August 21, 2012

Steven T. Miller
Deputy Commissioner for Services and Enforcement.
Internal Revenue Service
CC:PA:LPD:PR (REG–131491–10)
Room 5203
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Dear Mr. Miller and Ms. McMahon:

We are writing on behalf of four patient advocacy organizations – the American Kidney Fund, Dialysis Patient Citizens, National Kidney Foundation, and Renal Support Network[1] – to urge the U.S. Department of the Treasury and the Internal Revenue Service (IRS) (collectively, the Agencies) to clarify that individuals who develop irreversible kidney failure, also known as end-stage renal disease (ESRD), may continue to access the premium tax credit after their diagnoses and until they are enrolled in Medicare (they apply and receive Medicare coverage).

In the final regulations, "Health Insurance Premium Tax Credit,"[2] (Final Rule), the Agencies stated that:

> the IRS and the Treasury Department expect to publish additional guidance, see § 601.601(d)(2), clarifying when or if an individual becomes ''eligible for government-sponsored minimum essential coverage'' when the eligibility for that coverage is a result of a particular illness or condition. For example, as the preamble to the proposed regulations notes, the additional guidance would clarify the rules in the case of eligibility for Medicaid on the basis of blindness or disability.[3]

We strongly encourage the Agencies to state expressly that an individual does not become eligible for Medicare for purposes of qualifying and/or maintaining the premium tax credit until the individual applies for and receives Medicare benefits. This clarification would apply only to those individuals who would be under the age of 65 and qualifying for Medicare by virtue of their diagnosis of irreversible kidney failure.

Individuals with irreversible kidney failure are unique in terms of Medicare beneficiaries because they qualify for coverage by virtue of their diagnosis, as opposed to age. While these individuals appreciate the coverage Medicare provides, this coverage does not always cover all of their medical needs. As we describe below, many patients would prefer to maintain their commercial policies rather than be required to shift to Medicare. When Health Exchange plans become available, we believe patients enrolled in group and individual exchange plans will also want to maintain this coverage instead of having to shift into Medicare. The

[1]Descriptions of our organizations are attached as Appendix A.
[2]77 *Fed. Reg.* 30377 (May 23, 2012).
[3]*Id.* at 30379-80.

Department of Health and Human Services (HHS) has already clarified that the Medicare Secondary Payer rule will apply in the context of group health plans.[4] In the individual market, many of these patients would need to rely upon the premium tax credit to maintain their plans. Thus, we urge the Agencies to issue guidance clarifying that such individuals may retain access to the premium tax credits even though they would qualify for Medicare by virtue of their disease state.

I. Background on Patients with Kidney Failure

A. Facts about the Disease

Irreversible kidney failure is the final stage of chronic kidney disease. Approximately 500,000 Americans have kidney failure with about 400,000 receiving dialysis treatments. The disease disproportionately affects African-Americans. Irreversible kidney failure (end stage renal disease) often occurs with little or no warning.

Irreversible kidney failure is a clearly defined diagnosis. It is the final stage of chronic kidney disease. The NKF KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification[5] sets forth the clinical criteria upon which physicians rely to define the disease. Chronic kidney disease (CKD) is stratified into five stages, with irreversible kidney failure occurring in Stage V. Each level is defined according to the presence or absence of kidney damage and level of kidney function and is not tied to the type of kidney disease.

The KDOQI Guidelines define kidney failure as "either (1) a level of GFR[6] to <15 mL/min/1.73 m2, which is accompanied in most cases by signs and symptoms of uremia, or (2) a need for initiation of kidney replacement therapy (dialysis or transplantation) for treatment of complications of decreased GFR, which would otherwise increase the risk of mortality and morbidity."[7] ESRD is an administrative term created by the Medicare program. It encompasses patients who receive dialysis or transplants and is not specifically tied to a level of GFR.

Acute kidney failure differs from irreversible kidney failure in that patients with acute kidney failure recover the use of their kidneys in a short period of time (less than 3 months).[8]

Once diagnosed with irreversible kidney failure, patients have two treatment options – transplantation or dialysis. Most patients require dialysis, even as they wait for a transplant, because there are not adequate kidneys available for all of those in need.

