Medicare Parts C and D after the ACA

Thomas R. Barker

Partner

Presentation to the DC Bar

Agenda

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  - Enrollment
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- Part D
  - Introduction to the program
  - Enrollment
  - Benefits: what is a “covered Part D Drug”
  - Coverage gap
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  - Regulatory changes since the ACA
  - 2014 Timeline

Medicare Advantage

- Introduction to the program
  - Managed care in Medicare has been an option in the program since the 1970s.
  - It was not until 1997 (Balanced Budget Act; Pub. L. No. 105-33 (Aug. 5, 1997)) that the program really expanded.
    - Called "Medicare+Choice"
  - The MMA revitalized the program in 2003.
  - The Affordable Care Act made significant changes in the program in 2010 that are starting to be felt. What do these changes portend for the future of the program?
- Enrollment
  - Enrollment in Medicare Advantage is open to any Medicare beneficiary who is entitled to benefits under Part A and enrolled under Part B.
  - Individuals with ESRD may not enroll in an MA plan; however, an individual who develops ESRD post-enrollment may remain in the plan.
  - Currently, about 28% of Medicare beneficiaries in the United States (14.4M/50M) are enrolled in Medicare Advantage plans (Kaiser Family Foundation, June 10, 2013).

Medicare Advantage

- Enrollment (cont'd)
  - Beneficiaries generally have three broad types of plans open to them for enrollment:
    - Coordinated care plans (including regional plans). These include:
      - HMOs (with or without POS option)
      - PPOs
      - PSOs
      - SNPs
        - Authority for SNPs expires every couple of years and must be renewed. Note recent GAO report on SNP plan profits.
    - MSA plans and contributions to an MSA
    - Private fee-for-service plans
      - Note that MIPPA severely restricted the availability of PFFS plans.

Medicare Advantage

- Benefits
  - In general, a Medicare Advantage enrollee is entitled to:
    - All benefits available under Parts A and B
    - The benefit of all national coverage decisions
      - Although an MA plan can defer application of an NCD until the succeeding plan year based on a "significant change in cost"
    - The benefit of all local coverage decisions applicable in the plan area
      - A plan that operates in an area where there is more than one applicable local coverage decision can elect to apply the decision that is most favorable to MA enrollees across the entire plan area
    - Supplemental benefits (at plan option)
  - An MA plan may, however, offer alternative cost-sharing from traditional Medicare (e.g., combined A/B deductible) as long as the alternative cost-sharing is actuarially equivalent to original Medicare. But cost-sharing cannot differ from traditional Medicare for:
    - Chemotherapy services;
    - Dialysis services;
    - Skilled nursing care;
    - Other services identified by the Secretary (based on need for "predictability and transparency" for MA enrollees)
    - [Social Security Act § 1852(a)(1)(B)(iv), added by ACA]

Medicare Advantage

- Financing
  - The financing of MA plans has become increasingly complicated since the earliest inception of the program.
  - There are have been four discrete MA financing policies over the decades.
  - The current regime for financing MA plans (added by the ACA) arguably has the strongest intellectual and public policy foundation, but is also quite controversial and there are concerns that plans will drop out in the coming years, depressing enrollment.
  - Let's take a look at the four historical policies

Medicare Advantage

- Financing – Phase I (ca. 1976 – 1997)
  - From the beginning, Medicare managed care plan payments have been county-based.
  - Plans received a flat payment amount equal to 95% of the average adjusted per capita cost (AAPCC) of Medicare in the county in which the plan operated.
  - So for example: if the monthly AAPCC in Montgomery County, Maryland was $500 in 1977, and in Loudon County, Virginia, was $300, a Medicare managed care plan:
    - In Montgomery County received $475 per member enrollee per month; and
    - In Loudon County, received $285 PMPM
  - The public policy theory was that a Medicare managed care plan could operate more efficiently than the government and did not need to receive the full capitated payment.
  - As a practical matter, only staff-model HMOs (which were more prevalent in California and Minnesota) were able to make the program work.

