Overview of the New Medicare-Endorsed Prescription Drug Discount Card Program

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Outline of Talk

- **Discount Card Implementation Schedule**
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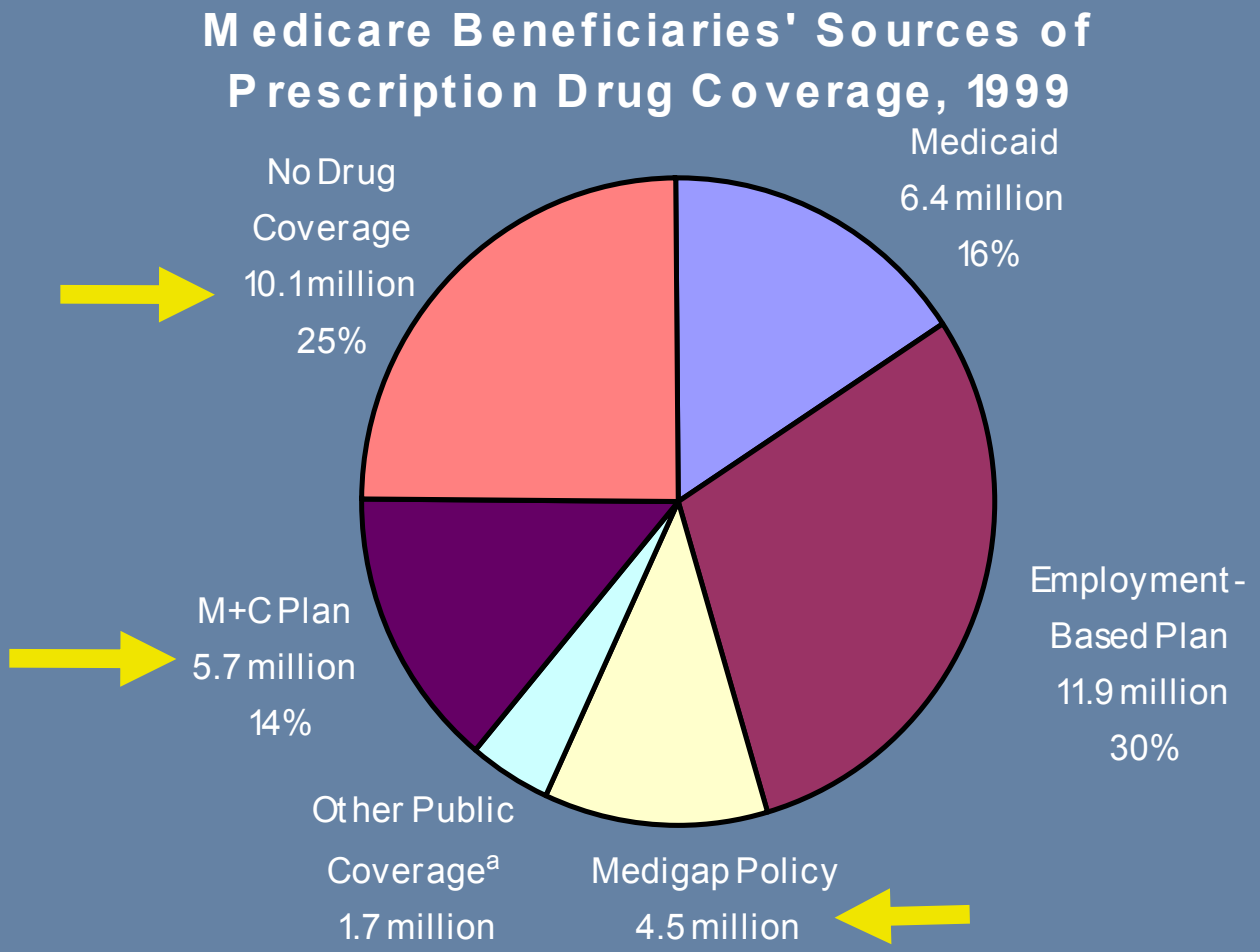
Key Dates in Implementation of Medicare Drug Discount Card Program

- Dec. 8, 2003: MMA is signed into law
- Dec. 15: CMS publishes interim final rule for discount card program
- Dec. 18-19: CMS holds pre-application conference for potential card sponsors and other interested parties
- Jan. 14, 2004: Deadline for public comment on interim final rule
- Jan. 30: Deadline for card sponsor applications to CMS
- End of March: Card sponsor contracts finalized
- April 1: Card sponsor information and outreach may begin
- April 30: CMS launches Discount Card Price Comparison Web site
- May 3: Card sponsors may begin enrollment
- June 1: Discount card program begins
- Nov. 15 - Dec. 31: Enrollees may elect to switch cards for 2005
- Jan. 1, 2006: Part D benefit starts; discount card program ends

Target Population: Medicare Beneficiaries with No or Limited Rx Drug Coverage



a. State-sponsored pharmaceutical assistance programs, VA, DoD, or M+C nonrisk contracts.

Source: Congressional Budget Office based on data from the 1999 Medicare Current Beneficiary Survey (October 2002).

