OVERVIEW OF THE EVALUATION OF THE SECTION 641 DEMONSTRATION

Section 641 of the MMA calls for a demonstration that would pay for drugs and biologicals that are prescribed as replacements for drugs currently covered under Medicare Part B. CMS is required to conduct,

> *an evaluation of patient access to care and patient outcomes of the project, as well as an analysis of the cost-effectiveness of the project, including an evaluation of the costs savings (if any) to the Medicare program attributable to reduced physicians' services and hospital outpatient departments' services for administration of the biological*.

The evaluation will address three major areas of Congressional concern: patient access; patient outcomes; and cost-effectiveness. A schematic of the approach is included in Figure 1. The evaluation will rely on both intramural and extramural research. In its simplest form, the evaluation will address the three major areas in the following way.

- **Patient access:** Data about changes in demonstration participants' access to care would be collected through a survey designed and administered by an ORDI contractor. The RFP calls for a completed sample size of 3,200 demonstration participants and suggests stratifying the sample into four disease groups: 1) cancer; 2) multiple sclerosis; 3) rheumatoid arthritis; and 4) other non-cancer related drugs.
- **Patient outcomes:** Data about participants' perceptions of the benefits of the demonstration will also be gathered in this same survey. Benefits may include improvements in perceived health status, satisfaction with the demonstration, and benefits intrinsic to the self-administration versus physician-administration of medications.
- **Cost-effectiveness:** ORDI staff will analyze Medicare and pharmacy benefit management claims to estimate the net cost of the demonstration project by comparing selected health care costs for demonstration participants (e.g., costs of drug, costs of physician or outpatient department visits) to those of a control population that are taking currently-covered drugs that will be replaced by the demonstration drugs.

The evaluation will be enhanced by analyses of data outside of the demonstration. These analyses will contribute to our understanding of the implications of extending coverage to these self-administered drugs and biologicals on patient outcomes and their relative cost-effectiveness to the Medicare program. Since there are likely to be more than 15 drug/condition combinations included in the demonstration, it will be beyond the scope of the evaluation to do these analyses for all of them. We will conduct these for those drugs and conditions that impact a relatively large population or likely pose a high cost to the Medicare program.

- **Patient outcomes:** Many of the stakeholders that pressed Congress for this demonstration argued that expanded access would not only be easier for the patients (because they can administer the drugs themselves), but some of the self-administered formulations might substantially improve patient outcomes, like lengthen periods of disease remission, enhance patient survival, and improve quality of life. One of the Evidence-based Practice Centers (EPCs) at AHRQ will be conducting a systematic review of the clinical and quality of life literature for selected cancer drugs included in the demonstration. Systematic reviews will also be conducted for the multiple sclerosis and rheumatoid arthritis drugs that will be included in the demonstration. A systematic review evaluates a new drug's performance characteristics, safety, efficacy, effectiveness, outcomes, appropriateness or economic impacts and rely on explicit, methodical techniques to limit bias and reduce chance effects, which can provide more reliable results upon which to draw conclusions and make decisions. Utilizing existing, recent systematic reviews, CMS will summarize the literature on outcomes, quality of life and

cost-effectiveness for other drugs included in the demonstration. This background summary will be included in the Report to Congress.

- **Cost-effectiveness:** In order to gain a broader and longer-term perspective of the likely cost-effectiveness of demonstration-covered medications to the Medicare program, CMS will again tap the intra-agency agreement with AHRQ. AHRQ will in turn contract with experts who have developed models of the cost-effectiveness of the demonstration drugs used to treat rheumatoid arthritis and multiple sclerosis. These models will incorporate systematic reviews of the relative efficacy and safety of demonstration drugs relative to the currently covered Medicare Part B drugs. They will utilize data from disease-specific patient registries that include periodic assessments of both cost and functional outcomes. CMS staff will develop one or two cost-effectiveness analyses of selected cancer drugs included in the demonstration. An analysis of the Medicare-SEER data will be used to provide data on the natural history of patients with the selected condition and current claims data would be analyzed to obtain model costs. Relative efficacy data will be obtained from the EPC-conducted review.

For further information or to submit comments on the design contact Penny Mohr at pmohr@cms.hhs.gov.

Note: All contracts for subtasks of this evaluation will be issued following standard government procurement guidelines.