Medicare Advantage

- Financing – Phase II (1998 – 2004)
  - By 1998, the flaws of the payment system were obvious
    - Low enrollment
    - Little participation
    - Limited benefit choices compared to original Medicare
    - Most notably, plan payments were not risk adjusted.
      - This had the effect of skewing enrollment only to healthy beneficiaries.
  - In the BBA, the Republican Congress and the Clinton Administration substantially revised the model. The BBA created the Medicare+Choice program and established county "benchmarks" for payment.
    - A county was assigned the highest of three benchmarks:
      - A blend of the county-AAPCC and the national M+C capitation rate (but held budget neutral to the AAPCC model)
      - A "minimum amount" trended forward for expenditure growth
      - 102% of the AAPCC.

Medicare Advantage

- Financing – Phase II (cont'd.)
  - Enrollment (cont'd.)
    - Initially, this methodology provided a substantial boost in payments to M+C plans
      - Enrollment grew from 4.7M enrollees in 1997 to 6.3M in 1998.
      - Enrollment peaked at 6.7M in 1999
      - Enrollment had declined to 5.0M in 2003
        - [Source: The Medicare and Medicaid Statistical Supplement, Centers for Medicare & Medicaid Services, Center for Drug and Health Plan Choice, Table 12.1]
  - In addition to the new payment methodology, the BBA provided for risk adjustment of M+C plan payments beginning in 2000
  - CMS has, over time, developed a very sophisticated risk adjustment model based on "hierarchical condition categories" into which each MA enrollee is placed. Each HCC has a weighting factor which is used to adjust the payment to the MA plan (thus, base plan payments are based on a beneficiary with a 1.0 risk score).
    - CMS has developed the RADV audits to reflect concern that risk adjustment encourages upcoding.

Medicare Advantage

- Financing – Phase III (2004 – 2011)
  - The Medicare Modernization Act (MMA, Pub. L. No. 108-173) again revised the payment methodology.
  - The result of the MMA changes was to dramatically increase enrollment.
  - During this period, enrollment more than doubled, from 5.0M to 10.8M
    - [Source: Id.]
  - Under the new payment methodology, plans received the greater of the payment amounts calculated under the BBA or a new methodology equal to the greater of 102% of the highest of the BBA-established amounts or the BBA-established amount for the prior year increased by the Secretary's estimate of the growth in A/B expenditures.

Medicare Advantage

- Financing – Phase III (cont'd.)
  - In addition, the MMA introduced a new method of setting rates for MA regional plans based upon competition:
    - Plans submit a "bid" to CMS that reflects their revenue requirements to offer the standard A/B Benefit package to the average Medicare beneficiary in the county.
    - Plans that bid below the benchmark receive their bid amount PLUS 75% of the difference between the bid and the benchmark
      - This 75% "rebate" must be given to plan enrollees in the form of extra benefits or buy-down of cost sharing
    - Plans that bid above the benchmark get paid the benchmark, but must charge beneficiaries a premium to make up the difference
  - In the vast majority of cases, plans bid below the benchmark, so most regional plans provide extra benefits.
  - The result of the MMA changes, over time, was to pay MA plans more (in some counties, significantly more) than FFS per capita payments.

Medicare Advantage

- Financing – Phase IV (2012 – present)
  - The ACA payment methodology for MA plans was designed largely to address the criticism that MA plans were being overpaid.
  - The ACA introduced two important concepts into MA plan payments:
    - Payments closer to the benchmarks
    - Payment based on quality.
  - Under the new payment regime, the country is divided into four quartiles. These quartiles, and the benchmark for each quartile:
    - High(est) Original Medicare costs: 95% of AAPCC
    - Low-high Original Medicare costs: 100% of AAPCC
    - High-low Original Medicare costs: 107.5% of AAPCC
    - Low-low(est) Original Medicare costs: 115% of AAPCC
  - In addition, plans can earn a bonus payment based on high quality:
    - An MA plan can receive a bonus payment if it scores well (four or five stars) on a five-star rating system.
    - 5% bonus for 4 or 5 star plans

Medicare Advantage

- Significant/Current Legal Issues
  - Pre-emption
    - The statute pre-empts state laws "with respect to" a Medicare Advantage plan, unless it is a law related to licensure or solvency. Social Security Act § 1856(b)(3).
    - This has been a fairly active area of litigation, that usually present in the context of the use of state tort laws to regulate the conduct of an MA plan or MA plan brokers.
    - State departments of insurance may attempt to get around the pre-emption provision by regulating downstream entities (e.g., physician practices).
    - Courts generally will accept the pre-emption statutory provision as a defense, although not necessarily as a source of removal to the federal courts.
  - Provider relations
    - This is a relatively new development as plans attempt to reduce their physician networks.
    - Physicians are going to federal court to push back against plans. *See* Ariana Eunjung Cha, "Doctors cut from Medicare Advantage networks struggle with what to tell patients," Washington Post, January 26, 2014 (p. 1).
    - Plans are defending based on ACA cuts in payment.

