



THE KIDNEY LINK

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IMPACT OF MEDICARE PART D ON STATE PHARMACEUTICAL ASSISTANCE PROGRAMS (SPAPs)—What it Means for Beneficiaries With CKD

With its implementation in January 2006, the Medicare Part D program has initiated significant changes in the operations of the Medicare and Medicaid programs. Prior to the Medicare Part D program, Medicaid covered the financial costs of prescription drugs for beneficiaries known as “dual eligibles.” Starting this year, however, Medicaid was no longer responsible for covering the costs of prescription drugs since “dual eligibles” were enrolled into the Medicare Part D program. The Medicare Part D program has also had a significant impact on the operations of the state pharmaceutical assistance programs (SPAPs). Since 1975, SPAPs have been helping elderly, uninsured and

underinsured patients by subsidizing the cost of renal therapeutics.¹ Medicare beneficiaries who did not qualify for Medicaid were in great need of the services offered by SPAPs since it helped provide wrap-around coverage for pharmaceuticals.

Under the Medicare Modernization Act (MMA), the operational definition of SPAPs has changed. SPAPs are state programs that will be providing financial assistance to Part D eligible individuals for supplemental prescription drugs not covered by their Part D prescription plans. With this change, only 28 states have operating SPAPs that qualify under the MMA.² To qualify as an SPAP under the MMA, an SPAP must meet certain requirements set forth by MMA.³ The

SPAP must coordinate its benefits with those of the Part D plans. An SPAP cannot impose eligibility restrictions on an individual based on the Medicare Part D plan he/she is enrolled in. The SPAP must supplement the Part D drug coverage. If an SPAP meets these requirements set forth by the MMA, SPAP payments will be counted as true out of pocket (TrOOP) costs, which can be beneficial for the Part D enrollee, allowing him/her to reach the catastrophic coverage level more quickly.⁴ With significant savings for SPAPs across the country,

states can potentially expand their programs to cover a larger percentage of low-income individuals who do not qualify for Medicare or Medicaid.

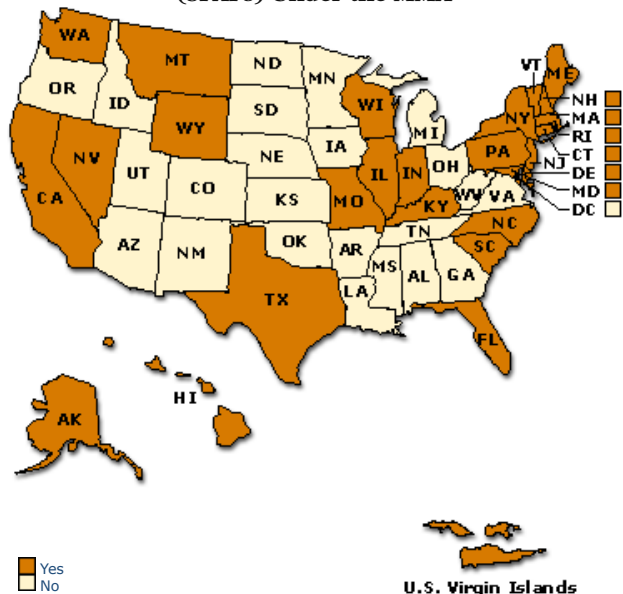
Of the Medicare population, 5.5 million Medicare beneficiaries suffer from chronic kidney disease (CKD). The Medicare Part D program does not cover prescription drugs used for treatment of anemia in individuals with end stage renal disease (ESRD)⁵; therefore SPAPs are essential in covering the financial costs of these drugs. With multiple plans being offered in the Medicare Part D program, it is important that beneficiaries with CKD choose plans that will help minimize their financial costs of renal therapeutics. To ensure that there is operational coordination between the Medicare Part D program and SPAPs, state policymakers can address the following issues:

- Auto enrollment of former SPAP beneficiaries into the most appropriate Medicare Part D plan;
- Definition of new SPAP eligibility requirements; and
- Definition of specific features of “wrap around” coverage offered by SPAPs for Part D enrollees.⁴

With sweeping changes being made to Medicare that provides health coverage for 14 percent of the population, it is imperative that Medicare beneficiaries are enrolled in the most comprehensive prescription drug plan that will not place them in any sort of financial jeopardy.

