Congressional Oversight of Medicare Program Intensifies: A Look at the Factors Surrounding the Scrutiny and Nephrology's Response

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In recent years, federal legislators and policymakers have increased their oversight of the Medicare program. This increased scrutiny accompanies federal budgetary constraint, the tenuous solvency of the Medicare program, changing congressional leadership, and safety concerns in health care. Two high-profile areas of focus have been the quality of care provided by physicians participating in the Medicare program and policies governing erythropoiesis-stimulating agents in the treatment of anemia. The nephrology community has sought to preserve its ability to provide appropriate, high-quality care to patients with chronic kidney disease (CKD). These efforts include establishing and monitoring quality measures and advocating for the best care and patient choice for those with CKD.

Index Words: Congress; Oversight; Pay for performance; Value-based purchasing; Quality measurement; Erythropoiesis-stimulating agents; Hemoglobin; Nephrology

The 18-month period from July 2006 to December 2007 was marked by a substantial increase in the degree of scrutiny applied to the Medicare program by members of Congress, and it seems apparent that this increased level of congressional oversight is the first phase of a new era of legislative involvement in federal health policy development. This oversight will impact all medical specialties and Medicare patient populations, including those with chronic kidney disease (CKD).

Many factors contribute to Capitol Hill's increased focus on the Medicare program. Chief among these are:

1. The omnipresent budgetary constraint that affects all domestic spending but particularly impacts the Medicare program because program expenditures continue to soar. The baby boomer generation has just begun reaching program-entitlement age, promising record-breaking Medicare expenditures.
2. The 2006 midterm elections shifted power to the Democrats. Republicans worked hard in their waning days to pass legislation paving the way toward a pay-for-performance (P4P) Medicare program. Democrats were then empowered to pursue their health policy objectives, such as expanding access to care and addressing the issue of the uninsured, which had not been areas of focus for 12 years.
3. Formulas for Medicare cost containment include continued use of the sustainable growth rate formula for reimbursing physician services. This approach has called for scheduled pay cuts for Medicare physicians for not only the past half dozen years but also the next 4 to 6 years as well and, thus, serves as an annual catalyst and vehicle for Medicare program review.
4. Legislators have been alarmed by the series of reports from the Institute of Medicine over the past decade pointing out the quality gaps in medical care and calling for increased accountability on behalf of Medicare providers.
5. In late 2006, the last of several studies was published examining the use of erythropoiesis-stimulating agents (ESAs) in the treatment of anemia. These reports showed evidence for increased mortality when hemoglobin levels were greater than 12 g/dL[1,2] and suggested that for-profit dialysis facilities systematically use more ESAs per patient than do not-for-profit facilities.[3] These publications led to a proliferation of articles in the trade and lay press looking at the pharmaceutical industry's involvement

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1548-5595/08/1501-0004$34.00/0
doi:10.1053/j.ackd.2007.10.001

in federal health policy development and focused legislative concern on this process.[4-9]

This article focuses on how the increased congressional oversight during this period has manifested itself in 2 areas of consequence to nephrology and kidney care delivery: P4P (or "value-based purchasing" [VBP] in Capitol Hill parlance) and federal policies affecting the provision of ESAs. Furthermore, we discuss how nephrology has responded and the potential impact of these policies on CKD care.

P4P/VBP

Efforts by the federal government to exercise greater oversight for Medicare beneficiaries are the result of 2 major forces: cost containment and value for the money spent for medical care. Several high-profile reports on patient safety and provider accountability were published by major advisory organizations in medicine. Typifying these reports are 2 published by the Institute of Medicine: the first released in 1999 and entitled *"To Err is Human"*[10] focusing on patient safety and the second *"Crossing the Quality Chasm: A New Health System for the 21st Century,"*[11] which looked more broadly at how the health care system could be reorganized to foster greater innovation and quality improvement. These reports book ended the election of President George W. Bush in 2000, supported the administration's promotion of marketplace-based reforms, and called for greater accountability of Medicare providers. The progression toward P4P/VBP in Medicare took a significant step forward on January 1, 2006, when the Centers for Medicare and Medicaid Services (CMS) implemented the Physician Voluntary Reporting Program (PVRP). This program was originally unveiled in mid-2005 and engendered substantial political maneuvering between Congress, CMS, and organized medicine. It represented an expedient method to move toward P4P/VBP by placing a basic measurement-reporting system in place. In this program, physicians could participate by reporting the results of selected outcome measures to CMS on Medicare claims through the use of a temporary service code known as a "G-code." Adapting the "G-codes" for PVRP created the vehicle for a future P4P/VBP process. Three of the 16 indicators in the starter set of outcomes measures pertained to end-stage renal disease (ESRD) patients: dialysis dose, hematocrit/hemoglobin levels, and receipt of arteriovenous fistulae. Two of the most recent 74 measures deal with dialysis-related issues.[12-14] None of the measures specifically addresses the needs of CKD patients.

The PVRP program was a substantive first step in federal efforts to achieve P4P/VBP in the Medicare program. Organizational difficulties marked its debut, and the absence of a payment to participating physicians clearly limited their enthusiasm for the program. Perhaps because of the limited initial success of PVRP and the impending conclusion of their tenure as the majority party in 2006, congressional Republicans took action. Before relinquishing the reins of leadership, they included a provision in the Tax Relief and Health Care Act of 2006 that established a Medicare quality measure-reporting program known as the Physicians Quality Reporting Initiative (PQRI).[15] The PQRI program established a voluntary, claims-based "pay-for-reporting" program and provided a 1.5% bonus, subject to cap, to eligible Medicare providers who report on at least 3 of a designated set of quality measures for services paid under the Medicare Physician Fee Schedule and provided between July 1 and December 31, 2007.

CMS devoted considerable resources to developing an infrastructure for the PQRI program, going so far as to create the CMS Special Program Office for Value-Based Purchasing under which the program would be administered. However, much like the PVRP program, there was substantial confusion implementing the PQRI program that raised doubt in the organized medicine community regarding its ultimate success. Physicians' concerns included the following: (1) how would issues of attribution of service and physician level reporting in large, multispecialty practices, be resolved; (2) what would be the impact of the "cap" on the bonus payment, and how might that limit the financial incentive to participate in the program; and (3) how would the concerns of specialties without 3 relevant measures be resolved? CMS staff made