Implementing the Medicare Drug Benefit

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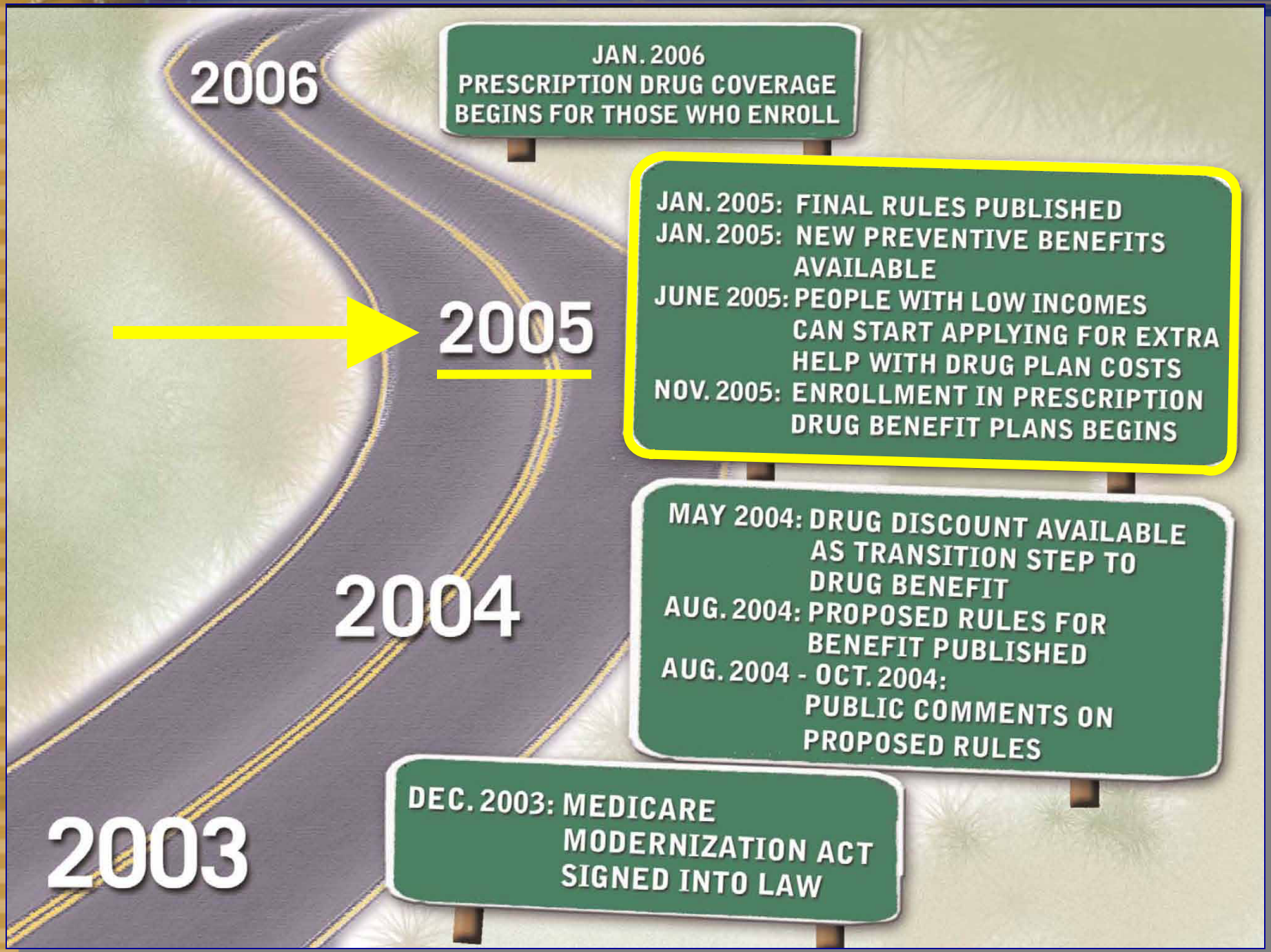
June 8, 2005

CMS
CENTERS for MEDICARE & MEDICAID SERVICES


2006
JAN. 2006
PRESCRIPTION DRUG COVERAGE
BEGINS FOR THOSE WHO ENROLL
2005
JAN. 2005: FINAL RULES PUBLISHED
JAN. 2005: NEW PREVENTIVE BENEFITS AVAILABLE
JUNE 2005: PEOPLE WITH LOW INCOMES CAN START APPLYING FOR EXTRA HELP WITH DRUG PLAN COSTS
NOV. 2005: ENROLLMENT IN PRESCRIPTION DRUG BENEFIT PLANS BEGINS
2004
MAY 2004: DRUG DISCOUNT AVAILABLE AS TRANSITION STEP TO DRUG BENEFIT
AUG. 2004: PROPOSED RULES FOR BENEFIT PUBLISHED
AUG. 2004 - OCT. 2004: PUBLIC COMMENTS ON PROPOSED RULES
2003
DEC. 2003: MEDICARE MODERNIZATION ACT SIGNED INTO LAW