Patients experience substantial changes in their lives once diagnosed with irreversible kidney failure. Dialysis is a life-sustaining treatment that patients must receive three to four times a week. Sessions last three to four hours. Patients with kidney failure often have multiple health issues that complicate their care. These can include anemia, bone disease, diabetes, and cardiovascular disease.

Although a kidney transplant "cures" the disease, patients often require multiple transplants during their lifetime. When a transplanted kidney fails, a patient returns to dialysis while waiting for a repeat transplant.

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[4] 77 *Fed. Reg.* 18310, 18315 (March 27, 2012).

[5] *Available at: http://www.kidney.org/professionals/kdoqi/guidelines_ckd/p4_class_g1.htm*

[6] The GRF is the glomerular filtration rate, which is a kidney function test in which results are determined from the amount of ultrafiltrate formed by plasma flowing through the glomeruli of the kidney. The amount is calculated from inulin and creatinine clearance, serum creatinine, and blood urea nitrogen. *See http://medical-dictionary.thefreedictionary.com/glomerular+filtration+rate.*

[7] *Id.*

[8] *See supra* note 5.

B. Insurance Coverage Available Today

The cost of receiving treatment – both in terms of time and money – is significant. Once an individual who is under 65 years of age is diagnosed with irreversible kidney failure, he/she must adjust not only to the treatment options, but also determine how to incorporate the time-intensive dialysis treatments into his/her schedule. Some patients, especially younger, healthier patients, may opt for home dialysis modalities, but the vast majority of patients receive treatments at dialysis facilities.

While there is no question that dialysis allows patients to continue living, the treatments can be exhausting. Maintaining the work schedule they had prior to diagnosis, while an important goal for many patients, may not always be possible. Because insurance coverage can be linked to work – either through employer-based plans or simply by the fact that the individual is earning money to pay premiums for individual commercial plans – the loss of a job can make it difficult for these patients to retain their insurance.

One patient recently described to us the challenges he faced. He was diagnosed with irreversible kidney failure as a young adult. He experienced weight loss, anemia, high blood pressure and required hemodialysis. Less than one year later, he received a kidney transplant. Paying for treatment was a constant concern; "I managed to hang on to my health insurance and received Medicare for a time. I did not have much money during this period of my life and paying for medicine, even with coverage, was often a problem for me."

1. Current Coverage Options for Patients with Irreversible Kidney Failure

Patients under 65 years of age currently have two options. First, they can apply for Medicare coverage once they are diagnosed with their disease. When an individual receives a diagnosis of kidney failure, he/she may submit an application to enroll in the Medicare program.[9] The physician completes a 2728 form documenting the patient's diagnosis as well.[10] If Medicare approves the diagnosis, the patient will usually begin receiving benefits on the first day of the fourth month of dialysis treatments.[11] This three month-waiting period correlates with the clinical definition that kidney failure that last no longer than three months is acute and reversible. This means that they may not enroll in Medicare until three months after their diagnosis.

If a patient has an employer-sponsored group health plan, however, he/she may continue to rely upon that coverage as primary for up to 30 months (which in total means having it an additional 33 months when the statutorily mandated 3 month waiting period is added to the 30 months). The Social Security Act expressly prohibits employers from dropping these patients from coverage as secondary payer if the individual has applied for and is enrolled in Medicare.[12]

When patients consider retaining their employer-sponsored coverage, they often focus on their cost sharing obligations under the group health plans, as well as their ability to maintain their preferred providers. For example, if the plan requires limited or no cost-sharing, a patient is likely to try to maintain coverage. In these instances, Medicare will cover the cost-sharing obligations up to the allowable Medicare amount.[13]

Once on Medicare by virtue of their disease, these patients receive the following coverage:

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[9] Medicare Coverage of Kidney Dialysis and Kidney Transplant Services; CMS Pub No. 10128; Rev. April 2012; Center for Medicare and Medicaid Services.

