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I. Background

A. Statutory Basis for the Program

The purpose of this interim final rule is to establish requirements for the Medicare Prescription Drug Discount Card and Transitional Assistance Program (hereafter referred to as the "Medicare drug discount card program"). This program was established by section 101, subpart 4, of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and is codified in section 1860D-31 of the Social Security Act (the "Act").

Section 1860D-31(a)(2)(A) of the Act requires us to ensure that eligible Medicare beneficiaries have access to negotiated prices for prescription drugs and transitional assistance under the Medicare discount card program within 6 months of the date of enactment of the program's authorizing statute. To enable us to meet this implementation deadline, the statute authorizes us to issue this interim final rule, which is effective immediately on an interim basis, as of the date of publication. Although the rule will be effective prior

to receipt of public comments, we will accept comments on this interim final rule during a 30-day comment period and may, at a future date, revise this regulation based on the comments we receive. In addition, we will continue to monitor the implementation of this program during its operation. If we become aware of operational difficulties in the program, or of activities resulting in fraud, waste, or abuse we may revise the policies announced in this rule using appropriate procedures.

Section 105(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides for expedited implementation by—

- Exempting the Medicare drug discount card program from the requirements of the Paperwork Reduction Act, including the public comment and Federal clearance processes associated with it;
- Exempting the drug discount card program from the requirement in the Congressional Review Act for a 60-day delayed effective date for major rules (5 U.S.C. 801(a)(3)(A)), and from the requirement under the Administrative Procedure Act (5 U.S.C. 553(d)) that regulations not become effective until 30 days after their publication.
- Allowing the Secretary of the Department of Health and Human Services (hereinafter the "Secretary") to enter into contracts without regard to provisions of law or regulation governing the performance, amendment, or modification of contracts that may be inconsistent with furthering the Medicare drug discount card program.

As provided under sections 105(c)(4)(A) and (B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, prohibiting judicial review of a CMS determination not to endorse a sponsor applicant and providing that, in the event any provision of section 1860D-31 of the Act is enjoined, the order will not affect the remaining provisions of section 1860D-31.

To meet the six-month implementation deadline, we will pursue a compressed timeframe for soliciting and reviewing endorsed sponsor applications.

B. Purpose of the Program

Congress intended for the Medicare drug discount card program to serve as a transitional program providing Medicare beneficiaries with immediate assistance with prescription drug costs during calendar year (CY) 2004 and CY 2005 while preparations are made for implementation of the Medicare drug benefit under Medicare part D in 2006. Medicare currently does not cover the