Medicare Challenges

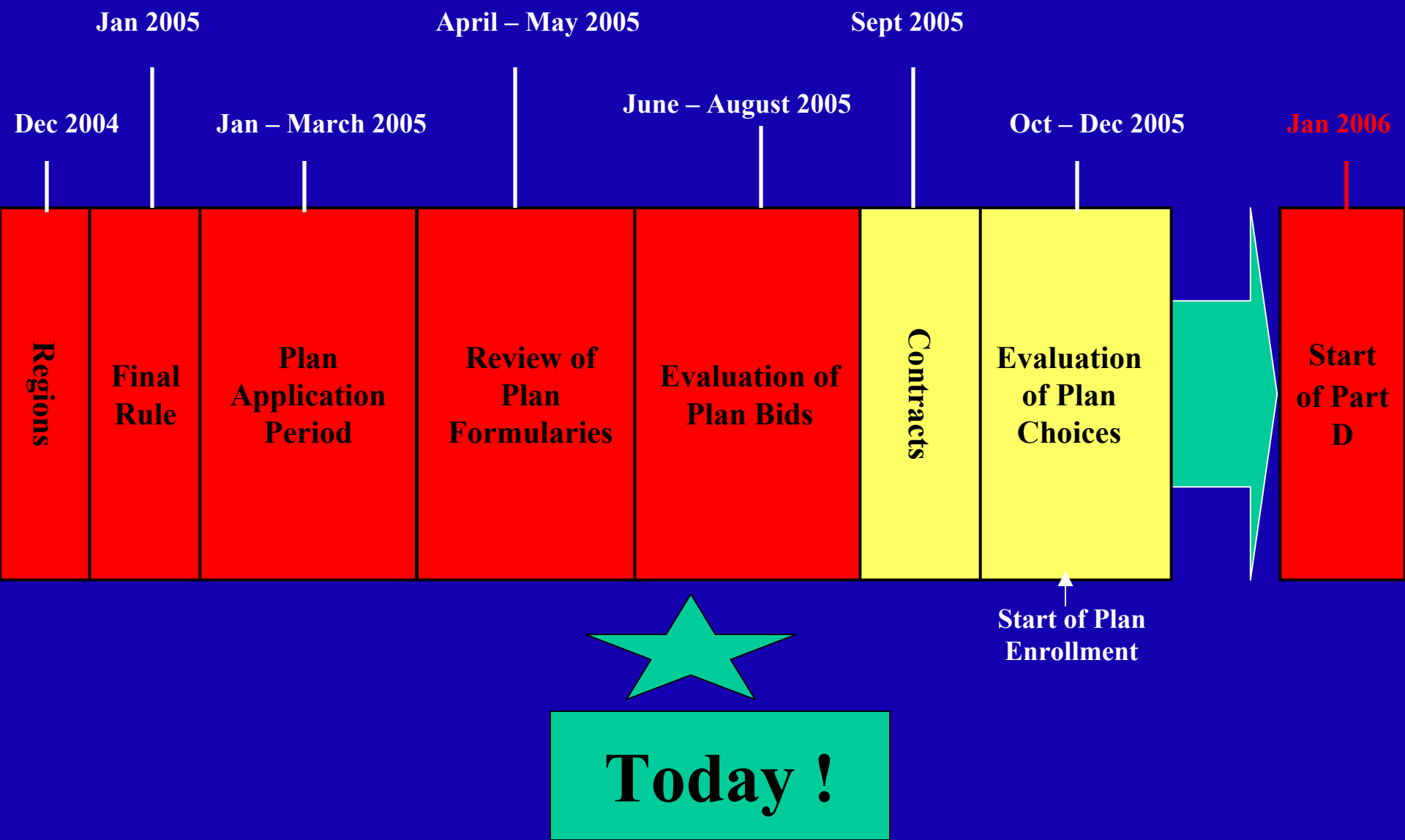
- Providing the best care for a Medicare population that has longer life expectancy
  - 87 years for 65 year old beneficiary today
  - Need medical management of chronic diseases, not just acute care
  - Need better coordination among providers
- High cost of health care for Medicare
  - Average increase of 13% per year overall
  - Medicare high utilization of care (includes prescription drugs, physicians, other providers)
- Rapid development of expensive technology and prescription drugs