For more information, please visit our website at www.womeingovernment.org/kidney or contact Kirtana Kalavapudi, Graduate Policy Fellow, at KKalavapudi@womeingovernment.org.

Qualified State Pharmaceutical Assistance Programs (SPAPs) Under the MMA



Source: Kaiser Family Foundation. 50 State Comparisons: Qualified State Pharmaceutical Assistance Programs (SPAPs)

AMERICAN ASSOCIATION OF KIDNEY PATIENTS (AAKP) SETS PUBLIC POLICY AGENDA FOR KIDNEY DISEASE-RELATED ISSUES

Statistics demonstrate that 20 million Americans are suffering from chronic kidney disease and another 20 million Americans are at risk of developing chronic kidney disease.⁶ With such a tremendous prevalence of chronic kidney disease in the United States, it is imperative that United States adopt public policies that will improve its efforts related to prevention and management of kidney disease. Studies have shown that the first year mortality rate for Americans with kidney disease is at 22 percent compared to 16 percent in Europe and only 9 percent in Japan.⁷ In order to improve public policy efforts related to kidney-disease related issues, the American Association of Kidney Patients (AAKP) supports the following initiatives that will improve the quality of health and life for Americans with kidney disease:

- **DIALYSIS CENTER ISSUES** – There is a large variation in the quality of care provided at dialysis centers across the country. In some cases, staff are unlicensed and inadequately trained. Congress should call for a GAO study to document the variations in standards of care, licensing of staff, training and availability of registered nurses, dieticians, social workers, etc. Increased composite rates should be directly related to patient health outcomes.
- **FISTULA FIRST** – Fistula First is a national initiative which aims to increase the use of AV fistulas for Hemodialysis access in Medicare beneficiaries with ESRD. Compared to catheters and AV grafts, AV fistulas have a lower change of infection and provide better results for dialysis patients. AAKP strongly supports CMS' "Fistula First" initiative and believes that Medicare should cover AV fistulas for beneficiaries with ESRD.
- **QUALITY OF LIFE** – The experience of other countries shows that several other factors in addition to just

"cleaning blood," such as treating depression, are critical to enhancing the quality of life for kidney patients. CMS needs to design and emphasize the importance of Quality of Life clinical measures.

- **HOME DIALYSIS** – Some patients prefer and have better health outcomes by receiving home dialysis. Payment allowing patients to take dialysis home should be reviewed and provided
- In addition to these issues surrounding dialysis, AAKP has two other public policy issues on its agenda this year. They include:

- **LIFETIME COVERAGE OF IMMUNOSUPPRESSIVE DRUGS** – Medicare coverage should be provided for the life of a kidney transplant to reduce the number of graft failures and reduce the need for dialysis and re-transplant. No one should lose their kidney(s) because they cannot afford their medications.
- **STUDY INCENTIVES FOR ORGAN DONATIONS** – AAKP supports modernizing incentives to meet the needs of kidney patients. We want Health and Human Services to conduct a study of the feasibility of financial incentives (such as travel expenses for donors) to increase the number of organ donations.

AAKP strongly believes that these initiatives would help ensure that all Americans with kidney disease receive better quality of care and improve their quality of life. AAKP is dedicated to advocating sound public policy to properly address issues related to quality and access to healthcare related to kidney disease and dialysis. *For more information, please visit American Association of Kidney Patients website at www.aakp.org or contact Kris Robinson, Executive Director & CEO, at krobinson@aaakp.org.*

ADVOCACY—PUTTING THE PEOPLE FIRST Senator Martha Scott, Democrat, Michigan

My mission as a legislator has always been to put the people first. My job is to craft legislation that will promote their safety, provide educational opportunities, and protect their health and well-being. As legislators, we also depend on the people as the source and inspiration for much of the legislation we craft. And much of the support for such legislation comes from their grass roots advocacy efforts.

