier you thought this couldn't be done in one of your responses. So, I am curious to what you think case management is. I got the indication that you thought only a doctor could do it or—

Dr. HILLMAN. No, quite the opposite.

Mrs. THURMAN. Okay.

Dr. HILLMAN. I think a physician doing case management is not an appropriate use of health care resources. That is why I detailed the Anticoagulation program, because it is basically a nursing program that has medical direction, has prescribed protocols. All of the interactions that the nurses have with patients are documented in the electronic record, which is confirmed and electronically signed off with the providers, but they all work on very specific guidelines.

The point about that program that I think I failed to make in my written testimony is that that case manager for anticoagulation basically is acting as a chronic disease manager, because when we looked at hospitalization rates between the control group, the usual care group, versus the group that was in the Anticoagulation Service, we looked at global hospitalizations. The difference there was huge, and I have the numbers in the written testimony. The reason we looked at global hospitalizations is because we found that in the education process or the behavioral training or development process of patients, that we were able to get them to call the nurses the minute something else changed in their health care. By getting that information sooner, the nurse was able to advise them on what to do either about their medication or about seeing a provider on an outpatient basis or adjusting some other aspect of their regimen that allowed them to avoid those hospitalizations.

I agree with basically everything that Dr. Anderson said, but we actually have a program that basically, with a little bit of expansion, accomplishes what he said. Unfortunately, we get no reimbursement for this whatsoever. While we have 1,000 patients enrolled in this program right now, and many of those patients inci-

dentally have a trial fibrillation and heart valve replacements that have been caused by chronic diseases related to sacheimic or coronary artery disease, diabetes, and hypertension. That is the value of the case manager.

Mrs. THURMAN. I would just say, based on the testimony on page 5, it says they are talking about giving M+C organizations that meet specific quality indicators extra payments, recognizing the cost of successful outpatient management. In this case, it was just the CHF. So, it sounds to me like they are noticing it in one area, but it should be recognized, I guess, in the fee-for-service for any kind of demonstration program we would do there as well.

Dr. HILLMAN. I agree with you 100 percent.

Mrs. THURMAN. Thank you.

Dr. HILLMAN. That is why we didn't participate in that disease management demonstration. It was too narrowly focused. There was a huge risk associated with it, in terms of its budget neutrality, and you were required to provide medications, and I think that is a fair criticism of that demonstration project. I don't really see that we are going to get much out of it, quite frankly.

Mrs. THURMAN. Thank you.

Chairman JOHNSON. Thank you, Karen.

There have been some questions raised. To just pursue Karen's questions in two aspects. First of all, I want the record to reflect very clearly that all of you at the table who are involved in disease management programs are providing disease management services, whether they are sort of narrow and computer-driven or whether they are more interactive and have a human being there actually doing a lot of following, and advising and communicating, and that Medicare does not reimburse you for them, for that aspect of your service.

I thought it was very interesting that you pointed out in Mr. King-Shaw's testimony, and I noticed it, too, that in the demonstrations, they are going to pay for this function, but in the Choice plans. It is one of the ways in which the Choice plans bear costs that Medicare doesn't bear, and it is one of the reasons I am so intent on at least reimbursing them at 100-percent fee-for-service because if they are going to perform, they have additional costs they have to bear.

I was very interested, Dr. Hillman, with your description of the amount of technology you have put in place just to have electronic records available throughout the very large serving area of your system, which I believe is multi-county, is it not, in Wisconsin?

Dr. HILLMAN. Yes, it is.

Chairman JOHNSON. It is a big system over rural and urban areas, but without that technology, you could not possibly implement disease management protocols, correct?

Dr. HILLMAN. That is correct. Here is the perverse incentive of the whole thing. Our reimbursement for Medicare fee-for-service is so low, about 70 percent of our costs, done by the CMS methodology. We have to raise our commercial fee-for-service rates, which increases, indirectly, the number of uninsured, which indirectly increases the number of people that are on Medicaid, which indirectly causes even lower fee-for-service payments on the services that we started providing to begin with. This is an untenable situa-

tion, and the only reason that you have it at Marshfield Clinic is because we are so mission-driven and passionate about delivering the quality-of-care that we do, that we have to believe, at some point in time, what goes around comes around.

Chairman JOHNSON. You are the only system I know of nationwide, and that doesn't mean there aren't any, it just happens to be that the others haven't come to my attention, that is systemically involved in disease management with no reimbursement and serving a very low-paying, but also a needy population.

Mr. Stark?

Mr. STARK. Are your Medicare fee-for-service rates lower than Wisconsin's Medicaid? I am curious. I don't—

Dr. HILLMAN. No. Despite the fact that we get probably I think it is 50 cents on the dollar for our Medicare reimbursement, Medicaid is actually a little bit less, although—

Mr. STARK. Does anybody pay a dollar?

Dr. HILLMAN. No, but they pay a whole lot more than 50 cents on the dollar.

Mr. STARK. Do you own your own hospitals or do you contract with—

Dr. HILLMAN. We do not. We are completely outpatient. I will tell you we do have a capitation contract with the State for medication, at least Security Health Plan, our subsidiary does, and that plan actually does retain some net earnings above what they pay us. So, we are able to sustain it on a capitated basis, but we do not have a gatekeeper system with that. We use the system that I described with the anticoagulation management in order to make that margin.

Chairman JOHNSON. In other words, a management system.

Dr. HILLMAN. That is correct.

Mr. STARK. If Medicare pays you 50 cents on the dollar, what is the next lowest commercial contract on fee-for-service; does it pay you 60 cents? You don't have to tell me the name of it, but the private insurer that then pays you the next lowest.

Dr. HILLMAN. Seventy cents.

Mr. STARK. Seventy cents, it is that big a gap.

Dr. HILLMAN. That is our own health plan.

Chairman JOHNSON. That is 70 cents versus 50 cents for Medicare and less than that for Medicaid?

Dr. HILLMAN. Yes.

Chairman JOHNSON. So, we are not so great.

Mr. STARK. Thank you.

Chairman JOHNSON. Let me go back to the malpractice issue that I had raised because I didn't actually raise it in the context that Karen heard it. Within a plan, I understand that there would be whatever the plan's liability is under that State law or whatever we do in Patient's Bill of Rights. If you are trying to coordinate care across individual physicians reimbursed under Medicare, now I think you do have a problem. If they are not part of the same group practice, if they are not part of the same system, I do not know how you identify that responsibility, and how you reimburse it. I think in identifying it, you would not be able to provide the nurse practitioners and staff because the liability is—I mean, to me, that is a real can of worms.

Dr. Hillman?

Dr. HILLMAN. The only way we can do it so to be self-insured, and that is what we do. That is why we have such a high interest in maintaining quality-of-care.

Chairman JOHNSON. That is interesting. You are self-insured for malpractice as well.

Dr. HILLMAN. That is correct.

Chairman JOHNSON. That is outstanding.

Before I conclude, I just want to say that I really appreciate Dr. Henschke's comments. We will work with you on your thoughts and opinions on the clinical trials program that is being proposed, if only because 10 years, give me a break. With the pace of medical change, at the end of 10 years we will know about a procedure that is no longer the state-of-the-art, so truly a ludicrous proposal on their part.

If you were to advise us as to how we could do a better job in terms of Medicare being a force for early diagnosis of lung cancer, what would you suggest we do?

Dr. HENSCHKE. Well, I don't know all of the complications of Medicare, but I—

Chairman JOHNSON. Well, the big complication, of course, is money, but, nonetheless, what would you suggest that we do in order to have a program that did do for lung cancer, basically, what we have done for breast cancer and colon cancer.

