The Medicare Modernization Act (MMA) of 2003 has changed the lives of seniors by providing them with access to medications that many have never had. Additionally, it has given them access to quality programs such as medical therapy management (MTM) that, for the most part, did not previously exist. However, the real question is whether the coverage and programs for seniors can be applied to the commercial population as well as to the Medicare population. Access to the Web site www.medicare.gov has provided managed care providers and the general public with a tremendous amount of information regarding drug costs, insurance premiums, what pharmacies charge, and what the manufacturers charge. Section 1013 provides data around outcomes that produce another level of transparency, whether good or bad, as seniors and other payers make decisions.

AHRQ’s Effective Health Care Program will be evaluating the safety and effectiveness of anti-TNF-α therapies in rheumatoid arthritis. The manner in which health plans and other payers may eventually cover or “tier” these agents is discussed, including some information on potential cost sharing.

Medication Coverage Based on Cost-Effectiveness Data

Today, drug benefits are tiered, based on whether an agent is generic or brand and whether it is on the formulary or not. One possibility for a future method of placing drugs on tiers could include checking whether there is data that demonstrate a tradeoff of savings on other health care costs; if so, then the drug would have more value. Reimbursement for health care services holds the patient responsible for a portion or percentage of the charge, with an attending strategy to serve as a means of reducing utilization if the health care service appears too costly to the individual patient. Cost sharing normally includes an annual deductible amount that would make patients more accountable for their medication use.

For example, is there a return on medical investments within a year? The most ideal model would include expenditures in one year and a return of the money in that same year. A model still suitable but not exceptional would be if the dollars are spent one year but the return is not for 5, 10, or 20 years; since there is still a return on medical investment, the model is still acceptable. Perhaps, however, the return on medical investment acts a little differently, wherein the return of that money expended takes a number of years to occur, such as in terms of the cost sharing and how an employer or the government may want to fund that medication. Some questions to ponder could include: Is there a return on work-place productivity? Is there a return on quality of life or activities of daily living? The formulary tiering, perhaps, ought to be based on these points of view, with a return on medical investment being the cost sharing to the consumer, and it ought to...
be zero. On the other hand, when considering improvement in quality of life, perhaps that is the highest cost sharing because the consumer has the most vested interest in seeing that come to fruition for himself or herself. While this may be so for the affective component of quality of life, it may also be so for the functional component since both impact work productivity. Much of this remains to be seen as the results of this research get transcribed.

Consider the following list (also see the information below about the "choices/decisions"):
- Physician counseling for smokers
- Total hip replacement for arthritis
- Outreach for flu and pneumonia vaccine
- Treatment for major depression
- Screening for colon cancer
- Implantable cardioverter-defibrillators to prevent sudden death
- Tight control of diabetes
- Resuscitation after in-hospital cardiac arrest
- Left ventricular assist devices for patients with severe heart failure
- Treating elevated cholesterol levels in people without heart disease
- Treatment for osteoporosis

After reviewing the list, you are then told that you have a choice of (a) covering these items, (b) possibly covering these items, or, (c) not covering these items. Then take another look at the list and decide, based on the fact that you can only have 3 a's, 3 b's, and 5 c's, “Which would you choose? What 3 items from this list would you definitely cover? What 3 items from this list might you cover, and what 5 from this list would you deny?” These are the decisions that lie ahead for payers, health care providers, managed care organizations, and pharmacy benefit managers, etc. in talking about cost-effectiveness analysis. From both an employer's and a payer's points of view, ethical decisions need to be made.

- Are payer groups ready to take a position on covering or not covering potential benefits based on cost-effectiveness data?
- Are employers ready to present this type of model to their employees to decide on which services or products to cover?

Other models to review would be that of the National Institute for Health and Clinical Excellence (NICE) program in the United Kingdom.1 If one payer follows this paradigm change, will that company be able to compete in the marketplace? Will employers buy the product—or won’t they?

A cost-effectiveness model suggests that, if it is not cost effective, then there may be no coverage or there may be more lengthy coverage such as through a step protocol or through a “criteria for use” protocol. There are a lot of social issues that need to be considered such as workplace productivity, activities of daily living improvement, quality-of-life improvement, end-of-life issues, and cancer care issues, all with regard to different payment models for products and services. As previously mentioned, there are many stakeholders, including payers, the Centers for Medicare & Medicaid Services, health plans, employers, consumers, physicians, pharmacists, hospitals, pharmaceutical manufacturers, distributors (e.g., sales, consultants, brokers), and other health care professionals. Payers either from the government or the private sector want this type of information. Consumers also want this type of information for areas such as end-of-life issues, cancer-related issues, and transplant issues.

## Summary

The data is compelling, but better systems are needed to mine the data. The various stakeholders are going to view the data provided by Section 1013 and use the results in many different ways. Among other things, these stakeholders will need to think about the impacts of coverage, noncoverage, ethical issues, and societal issues, on how they do their work and/or how they run their businesses. This model, if it succeeds in getting into the marketplace, is going to change this in a very material way. This program and the data development are first steps on a journey. The work of AHRQ related to Section 1013 is a great next step for the United States, but it is still in the early phases of the journey. This is really going to be a lifetime’s worth of work as we watch it play out.

## DISCLOSURES

This article is based on a presentation given by the author at a symposium titled “Cross-Firing the Impact of the AHRQ Effective Health Care Program on Access to Biologic Therapies” held on October 6, 2006, at the Academy of Managed Care Pharmacy’s 2006 Educational Conference in Chicago, Illinois. The symposium was supported through an unrestricted educational grant from Centocor, Inc. The author discloses that he has received an honorarium from PRIME, Inc. for participation in this supplement. He discloses no potential bias or conflict of interest relating to this article.

## REFERENCE