So what is advocacy? Advocacy means "to plead in favor of." It means defending or supporting a cause that you believe in. It means asking a community to address relevant issues that affect everyone. And by forming partnerships and coalitions with individuals or groups with common interests, you can strengthen your voice and increase your influence.

Now, advocacy takes work. And it takes commitment. First, you need to learn everything you can about your issue, both the pros and the cons. Then you need to identify groups that share your concerns. You need to meet with healthcare providers and experts. You need to meet with media representatives and state your case. You need to write letters to the

editors and opinion/editorials to local newspapers. You need to attend committee and board meetings of organizations that deal with your issues. And you need to talk with legislators and educate them about your issues and concerns.

You need to make people aware of the 20 million Americans who are affected by Chronic Kidney Disease (CKD), as well as the 20 million more that are potentially at increased risk, and they need to know that the prevalence of CKD is likely to double in the next four years. They must also realize the impact this will have on healthcare costs. They need to be told that anyone with family history of diabetes, hypertension, heart disease, or kidney failure is at risk. And they need to be made aware that older Americans, African-Americans, Asian-Americans, and Hispanic-Americans are at special risk.

This is exactly the strategy that Women In Government has implemented to raise awareness of CKD and to support legislative efforts focused on prevention. As a result, so far this year, some 28 states have introduced policy initiatives targeting improved CKD detection and management. From bills and resolutions that will create a statewide task force; to developing disease management



ANEMIA AND CHRONIC KIDNEY DISEASE

Anemia is one of the many complications associated with the onset of chronic kidney disease (CKD). Kidney disease has a significant effect on the levels of hemoglobin in the blood. Even if kidney disease is mild (creatinine levels lower than 2 mg/dl), nearly half of the patients have anemia. The kidneys have an important role in the production of red blood cells. The production of red blood cells is influenced by a hormone, erythropoietin, which is produced by the kidneys. This hormone is responsible for sending signals to the bone marrow to initiate the production of red blood cells.

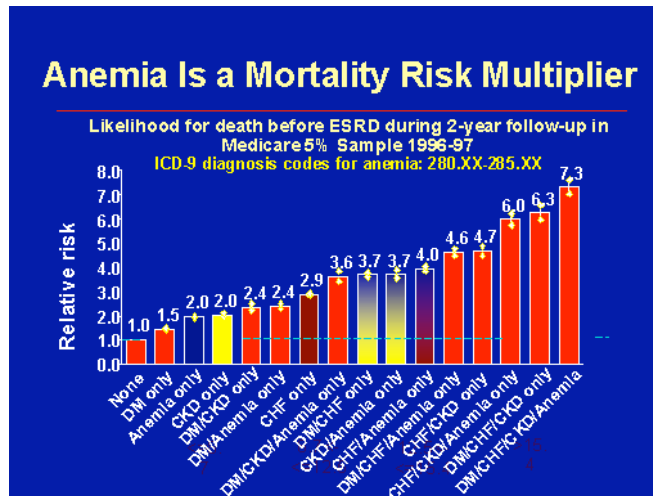
CKD, however, results in reduced kidney function and inadequate levels of erythropoietin. This leads to the development of anemia, which is essentially a deficiency of red blood cells. Red blood cells carry an energy-producing protein, hemoglobin, which is responsible for the transport of oxygen throughout the body. If an individual is anemic, he/she is not able to produce enough red blood cells, thereby resulting in a reduced ability to deliver to oxygen to the appropriate tissues. Untreated anemia can result in serious cardiovascular complications and increase the risk of death in individuals. Furthermore, anemia results in reduced aerobic ability, cognition and overall health of an individual. The graph demonstrates that individuals with CKD have

twice the relative risk of mortality if they are anemic. Essentially, anemia increases the relative risk of mortality especially in the presence of other chronic illnesses such as hypertension, diabetes or congestive heart failure.

