



# THE AMERICAN HEALTH QUALITY ASSOCIATION

1140 Connecticut Ave., N.W. Washington, DC 20036 (202) 331-5790 www.ahqa.org

## **Designing a Twenty-First Century Medicare Prescription Drug Benefit**

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**By David G. Schulke  
Executive Vice President  
American Health Quality Association**

The American Health Quality Association represents independent private organizations -- known as Quality Improvement Organizations (QIOs) -- that work under contracts with the Centers for Medicare and Medicaid Services (CMS) to improve the quality of care for Medicare beneficiaries in all 50 states and every U.S. territory. Congress created the QIOs to monitor and improve the quality of care delivered to Medicare beneficiaries and supports the national work of the QIOs with approximately \$333 million annually from the Medicare Trust Fund, or about \$8 per beneficiary per year.

Past policy efforts to develop a Medicare prescription drug benefit for the 21<sup>st</sup> century have focused almost exclusively on financing a benefit. Very little attention was given to including initiatives in the drug benefit to ensure a benefit is safe and continuously monitored to maximize the quality of outpatient pharmacotherapy.

In the 107<sup>th</sup> Congress the Energy and Commerce Committee became the first congressional committee to recognize this challenge by including language in House Report 107-551 directing the administrator of the Medicare prescription drug benefit to make Part D claims available to QIOs for quality improvement efforts. The American Health Quality Association commends the Energy and Commerce Committee for their leadership in this regard. It is absolutely critical to create an integrated quality improvement program. Otherwise, beneficiaries are likely to be ill-served by a carved-out drug benefit that operates separately from the Medicare hospital and outpatient benefits and data systems.

### **Building a Safe Drug Benefit.**

A Medicare outpatient prescription drug benefit presents an opportunity to improve the quality of life for our nation's seniors, but also brings the real risk of increased morbidity and

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**The American Health Quality Association represents organizations and health care professionals working to improve patient safety and the quality of health care nationwide.**

mortality associated with an increase in the use of medications. It is reasonable to predict that with an outpatient prescription drug benefit, more seniors will receive more drugs. Expanding access to and availability of drugs, without a complementary investment in quality improvement, will exacerbate the unacceptable cost and incidence of hospital and long-term care admissions associated with medication use. A recent meta-analysis of 11 different studies reviewing drug use in the elderly population found that “[t]he reported prevalence of elderly patients using at least one inappropriately prescribed drug ranged from a high of 40% for a population of nursing home patients to 21.3% for community-dwelling patients over age 65.”<sup>i</sup>

Pharmacoeconomists at The University of Arizona have tracked the costs associated with drug therapy since the early 1990s.<sup>ii, iii</sup> In the spring of 2001 these researchers published the following statement: “Overall, the cost of drug-related morbidity and mortality [in the ambulatory care environment] in the United States exceeded \$177.4 billion in 2000. Hospital admissions accounted for nearly 70% (\$121.5 billion) of total costs, followed by long-term-care admissions, which accounted for 18% (\$32.8 billion).”<sup>iv</sup>

### **Integrating Medical and Pharmacy Data Systems through Medicare QIOs.**

Historically, attempts to address the morbidity and mortality associated with medication use have been stymied by the inability of practitioners in various disciplines to access certain medical or pharmacy records that would otherwise provide a comprehensive picture of a patient’s true medication use history. As this committee discusses building a Medicare prescription drug benefit for the 21<sup>st</sup> century, it is essential that the new statutes and regulations include language that provide the QIOs with access to pharmacy claims data. Regardless of how a drug benefit is administered, the Secretary of HHS must have unrestricted access to pharmacy claims data to use in directing the activities of the QIOs. QIOs were created by Congress with the necessary confidentiality protections and staff expertise to permit them to combine medical and pharmacy data to guide health care systems improvement.

Most congressional proposals forwarded to date rely on the pharmacy benefit administrators to process pharmacy claims data and take certain quality improvement steps at the point of service when the pharmacy claims data suggests medication misadventures. The good work of the pharmacy benefit administrators is limited by the information present in the pharmacy claim. Without integration of the data present in the medical record and pharmacy record, systematic failures leading to inappropriate prescribing and dispensing will continue to happen everyday.

