Medicare Reform
Understanding Its Implications to Patients and Their Medication Coverage

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On December 8th, 2003, President Bush signed into law, the Medicare Modernization Act (MMA) that among other provisions created a voluntary drug benefit plan, now known as "Medicare Part D". After the proposed regulations were published in August 2004 the Centers for Medicare and Medicaid (CMS) conducted a series of activities to elicit public opinion from individuals and organizations. CMS received over 1,100 comments on the proposed rules. NATCO submitted comments on the proposal on September 17th, 2004.

NATCO, The Organization for Transplant Professionals Public Comment

NATCO commented that the organization had significant concerns that the drug categories outlined in the United States Pharmacopeia (USP) guidelines are not as comprehensive as they need to be to provide adequate coverage for individuals who have received a transplant; in particular, the classes in Part D do not include immunosuppressive drugs specifically prescribed for transplant nor do they include the other drugs that are regularly used in conjunction with immunosuppressive drug therapies in treating transplant patients in the short and long term.

While most transplant recipients receive coverage through Medicare Part B or through private insurance for the immunosuppressive drugs they must take to prevent rejection, there are a significant number of Medicare-enrolled recipients who are not eligible or who do not have insurance; therefore, they must pay for their immunosuppressive drugs out of their own pocket. Recipients are ineligible for Part B coverage of immunosuppressive drugs if the Medicare program did not pay for the transplant. These individuals will be eligible for coverage of their outpatient immunosuppressive drugs through the Medicare Part D plan, regardless of any other source of outpatient drug coverage.

The proposed "Immune Suppressants" pharmacologic class combines immunosuppressive asthma, rheumatoid arthritis, dermatologic, and cancer drugs into the same class as transplant-related immunosuppressive drugs. Under the Medicare statute, a minimum of two drugs is required per pharmacologic class. The current structure of the Model Guidelines would likely restrict transplant recipients' access to immunosuppressive drugs. Even requiring two drugs per recommended subdivision would not guarantee access. The result could be rejection of the transplanted organ, which will result in significantly higher costs to Medicare, not to mention the impact on the recipient, who will become acutely ill or perhaps die.

From NATCO's response to the U.S.Pharmacopeia:

> "To address these concerns, we recommend creating a new therapeutic category for immunosuppressive drugs, including immune stimulants, immune suppressants and other agents. While this is what many health care professionals are accustomed to seeing, it would also be flexible enough to allow prescription plans to design a formulary that promotes cost effectiveness and patient access to key transplant-related immunosuppressive drugs."

Response to Comments by Officials of the USP/CMS

Based on comments received on the proposed rule and the proposed formulary guidance, CMS modified pharmacy and therapeutics committee membership requirements, the processes to ensure that beneficiaries will be able to get drugs that might not be among the plan's preferred drugs in a timely manner, and to make sure that the formulary will not exclude access to drugs that would discriminate against beneficiaries with certain illnesses. This set of checks and oversight activities will give Medicare beneficiaries broad access to the types of coverage that are already providing effective benefits to millions of seniors and people with disabilities.

Summary of Medicare Part D Prescription Drug Benefit

Standard Benefit in 2006 is:

- In 2006, the beneficiary pays $35 per month premium ($420 per year) if they want this coverage. Beneficiaries are not required to enroll in Part D, but if they enroll later they will pay a higher monthly premium than normal.
- Beneficiary pays $250 annual deductible before Medicare pays anything.
- Beneficiary pays 25% of the costs of the next $2,000 of drug expenses (beneficiary pays $500 of next $2,000 of drugs costs plus all of the first $250 of drug costs for a total of up to $750).
- After $2,250 of drug costs, there is no coverage until the beneficiary has paid another $2,850 worth of drug expenses (beneficiary pays up to $3,600 for up to $5,100 in drug costs).
- Catastrophic coverage begins after beneficiary has paid $3,600 of out-of-pocket expenses ($5,100 total drug costs). The beneficiary pays the greater of $2 for generic, $5 for brand name drugs, or 5 percent of the costs, whichever is greater.
- Low-income individuals (depending on their income) pay a much smaller amount of their drug costs (see "Assistance to low-income beneficiaries for the Part D prescription drug benefit" information below the next two charts).