[10] End Stage Renal Disease Medical Evidence Report, *www.cms.gov/Medicare/CMS-Forms/CMS-Forms/.../CMS2728.pdf.*

[11] The waiting period for Medicare ESRD benefits is waived in case of home dialysis patients or pre-emptive transplant. A patient may receive benefits as early as the first month of dialysis if (1) the patient takes part in a home dialysis training program offered by a Medicare-approved training facility and (2) the patient's physician indicates the patient will be able to perform his or her own dialysis a patient may receive benefits beginning the month he/she is admitted to a Medicare-approved hospital for a kidney transplant (or for health care services the patient needs prior to a transplant) if his or her transplant takes place in the same month or within the following two months. Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 11.

[12] 42 U.S.C. § 1395y.

[13] Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 14-15.

- Access to health care providers who participate in Medicare;
- Part A coverage with the cost sharing requirements;
- Part B coverage with the cost sharing requirements; and
- Access to Part D with the cost sharing requirements.[14]

Medicare does not cover:

- Surgery or other services needed to prepare for dialysis, including surgery for a blood access fistula, until the first day of the fourth month after the beneficiary enrolls in Medicare;
- Paid dialysis aides to help with home dialysis;
- Any lost pay to the Medicare beneficiary or any person helping him or her during self-dialysis training;
- A place to stay during treatment; and
- Blood or packed red blood cells for home self-dialysis unless part of a doctor's services.[15]

In addition, patients with irreversible kidney failure cannot join a Medicare Advantage Plan,[16] unless they developed irreversible kidney failure while they were already enrolled in the plan.[17] This rule means that individuals who enroll in Medicare by virtue of their disease do not have access to these plans. The only exception is if there is an ESRD Special Needs Plan (SNP) in the area.[18] Patients may prefer Medicare Advantage plans because of the care coordination options, but many tell us they would prefer to participate in these plans because of better coverage for prescription drugs.[19]

If a patient is fortunate enough to receive a kidney transplant, his/her coverage under Medicare remains in place up to three years after the transplant.[20] However, that patient must continue taking immunosuppressive medications indefinitely to prevent his/her body from rejecting the kidney. On average, most patients require a new organ within five years of the original transplant. This situation means that patients are shifting insurance in order to cover their dialysis, transplant, and post-transplant care.

2. Patient Concerns with the Medicare Benefit

Although useful, Medicare coverage is not perfect. Because of the differences between commercial plans and Medicare, many patients would prefer to retain their commercial coverage if they could. One of the most frequently voiced concerns relates to the cost sharing requirements of Medicare. Other concerns include the scope of benefits and impact on family members.

a. Cost-Sharing Requirements

The cost-sharing burden on Medicare beneficiaries can be substantial. In 2009, ESRD Medicare patients' cost-sharing obligations were approximately $4.2 billion.[21] If a beneficiary paid into Medicare

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[14] Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 9.
[15] *Id.* at 12 & 19.
[16] In 2011, CMS established a new requirement that Medicare Advantage Plans limit beneficiaries' out-of-pocket expenditures to no more than $6700. *See* 75 Fed. Reg. 19677, 19712 (April 15, 2010).
[17] Centers for Medicare and Medicaid Services Medicare Managed Care Manual, Chapter 2, Section 20.2.2
[18] *Id.* at Section 20.2.2(7).
[19] *See* Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 54.
[20] *See id.* at 12.
[21] United States Renal Data System, *2011 Atlas of CKD & ESRD*, Vol. 2, Figure 11.1, http://www.usrds.org/atlas.aspx.

through tax assessments, he/she will not be responsible for a monthly premium to pay for Part A services.[22] If they have not, however, the standard premium is up to $451.00 in 2012.[23]

Because dialysis treatments fall under Part B, these premiums are more relevant and more onerous for individuals enrolled in Medicare by virtue of irreversible kidney failure. The standard Part B premium for 2012 is $99.90 per month, although it might be higher based on a beneficiary's income.[24] Beneficiaries pay the premium either through a deduction in their monthly Social Security or Railroad Retirement payment or when billed by the Medicare program every three months.[25]

Another critical cost-sharing component is the Medicare deductibles. Beneficiaries are generally required to pay a $1,156 deductible for Part A services[26] and a $140 deductible for Part B services.[27]

In addition, beneficiaries are also responsible for paying providers 20 percent of the Medicare-approved amount for all covered dialysis-related services provided in or by dialysis clinic.[28] While some beneficiaries have access to Medigap coverage,[29] most beneficiaries who qualify by virtue of their disease state may not purchase this coverage.[30] This fact means the burden falls on them to cover these costs. For dialysis patients, they owe this 20 percent for each of the treatments they receive three times a week, in addition to copayments for physician visits and the out-of-pocket costs associated with prescription drugs.