Part D Challenges

- **Access**– To ensure that plans are available nationwide-both Prescription Drug Plans and Medicare Advantage
- **Operations**—To ensure that plans provide high quality service to beneficiaries and are able to operate effectively
- **Education, Outreach, and Enrollment**—To ensure 42 million Medicare beneficiaries can make confident decisions on their prescription drug coverage

Part D Implementation

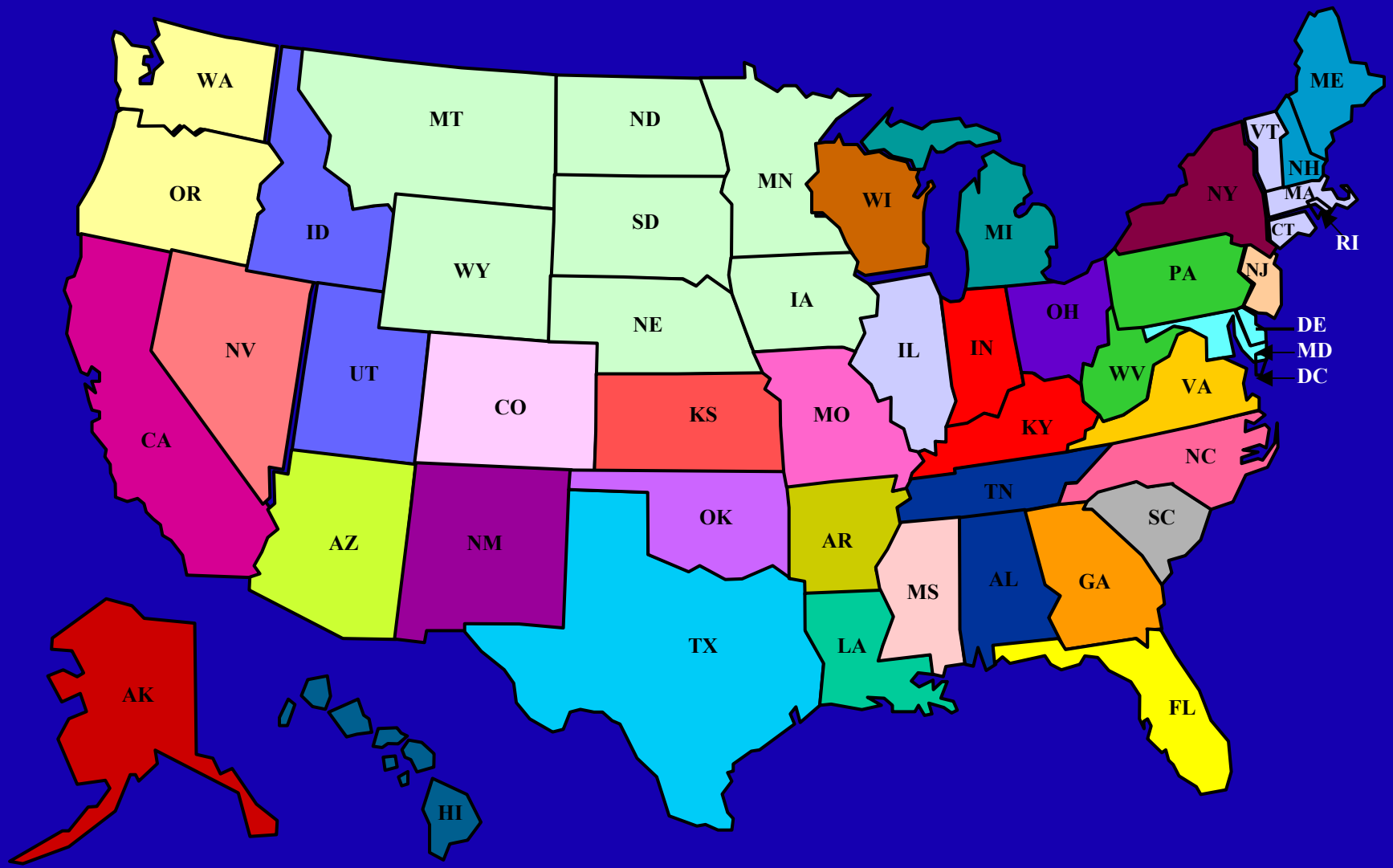
Part D Implementation Timeline



MA and PDP Regions Announced

