Modifying Medicare Part B Reimbursement Rules to Put Patients First

By Newt Gingrich and Robert Egge

Available at www.healthtransformation.net[1]

CMS has enormous power to shape the health and healthcare marketplace through the reimbursement structures and regulations it imposes. Moreover, in a number of areas, it has recently taken bold actions to help move us toward a 21st Century Intelligent Health System, where every American will have more choices of greater quality at lower cost.

One of the hallmarks of such a system is that it be centered on the individual, including providing information, access and incentives that allow the individual and the physician to make choices based on what is best for the individual patient, given his or her particular condition, make-up and needs. As scientific breakthroughs and advances increasingly move us toward a personalized health system, being able to select unique, personally-specific combinations of treatments and medicines is vital.

Also central to a 21st Century Intelligent Health System is the concept of value-based competition, where providers, health plans, and other healthcare professionals are

[1] Please visit www.healthtransformation.net to view this paper and any subsequent updates. To provide comments and feedback, contact Robert Egge at the Center for Health Transformation (202-375-2001).

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rewarded—and procedures and products are encouraged and utilized—based upon the true value they bring to the consumer.

Strong competition delivers greater value to consumers by encouraging providers to offer higher quality goods and services at lower cost. And, for precisely this reason, promoting market competition is a universally accepted goal of Federal policy – the Federal Trade Commission (FTC) was created in 1914 specifically to ensure markets remained competitive.

While the FTC provides general policy guidance, CMS is responsible for the healthcare administration of the more than 40 million Medicare beneficiaries. Medicare payment for Part B drugs is being addressed in a proposed rule, the Physician Fee Schedule, later this month, and CMS is seeking comments regarding changes in a relatively new payment system (ASP – Average Sales Price) enacted in January of 2005.

One change that should be addressed is related to those Medicare Part B reimbursement rules that apply to the bundling of separate cancer drugs. These life-saving drugs for patients suffering from cancer represent the most expensive class of drugs purchased by Medicare. A loophole in these Part B rules encourages anti-competitive practices that harm the health of Americans, increase co-payments for Medicare beneficiaries suffering from cancer, and increase the Medicare costs which are paid by America's taxpayers.

MedPAC, the body which advises Congress on Medicare issues, was directed by Congress to conduct two studies on Medicare Part B payment changes. The studies were to focus on quality of care and physician practices, among other things. On October 6,

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2006, MedPAC presented its key findings at a public meeting. The report included a very critical finding on a practice called “bundling,” which one Commissioner termed **“predatory” and designed to force physicians to make choices that are not clinically based**. This criticism is consistent with that of some oncologists affected by the practice; it has been called “not good medicine” and “unethical.”[2]

For the sake of cancer patients, providers and taxpayers, we strongly encourage CMS to take the lead in reforming this loophole. CMS should act to prevent the very anti-competitive conditions that the FTC was created to prevent. The FTC has acted forcefully in industries such as software, when only prices to consumers were at issue. In the case of drug bundling – when it is not just prices, but the health of those suffering from cancer that is at stake – does CMS need another reason to act swiftly?

It is imperative that CMS act now to change Part B reimbursement rules. Business must be prevented from using bundling arrangements in order to extend the monopolistic power that exists in one market into a separate, otherwise competitive market.

Further, these same rules should be changed so that doctors do not have an incentive to favor more expensive drugs due to their correspondingly higher reimbursement rate (an inevitable consequence of employing a percentage-based reimbursement system rather than a fixed-fee system).

[2] Personal correspondence received from Peter D. Eisenberg, M.D., on September 18, 2006. Shared with permission.

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THE AMGEN EXAMPLE

A real-life example of the consequences of current policy has been noted in the bundling strategy employed by Amgen, a firm that appears to be leveraging its position as the sole provider of white blood cell growth factors (WBCGFs), a class of life-saving drugs without clinical alternatives, to increase its influence over the market for red blood cell growth factors (RBCGFs), a class of drugs where it would otherwise face strong competition. All told, taxpayers spent over $2.5 billion dollars in 2005 on these medications. While the Average Sales Price (ASP) system is in its infancy, this loophole, if not corrected, could have broad ramifications for future products and patient care.

Due to intellectual property protections, Amgen controls the WBCGF market with its two therapies, Neupogen® and Neulasta®. Chemotherapy damages a patient's white blood count and thereby weakens their immune systems. These drugs are the sole clinical alternatives physicians can use to restore patient white blood counts after chemotherapy. By strengthening their immune system, these drugs help cancer patients avoid the deadly choice between maintaining an immune system that can ward off life-threatening infections, and sustaining the course of chemotherapy that can control or eliminate their cancer.