Because enrollment is linked to disease status, children may also receive Medicare coverage if they have irreversible kidney failure. In such instances, they (or more precisely their families) carry the same cost-sharing burdens; however, the rates paid to the dialysis facilities are adjusted based on the child's age and the type of dialysis they receive.[31]

There is no single set of cost-sharing requirements for commercial insurance, as we discussed when we meet earlier this month. Our members tell us consistently that these obligations can often be lower than those in Medicare, especially if they are enrolled in a managed care plan. Moreover, individuals who meet certain income requirements and opt to purchase insurance through the health insurance exchanges under the Patient Protection and Affordable Care Act will face reduced cost-sharing burdens in the future.[32] The Act limits cost-sharing obligations by setting caps on out-of-pocket expenses and by providing certain credits and subsidies to eligible individuals.[33] We are working with our memberships to try to develop data explaining the range of cost-sharing obligations to provide you in the near future.

b. Scope of Benefits

As noted above, Medicare coverage, while very good, does not cover all of the costs associated with receiving treatment for irreversible kidney failure. Additionally, patients are finding it more difficult to retain their preferred providers when they shift to Medicare.

One example of a crucial short-fall in the Medicare program is the lack of coverage for vascular access placement when it is needed. Even though vascular access surgery should be performed before the initiation of

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[22] *See* Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 7.
[23] 2012 Medicare Costs, *www.medicare.gov/cost*
[24] *Id.*
[25] Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 8.
[26] *www.medicare.gov/cost*
[27] *Id.*
[28] Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 21.
[29] An overview of Medigap policies and cost-sharing obligations is in Appendix B.
[30] Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare; CMS Pub No. 02110; Rev. Dec. 2011; *see Appendix B* for a list of states that require coverage for individuals under age 65.
[31] Medicare Coverage of Kidney Dialysis & Kidney Transplant Services at 21.
[32] *See* www.kff.org/healthreform/upload/8061.pdf.
[33] *Id.*

dialysis, Medicare does not reimburse for this service until the first day of the fourth month after a patient's diagnosis with ESRD. In short, dialysis works by taking a patient's blood out of the body and removing toxins through a process known as aphoresis. To access the blood, patients must have one of three accesses – a catheter, a synthetic graft, or an AV fistula. There is clear medical consensus that a permanent access, such as a graft or fistula, is preferred because it improves patient outcomes and reduces morbidity and hospitalizations.[34] Placement of the fistula prior to initiating dialysis will be clinically preferable. Medicare does not cover the procedures that create these accesses until the first day of the fourth month after an individual enrolls in Medicare, which is after dialysis is initiated; however, many commercial plans would cover these services in a more timely fashion.

Patients often have multiple comorbidities by the time their irreversible kidney failure has been diagnosed. In many instances, these individuals have developed a strong treatment relationship with specific providers to address these diseases and conditions. Not all of the providers may accept Medicare, and patients do not want to have to find new providers because they are required to change health plans.

c. Impact on Family Members

Another important consideration for patients is the impact shifting to Medicare has on their families' ability to maintain their commercial coverage. There is no question that a shift of coverage can be extremely problematic when the family is relying upon an employer-sponsored plan. However, this problem also exists when patients and their families rely upon individual coverage. When one family member is required to shift to Medicare for coverage by virtue of his/her diagnosis of irreversible kidney failure, the family's ability to maintain the same plan may change as well. While it may be possible to maintain the coverage, in some instances the family would be required to find a new plan that could result in the need to change doctors and pay more out-of-pocket costs, creating an unnecessary hardship on these families.