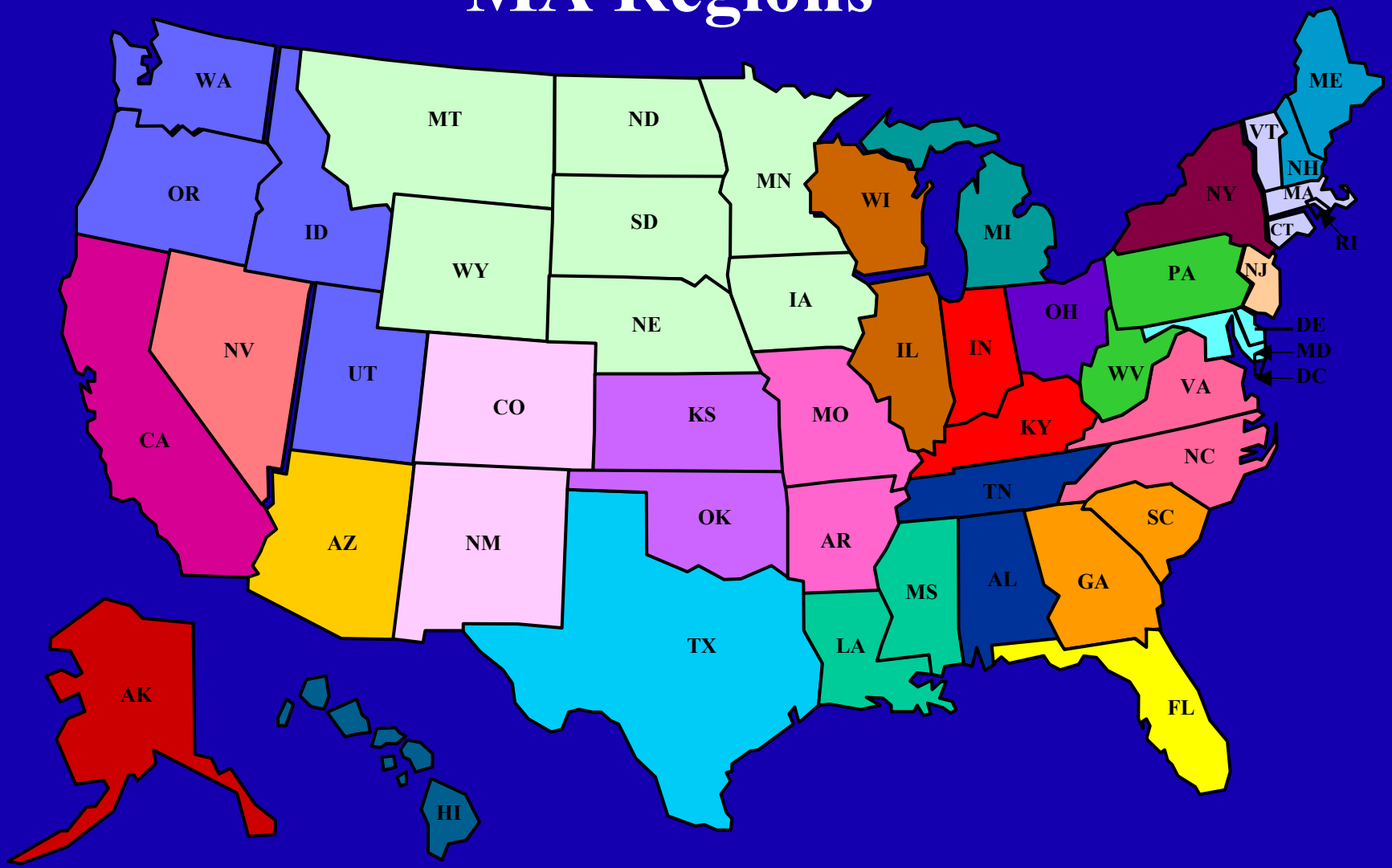
- On December 6, 2004, CMS announced the establishment of 26 MA regions and 34 PDP regions.
- Regions designed to maximize plan participation
- Regional PPOs must cover entire region

PDP Regions



Note: Each territory is its own PDP region.

MA Regions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Publication of Final Rule

- CMS released the final rule for the Medicare Prescription Drug benefit on January 21, 2005.
- We received 7,696 items of correspondence containing comments on the August 2004 proposed rule.