Patients with CKD and anemia can be treated with epoetin alfa (EPO), which stabilizes the levels of erythropoietin. Given on a long-term basis, EPO can help the body restore the number of red blood cells and prevent anemia-related complications from developing or even progressing to serious conditions. Patients using EPO must take iron supplements in order to help in the production of red blood cells and it is essential that a patient's iron and hemoglobin levels are monitored regularly to ensure that the EPO therapy is working. Studies have also demonstrated that EPO therapy slows down the progression of CKD. This delays the initiation for dialysis treatment, the progression to end-stage renal disease, and could reduce the short- and long-term morbidity associated with

CKD. Anemia in CKD intensifies the morbidity and mortality related to CKD. Therefore, it is essential early diagnosis for anemia is conducted in patients with CKD to ensure early intervention and proper disease management.

Source: Dr. Robert Provenzano. *Anemia in the Patient with CKD: Detection and Treatment*. Presented at the CME Symposium. Detroit, Michigan. June 20, 2006.

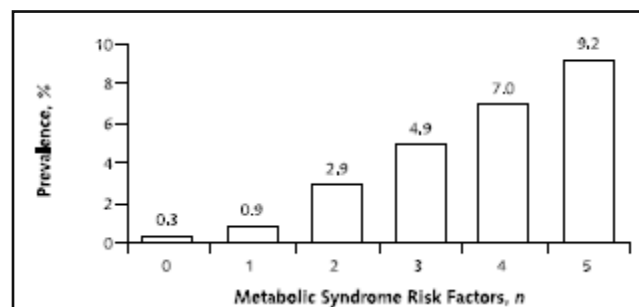


Source: Collins, Allan. (November 2002). *The Hemoglobin Link to Adverse Patient Outcomes*. Presented at the American Society of Nephrology Satellite Symposium.

CONNECTION BETWEEN METABOLIC SYNDROME AND CHRONIC KIDNEY DISEASE

The prevalence of chronic illnesses such as diabetes, obesity, hypertension, and kidney disease are on the rise in the United States. Research studies have demonstrated that genetic and environmental factors have a significant impact on the prevalence of chronic illnesses among individuals.⁸ Recent data demonstrates that 23.9 percent of adults (20 years and older) in the United States are obese.⁹ The rise in prevalence of obesity has significant implications for individuals, especially increasing their risk of developing metabolic syndrome. Metabolic syndrome is characterized by abdominal obesity, high blood pressure, high fasting glucose levels, high triglyceride levels, and low levels of high-density lipoproteins (HDL), often

Prevalence of Chronic Kidney Disease by Number of Metabolic Syndrome Risk Factors



Source: Chen J et al. (2004). *The Metabolic Syndrome and Chronic Kidney Disease in U.S. Adults*. *Ann Intern Med* 140:167-174.

called "good cholesterol". In 2002, the National Health and Nutrition Examination Survey (NHANES) estimated that 47 million individuals in the United States have been identified with metabolic syndrome. Increasing prevalence of metabolic syndrome in the United States can be associated with increased risks for diabetes and cardiovascular disease.¹⁰

Individuals with metabolic syndrome have a high risk of developing cardiovascular disease, which is associated with chronic kidney disease (CKD).¹¹ To establish an association between metabolic syndrome and CKD, researchers conducted a population-based study of more than 6000 individuals (20 years and older), who demonstrated risk factors associated

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with metabolic syndrome. As shown in the graph below, the impact of the presence of metabolic syndrome with the development on CKD is clearly documented. As the number of metabolic syndrome factors increases, the prevalence of CKD also increases. The study also demonstrated that the association between metabolic syndrome and CKD was independent of influential factors such as age, sex, race or ethnicity, thereby strengthening the validity of the findings.¹² In short, metabolic syndrome has been shown to be an independent risk factor in developing chronic kidney disease. With an alarming prevalence of metabolic syndrome among individuals in the United States, it has serious public health implications that warrant the need for implementing chronic disease prevention programs across the country.