## **Integration of Data Systems through QIOs Is Critical—A Study of Outpatient Beta-Blocker Use in Heart Attack Victims.**

QIOs use data to track progress and improve provider performance, reducing errors by focusing on treatment processes, mostly pharmacotherapy. Since 1996, QIOs have worked on local projects to improve clinical indicators in care for diseases and conditions that broadly afflict seniors. Among the diseases targeted for quality improvement by the QIOs, treating heart attack victims with beta-blockers offers an example of how the QIOs could further their current inpatient efforts with appropriate access to data gathered with an outpatient prescription drug benefit.

Medical practitioners have known for several decades that the secondary prevention benefits of beta-blocker therapy after heart attack include reduced hospital readmissions, reduced incidence of further heart attacks, and decreased overall mortality.<sup>v</sup> The evidence is so convincing that the American College of Cardiology and the American Heart Association guidelines for the management of heart attack recommend routine beta-blocker therapy for all patients without a contraindication.<sup>vi</sup> Despite the evidence and expert recommendations, the use of beta blockers after heart attacks remains considerably suboptimal, with 20-30% of appropriate patients lacking this essential therapy.<sup>vii</sup> The reason is unlikely to be cost. Beta-blocker therapy in the outpatient setting is one of the most affordable medications available to patients. A 90-day supply of this life-saving medication usually costs less than \$10.00.

QIOs work to ensure that patients discharged from the hospital following a heart attack leave the hospital with a prescription for a beta-blocker. In the November 2002 issue of the *Journal of the American College of Cardiology (JACC)*, researchers report that many patients never fill prescriptions for their discharge medication, and many of those that do discontinue the use of beta-blockers shortly after filling the prescription. The study's authors conclude: "Patients not discharged on beta-blockers are unlikely to be started on them as outpatients. For patients who are discharged on beta-blockers after AMI, there is a significant decline in use after discharge. **Quality improvement efforts need to be focused on improving discharge planning and to continue these efforts after discharge.**"<sup>viii</sup> During the QIO's Sixth Scope of Work (1999-2002), QIOs were responsible for improving the national rate of beta-blocker order at discharge by 7%.<sup>ix</sup>

In his study published in *JACC*, Butler and colleagues found that the first step to preventing heart attack recurrence is to make sure a prescription is written and ordered at the time of the patient's discharge from a heart attack hospitalization. If this is done, the study shows there is a 10

TIMES greater likelihood of getting that patient started on inexpensive, effective beta blocker drugs that 20-30% of Medicare heart attack patients still do not receive, almost 40 years after the first marketing of propranolol, the first beta blocker.

The authors of the study utilized data for the dually enrolled population of patients (those receiving Medicare and Medicaid benefits simultaneously), as this is the only population of seniors for which there is comprehensive drug therapy claims data. This same kind of monitoring should be available for all beneficiaries. It is critical for Medicare to have the drug claims/ utilization data so QIOs can identify heart attack patients who don't fill a prescription for beta blockers post discharge, or who stop filling prescriptions (almost one quarter do after 6 months, according to the study) – and give their physicians assistance in getting the prescription started or changed (the latter might be needed if the patient didn't like the particular beta blocker initially prescribed and has consciously stopped taking it due to unacceptable or intolerable side effects). QIOs are ideally suited to identify patients at highest risk for hospital readmission or death due to poor beta-blocker adherence (i.e., patients taking beta-blockers post heart attack). We believe the QIOs unique ability to integrate medical information with pharmacy claims/utilization data complement pharmacy adherence programs that may be currently managed by benefit administrators.

### **QIO Confidentiality Requirements.**

The confidentiality of information collected or developed by a Medicare QIO is assured by Section 1160 of the Social Security Act. It was the intent of Congress in drafting this provision to provide safeguards for information identifying a specific patient, practitioner or reviewer. These safeguards foster an environment that is conducive to quality improvement efforts.

