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Examining Reforms to Improve the Medicare Part B Drug Program for Seniors

Committee on Energy & Commerce

U.S. House of Representatives

Friday, June 28, 2013

Testimony of Dr. Larry Melton, MD, PhD, FACP

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Board of Directors, American Society of Transplantation (AST)

Thank you Chairman Upton (R-MI), Ranking Member Waxman (D-CA), and Congressman Burgess (R-TX) for the opportunity to briefly address the Energy & Commerce Committee as it examines reforms to improve the Medicare Part B Drug Program. I applied this Committee for its leadership and ongoing commitment to strengthening our nation's healthcare system.

I am Dr. Larry Melton, Medical Director Kidney/Pancreas Transplantation at Baylor University Medical Center. In my many years of practice and work in Dallas, Texas, I've become familiar with a variety of Medicare Program challenges and policy imperfections that could be improved to save both lives and federal resources. Within my field of organ transplantation, the most obvious and flawed Medicare policy is the program's arbitrary 36 month coverage restriction for patient's immunosuppressive drugs post transplantation.

As you may know, organ transplant recipients must take immunosuppressive medications for the lifetime of their transplanted organ. If immunosuppressive medications are discontinued, rejection and loss of the transplanted organ are almost certain to occur. Under its current policy, Medicare continues to waste the federal government's investment in kidney transplantation while at the same time paying indefinitely for more costly therapies. It is the equivalent of the Federal Government buying a new car, providing enough gas to drive around the block, and then abandoning the vehicle.

When kidney's fail, patients only have two treatment options: dialysis or transplantation. Since 1972, Medicare has covered people with End Stage Renal Disease (ESRD) – permanent kidney failure requiring dialysis or a kidney transplant – without regard to age or SSDI status. There is no Medicare coverage limit for a dialysis patient. By contrast, kidney transplant recipients lose Medicare coverage at an arbitrary 36 months after transplant. In 1972, it was estimated that the ESRD program would cost \$250 million. Today, the program costs in excess of \$250 billion.

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WORLD TRANSPLANT CONGRESS 2014

July 26–31, 2014 San Francisco, CA These figures are staggering and there is no question that a functioning transplant with immunosuppressive drug coverage is vastly less expensive than the cost of dialysis. When renal allografts fail, patients again require dialysis and may even be candidates for re-transplantation, both of which would be covered by Medicare. Extending immunosuppressive coverage beyond the 36 month limit would decrease the risk of allograft failure due to patients not taking their immunosuppression.

A conservative estimate is that 20 individuals will die today awaiting a life-saving donor organ. Donor organs are a precious resource that fall far short of meeting the actual demand. As we have seen again from recent high profile media coverage organ demand far exceeds supply, as a result, the transplant community works diligently to ensure that every donor organ is given the best opportunity to save and extend life for as long as possible. Current Medicare policy inhibits our ability to that.

A variety of national and international medical journals have focused attention on the U.S. policy of limited immunosuppressive drug coverage and the kidney failure that follows. In particular the New England Journal of Medicine (NEJM) highlighted a survey conducted by the American Society of Transplantation (AST) that found that 70 percent of U.S. kidney-transplantation programs reported that their patients had an "extremely serious" or "very serious" problem paying for immunosuppressive medications, and 68 percent reported deaths and graft losses attributable to cost related non-adherence." The study further found, "Since patients with kidney failure need either long-term dialysis or a functioning renal allograft to survive, failing to pay for ongoing immunosuppression ensures that Medicare's initial investment in kidney transplantation is squandered, that patients die prematurely, and the U.S. taxpayers pay for a more expensive but inferior therapy after some transplants fail unnecessarily." At present, Medicare spends approximately \$70,000-80,000 per year on a dialysis patient, which Medicare covers indefinitely. However, Medicare on average spends less than a quarter of that cost for a kidney transplant recipient after a year of the transplant.

For more than a decade, members of this Committee have introduced and supported legislation, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act", to address Medicare's deficiencies in this area. Most recently, Congressmen Michael Burgess, MD (R-TX), and Ron Kind (D-WI) have led the bipartisan effort to secure passage of this reform. Although the legislation consistently enjoys significant bipartisan and bicameral support...this basic correction to better protect patients and federal resources routinely runs out of time and falls short of passage at the conclusion of each session of Congress. I strongly encourage everyone on this Committee to co-sponsor, support and pass H.R. 1428 during the 113th Congress. The legislation saves lives, preserves life-saving donor kidneys, and reduces the cost burden to the federal government – a win-win for patients and the U.S. Treasury.

The bill would allow individuals who are eligible for immunosuppressive drugs whose insurance benefits under Part B have ended due to their 36 months running out to remain in the program ONLY FOR THE PURPOSE of receiving immunosuppressive drugs. If they have group health insurance, they would not qualify for coverage beyond the 36 months. This legislation is intended to be a coverage backstop only for those who otherwise have no coverage. This legislation ensures that Medicare would remain the payer of last resort and would not usurp coverage offered by private insurers.

It is not sound public policy, or cost effective for Medicare, to cover the initial costs of a kidney transplant and then stop immunosuppressive drug coverage after 36 months. That can, and all too often does, lead to someone rejecting the transplanted kidney because they cannot afford their medicine. It is unfair to living donors and to those families who have donated the organs of a deceased

loved one, for the federal government not to do everything possible to maintain the transplanted kidney and gift-of-life that they have provided. Ironically, when patients lose their transplants, they resume Medicare eligibility for all medical needs, including dialysis or even another transplant.

On behalf of kidney patients, families, physicians, surgeons and all involved in the transplant process, I ask that this Committee make the 113th Session of Congress the last Congress in which many patients will lose Medicare coverage and jeopardize their kidney transplant after only 36 months. The Burgess-Kind legislation, H.R. 1428, simply corrects a costly policy inequity. It covers transplant anti-rejection medications only. Beneficiaries would pay the Part B premium. All other Medicare coverage would cease 3 years after the transplant, as under current law. It is a specific fix and improvement that benefits all involved. This is common sense.

Chairman Upton, Ranking Member Waxman and Congressman Burgess...I thank you for the opportunity to focus a few minutes on what we in the organ transplant community view as a very necessary reform to the Medicare Drug Program.

THANK YOU.