



for example, lumping all the different immunoglobulin products into one group and then deciding to reimburse the cheapest is scientifically unjustifiable and medically dangerous for patients who react and tolerate different products differently. Deciding that PPTs such as albumin are classifiable as generic drugs, as was attempted in an economically challenged European country recently, fails to recognize the differences between products which may well affect patient care.

The way forward

So, as a historical figure once said “What is to be done?” It behooves all those responsible for the treatment of patients with rare disorders, including those dependent on PPTs, to advocate for very careful application of these measures described in this article. If measures such as cost-effectiveness and biosimilarity are really about the best use of the health care dollar, then recognition is needed for the special place of rare and chronic disorders. Otherwise patients will be harmed, and quite likely health care costs will increase. And that is something which everybody seeks to avoid. ☞

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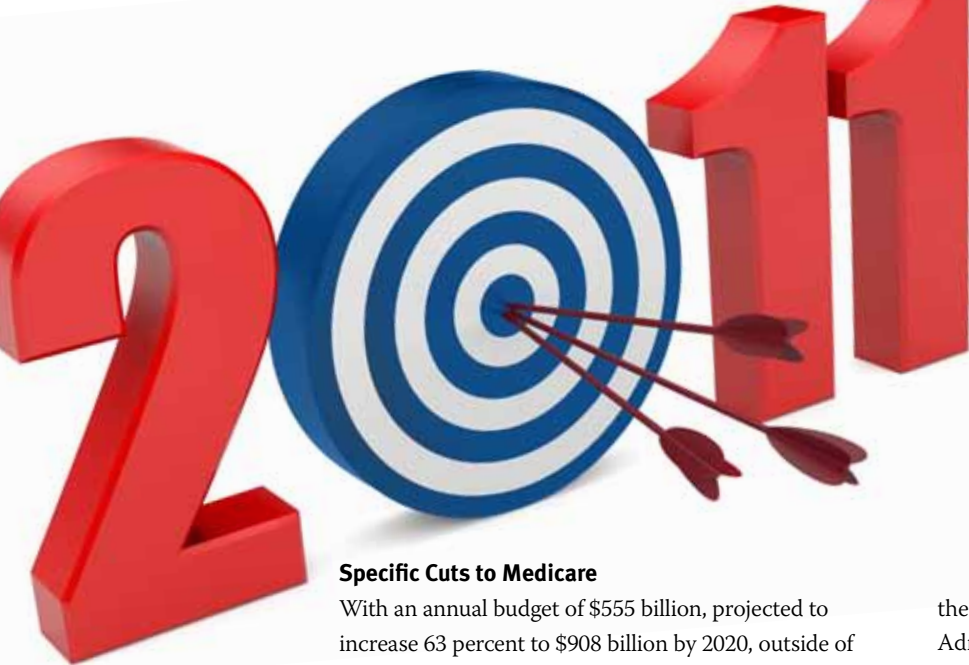
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DEFICIT REDUCTION EFFORTS TARGET MEDICARE

BY EVERETT CROSLAND

ON NOVEMBER 21, 2011, the members of the Congressional Joint Select Committee on Deficit Reduction—commonly known as the Super Committee—announced that it had failed to reach an agreement to cut the federal deficit by the statutorily required minimum \$1.2 trillion. The Super Committee's failure triggers a statutory procedure known as sequestration, resulting in indiscriminate across-the-board cuts to the federal budget equaling \$1.2 trillion beginning January 1, 2013.

Largest among the many government programs facing across-the-board reductions are defense and Medicare, with cuts to Medicare capped at 2 percent of total Medicare spending. However, even with the 2 percent cap, Medicare sequestration would result in cuts of as much as \$123 billion over 10 years. Motivated by the blunt force of sequestration, it is likely that Congress will take up the charge of the failed Super Committee and seek targeted savings. While the magnitude and indiscriminate nature of sequestration is daunting, it pales in comparison to the likely prospect that Congress, unrestricted by statutory limits, will focus much of its deficit reduction attention on finding savings in Medicare.