The Health Strategies Consultancy

Categories of Eligible Individuals

Discount Card Eligibles

- **Any beneficiary enrolled in Medicare Parts A or B**
- **No income limit**
- **Not enrolled in Medicaid or entitled to drug coverage under a Sec. 1115 Medicaid waiver**

Transitional Assistance Eligibles

- **Enrolled in Parts A or B**
- **No Rx coverage under:**
  - Group health plan or individual health insurance policy
  - VA or DoD
  - FEHBP
- **Income less than 135% FPL***
  - Eligibility will be self-declared
  - CMS authorized to verify eligibility

*135% of FPL in 2004 is $12,120 for a one-person household and $16,360 for a two-person household.

Enrollment

- **Enrollment in discount card program is voluntary**
  - CMS estimates 7.3 million enrollees in 2004 and 2005
  - 4.7 million enrollees expected to be TA eligible
- **Enrollment allowed in only one Medicare-endorsed card at a time**
  - There will be one “coordinated election period” to switch cards
  - Enrollees may continue to use other, non-endorsed cards
- **Cards may charge annual enrollment fee of up to $30**
  - CMS will pay enrollment fee directly to card sponsors for TA eligible beneficiaries
  - States may pay for enrollees with incomes above 135% of FPL, but with State-only funds

Transitional Assistance for Low-Income Enrollees

- **$600 Federal subsidy provided in 2004 and 2005 to card enrollees with incomes below 135% FPL**
  - Unused funds from 2004 may rollover to 2005
  - Amount in 2005 will be pro-rated if mid-year enrollment
- **CMS will pay annual enrollment fee (if any) directly to card sponsors**
- **Beneficiaries required to make copayments, based on percent of negotiated prices**
  - 5% co-pay if income is below 100% FPL*
  - 10% co-pay if income is between 100% and 135% FPL*
  - States may “wrap around” to cover co-pays, but expenditures not eligible for Federal Medicaid matching funds

*100% of FPL in 2004 is $8,980 for one-person household and $12,120 for two-person household. 135% of FPL is $12,120 and $16,360, respectively.

Card Sponsor Requirements

- **CMS will not limit the number of discount card programs operating in a State**
- **Minimum application requirements for card sponsors:**
  - At least three (3) years of experience in pharmacy benefit management (as defined specifically in the regulation)
  - Current operation of a pharmacy benefit program, drug discount card program, or low-income drug assistance program that serves at least 1 million covered lives
- **Card sponsors must have pharmacy network, other than mail-order, that meets TRICARE 2003 pharmacy access standards**
  - Pharmacy network may be supplemented by mail-order pharmacies
- **Card sponsors must be able to administer "transitional assistance" funds, including roll-over funds**
- **MedicareAdvantage plans that sponsor a discount card have exclusive enrollment rights to their plan members**

Drug Pricing Requirements

- **Card sponsor must guarantee enrollees access to "negotiated price"**
  - Negotiated price is "discounted price, including any dispensing fee, which takes into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, or direct or indirect remunerations." (42 CFR 403.802)
- **Card sponsors must pass a "share" of negotiated price concessions to enrollees through negotiated prices**
- **Negotiated prices will not be included in Medicaid best price calculations**
- **CMS estimates per prescription savings of 10%-15% off retail (cash) price**
  - Rule does not require card sponsors to guarantee level of savings

Price Information Disclosure Requirements

- **Card sponsors must report the following to CMS:**
  - Negotiated prices for every covered drug at NDC level
  - Aggregate savings obtained from manufacturers and pharmacies
  - Aggregate savings shared with discount card enrollees
  - Dispensing fees by pharmacy
  - Notice and rationale for increases in negotiated prices due to reasons other than AWP changes
- **Confidentiality of pricing data as under Medicaid**
- **Pharmacies must inform enrollees at point-of-sale of any difference between price of prescribed drug and price of lowest priced available generic alternative**
- **CMS will establish a price comparison Web site and issue printed comparison guides**
  - Card sponsors may update weekly

Formulary Requirements

- **Authorizing law does not specifically mention formularies, but…**
- **Sum of regulatory requirements on card sponsors suggests interpretation that all card sponsors must use a formulary**
- **CMS has defined a list of 209 therapeutic categories**
  - CMS states that this is a "minimum requirement"
  - Card sponsors may add more categories or further differentiate categories through P&T committees
- **Formularies must include one brand drug in each of the 209 therapeutic categories**
  - For drugs that can be classified into more than one category, a drug can be used only once to satisfy this requirement
- **Formularies must include one generic drug in 115 (55%) of the 209 categories**
  - 115 categories represent about 95 percent of the categories that include a Class A generic drug, according to CMS and the FDA Orange Book
- **Conclusion: Card sponsors will have to negotiate many manufacturer contracts very quickly to meet minimum formulary requirement**

Concluding Thoughts

- **Nature of drug price disclosures—how well will beneficiaries understand and process drug pricing information (e.g., savings compared to what?)**
- **Will CMS-mandated "therapeutic categories" produce manufacturer rebates and thus added value for beneficiaries?**
- **Discount card program is "first date" between CMS and pharmaceutical/PBM industry**
  - Strong interest thus far from potential card sponsors
  - Opportunity in marketing of card and establishing brand visibility
  - CMS balancing regulatory oversight and incredibly fast "go-live" imperative, while also learning about very complex industry
  - Both partners building relationship needed for success of Part D