Dr. HENSCHKE. I think one could develop demonstration projects. Medicare, I have talked to Medicare. They were very interested in the results, but they said it is Congress who has to mandate any screening policy. So—

Chairman JOHNSON. That is true. For instance, sometimes we are able to mandate screening policies when there are a combination of factors that will identify those who are prone. So, sometimes we have done that. We do that in colonoscopies. Certain procedures are available—am I correct, staff? Yes, certain procedures are available if you meet certain criterion, and other lower cost procedures are available if you don't meet those criteria.

So, if you will give that some thought and get back to us, we will be very grateful.

Dr. HENSCHKE. Thank you very much.

Chairman JOHNSON. Thank you very much.

I thank the panel for their thoughtful comments today, and I thank the Members for their participation on a Tuesday. I notice the Democrats are in town, and the Republicans aren't. I thank you for that and commend you.

[Whereupon, at 5:29 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of Richard Burford, Product Marketing Manager, 3M Health Information Systems, Wallingford, Connecticut

“On behalf of 3M Health Information Systems (3M HIS), I am pleased to submit written comments to the House Ways and Means Subcommittee on Health hearing to be held on disease management on April 16th, 2002. Our comments make the case for the importance of coordinated of care and the need for greater coordination of care in federally funded health care programs. For the sake of simplicity, our comments are submitted in the attachment in a question and answer format.

3M HIS is a market leader in the healthcare information technology business. 3M HIS specializes in coding and classification tools in acute care and the payer mar-

ket. The views advanced in our written comments result from our experience in working in the managed care arena and, particularly, with companies in the business of delivering care management and case management services.”

A Case for Better Coordination of Care

What is coordinated care and care management? Why is it important?

- “Coordinated care” is getting the right health care services to the right patients at the right time and in the right setting. Delivering well-coordinated care is important for maintaining and improving the health status of beneficiaries.
- Effective care management is also important for successfully managing the financial risk of an enrolled population.

What are the basic steps in the care management and care coordination process?

- The first step to delivering high quality care management services is understanding the disease burden of the enrollees. Enrolled **members** with chronic health conditions must be identified, classified into clinically meaningful groups and stratified according to severity. Disease progression and anticipated costs must be projected.
- Next, specific beneficiaries are then targeted for case management intervention. Case management interventions (care plans) are devised and implemented to promote effective, high quality care. The result is effective case management programs that meet the needs of enrollees by improving their health status while reducing health plan financial risk.

How did the original intent of managed care related to better coordination of care?

- In managed care, payment methods were originally designed to foster and promote the provision of coordinated care. However, capitation, which is the predominant method of payment under managed care, does not provide adequate incentives to foster well coordinated care.
- Under capitation, health plans accept an annual fixed fee to deliver a defined set of health care services to an enrolled population and, thereby, assume financial risk.
- If the capitated revenues health plans receive do not cover the costs of administering and delivering covered health care services, health plans lose money. This creates an incentive for health plans to enroll healthy beneficiaries that are expected to have low costs and to avoid beneficiaries with chronic illnesses that are expected to have high costs.
- The beneficiaries with chronic illnesses are the very ones that would benefit most from care coordination and case management services.
- To introduce positive incentives for the delivery of well coordinated care, payments to health plans must be adjusted to compensate for differences in the health status or disease burden of beneficiaries enrolled in the plan (risk adjustment) Also, direct payments for case management services can be made, specifically, for those beneficiaries that would benefit most from care coordination.

Why is effective case management and care coordination important to the future success of the Medicare+Choice program?

- Just 15.7 percent of Medicare beneficiaries account for 76.6 percent of all Medicare program payments. (1997 Medicare data)
- 76.2 percent of Medicare beneficiaries are relatively healthy and account for only 7.1 percent of Medicare program payments. (1997 Medicare data)
- Because of this high concentration of expenditures in a small number of Medicare beneficiaries, targeting enrollees for case management services and implementing effective programs of care coordination is vital to the future success of the program.
- Coordinated care is especially important for the high cost, chronically ill beneficiaries. These are the patients that, frequently, are at highest risk for deteriorating health status and the related “exponentially” increasing costs for health care services.

What are some key characteristics of a properly designed system of coordinated care?

An effective system of coordinated care should accomplish the following:

- Predict future health care resource use of beneficiaries (costs), especially for the frail elderly and individuals with special health care needs.
- Provide for effective systems of targeting cases for case management intervention and tracking the cases over time.
- Pay health plans fairly for the delivery of case management services, taking into account differences in the health status of the populations they serve.
- Be based on a clinical model that is easy to understand and verify.
- Provide clinically meaningful information to health plans in order to promote care coordination, quality improvement, disease management and provider profiling.
- Demonstrate value, i.e., the efficacy of the care management processes.
- Provide Medicare with accurate data on the competitive performance of health plans in delivering coordinated care.

What are the benefits of an effectively designed system of coordinated care?

- Health plans are paid fair and equitable capitation rates that give them incentive to serve all beneficiaries, regardless of their health status. Thus, negative program incentives that promote selective enrollment of healthy beneficiaries and the “de-selection” of sick beneficiaries are eliminated.
- Health plans are able to shift their operating emphasis from managing risk to delivering coordinated care that was the original vision of managed care.

Statement of the Advanced Medical Technology Association (AdvaMed)

AdvaMed, the Advanced Medical Technology Association, is pleased to submit this comment for the record on the important role that disease management can play in the delivery of high quality, cost effective medical care to the growing number of seniors and people with disabilities under Medicare.

AdvaMed is the world’s largest association of medical technology manufacturers, with over 1,100 members worldwide. Our members develop and produce the advanced medical technologies that are integral to disease management and other innovation forms of high quality health care delivery.

Disease management technologies have a key role to play in Medicare in the 21st century: improving patient care, improving health system efficiency, and reducing overall costs. Realizing these benefits will be critical in the coming years as Medicare faces a rapid increase in the number of beneficiaries it serves. AdvaMed supports efforts by Congress and the Centers for Medicare and Medicaid Services (CMS) to expand access to technologies that facilitate the management of disease—by ensuring adequate reimbursement and coverage.

AdvaMed believes the following three key points are important to keep in mind when considering the increasingly important role of disease management technologies:

- (1) The aging population of the U.S. demands technology solutions to manage chronic disease and reduce disability.
- (2) Technologies will likely bring the greatest strides in the future towards improving the management of chronic and short-term diseases.
- (3) Medicare should take steps to encourage more timely adoption of medical technologies that facilitate disease management.

The aging population of the U.S. demands technology solutions to manage chronic disease and reduce disability.

The United States faces unprecedented challenges in the number of elderly patients who will rely on Medicare to ensure their health and well-being. Based on historic trends, the most expensive patients are those that need ongoing institutional care—and the costs of caring for patients in nursing homes accounts for a growing share of our health care budgets. Other expensive critical care services also are expected to become more numerous as the elderly population grows.

Fortunately, technologies offer the potential for many to change the paradigm of care and reduce hospitalizations and allow patients with serious chronic conditions to lead active, productive, independent lives. Recent advances offer cost-effective so-

lutions to some of the conditions that are the costliest to Medicare, such as congestive heart failure, diabetes, and coronary artery disease.

Study results announced in March at the 2002 American College of Cardiology Annual Scientific Session show one way that advanced medical technology can improve health care quality and efficiency. The study found that a breakthrough technology called cardiac re synchronization therapy can reduce by 50% the number of hospitalizations for congestive heart failure. Heart rhythm disorders currently account for more than 761,000 hospital visits annually at a cost of more than \$6,000 apiece.

Drug-eluting stents (stents that slowly release medication after being implanted to keep the coronary artery open) show promise in eliminating the problem of arteries renarrowing, or restenosis—which is a major cause of repeat medical procedures in patients with coronary artery disease. In recent clinical trials, drug-eluting stents completed eliminated restenosis. This “could become one of the biggest breakthroughs in treating cardiovascular disease,” according to the American Heart Association.