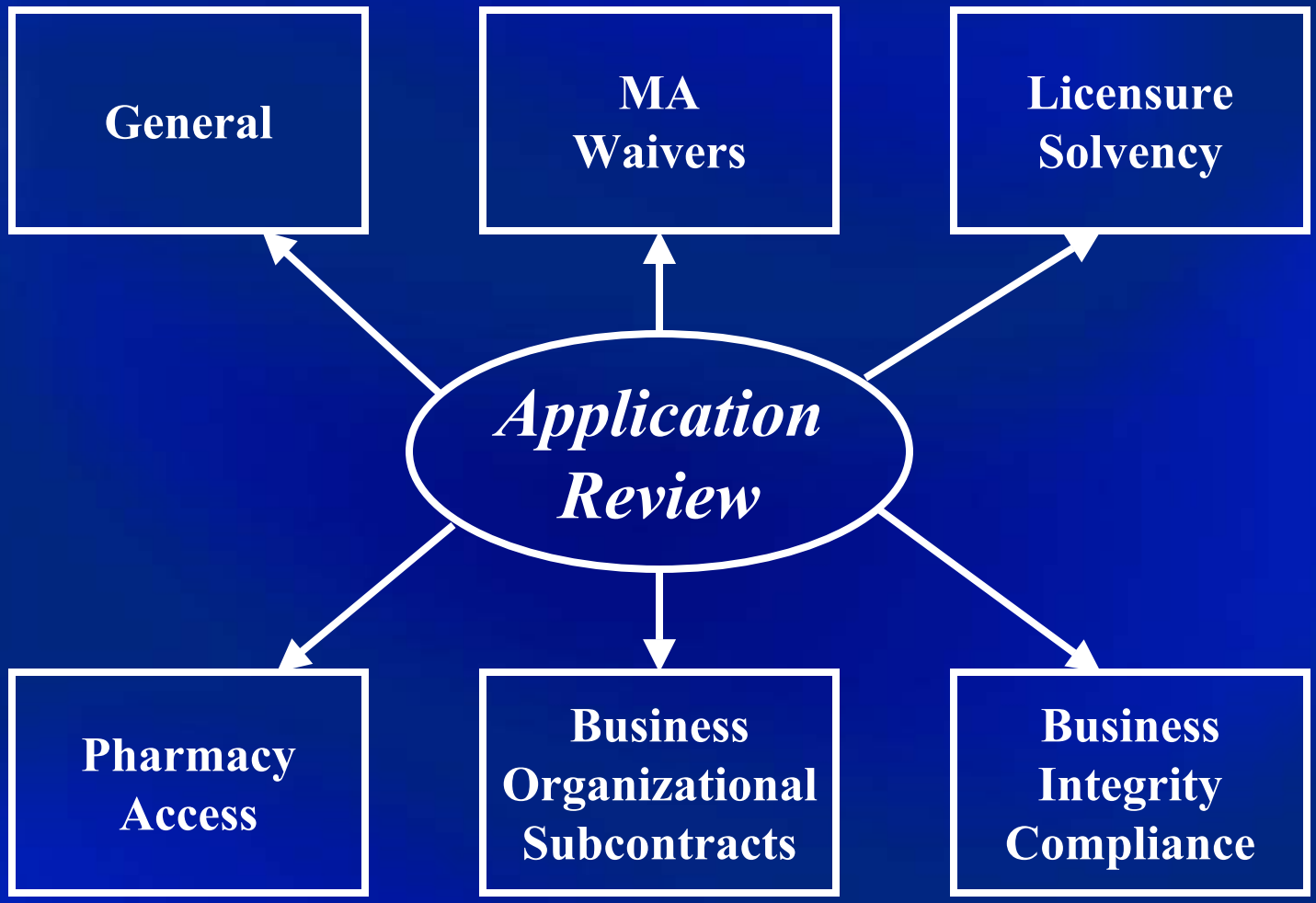
Training and Assistance for Plan Sponsors

- ☑ Application Conference - January
- ☑ Weekly calls through June
- ☑ Bidding conference – Early April
- ☐ Submitting claims data for Part D
  - ☐ July 18-20th in Baltimore
  - ☐ July 26-28 in Las Vegas
  - ☐ August 1-3 in Chicago
  - ☐ August 9-11 in New Orleans
- ☐ Payment and enrollment conference
  - ☐ August 29th – September 2nd in Baltimore

Additional Guidance Released

- Application Materials
- Formulary Review Guidance
- LTC Guidance
- Transition Process Guidance
- Fiscal Solvency Standards
- Prescription Drug Event Data
- Employer waiver guidance
- Bid materials

Application Review



Formulary: What is a Part D Drug?

- A Part D drug includes any of the following if used for a medically accepted indication:
  - A drug dispensed only by prescription and approved by the FDA
  - A biological product dispensed only by a prescription, licensed under the Public Health Service Act (PHSA), and produced at establishment licensed under PHSA
  - Medical supplies associated with the injection of insulin (e.g., syringes, needles, alcohol swabs, swabs)
  - A vaccine licensed under the PHSA

Formulary: What is a Part D Drug?