II. Individuals with Kidney Failure Will Be Adversely Affected If They Are Prohibited from Access the Premium Tax Credit because of their Diagnosis of ESRD

We believe that the Agencies should clarify that individuals diagnosed with irreversible kidney failure are not eligible for equivalent coverage when they are diagnosed with the disease until such time as they actually enroll in Medicare because, among other things, Medicare for this population is not the same as traditional Medicare for those older than 65 years of age. Without the premium tax credit, many of these individuals would simply be forced to enroll in Medicare because they would not have the financial ability to maintain their individual exchange plans without such assistance.

As highlighted above, Medicare coverage based on an individual's diagnosis of irreversible kidney failure is not identical to traditional Medicare coverage for those older than 65 years. The chart below summarizes these differences.

Summary of Differences

	Qualification based on Irreversible Kidney Failure	**Qualification based upon Age**
Enrollment	Must have diagnosis and complete application	Automatic
Waiting Period	3 months	None
Impact of Group	Choice to maintain up to 30 months	Ends

[34] *See* Arteriovenous Fistula First, *History of the Fistula First Project*, http://fistula.memberpath.com/AboutAVFistulaFirst/History.aspx.*;* Eduardo Lacson Jr. *et al*., *Balancing Fistula First With Catheters Last*, 50 AM. J. KIDNEY DISEASE 379, 381-82 (2007) ("Although not necessarily causal, the relative risk of death associated with catheter use compared with fistulas is increased by 1.4- to 3.4-fold. . . . Catheters are associated not only with greater hospitalization rates because of sepsis, but also with greater rates of all-cause hospitalization.") (citing K. R. Polkinghorne *et al*., *Vascular Access and All-Cause Mortality: A Propensity Score Analysis*, 15 J;AM. SOC NEPHROLOGY 477, 479-80 (2004)).

	Qualification based on Irreversible Kidney Failure	Qualification based upon Age
Health Plan Coverage		
Coverage	Restrictions in coverage result in some treatments crucial to receiving successful treatment not being covered or not covered in a timely manner	N/A
Cost-Sharing	Burden greater on dialysis patients who require treatments 3 times a week	Same percentage, but most patients require fewer services per month for such an extended period of time
Access to Medigap	Prohibited from purchasing in many states	Have access to these plans regardless of where they live
Duration of Plan	Maintain coverage as long as on dialysis If receive a transplant, Medicare coverage ends after 36 months If organ fails, will return to dialysis	No end period
Access to Managed Care in Medicare	Prohibited from participating	Permitted to select Medicare Advantage plan

While it is true that many of the details about how individual exchange plans will operate remain undefined, the patients we support believe that in some instances these plans will provide more complete coverage than Medicare, reduce their out-of-pocket costs, and allow for improved care coordination. In particular, these patients should have the right to maintain their commercial coverage to avoid being on and off Medicare several times during their lifetimes. Thus, we urge the Agencies to allow them to have the choice to evaluate these plans and make the decisions that are right for themselves and their families by clarifying that they will be able to maintain access to premium tax credits even if they are diagnosed with irreversible kidney failure.

III. Conclusion

We appreciate the opportunity to continue an ongoing dialogue with the Agencies about the Final Rule and subsequent guidance. We would welcome the opportunity to answer any questions or provide you with additional information. Please do not hesitate to contact Kathy Lester at (202) 457-6562 or klester@pattonboggs.com to help coordinate our follow-up.

Sincerely,

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President and CEO
American Kidney Fund

Hrant Jamgochian, J.D., LL.M.
Executive Director
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Renal Support Network

Appendix A

American Kidney Fund. The American Kidney Fund fights kidney disease through direct financial support to patients in need, health education and prevention efforts. It leads the nation in charitable assistance to dialysis patients. Last year, nearly 90,000 people – almost 1 out of every 4 U.S. dialysis patients – received assistance from the American Kidney Fund for health insurance premiums and other treatment-related expenses. The American Kidney Fund reaches millions of people annually through its national campaign, *Pair Up: Join the Fight to Prevent Kidney Disease*; free kidney health screenings; health education materials and courses; online outreach, and a toll-free health information HelpLine (866-300-2900). For more information, visit www.kidneyfund.org.