A landmark study published last year by Duke University researcher Kenneth Manton, PhD illustrates one way that innovative tests and treatments are reducing the number of people who need disease management and yielding long-term savings. Manton’s research finds that, due in part to advances in medical technology, the rate of chronic disability among Medicare-age patients has fallen significantly over the last two decades. In fact, today there are 1.4 million fewer Medicare beneficiaries with chronic disability than would have been the case without these gains. This reduction saved Medicare an estimated \$19 billion in 1999.

Technologies will enable the greatest strides in the future towards improving the management of chronic and short term diseases.

Medical technology innovations are helping make effective disease and case management a reality. Many emerging breakthroughs are empowering patients to take a more active role in the effective management of their disease or condition.

Recently FDA approved the first-ever cardiac pacemakers with remote monitoring capability. This technology enables patients to transmit information about their heart condition and pacemaker performance from home directly to their caregiver. These “virtual office visits” promise to improve patient care and increase efficiency in treating patients with chronic heart conditions through more timely follow-up and better overall patient management.

Advances in diabetes detection and monitoring are playing key roles in the management of the disease. Diabetes and its related complications consume one of every four Medicare dollars. The Centers for Disease Control and Prevention (CDC) warns it is “a major public health threat of epidemic proportions.”

Recently, the first-ever non-invasive blood glucose monitor became available in the U.S. HHS Secretary Tommy Thompson remarked that introduction of the device “heralds the advent of new technologies that promise dramatic improvements in the quality of life for the millions of Americans who have diabetes.”

In 2001, new technologies also were introduced to make blood glucose monitoring simpler and less painful. One product made available last year was the world’s first combined blood glucose monitoring and insulin dosing system. In addition, a growing number of monitors were introduced that allow patients to draw blood samples from sites other than the fingertip, such as the arm. HHS Secretary Thompson also recently called on doctors to test many people for “pre-diabetes,” a condition of elevated blood glucose levels that often leads to diabetes.

Advanced diagnostic technology called prothrombin self-testing allows patients on blood-thinning drugs like Coumadin to closely monitor their clotting time (prothrombin time) at home. Information from the test enables the physician to adjust the blood-thinning medication to avoid serious complications like bleeding and stroke.

The genomics revolution also is yielding gains in disease management. New genomic disease management tests, by providing new information not currently available through existing methods, enable physicians to diagnose disease more quickly and accurately, to determine the most appropriate treatment and to monitor disease progression and reoccurrence during therapy. These tests also enable the detection of disease at the very early or developing stages when treatment is likely to be most effective.

In addition, many new information management technologies are emerging to help providers successfully monitor and care for patients across the spectrum of the health care delivery system.

Medicare should take steps to encourage more timely adoption of medical technologies that facilitate disease management.

Unfortunately, Medicare procedures and policies often discourage the adoption of new medical technologies that can facilitate disease management—or reduce the need for it altogether.

Diabetes testing policy:

CMS has issued several policies to reduce reimbursement and restrict access to the glucose monitoring technologies patients need to achieve tight glucose control. Congress and CMS must work to remove these restrictive policies and ensure that Medicare patients have access to advanced monitoring technology.

Recently CMS finalized a policy to cut reimbursement for blood glucose testing by 26%. The Congressional Diabetes Caucus had expressed concern to CMS that it was employing a flawed process to make this cut.

In early 2000, CMS issued an extremely burdensome policy that is discouraging close monitoring of glucose levels for patients in nursing homes. Despite the fact that glucose monitoring is designed to show a trend in glucose levels over time, CMS has said that nursing home caregivers must obtain a physician's order for each individual measurement that is taken. Because it is impractical and time consuming to obtain a physician's order for each measurement, this requirement has meant that nursing homes must either perform fewer glucose tests or absorb the cost of perform needed tests.

CMS further restricted Medicare patients' access to glucose testing in a recent policy that allows them to purchase glucose monitors and test strips only from retailers that are Medicare suppliers. However, because of Medicare's burdensome and complex requirements for gaining recognition as a Medicare supplier, many small retailers choose not to apply for this status. This policy, which has never been applied to any other product or service under Medicare, could make it difficult for many patients to purchase the glucose monitors and supplies they need, especially in rural areas that lack a Medicare supplier.

Innovative diagnostic tests:

In addition to problems specific to diabetes tests, other diagnostic tests integral to successful disease management face significant barriers at Medicare.

A report issued by the Institute of Medicine (IoM) on Medicare policy and procedures for diagnostic tests states that "current Medicare payment policy for outpatient clinical laboratory services seems not only outdated, but also irrational." The report concluded that "Medicare needs a more timely and appropriate method for integrating the proliferation of new technologies anticipated in the near future."

Legislation pending in the Senate and passed by the House as part of the Medicare Regulatory Relief bill (H.R. 3391) would help address the serious problems in Medicare's procedures for new diagnostic tests. It would establish an open public process for gathering input on reimbursement decisions for new tests and require Medicare to establish objective criteria for setting payment rates.

Hospital inpatient coding and payment:

CMS typically takes two years or more to fully integrate new medical technologies like coronary stents into the hospital inpatient payment program. A regulation published by the agency last year on adoption of new medical technologies into the inpatient setting leaves in place current delays in Medicare coding and payment decisions that create barriers to patient access to medical technologies.

Congress and CMS must take steps to support patient access by eliminating delays in assignment of new codes and adequate payment rates for new inpatient technologies. H.R. 2973, bipartisan legislation introduced in the House by Reps. Jim Ramstad (R-MN) and Karen Thurman (D-FL), would take steps to improve patient access to innovative technologies in the inpatient hospital setting.

Medicare technology adoption delays:

According to a report by the Lewin Group, Medicare can take 15 months to five years or more to integrate new medical technologies into the program. This has a significant impact on patient and provider access to innovative disease management technologies like remote monitoring devices, gene-based testing and diabetes monitoring.

H.R. 3391 contains provisions from H.R. 2973 to improve accountability and coordination between offices in CMS that make coverage, coding and payment decisions on new technologies.

Healthcare information technology:

In its report *Crossing the Quality Chasm*, the IoM said “health care delivery has been relatively untouched by the revolution in information technology that has been transforming nearly every other aspect of society.” Many of these information technologies play a key role in successful disease management. Medicare must ensure that health care providers have the resources they need to adopt effective new information technologies.

AdvaMed appreciates the Subcommittee’s interest in technologies that facilitate disease management and other innovative forms of high quality health care delivery. Given the vital role disease management technologies play in improving patient care, spurring health system efficiency, and reducing overall costs, AdvaMed and its member companies look forward to the opportunity to work with the Subcommittee on these issues in the future.

Statement of Robert Bonow, M.D., President-Elect, American Heart Association

My name is Robert Bonow, MD, and I am the president-elect of the American Heart Association. On behalf of the American Heart Association and its over 22.5 million volunteers and supporters, I am pleased to submit this statement for the hearing record.

Since 1924, the American Heart Association has dedicated itself to reducing disability and death from cardiovascular disease and stroke through research, education, community-based programs and advocacy. Providing effective, credible scientific information is vital to our mission. The American Heart Association and the American Stroke Association, a division of the American Heart Association, actively participate in efforts to improve the delivery of disease-specific health care through the widespread adoption and implementation of scientifically based standards and guidelines.

Cardiovascular Disease and Stroke Contribute Significantly to Chronic Illness in the United States

More than 125 million Americans have at least one chronic illness. This number is approximately 40% of the total U.S. population, and approximately 40% of those patients have at least two chronic conditions. The direct medical costs of chronic conditions in the U.S. will total \$600 billion per year, and the care and management of patients with chronic disease represents the single largest cost to our health care system.¹ Significantly, the cost of cardiovascular disease and stroke in the United States in 2002 is estimated at \$329.2 billion.

