<u>February 17, 2005 Teleconference Outline</u> <u>Thomas R. Barker, Esq.</u> <u>Deputy General Counsel</u> <u>U.S. Department of Health and Human Services</u>

* Disclaimer: The views expressed herein and on this teleconference are solely those of the author and do not necessarily reflect the views of the U.S. Department of Health and Human Services, the Centers for Medicare & Medicaid Services, or any other department or agency of the federal government. To the extent that anything herein contradicts any provision of a Notice of Proposed Rulemaking, a final regulation, or any other guidance issued by any agency of the federal government, the terms of that Notice of Proposed Rulemaking, final regulation, or guidance (as the case may be) shall control.

OUTLINE

I. Significant legal issues in the development of the MMA Titles I and II regulations

- A. What counts as TrOOP?
- B. Low-income subsidy
- C. Auto-enrollment
- D. Employer subsidy
- E. Any willing pharmacy
- F. Long-term care pharmacies
- G. Pre-emption

II. TrOOP

- A. Coverage Gap
- B. Theory of the coverage gap
- C. What spending counts in the coverage gap?
- D. Changes between NPRM and final rule
- III. Low-Income subsidy
 - A. Explanation of subsidies
 - B. Issues
 - 1. Where to apply for subsidy
 - 2. Availability of judicial review
- IV. Auto-enrollment
 - A. General Medicare population
 - B. Dual-eligibles

V. Employer subsidy

- A. Reasoning
- B. To whom available
- C. Terms of subsidy
 - 1. Actuarial equivalence
 - 2. Amount
 - 3. Tax consequences
- D. CMS Policy concerns
 - 1. Prevent windfalls
 - 2. Minimize employer dropping
 - 3. Limit cost of subsidy and Part D benefit
- E. Solution to CMS policy concerns
 - 1. The "two-prong" test

VI. Any willing pharmacy

- A. Statutory mandate
- B. "Preferred" pharmacies
- VII. Long-term care pharmacies
 - A. Statutory requirement
 - B. Policy considerations
 - C. Issue
 - D. Provisions of final rule

VIII. Medicare Advantage pre-emption

- A. M+C Pre-emption rules
- B. MA pre-emption rules
- C. Concerns and policy issues