For more information, please visit our website at www.womeningovernment.org/kidney or contact Kirtana Kalavapudi, Graduate Policy Fellow, at KKalavapudi@womeningovernment.org.

“Preventing Chronic Kidney Disease: What Policymakers Need to Know,” Brochures Available!

To receive a free hardcopy of the “Preventing Chronic Kidney Disease: What Policymakers Need to Know,” please contact the Policy Resource Center by email at kidney@womeningovernment.org or by calling 1-888-333-0164.

ADVOCACY con't from page 2

programs for Medicare and Medicaid beneficiaries, their efforts are paying off.

You know how they say it takes a village to raise a child? Well sometimes it takes a village to advocate for changes in public policy. So, by mobilizing a broad-based coalition, you can direct that policy. Sure, it is hard work, but you are used to that. The strength of Women In Government lies in its ability to provide the leadership, networking opportunities and educational resources to tackle complex public policy issues.

To achieve success, just keep on doing what you do best. Women In Government embraces a bold, courageous, and passionate vision that empowers and mobilizes women legislators to effect sound policy. Those are the precise characteristics of a committed and dedicated advocate. And, as long as there are those who cannot speak for themselves, we must take up their causes and continue to advocate until their needs are met. And it will always be “The People First.”

Margaret Mead, the well-known and respected American anthropologist, was a true advocate in public policy. Ms. Mead said: “Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it's the only thing that ever has.” Through our joint efforts you are indeed changing the world. *For more information about advocacy efforts regarding CKD in Michigan, please contact Senator Scott at SenMScott@senate.michigan.gov.*

(ENDNOTES)

- ¹ NCSL Report. State Pharmaceutical Assistance Programs in 2006: Helping to Make Medicare Part D Easier and More Affordable. Accessed September 28, 2006 from <http://www.ncsl.org/programs/health/SPAPCoordination.htm>.
- ² State Coverage Initiatives: States Struggle With Implementation of Medicare Part D. Accessed September 27, 2006, from www.statecoverage.net/stateofthestates/medicarepartd.html
- ³ Kaiser statehealthfacts.org: 50 State Comparisons: Qualified State Pharmaceutical Assistance Programs (SPAPs) under the MMA, as of May 17, 2006.
- ⁴ Fox, Kimberley. (2004, August 17). Making It Work: State Leadership on Medicare Rx Implementation and Coordinating with State Pharmacy Assistance Programs. Presented at the National Conference for State Legislators.
- ⁵ Kidney Medicare Drug Awareness and Education Initiative. Accessed September 27, 2006 from www.kidneydrugcoverage.com.
- ⁶ National Kidney Foundation, 2006.
- ⁷ United States Renal Data System, 2005.
- ⁸ Centers for Disease Control and Prevention. Overweight and Obesity: Frequently Asked Questions. Accessed on October 5, 2006 from <http://www.cdc.gov/nccdphp/dnpa/obesity/faq.htm#adults>.
- ⁹ Centers for Disease Control and Prevention. State-Specific Prevalence of Obesity Among Adults – United States, 2005. MMWR 2006;55:1985-988.
- ¹⁰ Ford ES, Giles WH, Dietz WH. (2002). Prevalence of the metabolic syndrome among US adults: findings from the third National Health and Nutrition Examination Survey. JAMA 289:76-79.
- ¹¹ Isomaa B, Almgren P, Tuomi T, Forsen B, Lahti K, Nissen M, et al. (2001). Cardiovascular morbidity and mortality associated with the metabolic syndrome. Diabetes Care 24:683-689.
- ¹² Chen J et al. (2004). The Metabolic Syndrome and Chronic Kidney Disease in U.S. Adults. Ann Intern Med 140:167-174.

In 2007, the Chronic Kidney Disease Policy Resource Center will be changing to the Kidney Resource Center. The Resource Center will expand its educational materials and cover a broader range of health issues related to kidney cancer, organ donation, and kidney disease. Please look for website updates and for more information, please contact us at kidney@womeningovernment.org or by calling 1-888-333-0164.

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