Of these chronic illnesses, cardiovascular disease accounts for almost as many deaths as the next seven leading causes of death combined, costing this country almost \$300 billion a year in healthcare expenditures and lost productivity—more than any other single disease. Some 60 million Americans—about 1 in 5—suffer from some form of cardiovascular disease, ranging from high blood pressure to myocardial infarction, angina pectoris, stroke, congenital vascular defects and congestive heart failure. One form of cardiovascular disease alone, heart disease, is the number one killer in the U.S., and another form of cardiovascular disease, stroke, is the third leading killer.

Disease Management as an Approach to Confronting Chronic Illness

Disease management is one strategy used to confront the challenges presented by chronic illness. It is a term widely and inconsistently used. Hundreds of “disease management programs” exist for a wide array of chronic illnesses, including congestive heart failure, diabetes, asthma and depression. Increasingly, disease management is being offered as an approach to health care management in the public and private sectors. For example, Federal agencies are currently evaluating the cost effectiveness and patient outcomes of programs that rely on disease management techniques to deliver patient care; a number of states are offering disease management services through their Medicaid programs; key members of Congress are intro-

¹ Lawrence Fisher & Karen L. Weihs, *Can Addressing Family Relationships Improve Outcomes in Chronic Disease?* 561 *Journal of Family Practice* 561 (June 2000).

ducing legislation to fund new disease management initiatives; and pharmaceutical benefit managers (PBMs) are contracting with states to provide disease management services through pharmaceutical assistance programs for seniors. There are as many definitions of “disease management” as there are programs that claim to provide disease management services.

Although advocates for the approach argue that it lowers costs, improves patient care, and allows for effective evaluation of services, some policy experts suggest that disease management programs may actually lower costs at the expense of patients’ healthcare needs, or alternatively, that it may actually increase health care costs through added services (which may include administrative costs and other indirect costs). In addition, the effectiveness of disease management in improving clinical outcomes is currently being evaluated.²

The American Heart Association Urges Policymakers to Focus on Quality as the Guiding Principle

Disease management is an evolving concept. As government, health plans and clinicians have adopted disease management models to fit their own needs and goals, the various meanings of disease management have diversified. In practice, disease management can cover a range of potential activities, from distributing pamphlets to patients that instruct them on self-management techniques related to their particular condition to relying on a case manager to develop patient-specific care plans.³

The American Heart Association finds the concept of disease management promising, but also urges the Subcommittee to consider two issues—

- (1) any quality standards or performance measures for cardiovascular disease and stroke must be based appropriate, objective and scientifically-derived, evidence-based guidelines; and
- (2) quality of care must be prioritized over cost-containment or other financial incentives in all disease management initiatives. Disease management should be primarily about improving patient outcomes and only secondarily about cost containment.

For disease management to truly put patients first, clinical guidelines must rely on a template that emerges from medical community consensus. Additionally, appropriate disease-specific programs should reach low-risk patients as well as high-risk patients to best serve long-term health needs. In short, to focus on appropriate patient-centered clinical guidelines, medical community standards must serve as the fundamental framework for any disease management program that hopes to draw widespread approval and acceptance.

How Congress chooses to confront this issue for Medicare beneficiaries will likely impact the entire U.S. healthcare system. As noted in a recent MedPAC report to Congress, “. . . because Medicare is the single largest purchaser of health care in the country, its actions influence the care that all patients receive nationwide.”⁴

The American Heart Association Provides Leadership and Consensus

It is fitting that the American Heart Association adds its voice to the many that are currently speaking to the issue of disease management. Although within most clinical areas there are many organizations, health plans and manufacturers that promote clinical guidelines based in part on the clinical literature, few organizations have the expertise or resources to establish and continually update consensus based standards that represent a holistic view of cardiovascular and stroke care. Importantly, the American Heart Association represents not just providers but all stakeholders in cardiovascular and stroke care—physicians, nurses, emergency medical support personnel and others. Most significantly, the American Heart Association represents the patient.

The American Heart Association is at the forefront of investigating ways to improve the quality of care for patients with cardiovascular disease and stroke. We have developed and are currently operating a number of patient-centered programs. Our programmatic efforts have increased and evolved with the dynamic advances made in cardiovascular and stroke care.

²Finley A. McAlister et al., *A Systematic Review of Randomized Trials of Disease Management Programs in Heart Failure*, 110 *American Journal of Medicine* 378, 381 (April 1, 2001).

³Jeff Tieman, *Disease Management Making a Case for Itself Clinically and Financially*, *Modern Healthcare*, July 9, 2001.

⁴Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Applying Quality Improvement Standards in Medicare* (January 2002).

In essence, the American Heart Association's existing programs and guidelines provide a foundation for managing disease. We are extremely proud of the process through which our guidelines are developed and place great emphasis on ensuring objectivity and sound science. The American Heart Association and the American College of Cardiology have developed joint guidelines on the treatment and management of heart disease, including guidelines for acute myocardial infarction, unstable angina, congestive heart failure, chronic coronary disease and secondary prevention.

The American Heart Association and the American College of Cardiology also work in partnership in the development of performance measures, including developing measures for acute myocardial infarction and chronic heart failure. The American Stroke Association, a division of the American Heart Association, develops scientific guidelines for managing and treating stroke and is currently developing performance measures for stroke.

Our programs are developed based on our scientific guidelines. The following is a brief description of two of our programs designed to improve the quality of care for cardiovascular and stroke patients.

- *Get With the Guidelines*—This program is an acute care hospital-based program that helps manage risk factors in coronary artery disease and stroke patients. *Get With the Guidelines* strives for long-term behavioral change by focusing on workable patient management strategies in the hospital setting. *Get With the Guidelines* incorporates a multi-disciplinary approach to risk factor management. The program encourages links between cardiologists, neurologists, primary care physicians, nurses and pharmacists. It also provides resources to build consensus and optimize discharge protocols.
- *Acute Stroke Treatment Program*—This multimedia toolkit includes guidelines and criteria for hospitals to use in meeting the standards of a primary stroke center. The criteria follow the consensus of the Brain Attack Coalition guidelines and helps hospitals evaluate their capacity to treat stroke patients.

The American Heart Association's work on disease management is ongoing. We are currently reviewing various models of disease management, particularly in the area of cardiovascular disease and stroke. We are analyzing the effectiveness of these models and hope to use this information to refine our current policies, programs and other efforts, if needed.

Conclusion

In addition to the use of appropriate clinical guidelines, it is critical to ensure that disease management programs are driven by the clinical needs of patients rather than cost containment or financial profit. While we recognize the need for cost containment and careful allocation of health care resources, improving the quality of care must be the primary goal of any disease management program. The American Heart Association appreciates the opportunity to provide these comments to the Ways & Means Health Subcommittee on this timely and important issue, and we look forward to working with the Subcommittee as it continues to consider the appropriate integration of disease management into the Medicare program.

Statement of the Hon. Richard Burr, a Representative in Congress from the State of North Carolina

I would like to offer my thanks and praise to the Chairman for calling this hearing on disease management in Medicare. I have long been committed to providing the best possible services to Medicare beneficiaries and to creating incentives for the development of innovative new medical technologies that will improve care. Disease management offers the opportunity to do both.

I have introduced a bill that takes a simple but important first step toward Medicare coverage of emerging remote technologies that play an increasing role in disease management. The bill would improve patient care while moving forward the modernization of Medicare's benefit package. I look forward to working with you on disease management, and enlisting your support for H.R. 3572, the Medicare Remote Monitoring Services Coverage Act.

Emerging Disease Management Approaches Emphasize Technology

Several broad market trends are placing new focus on disease management today.

- Managed care plans are shifting their focus from tightly controlled access to services to more loosely structured preferred provider organizations, resulting in increased outsourcing of disease management services.