### **Recommendations.**

The American Health Quality Association has drafted the following legislative specifications we ask the Committee to include in this year's Medicare outpatient prescription drug benefit bill.

### **Legislative Specifications for the 108<sup>th</sup> Congress.**

**1) Give the QIOs responsibility for the outpatient drug benefit analogous to the responsibility they have for all other Title 18 benefits:**

Add new 'SEC \_\_\_\_ . REVIEW AUTHORITY--. Section 1154(a)(1) is amended by adding ' and section \_\_\_\_ after '1876'.

**2) Instruct the QIOs to make assistance available to providers, practitioners and benefit administrators to improve the quality of care under the new drug benefit.**

PRESCRIPTION DRUG THERAPY QUALITY IMPROVEMENT.—Section 1154(a) is amended by adding a new paragraph 17:

“(17) With respect to items and services provided under Title XVIII Part \_\_\_\_ the organization shall execute its responsibilities under subsection (a)(1)(A) and (B) by making available to providers, practitioners and benefit administrators assistance in establishing quality improvement projects focused on prescription drug or drug-related therapies. For the purposes of this part and title XVIII, the functions described in this paragraph shall be treated as a review function.”

**3) Include legislative language instructing prescription drug benefit administrators to provide patient specific pharmacy claims and drug utilization data to the Secretary of HHS. Suggested wording:**

“REQUIREMENTS FOR PRESCRIPTION DRUG PLAN SPONSORS, CONTRACTS, ESTABLISHMENT OF STANDARDS. — Any agreement between the Secretary and a benefit administrator for this purpose shall provide the Secretary with all patient specific pharmacy claims and drug utilization data.”

**4) Include legislative language providing appropriate availability of prescription drug claims data to the QIOs for quality improvement purposes. Suggested wording:**

“DATA AVAILABILITY. — The Secretary shall provide the utilization and quality control peer review organizations with the patient specific pharmacy claims and drug utilization data to permit the organizations to perform the functions described in 1154(a)(17).”

<sup>i</sup> Lui GG, Christensen, DB, “The Continuing Challenge of Inappropriate Prescribing in the Elderly: An Update of the Evidence.” *J Am Pharm Assoc*, 42(6), p847-857, 2002.

<sup>ii</sup> Johnson JA, Bootman JL, “Drug-related morbidity and mortality. A cost-of-illness model.” *Arch Intern Med (United States)*, 155(18), p1949-56, 1995.

<sup>iii</sup> Harrison DL, Bootman JL, Cox ER. “Cost-effectiveness of consultant pharmacists in managing drug-related morbidity and mortality at nursing facilities.” *Am J Health Syst Pharm*, 55(15), p1588-94, 1998.

<sup>iv</sup> Ernst FR, Grizzle AJ, “Drug-related morbidity and mortality: updating the cost-of-illness model.” *J Am Pharm Assoc*, 41(2), p191-199, 2001.

<sup>v</sup> Soumerai, SB, McLaughlin TJ, et al. “Adverse outcomes of underuse of beta-blockers in elderly survivors of acute myocardial infarction.” *JAMA*, 227, p115-121, 1997.

<sup>vi</sup> Ryan TJ, et al. “ACC/AHA guidelines for the management of patient with acute myocardial infarction. A report of the ACC/AHA Task Force on Practice Guidelines (Committee on Management of AMI).” *J Am Coll Cardiol*, 28, p328-348, 1996.

<sup>vii</sup> Krumholz HM, et al. “National use and effectiveness of beta-blockers for the treatment of elderly patients after AMI: National Cooperative Cardiovascular Project.” *JAMA*, 280, p623-629, 1998.

<sup>viii</sup> Butler J, et al. “Outpatient adherence to beta-blocker therapy after AMI.” *J Am Coll Cardiol*, 40(9), 1589-1595, 2002.

<sup>ix</sup> Jencks SJ, et al. “Change in the Quality of Care Delivered to Medicare Beneficiaries 1998-1999 to 2000-2001.” *JAMA*, 289, p305-312, 2003.