- What is excluded as a Part D drug?
  - Drugs for which payment "as so prescribed and dispensed or administered" to an individual is available under Parts A and B
  - Drugs/classes of drugs which may be excluded under Medicaid, except for smoking cessation agents (excluded drugs may be paid for by Medicaid):

Formulary: Excluded Drugs

- Agents when used for anorexia, weight loss, or weight gain;
- Agents when used for cosmetic purposes/hair growth;
- Agents when used for symptomatic relief of cough & colds;
- Prescription vitamins & mineral products (except prenatal vitamins & fluoride preparations);
- Nonprescription drugs;
- Covered outpatient drugs when manufacturer seeks to require associated tests or monitoring as a condition of sale;
- Barbiturates;
- Benzodiazepines

Formulary Review: Rationale

- MMA requires CMS to review Part D formularies to ensure
  - beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states
  - formulary design does not discriminate or substantially discourage enrollment of certain groups

Formulary Review: A Visual Perspective

Formulary Review: Approach

- Ensure the inclusion of a broad distribution of therapeutic categories and classes
- Utilize reasonable benchmarks to check that drug lists are robust
- Review tiering and utilization management strategies
- Identify potential outliers at each review step for further CMS investigation
- Obtain reasonable clinical justification when outliers appear to create access problems

Formulary Review Checks

- Review of USP Categories and Classes
- Comparison to AHFS Categories and Classes
- Two Drugs per Category and Class
- USP Formulary Key Drug Types
- Tier Placement
- Widely Accepted Treatment Guidelines
- Therapeutic Categories or Pharmacologic Classes Requiring Uninterrupted Access
- Common Drugs for Medicare Population
- Quantity Limit Review
- Prior Authorization Review
- Step Therapy Review
- Insulin Supplies and Vaccines Review
- Long-Term Care Accessibility Review

Bidding/Payment

- Four components of payment
  - Direct subsidy
  - Reinsurance
  - Low income cost sharing
  - Risk corridors
- Direct subsidy based on bid
- Reinsurance and low income cost sharing
  - Interim prospective payment based on bid
  - Final payment based on actual costs
- Risk corridors determined based on actual costs

Plan standardized bid

- Organization projects cost for standard benefit based on population assumed to enroll
- Standard benefit excludes beneficiary cost sharing, reinsurance and low-income cost-sharing subsidies
- Projected costs adjusted by the projected risk score of population to get standardized bid
- Bids will be aggregated to generate a single national average monthly bid amount

Bid Review and Approval

- Review bids -- due June 6
- Determine reasonableness of assumptions/methods
  - Compare to appropriate benchmarks
  - Statistical analysis of bids submitted
    - Compare to national, regional, organizational bids
- Negotiate
- Bid Approval
- Audit

Plan Marketing Materials

- Dissemination of Part D plan information:
  - Must be disclosed to each enrollee annually and at the time of enrollment
  - Disclosure upon request to any Part D eligible individual