- A growing sense of self-empowerment among patients with chronic conditions is leading to the development of patient-focused solutions.
- Finally, advances in telecommunications are facilitating improved interactions between patients and health care professionals. Data advances that automate information collection and patient tracking are making it easier to identify and treat patients with chronic conditions.

Emerging disease management vendors are employing technology to enhance their product offerings. Patient-focused services feature disease assessment surveys, personal action plans, and on-line information and support, while services tailored to clinicians include tools to track patients, frequently asked practice questions, and online clinical care guidelines.

Among the most significant technology-focused services are those that strengthen the link between patients and physicians. These services provide for interactive case management and support, “push” surveys that solicit patient information and feedback, live chats with nurses or other health experts, and home monitoring with automatic or manual data transmission.

While traditional disease management approaches have emphasized case management by nurses as a key interaction between patients and clinicians, emerging disease management techniques feature home data monitoring and interactive case management and support, along with nurse case management, to create greater linkages between patients and clinicians.

Analyses by firms that specialize in disease management show that technology-centered approaches reduce hospitalizations and medical costs and lead to greater physical health and patient satisfaction. The development of new technologies expands the promise of emerging disease management approaches.

Lack of Medicare Coverage Hinders Broader Adoption of Remote Monitoring

Despite the innovations emerging in disease management, many new clinical information and remote management technologies have failed to diffuse rapidly. A significant barrier to wider adoption of disease management approaches that utilize remote monitoring services is the lack of payment mechanisms in fee-for-service Medicare to reimburse for remote, non-face-to-face management services provided by a physician.

Consider the implications for an elderly Medicare beneficiary with a heart condition similar to the Vice President's. If, for example, the beneficiary receives a shock from her implantable cardioverter defibrillator (ICD) over the weekend when her heart specialist is not in the office, the patient would likely go to the emergency room where there may not be a heart specialist on staff familiar with her condition.

Yet if the beneficiary had remote monitoring technologies in her home, she could immediately forward information concerning her heart and the ICD securely through the Internet to her physician. The heart specialist could then decide if the patient should come into the clinic on the next business day or to proceed immediately to an emergency room. More likely, the patient would be reassured that everything is appropriate, thus saving an often stressful and expensive trip to a hospital emergency room.

Under existing Medicare payment rules, many physician billing codes are primarily for face-to-face interactions between the physician and patient. The payments often do not account for the clinician time involved in non-face-to-face interactions that are necessary for interpretation and response to data from remote management technologies. As a result, the payment systems do not adequately reflect the value of physician services involving remote monitoring services, and serve as an impediment to disease management approaches that involve remote monitoring services.

The Medicare Remote Monitoring Services Coverage Act

To provide greater incentives for the adoption of remote patient management services, changes in Medicare reimbursements are necessary. My bill—H.R. 3572, the Medicare Remote Monitoring Services Coverage Act—takes an initial step toward covering remote monitoring services. It would create parity between certain face-to-face and remote services. Under the bill:

- Remote monitoring services that are found to be comparable to face-to-face, encounter-based, monitoring services will be given the same coverage and level of Medicare payment as the comparable encounter-based physician service.
- Remote monitoring services are defined to be services provided through a system of technology that allows a remote interface to collect and transmit clin-

ical quantitative data between a patient and a provider, for the purposes of clinical review or response by the provider.

- The Secretary of Health and Human Services would have the discretion to determine comparability between face-to-face and remote monitoring services. The remote monitoring services would be subject to the same frequency guidelines developed now or in the future for the comparable in-office services.
- The provision is designed to be budget-neutral. We anticipate that remote monitoring services will substitute for the existing in-office services only when appropriate. In the event utilization increases, the bill includes a mechanism to ensure budget neutrality.

There are several benefits of the legislation.

- It will improve patient access, care, and management, as well as spur the development of new technologies and disease management approaches that will improve services further. For patients in more rural settings, it may be the most practical means for patient management in order to make timely adjustments in the program of care before a more serious health event occurs.
- The proposal attaches value to physician time dedicated to remote management technology and will encourage physician use of tools that improve services to patients. It will also enable enhanced care and real-time feedback that will avoid unnecessary hospitalizations and patient anxiety.
- It ensures that payment will only be provided for services that are comparable to those provided in face-to-face interactions. The Centers for Medicare and Medicaid Services would retain authority through existing initiatives to monitor the quality of such services.

Conclusion

Madam Chairman, let me once again commend you for your leadership in calling this hearing today. Advances in technology are expanding the promise of disease management, and Medicare must take advantage of the opportunity to improve care for those with chronic conditions. My bill provides a simple but important first step toward the coverage of new remote technologies featured in emerging disease management approaches today. I urge you to join me as a cosponsor of the bill, and I look forward to working with the members of this Committee, as well as with my fellow colleagues on the Energy and Commerce Committee, to passing the bill this year. Thank you very much for the opportunity to present my views.

Statement of Christobel Selecky, Chair, Government Affairs and Health Policy Committee, Disease Management Association of America

Chairwoman Johnson and distinguished members of the Subcommittee, it is a pleasure to have the opportunity to provide testimony to the Subcommittee on the strong value of disease management programs to improve quality and control costs under the Medicare program. My name is Christobel Selecky and I am a member of the Board of Directors of the Disease Management Association of America (DMAA) and also the Chair of their Government Affairs and Health Policy Committee. I am also the Chief Executive Officer of LifeMasters Supported SelfCare, a privately held Disease Management Organization (DMO).

Overview.

Comprehensive Disease Management (“DM”) programs have demonstrated their effectiveness in improving health status, health care quality, patient and provider satisfaction, and financial outcomes for populations with congestive heart failure (CHF), diabetes, coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD), end-stage renal disease (ESRD), asthma, obesity, and several other chronic illnesses. Commercial, Medicare FFS, Medicare+Choice, and some state Medicaid plans have already implemented DM programs and benefited from these clinical and financial outcomes. A majority of large private payors have already launched major disease management programs and have signaled their commitment to DM as the core element of their new medical management strategy.

The Disease Management Association of America fully supports and commends the Congress and the Centers for Medicare and Medicaid Services (“CMS”) for promoting the expansion of DM programs in its efforts to modernize and revitalize Medicare+Choice, and through the coordinated care, Benefits Improvement and Protection Act (BIPA), and other demonstration projects.

In order to build on the incremental progress made to date, DMAA strongly urges federal policymakers to offer the benefits of full-service DM programs to all enrollees in:

- The traditional Medicare fee-for-service (“FFS”) program;
- Any new Medicare+Choice programs, such as point of service, PPO, or MSA products; and
- All State Medicaid programs, including FFS and managed care alternatives.

Disease Management and the DMAA.

Disease Management is an approach to patient care that seeks to limit “preventable” events by maximizing patient adherence to prescribed treatments and to health-promoting behaviors. For patients with chronic diseases, the anticipated benefits of disease management include superior clinical outcomes; improved functional capacity and quality of life; lower health care costs; reduced need for hospitalization, surgery or other invasive care; and greater access to care support service.

The Disease Management Association of America (DMAA) is the only association in America dedicated exclusively to the DM industry. The DMAA draws members from throughout the United States and has representatives from all segments of the DM industry, including health plans, hospitals, employers, pharmaceutical companies, physicians, and stand-alone DM organizations. The DMAA seeks to advance the use of DM programs as a means to build a better **system of care** that will predictably improve quality and reduce costs in private and public sector health care programs. DMAA also works to promote research, accreditation, education, and the science of DM, and to increase the effectiveness of DM programs.