Dialysis Patient Citizens. A national, patient-led, non-profit dedicated to improving the quality of life of dialysis patients through education and advocacy. Membership is free of charge and is open to dialysis and pre-dialysis patients and their family members. DPC strives to improve dialysis patients' quality of life by developing awareness of dialysis issues, advocating for dialysis patients, promoting favorable public policy and improving the partnership between patients and caregivers. For more information visit: www.dialysispatients.org.

National Kidney Foundation. The National Kidney Foundation (NKF) is the oldest voluntary health organization in the U.S. dedicated to preventing kidney diseases, improving the health and well being of individuals and families affected by these diseases, and increasing the availability of organs for transplantation. NKF's initiatives in awareness, prevention and treatment are directed towards hundreds of thousands of healthcare professionals, millions of patients and tens of millions of Americans at risk. For more information visit www.kidney.org

Renal Support Network. The Renal Support Network (RSN) is a nonprofit, patient-focused, patient-run organization that provides non-medical services to those affected by chronic kidney disease (CKD). RSN was founded by Lori Hartwell, who has lived with kidney disease since 1968. RSN strives to help patients develop their personal coping skills, special talents, and employability by educating and empowering them (and their family members) to take control of the course and management of the disease.

Appendix B: Overview of Medigap

A Medigap policy is health insurance sold by private insurance companies to help fill the "gaps" in Original Medicare, such as deductibles and co-insurance. Not all insurance companies will sell Medigap policies to people with Medicare under 65 and, if they do, these policies will likely cost patients with ESRD (and who are under 65) more than if they were 65 or older.

The costs associated with Medigap policies can vary widely depending on the issuing insurance company. According to the Medicare website, they can be priced or rated in three different ways:

1) Community Rated Policies: Under these policies, the same monthly premium is charged to everyone in a certain area who has the Medigap policy, regardless of age. While premiums will never increase because of age, they might increase because of inflation or other factors.

2) Attained-Age-Rated Policies: Under these policies, the premium is based on your current age (the age you have "attained") so the patient's premium goes up as he or she gets older. Premiums might also increase because of inflation and other factors.

3) Issue-Age-Rated Policies: Under these policies, the premium is based on the age the patient is when he or she buys the Medigap policy. Premiums might also increase because of inflation and other factors.

The chart summarizes the cost-sharing obligations under Medigap plans:[35] If the box is marked with an X, the Medigap policy covers 100% of the benefit. If the row lists a percentage, the Medigap policy covers that percentage of the benefit. If the row is blank, the policy does not cover the benefit.[36]

Medigap Benefits	Medigap Plan A	B	C	D	F*	G	K	L	M	N
Medicare Part A Coinsurance and hospital costs up to an additional 365 days after Medicare benefits are used up.	X	X	X	X	X	X	X	X	X	X
Medicare Part B Coinsurance or Copayment	X	X	X	X	X	X	50%	75%	X	X***
Blood (First 3 Pints)	X	X	X	X	X	X	50%	75%	X	X
Medicare Part A Deductible		X	X	X	X	X	50%	75%	50%	X
Medicare Part B Deductible			X		X					
Medicare Part B Excess Charges					X	X				
Out-of-Pocket Limits							$4660	$2330		

* Plan F also offers a high-deductible plan.

** After an individual meets his or her out-of-pocket yearly limit and yearly Part B deductible ($140 in 2012), the Medigap plans pays 100% of covered services for the rest of the calendar year.

***Plan N pays 100% of Part B co-insurance, except for a copayment of up to $20 for some office visits and up to a $50 copayment for emergency room visits that do not result in inpatient admission.

[35] Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare at 11.

[36] *Id.*

As of December 2011, the following states require insurance companies to offer at least one kind of Medigap policy to people with Medicare under 65:[37]

California*	Maine	North Carolina
Colorado	Maryland	Oklahoma
Connecticut	Massachusetts*	Oregon
Delaware**	Michigan	Pennsylvania
Florida	Minnesota	South Dakota
Georgia	Mississippi	Tennessee
Hawaii	Missouri	Texas
Illinois	New Hampshire	Vermont*
Kansas	New Jersey	Wisconsin
Louisiana	New York	

* A Medigap policy is not available to people with ESRD under 65.
** A Medigap policy is only available to people with ESRD.

[37]Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare at 40.