Amgen's bundling policy reportedly ties together its products in the WBCGF market with Aranesp®, its product in the RBCGF market. RBCGF therapies are also essential for

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chemotherapy recipients but in this market,[3] another product, Ortho Biotech's Procrit®, is available for sale.[4]

Reports indicate that Amgen provides deep discounts on its WBCGF drugs only to those medical practices that purchase a sufficient volume of Aranesp®, its RBCGF therapy. Without these discounts, these practices can only purchase WBCGFs from Amgen at a price above Medicare's reimbursement rate. Consequently, physicians are put in the untenable position of either losing money with every WBCGF treatment, or letting their selection of RBCGF therapy be driven by cost, rather than effectiveness for the patient.

Bundling, in and of itself, is a relatively common practice within the pharmaceutical industry. Were there alternatives to Amgen's two WBCGF products or if receiving WBCGF were not essential for those receiving therapy, this case might not be a particularly noteworthy situation. But Amgen's bundling policy exploits both these conditions – its WBCGF monopoly and the chemotherapy recipient's dependence on this medication – to extend its WBCGF monopoly position into the otherwise competitive RBCGF market as well.

Recently, a number of oncologists have reported that Amgen has informed them that they must buy a certain amount of RBCGF products in order to receive rebates on another

[3] The "non-ESRD" market refers to those needing a therapy to boost their red blood cell count and who are not dialysis patients. For those who do suffer from ESRD, Amgen's Epogen® or Aranesp® are currently the only available therapies.

[4] Ortho Biotech, the marketer of Procrit®, is a sister company to Johnson & Johnson Healthcare Systems, which is a member of the Center for Health Transformation. Neither Johnson & Johnson Healthcare Systems nor Ortho Biotech has compensated the Center for Health Transformation in any way for the preparation or publication of this report. For a complete list of members, please visit www.healthtransformation.net.

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WBCGF Amgen product. This forces the oncologists to purchase Amgen's RBCGF product or lose money each time they provide Amgen's WBCGF product.

Such a policy puts physicians, given their ethical commitment to look after the best interests of their patients, in an untenable position. No physician can deny a chemotherapy recipient the use of a WBCGF therapy. Physicians, under the Amgen policy, essentially have three choices:

- Purchase Amgen's RBCGF therapy, Aranesp®, with sufficient frequency so that, *regardless of whether they believe it is the best choice for the patient*, the physician's practice can purchase a WBCGF therapy at a price below Medicare reimbursement rate;
- Purchase Ortho Biotech's RBCGF therapy, Procrit® when they think it is in the best interests of their patients, and resign themselves – if they can afford to do so – to purchasing WBCGF at a significant loss to the practice; or,
- Purchase Ortho Biotech's RBCGF therapy, Procrit®, when they think it is in the best interests of their patients, and send their patients to another facility for the administration of WBCGF even if they believe this will result in an unnecessary inconvenience for cancer patients and ultimately poorer quality of care.

The net impact of Amgen's bundling practices is to reduce competition in the RBCGF market, resulting in increased co-payments for Medicare beneficiaries and increased Medicare costs paid by America's taxpayers, as well as potential harm to the health of Americans.

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As one oncologist explained in his correspondence with the Center for Health Transformation:

> "My partners and I are flabbergasted that Amgen, a rather sophisticated organization, would be so brazen as to put us in the position of choosing between treating our patients appropriately and buying their drugs."[5]

This letter is similar to correspondence the Center has received from other physicians, all agreeing on points of substance and impact.

SUMMARY AND RECOMMENDATIONS

A goal of CMS rules regarding payments for Part B drugs must be to foster competition, not restrict it, as competition can lead to more innovation and better outcomes, as well as financial savings for the government and Medicare beneficiaries themselves.

If CMS allows current rules to stand without modification, patients and their physicians will continue to have fewer therapeutic options and these options will be available at higher prices than they would be under competitive conditions. We should not permit a company to use one drug to drive utilization of another drug when the result is limited physician choice, the potential for inferior patient care, higher co-payments for Medicare beneficiaries suffering from cancer, and higher cost to the federal government.

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CMS should act in the 2007 Proposed Physician Fee Schedule to ensure that life-saving drugs without clinical alternatives are not bundled in order to drive the utilization of drugs that face competition.

Furthermore, CMS should shift its reimbursement rate for physicians to a fixed-fee basis rather than a percent-of-cost basis. A percent-of-cost system inherently incents doctors to use the most expensive drug. That is clearly an unsound long-term policy, which maximizes costs and minimizes competition.

CMS can address this alleged predatory action by allocating manufacturer discounts appropriately in the final Physician Fee Schedule. In so doing, CMS will expand the ability of cancer patients to receive the treatment their physicians deem best for them – and will ensure that they have every opportunity to enjoy better health at lower cost.

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