The DMAA has established an industry-standard definition¹ of qualified disease management programs and entities. The DMAA definition—established in consultation with primary care and specialty physicians, and incorporating private practice, health plan and institutional perspectives—has been relied upon widely by CMS (the definition is cited by CMS in its February 22, 2002 solicitation for proposals to conduct the DM demonstration projects authorized in the BIPA, by DM accreditors (NCQA, URAC and potentially JCAHO) and by payors and providers.

Disease Management Improves Health Status & Quality and Helps Control Costs.

Disease management programs produce significant clinical improvements at the same time that they achieve financial savings. For example, one study published in a peer-reviewed cardiology journal (*Am Heart J* 1999; 138: 633–640) followed the progress of a population of CHF patients enrolled in a multidisciplinary DM program including patient education, interactive vital sign and symptom monitoring, nurse support and physician intervention. Clinical impacts measured twelve months after enrollment included an 18 percent reduction in inpatient days, a 36 percent reduction in inpatient admissions, a 31 percent decrease in emergency department visits, and a 20 percent decline in average length of stay. Patient satisfaction surveys showed a 16 percent improvement. Financial savings for the group were reflected in a 54% drop in disease specific claims and a 42% average reduction in all claims. Numerous similar examples of such impressive outcomes are fully described in DMAA’s Medicare and Medicaid “White Paper” (available at www.dmaa.org).

DM has already been proven to be successful in Medicare and Medicaid populations. In Hawaii, American Healthways, a DMAA member DM company, provided

¹Disease management is a multidisciplinary, systematic approach to health care delivery that: (1) includes all members of a chronic disease population; (2) supports the physician-patient relationship and plan of care; (3) optimizes patient care through prevention, proactive, protocols/interventions based on professional consensus, demonstrated clinical best practices, or evidence-based interventions; and patient self-management; and (4) continuously evaluates health status and measures outcomes with the goal of improving overall health, thereby enhancing quality of life and lowering the cost of care. Qualified Disease Management programs should contain the following components:

- Population Identification processes;
- Evidence-based practice guidelines;
- Collaborative practice models that include physician and support-service providers;
- Risk identification and matching of interventions with need;
- Patient self-management education (which may include primary prevention, behavior modification programs, support groups, and compliance/surveillance);
- Process and outcomes measurement, evaluation, and management;
- Routine reporting/feedback loops (which may include communication with patient, physician, health plan and ancillary providers, in addition to practice profiling); and
- Appropriate use of information technology (which may include specialized software, data registries, automated decision support tools, and call-back systems).

diabetes disease management services to 6,000 Medicare FFS cost contract beneficiaries enrolled in HMSA. In the first year, the program yielded a 17.2% reduction in total claims savings over the population resulting in a \$5 million net savings to CMS. In Florida, LifeMasters has been providing CHF disease management services to approximately 3,000 FFS Medicaid recipients in the northern half of the state for almost two years. After just one year, total claims costs for this population were reduced by 21% resulting in a \$3 million net savings to the state. In addition to cost savings, quality of care and satisfaction for these populations was significantly improved.

One DMAA member company's calculations indicate that the difference between annual baseline costs for CHF in the Medicare FFS program and the company's claims-reconciled costs for patients in a disease management intervention for one year is over \$14,000. Extrapolating savings across the Medicare program using a conservative figure of \$11,000 for both the Medicare+Choice and FFS programs, CHF disease management alone could produce total Medicare savings of over \$8.3 billion annually. The FFS program would account for \$7 billion, or nearly 85 percent of the total savings opportunity, suggesting the critical need for testing the expansion of disease management to this segment of Medicare.

DM programs also improve access to care. Sophisticated information technology is used to both identify and enroll *all* persons with a given health condition. This proactive outreach process helps to include individuals who are otherwise isolated from the health care system. And many programs run by DMAA members are administered on a multi-lingual basis in languages such as Spanish, Cantonese and Mandarin.

DM programs can also play a crucial role in reducing medical errors and improving quality. The recent Institute of Medicine (IOM) reports on medical errors² and the deteriorating quality of healthcare in America³ argue that DM is not only integral to preventing medical errors, but also to protecting and improving overall health care quality, especially for the chronically ill. As the IOM studies emphasized:

- One of the chief culprits in medical errors is the lack of care management and coordination, resulting from the decentralized and fragmented nature of the health care delivery system, and the multitude of unaffiliated providers practicing in different settings without access to complete medical record information or coordination (such as can be provided by DM organizations).
- More than 100 million Americans have at least one chronic illness. "Clinicians, health care organizations, and purchasers . . . should focus on improving care for common, chronic conditions such as heart disease, diabetes, and asthma that are now the leading causes of illness in the United States and consume a substantial portion of health care resources. These ailments typically require care involving a variety of clinicians and health care settings, over extended periods of time . . . who work so independently from one another that they frequently provide care without the benefit of complete information about patients' conditions, medical histories, or treatment received in other settings."

Disease Management is Needed "Inside" Medicare and Medicaid.

Diseases such as arthritis, asthma, cancer, chronic obstructive pulmonary disease, CHF, depression, and diabetes account for 60 percent of medical costs in the United States. Cardiovascular disease is the leading cause of death among both men and women and across all racial and ethnic groups. About 58 million Americans live with some form of the disease. In 1999 alone, cardiovascular disease cost the nation an estimated \$287 billion in health care expenditures and lost productivity, and this burden is growing as the population ages. In the Medicare population, a 1993 chronic care demonstration proposal indicated that roughly 10 percent of the Medicare beneficiaries accounted for 70 percent of the \$129.4 billion in total Medicare expenditures. The majority of these 10 percent suffered from chronic illnesses. Medicare has recognized that an acute care system is no longer appropriate where the major morbidity, mortality and cost drivers of our era are chronic conditions. However, Medicare and Medicaid have thus far lacked the legislative and regulatory authority

²*To Err is Human: Building a Safer Health System*, Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Eds., Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, D.C. (1999). <<http://books.nap.edu/books/0309068371/html/R1.html#pagetop>>

³*Crossing the Quality Chasm: A New Health System for the 21st Century*, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, D.C. (2001). <<http://www.nap.edu/books/0309072808/html/>>

to implement demonstrations on a wide scale to provide fair access to all beneficiaries.

DMAA believes that comprehensive DM, if fully employed in Medicare and Medicaid, can:

- Improve the **safety and quality** of care by adhering to evidence-based treatment guidelines and outcomes data, and by providing patients with a safety net between physician and hospital visits, thereby reducing drug and treatment errors and improving care coordination (identified by the Institutes of Medicine as the two principal problems with the America health care system)
- Improve **access** to care by around the clock nursing and high-tech contacts, and by assisting rural caregivers and their patients who do not have the benefit of easy entrée to in-person care
- Improve **patient self-management** of, and responsibility for, preventing and treating their conditions by its innovations in patient-centered and collaborative education
- Improve financial **cost containment without sacrificing quality or patient satisfaction** by serving as an alternative to the increasingly unacceptable cost-containment techniques of managed care, such as utilization review, gatekeeper restrictions, referral limitations, and drug restrictions
- Enhance efforts in the **Public Health** arena by providing health improvement programs on a population basis; creating financial incentives to promote and deliver preventive interventions on a large scale using advanced outreach technologies, especially secondary preventive measures; and encouraging those segments of the private sector that have not yet embraced DM to do so.

DM should be implemented in Medicare FFS, Medicare+Choice, and Medicaid according to the following principles endorsed by the DMAA:

- There should be **no discrimination** against FFS enrollees, who currently lack any access to the benefits of DM programs available to Medicare+Choice and certain Medicaid enrollees (or have lost access to these programs as a result of the loss of their Medicare+Choice coverage).
- Medicare and Medicaid FFS programs should **directly contract** with DM organizations to offer such benefits on a population basis. Further, DM programs and demonstration projects sponsored by CMS should reflect models of DM which have been successfully utilized in the commercial sector. Specifically, these programs should not require that DM be linked with the provision of a drug benefit which is not a standard offering of DM providers.
- Medicare and Medicaid managed care programs should provide **financial and other incentives** to private health plans and public managed care programs and their enrollees to join HMOs, PPOs, MSAs, point of service plans, and other alternatives to traditional FFS.
- DM programs should be compensated for their services on an equitable and competitive basis that compensates them for their investments, provides them with incentives to maximize both clinical and financial outcomes. Historically fees paid to DM organizations are a fraction of the savings generated for their payor customers.