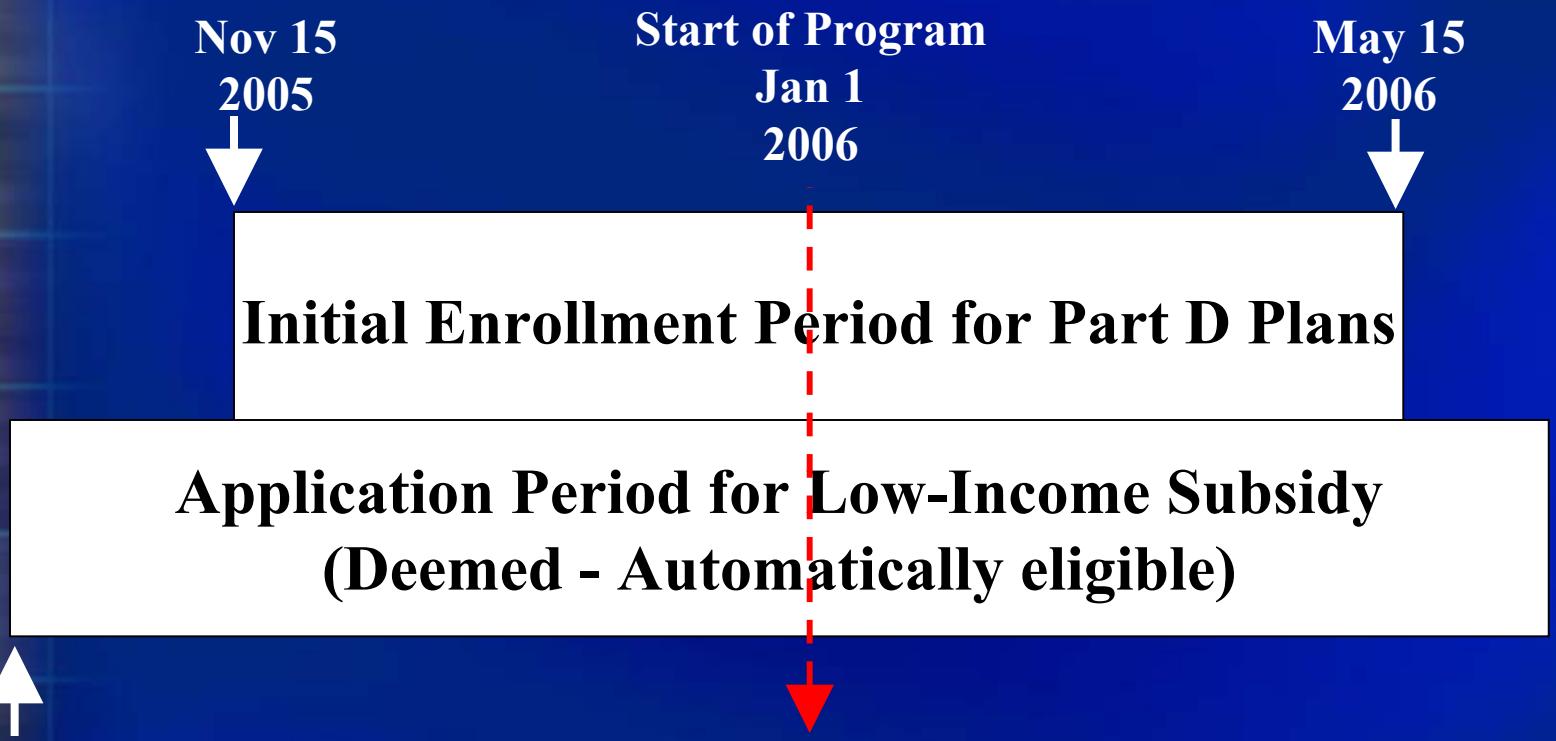
Marketing Guidelines

- CMS is drafting Part D marketing guidelines in two installments:
  - Installment I addresses the review and approval of marketing materials
  - Installment II will provide specific guidance on the process of marketing the Part D benefit

Contracts

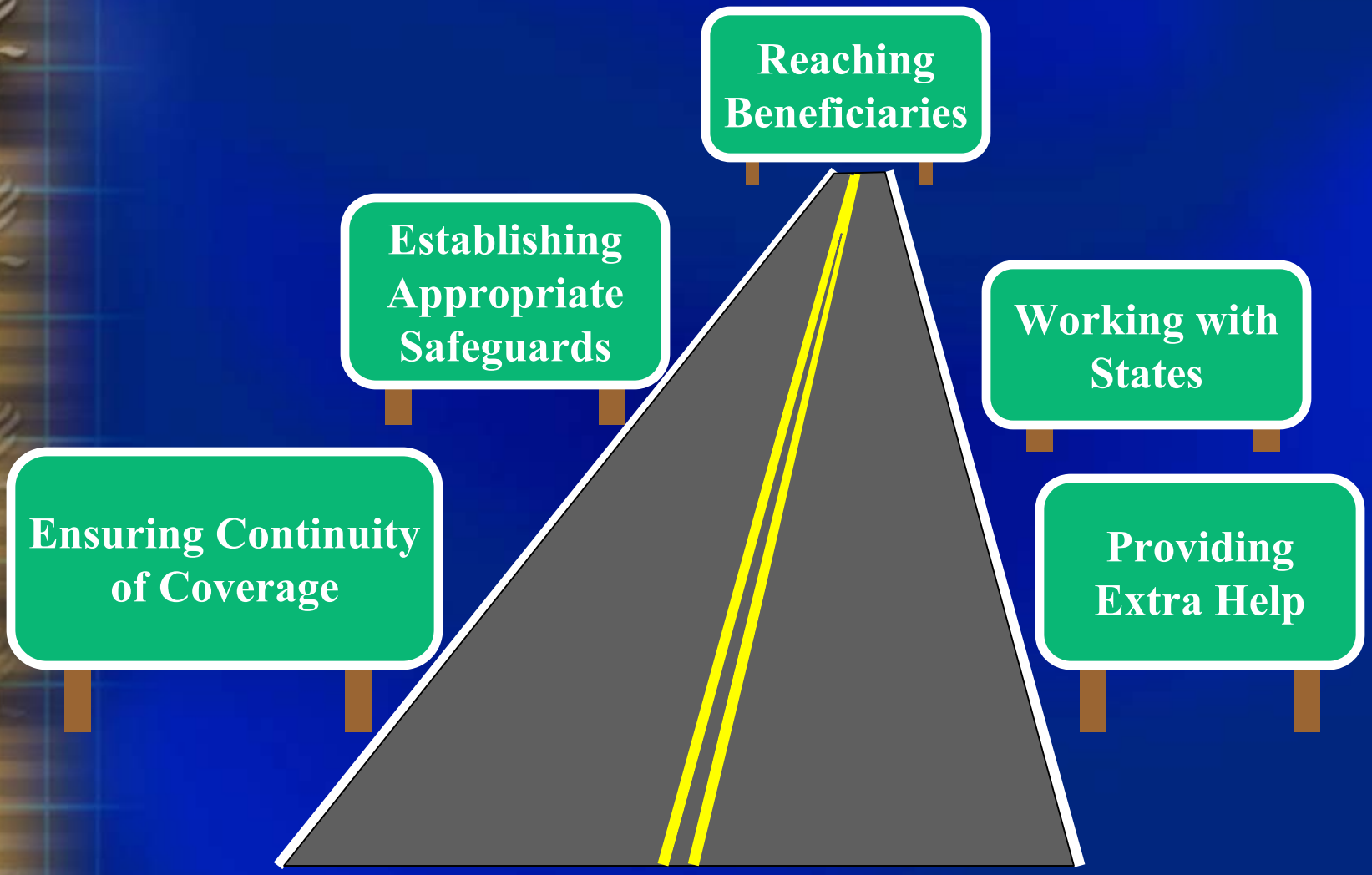
- Draft contract will be out this month with at least a two week comment period
- CMS expects to complete contracting process by early September