Specific Cuts to Medicare

With an annual budget of \$555 billion, projected to increase 63 percent to \$908 billion by 2020, outside of defense spending, Medicare is indisputably the largest target for cost cutting. Recognizing this, industry leaders, consumer organization advocates, and other special interest groups have provided myriad proposals for solving America's deficit problems. Unfortunately, many of these proposals have included substantial cuts to Medicare.

Among these possible proposals a choice few stand out as especially concerning for the plasma protein therapeutic community for their potential to restrict patient access and undermine plasma protein therapy innovation, including

- › cutting average sales price prescription drug reimbursement in the physician office;
- › increasing cost-sharing on the part of Medicare beneficiaries;
- › shifting products from Medicare Part B to Medicare Part D; and
- › least costly alternative determinations.

In addition to cuts to Medicare, proposals to expand the deep discounts of the Health Resources and Services Administration (HRSA) 340B program to the inpatient setting and to aggressively cap long-term Medicaid spending are among other policies under discussion. The combination of cuts to Medicare, Medicaid limits, and the expansion to 340B would severely impact patient access to safe and effective treatment, interrupt patients' site of care, and increase beneficiary costs.

Medicare a Long-Term Target For Deficit Reduction

Despite the potential that the proposed cuts to Medicare will be detrimental to the health of patients and the healthcare system at large, it is likely that the Super Committee process was merely the first stage in a series of deficit reduction activities predominantly focused on Medicare.

With the failure of the Super Committee, the second stage of deficit reduction is under way as the law delaying cuts to physician reimbursement through adjustment to the sustainable growth rate (SGR) is set to expire at the end of 2011. In general, the Medicare SGR is a method to ensure

PALTO / SHUTTERSTOCK

October 1, 2011

The spending caps passed as part of the BCA being to take effect with the start of Fiscal Year 2012

October 14, 2011

Deadline for Congressional Committees to submit deficit reduction recommendations to the Super Committee

December 23, 2011

Congress must vote to pass or deny the Super Committee's legislation. No amendments or filibuster are allowed

August 2, 2011

Creating the Super Committee, the BCA is passed in the 11th hour, narrowly avoiding government default

August 16, 2011

Members of the Super Committee are appointed

2011

November 23, 2011

Deadline for the Super Committee to provide Congress with legislation that reduces the deficit by \$1.2 trillion - **Failed**

Deficit Reduction





that the yearly increase in the expense per Medicare beneficiary does not exceed the growth in Gross Domestic Product (GDP).

Potential for Steep Cuts to Physician Payments

If Congress does not act to avoid a negative SGR adjustment to physician fees before January 1, 2012, physicians will face a 27.4 percent cut in their reimbursement for services they provide to Medicare patients. Given the potential for widespread patient access issues that would arise as a result of such a drastic cut, it is likely that Congress will attempt to resolve the issue by offsetting the cost of maintaining physician fees with cuts to other parts of Medicare. However, this is no easy task. It is projected that a ten year fix to physician reimbursement would cost as much \$289.7 billion over 10 years, making the more likely solution a one or two year fix, which would cost \$21 billion and \$38 billion respectively. Regardless, it is expected that Medicare could ultimately be targeted through SGR negotiations prior the end of the year.

While the first and second stages of the deficit reduction process present an alarming prospect for the plasma protein therapeutics community, policy experts are anticipating the process to play out in a third stage over the course of 2012.

Additional Deficit Reduction Factors

In the final two months of 2012, Congress will face the expiration of tax cuts enacted in 2001 and 2003 under President Bush, and extended in 2010 by President Obama. Realizing the bargaining opportunities that will be provided by the expiration of tax cuts and the impending sequestration, some members of Congress have suggested the replacement of the sequestration provisions with targeted deficit reduction measures, thus setting the stage for more negotiations that would likely take place at the end of the campaign season in November 2012.

Conclusion

PPTA recognizes that reducing the deficit is challenging and essential to stimulating job growth, however, indiscriminately cutting Medicare reimbursement cannot be the solution. Indeed, there are areas for reform and opportunities for savings in the Medicare program, but these reforms and savings must be realized through a measured and rational process that recognizes the unique needs of plasma protein therapy patients and the plasma protein industry.

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