As the only association in America dedicated exclusively to the DM industry, we would like to offer the services and expertise of DMAA's staff and member organizations to serve as a resource to the Subcommittee as you explore the various ways in which Disease Management can improve the delivery of healthcare in the United States.

Thank you for the opportunity to provide these views to the Subcommittee.⁶³

The **Disease Management Association of America**, a non-profit, voluntary membership organization, founded in March of 1999, is the only industry organization dedicated to advancing disease management. DMAA's members represent disease management organizations, health plans, employers, pharmaceutical companies and benefits managers, hospitals, physicians, and other stakeholders in the disease management community.

Statement of Sandeep Wadhwa, M.D., MBA, Vice President, Disease Management Services, McKesson Health Solutions, McKesson Corporation, San Francisco, California

I am pleased to submit this statement on behalf of McKesson Corporation to the Subcommittee on Health of the House Committee on Ways and Means, subsequent to the April 16 hearing on Promoting Disease Management in Medicare. McKesson Corporation strongly supports the creation of a disease management benefit for Medicare and Medicaid recipients. Furthermore, McKesson recommends the expansion of disease management services to recipients of Federal government sponsored health care benefits (Veterans Health Administration beneficiaries, military personnel and dependents and Federal employees) and to rural underserved populations.

As the world's largest healthcare services company, McKesson is an industry leader in the provision of disease management services for commercial, Medicaid and Medicare populations. The Disease Management Purchasing Consortium and the Health Industry Research Company have both recognized McKesson as a Top Ten disease management firm from more than 160 companies. Our disease management clients cover a broad host of purchasers of health care, including commercial health plans such as Blue Cross Blue Shield of Texas, Anthem Midwest, and Blue Cross Blue Shield Federal Employees Plan; state Medicaid programs and managed care plans such as the State of Washington and Columbia United Providers; and high risk insurance pools like CoverColorado. As such, we are uniquely positioned to provide Congress with information on currently available solutions, as well as ideas for improving the health status of populations while decreasing health care costs through the use of disease management programs.

McKesson is the industry leader in care management services and software and has market leadership positions in demand management and utilization criteria. Furthermore, we are leading providers of physician and quality profiling software and case management workflow software. As an early provider of these programs, we have been delivering disease management services since 1996. McKesson's disease management programs leverage our experience with patient services, pharmacy management, and health care quality improvement activities. Many of these programs and services reflect the capabilities and expertise of our 165 year old company, one of the largest nationwide distributors of pharmaceuticals and health care products and the largest health information technology company in the world.

The disease management industry arose from the recognition that the nation's health care system is largely geared towards meeting the acute and symptomatic needs of patients, rather than the long-term needs of those with chronic diseases. However, by providing proactive rather than reactive care, disease management services can help retard the progression of disease by encouraging a more rapid adoption of evidence-based standards of care which reduces the likelihood of acute care intervention.

Disease management is one of the few health care innovations that can improve health status and access to care while reducing net expenditures. In developing this program for Medicare beneficiaries, McKesson recommends that Congress initially focus on those conditions for which there are national, evidence-based guidelines of care and that lend themselves to a net savings. In addition, it is important to focus on conditions where the gap between the standards of care and actual practice leads to hospitalizations and emergency room visits, both of which might otherwise be avoided through adherence to the guidelines. Conditions that meet these criteria include congestive heart failure, diabetes, asthma, and chronic obstructive pulmonary disease (COPD).

Demonstrated Results

McKesson's success with disease management is a function of leveraging information technology through the creation of clinical decision support software, utilization of advanced relational database management systems, and application of state-of-the-art call center technology. Our system relies on both "high tech" information technology and "high touch" nursing to achieve its impact. We position our services to complement and extend, and not threaten or disrupt, the patient-physician relationship. Our aim is to reinforce physician treatment plans that are often misunderstood or incompletely understood as well as to promote awareness and adherence to evidence-based guidelines.

McKesson's disease management services are delivered by health care professionals. We rely primarily on nurses to provide patient counseling and education through telephonic nursing, also known as telenursing. These health care professionals are able to impart evidence-based education and assess patients' under-

standing of their condition and barriers to compliance. In addition to proactive monitoring and counseling, our disease management programs offer patients around the clock access to nurses who are able to answer patients' symptom-related concerns and safely direct patients to the appropriate level of care. Telephone access to nurses for health care advice and support also benefits the Medicare patient or those living in rural, underserved areas without ready access to a physician's office or to emergency room facilities. Our nurse triage function complements the proactive components to reduce inappropriate utilization of services.

McKesson programs have demonstrated dramatic improvements in the health status of patients, with marked reductions in hospitalization and emergency room visits that have resulted in net reductions in health care costs. In order to achieve improved outcomes, our programs focus on teaching patients self-management principles, symptom control strategies, and optimal medical management practices. In patients with congestive heart failure, which is the leading cause of admissions in Medicare, we demonstrated for one disease management client an 89% increase in the usage of ACE-inhibitors, heart failure drugs which lower mortality and morbidity rates. With the same client, we also documented a 24% increase in influenza vaccination and a 44% increase in patients' adherence to a low salt diet. These changes in care management and patient behavior led, over the course of one year, to a 51% reduction in inpatient costs, 36% reduction in emergency room visits and an overall reduction in claims costs of 24%. Furthermore, patients in this program reported very high satisfaction with the service and noted improvements in their overall quality of life.

Our diabetes program not only helps patients improve their blood sugar values, but also focuses on reducing risk of strokes and heart attacks, which account for the overwhelming morbidity and mortality in diabetics. For one client, we have demonstrated a 33% increase in patients' use of glucose meters and a 70% increase in the use of aspirin, which contributed to a documented 35% reduction in hospitalization and 28% reduction in diabetes-related missed work days.

Overall, annual net savings in health care costs inclusive of program fees for disease management for our congestive heart failure program range from \$610 to \$4,872 per patient. For diabetes, annual net savings range from \$755 to \$2,138 per patient, and for asthma, we have net savings ranging from \$223 to \$899 per patient. We have demonstrated these results in commercial, Medicare and Medicaid settings, and with government employees. McKesson has conducted evaluations using different study designs, including pre/post evaluations, prospective cohort evaluations, and randomized controlled trials. We believe that the benefits of disease management programs can be evaluated using the most rigorous study designs

Market Segments

Medicare

To date, disease management programs have largely been an innovation in the commercial insurance market and serve the families of adult workers. However, the burden of chronic disease is disproportionately higher in the elderly, and concomitantly leads to increased costs of care and utilization of services in that population segment. McKesson believes that Medicare rates of hospitalization and emergency room use can be reduced, sometimes dramatically, in patients with chronic diseases, particularly those with congestive heart failure, asthma, diabetes, and COPD. These conditions are highly prevalent in the Medicare population, and the avoidance of unnecessary hospitalizations and emergency room visits can result in sizable savings while improving the quality of lives of Medicare beneficiaries. For example, for one Medicare+Choice client, we demonstrated a 48% reduction over six months in bed days in a program designed to treat congestive heart failure.

The Medicare population is expected to double over the next 30 years.¹ Disease management programs can serve as a fiscally prudent measure to temper the rate of growth in the costs of Medicare services. In addition, when a prescription drug benefit is created for Medicare recipients, disease management programs can help rationalize the appropriate use of medications and greatly improve healthcare outcomes.