2006 Enrollment Timeline



Special Issues

Dual Eligibles: Transition to Medicare Prescription Drug Coverage



Transition Process

- The final regulation requires plan sponsors to have a transition process for new enrollees prescribed Part D drugs not on the plan's formulary.
- This applies to Part D drugs.
- CMS issued guidance on March 16, 2005.

Long Term Care Coverage

- The Plan Sponsor's Formulary *is* The Formulary
- Plans must accommodate within a single formulary all medically necessary medications at all levels of care
- Coverage may include, not limited, to liquids that can be administered through feeding tubes, IV, or IM injections

LTC Guidance

- Convenient Access
  - PDPs required to accept any willing pharmacy (must meet performance requirements)
  - LTC facility can continue to contract exclusively if chooses as long as all Plan Sponsors in covered area are available
  - PDPs MUST demonstrate a network of "convenient" access

Beneficiary Outreach

Education, Outreach, and Enrollment
A Monumental Task

- Educate 41 million Medicare Beneficiaries so they can make confident choices on prescription drug coverage

- **Target Populations**
  - General- Seniors/People with disabilities
  - Low Income
  - Retirees
  - Medicare Advantage

Evidence-Based Outreach Strategy

- Targeted Strategies & Messages for Major Groups
  - Polling, Market Research
- Key Partnerships
- Communications Tools
  - Paid & Earned Media
  - Partners
  - Plans
- Metrics & Measurement
  - To County Level

Campaigns Within the Campaign

- Financial Planners
- Pharmacies
- Plans
- Employers and Unions
- Disease Organizations
- Disability/Mental Health
- Physicians
- Asian Americans
- HIV/AIDS
- African Americans
- States
- American Indian/Alaskan Native
- Long Term Care

Getting the Message Out: Timeline

- **Multi-Phased Message Platform**

Initial Awareness (January–October 2005)

- Focus on developing partnerships
- General population enrollment (January - September)
- Low-income subsidy application (May – October)

Beneficiary Decision (October–December 2005)

- Motivate, educate, and assist beneficiaries to enroll
- Low-income subsidy application continues
- General population enrollment
- Transition to Medicare coverage for beneficiaries with Medicaid

Urgency (January–June 2006)

- Target beneficiaries that have not yet enrolled in order to avoid increased premiums

General Messages

- Drug coverage will be available to everyone with Medicare
- Medicare will provide help with your drug costs, no matter how your drugs are paid for now
- Extra help will be available for those in need
- A choice of plans will be available
- All plans will include both brand name and generic drugs

Dual Eligibles: Key Messages

- You will start getting comprehensive drug coverage from Medicare (not Medicaid) beginning Jan 1, 2006
  - No premiums, deductibles, or coverage gaps, and only small co-pays
- You will get important information this summer and specific information in the Fall about this comprehensive coverage
- If you don't choose on your own by January, you will be assigned to a comprehensive Medicare plan, and you can switch to a different plan at any time
- Your plan must cover all medically necessary treatments and your plan must work with you and your doctors to make sure you keep getting all the drugs that you need

Other Beneficiaries Eligible for Extra Help: Key Messages

- Medicare is providing extra help for beneficiaries with limited resources
- No question: If you think you're eligible, it's worth it to get an application and apply – it's comprehensive coverage
- The application, available online in July, is short and requires no additional financial records
- Look for an application in the mail from SSA coming in May or June – it's important

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