Your costs (based on costs for 2006)...			
If your annual drug costs are between...	You pay...	Up to a maximum of...	Your total costs are: the annual premiums ($420 in 2006) plus...
$0-250	100%	$250	$250
$251-$2,250	25%	$500	$750
$2,251-$5,100	100%	$2,850	$3,600
Over $5,100	5%	No limit	$3,600 plus 5% of drug costs above $5,100

Chart by Congressional Budget Office

Individuals with incomes below 135% of the poverty level pay no monthly premium, no deductible, and have no "gap" in coverage, thus pay less for their prescription drugs than stated above if they enroll in Part D.

Annual increases for Part D that you pay...					
Year	Estimated annual premium	Annual deductible	Main benefit limit	Catastrophic coverage begins at	Gap in coverage
2006	$420	$250	$2,250	$5,100	$2,850
2007	$444	$275	$2,470	$5,596	$3,126
2008	$492	$300	$2,710	$6,158	$3,448
2009	$516	$325	$2,920	$6,596	$3,676
2010	$564	$350	$3,170	$7,165	$3,995
2011	$588	$380	$3,400	$7,715	$4,315
2012	$648	$410	$3,690	$8,360	$4,670
2013	$696	$445	$4,000	$9,068	$5,066

Chart by Congressional Budget Office

Assistance to low-income beneficiaries for the Part D prescription drug benefit will affect more than nine million beneficiaries –

- Beneficiaries eligible for both Medicaid & Medicare (dual eligible) with assets of $2,000 for single person and $3,000 for couples –
  - No monthly premium or annual deductible.
  - Beneficiary pays $1 for generic and $3 for brand name drugs if below poverty level, or pays $2 for generic or $5 for brand name drugs if income is above poverty level and below 135 percent of poverty level.
  - Medicare pays all other drug costs (no “gaps” in service).
- Beneficiaries below 135 percent of poverty with higher assets ($6,000 for a single person and $9,000 for couples) –
  - No monthly premium or annual deductible.
  - Beneficiary pays $2 for generic or $5 for brand name drugs.
  - Medicare pays all other drug costs (no “gaps” in service).
- Beneficiaries below 150 percent of poverty level, not eligible for above programs, and have assets below $10,000 for single person or $20,000 for couples –
  - Monthly premium based on sliding fee scale.
  - $50 annual deductible.
  - After the deductible, beneficiary pays 15 percent of drug costs for next $2,200 of drug costs.
  - Medicare pays until $5,100 of drug costs.
  - After $5,100 of drug costs, beneficiary pays $2 for generic or $5 for brand name drugs.

The Effects of Medicare Part D on Transplant Patients

Primary provisions of the Medicare Part D benefit plan include continued coverage of immunosuppressive medications under Medicare Part B. Medicare Part D does not provide wrap around coverage, but rather is a separate medication coverage plan. It is probable that when Part D is initiated, Medigap will no longer be available to beneficiaries. Therefore, it will be necessary for transplant recipients to satisfy the co pay and deductible requirements of Part B as well as those of the Part D plan simultaneously. Sample: A married transplant patient with a combined annual income of $17,000, and a prescription drug cost of $18,000 annually, with a 20% Medicare co payment of $3,600 will have an estimated out-of-pocket of

$147 annually. The same patient with an annual income of $19,000 will pay $709. An annual income of $20,000 pays $1,800.

In summary, the drug prescription plan will assist low-income beneficiaries most significantly according to the outlined formula. There will also be a significant cost sharing for transplant recipients. For this reason, exploration should be considered to seek out additional resources to "wrap around" Medicare Part D coverage in the absence of Medigap assistance. The transplant community needs to play an active role in the proceedings leading up to the 2006 implementation date. Enrollment into the plan is scheduled to begin in November 2005.

Additional Readings and Resources:

www.usp.org
www.natco1.org
www.socialsecurity.gov
www.trispan.com
www.cms.gov
www.nephronline.com
www.whitehause.gov/news/releases/2003/
www.cms.hhs.gov
www.hhs.gov
www.medicare.gov

Reference: Marian O'Rourke RN, CCTC, Tulane University, *Medicare Reform* presented at the 2005 NATCO/ASTS Winter Meeting, Miami, FL.