Medicaid

As states continue to grapple with rising Medicaid expenditures, disease management can serve as an important service to control health care costs. McKesson believes that the greatest opportunity is in the Medicaid elderly and disabled cat-

¹ Board of Trustees of the Federal Hospital Insurance Trust Fund. Annual report of the Federal Hospital Insurance Trust Fund. Washington, D.C.: USGPO, 2000.

egories. Eleven million of the 40 million Medicaid recipients qualify for Medicaid on the basis of disability or age.² Despite being roughly 25% of the population, this group accounts for nearly 66% of the Medicaid costs.³ Furthermore, very few disabled and elderly Medicaid recipients are covered by managed care organizations due to their very high costs and pre-existing conditions. Therefore, these vulnerable patients lack many of the care coordination services common to managed care organizations. Disease management programs provide patient counseling, care coordination, and a patient advocate who is able to counsel patients and help them navigate through a complex health care system.

McKesson has several Medicaid clients. We have contracted directly with the state in some cases and with Medicaid managed care plans in other cases. Although Medicaid reimbursements are lower than reimbursements from commercial payers, there is usually higher utilization of services in Medicaid programs. In an asthma disease management program conducted for Medicaid recipients in a Mid-Atlantic state, we have demonstrated a 37% reduction in hospitalizations and a 22% reduction in emergency room visits, which resulted in a 19% return on investment for the health plan.

Government Employees

McKesson also recommends that the benefit design for Federal Government employees be expanded to include disease management services. Focusing on conditions such as asthma, diabetes, congestive heart failure, and COPD can result in net reductions in health care costs and an improvement in the health status of employees or dependents with these conditions.

We believe that current and former military personnel also should be included in this initiative. The Veterans Health Administration (VHA) system is rapidly expanding and faces increased costs associated with providing care for veterans, particularly those who served in World War II and Korea. Tricare and the VHA are beginning to conduct pilot trials of disease management services and have solicited bids from companies including McKesson. We strongly support expansion of these trials with a focus on solutions that are scalable across wide geographic settings.

Rural, underserved populations

Disease management services are particularly relevant in underserved areas. For the 61 million Americans who live in rural settings, access to health care is an issue of major concern.⁴ In these settings, investments to promote patient self-management and education are particularly fruitful. By increasing compliance and self-reliance, disease management can help lessen the demand and, therefore, the need, for scarce health care resources. Telenursing services in disease management programs are able to efficiently and economically overcome geographic barriers for care provision. Disease management services can act as a physician extender in these underserved areas. McKesson strongly recommends the implementation of disease management programs in rural, underserved areas and suggests pilot projects to demonstrate the effectiveness of disease management services in these settings.

Conclusion

Disease management has emerged as a private sector solution that provides incremental technology and professional resources to improve care for those with chronic conditions. These services improve the health of patients by decreasing symptoms and improving their quality of life. Disease management also reduces the frequency of emergency room visits and hospitalizations as patients learn to effectively manage their diseases. Overall, we believe that the savings from reductions in hospitalizations and emergency room visits outweighs the costs of delivering these programs.

McKesson urges the creation of a disease management benefit for Medicare recipients. The impact of these programs is greater for vulnerable populations such as the poor, elderly, and disabled, where the frequency and costs of chronic conditions are higher and health care delivery is generally highly fragmented. The outcomes-focused, evidence-based interventions provided in disease management programs improve patients' ability to participate in their care and help physicians by reinforcing medical recommendations. As Congress grapples with improving the quality and delivery of health care, we support the greater utilization of disease management pro-

²Hoffman C, Schlobohm A. *Uninsured in America: a Chart book*. 2nd ed. Washington, D.C.: Kaiser Commission on **Medicaid** and the Uninsured, March 2000.

³**Medicaid**: a primer. Washington, D.C.: Kaiser Commission on **Medicaid** and the Uninsured, 2001.

⁴National Rural Health Association. *Annual Report 2000*.

grams as a vital way to enhance care outcomes for the elderly while concurrently reducing the cost of delivering better care.

We look forward to working with members of this subcommittee as you address these important concerns.

Statement of RMS Disease Management Inc., McGaw Park, Illinois

RMS Disease Management Inc., an affiliate of Baxter Healthcare Corporation, provides disease management (DM) services for patients with chronic kidney disease. Founded in 1996, RMS coordinates care for approximately 5,000 patients across the United States. Clients include regional and national health plans as well as the State of Florida's Medicaid program.

We strongly support the Subcommittee's efforts to expand disease management programs in the Medicare fee-for-service (FFS) population. Disease management has been proven to improve both clinical and economic outcomes while concurrently increasing patient and provider satisfaction. Applying DM to the FFS population offers the government a singular opportunity to improve the quality of care for Medicare beneficiaries, while also addressing increasingly critical funding issues.

Comprehensive disease management programs directly address the issues raised in the March 2001, Institute of Medicine 2 Report "Crossing the Quality Chasm: A New Health System for the 21st Century". Specifically, DM programs supply the patient centered data, necessary information systems, aligned incentives, and integrated care coordination that the report authors believe are required to close the chasm.

End-stage renal disease provides an ideal opportunity for applying disease management principles due to the characteristics of this population and its care. These characteristics include:

- A clearly defined population using the HCFA 2728 form
- Patients typically have multiple co-morbidities in addition to their renal disease which requires complex care that takes place in a variety of care settings
- Care delivered is fragmented as a result of multiple physician specialists and allied care professionals working in an uncoordinated manner
- High annual costs
- Incomplete capture of patient care data in one medical record file
- Important need for ongoing patient counseling and education

The RMS program has been designed and implemented to address all of these issues and needs. RMS uses evidence-based medicine, state-of-the-art information technology, and highly experienced nurses to provide care support for renal patients and their attending physicians 24 hours per day, 7 days a week. Patients receive education, counseling, and care coordination based on individual care plans created by their physicians. Physicians receive incremental nursing support and comprehensive patient data that otherwise would not be available to them. Activities in the field are overseen by board certified nephrologists and a nationally recognized Medical Advisory Board.

Program results published in the peer-reviewed American Journal of Kidney Diseases, May 2001, showed a 35 percent reduction in hospitalization and 20 percent reduction in mortality for patients whose care was coordinated by RMS. Emergency room visits have dropped by over 75 percent compared to the pre-program baseline. Further, self-reported patient and provider satisfaction is also consistently very high.

We believe expanding the availability of disease management to the fee-for-service ESRD population will achieve similar benefits to those that have been obtained in managed care populations. In its deliberations, we would suggest the Subcommittee consider the following:

- (1) Establish high standards for defining disease management programs. There is widespread variability as to what constitutes "true" disease management. As a starting point, we propose that the accreditation guidelines established by NCQA be used as a baseline.
- (2) Ensure that payment mechanisms for patient categories are properly risk adjusted and funded. For example, current ESRD AAPCC rates do not fully account for the impact of diabetic status, MSP, and transplant. This results in wide disparities between the actual cost of care and the AAPCC payments for ESRD patients.

- (3) Create payment methodologies that reflect how most disease management organizations are structured. Unlike managed care organizations, most disease management organizations are not set up to contract with providers or pay claims.
- (4) View disease states in their totality. In the case of chronic kidney disease, costs can be reduced significantly if disease management intervention begins before onset of ESRD and dialysis. Currently, the care and payment systems are not constructed in a way that captures patients before the emergent need for dialysis. Therefore, the appropriate patient care and education does not take place, which results in unnecessarily high costs and sub-optimal clinical outcomes.

Again, RMS is strongly supportive of the Subcommittee's initiative to capture the benefits of disease management for the fee-for-service population and appreciates the opportunity to comment.