Medicare Advantage

- Regulatory Changes Since ACA
  - CMS issued a significant MA Policy and Technical rule on January 10, 2014 (79 Fed. Reg. 1918).
  - Major changes in policy
    - Easing ability of CMS to terminate non-performing plans
    - Authority to issue sanctions and CMPs
    - Beneficiary documents
    - Implementing overpayment provisions of ACA (reverse False Claims Act)
    - RADV Appeals
- 2014 Timeline
  - Call letter: Week of February 17, 2014
  - Policy and technical rule finalized: late March, 2014
  - Annual Notice: April 7, 2014
  - Bids Due: June, 2014

Part D

- Introduction to the program
  - Prior to 2006, the Medicare program generally did not pay for outpatient drugs unless:
    - Incident to a physician service and not usually self-administered;
    - Specifically identified in the statute;
    - Necessary for the effective use of DME
  - The MMA, for the first time, provided coverage for most outpatient drugs.
  - Unlike traditional Medicare, however, beneficiaries can only receive the benefit through a private plan. There is no "Part D government plan" or government plan design.
- Enrollment
  - Available to anyone entitled to Part A or eligible to enroll in Part B.
  - Enrollment is through a private plan – beneficiaries choose a plan on their initial enrollment into Medicare or, thereafter, through an open enrollment period (Fall of each year).
  - Like Part B, there is a penalty for late enrollment in Part D.
    - Exception for creditable coverage.

Part D

- Benefits
  - Although there is no "standard" Part D benefit, there is a standard benefit design. Plans must either offer the standard benefit design or actuarially equivalent coverage.
  - Standard design
    - Premium
    - Deductible
    - 25% coinsurance between deductible and coverage gap
    - Coverage gap (phasing out)
    - Catastrophic insurance
      - 5%/95% cost-sharing
  - Very few people (8%) choose the standard benefit
    - [Source: MedPAC, Report to Congress: Medicare Payment Policy, Ch. 13, p. 347, Table 13-5 (March, 2012)])
    - Most enrollees choose actuarially equivalent coverage (no deductible; co-payment in lieu of coinsurance; generic-only coverage in coverage gap).
  - Premiums have been amazingly stable since 2006, suggesting that the cost of the program has been below budgeted expectations.

Part D

- Benefits (cont'd.)
  - The entitlement of Part D is to "coverage of covered Part D drugs"
  - A Part D drug is one that meets the following criteria:
    - Approved by the FDA
    - Can only be dispensed pursuant to a prescription
    - Coverage not otherwise available "as so prescribed and dispensed or administered with respect to that individual" under Parts A or B
      - Note issues with NCDs; carrier restrictions on Part B drugs (e.g., SAD list)
    - Dispensed for a "medically accepted indication"
      - "Medically-accepted indication" means off-label use with compendia support.
      - Note that this is CMS' interpretation of a gramatically vague sentence.
        - See *Layzer v. Leavitt*

Part D

- Coverage gap
  - From the inception of Part D, there has been a coverage gap ("donut hole") in the standard benefit design. The vast majority of actuarially equivalent plans do not cover the gap (some with generic-only coverage).
  - The ACA began to phase out the coverage gap through two mechanisms:
    - First, manufacturers that participate in Part D must provide a 50% discount off the negotiated price of their drug for Part D beneficiaries in the coverage gap.
      - Failure to provide the discount means that the drug will not be covered under Part D.
    - Second, of the remaining 50% coinsurance, CMS is buying down half of the remaining coinsurance (effectively increasing the government subsidy to Part D plans) over ten years.
      - Thus, by 2022, from the perspective of beneficiaries, the standard benefit through the coverage gap will maintain 75%/25% coverage.

Part D

- Formulary Requirements
  - If a plan utilizes a formulary, CMS must approve the formulary that the plan submits.
  - USP develops model formulary, although plans are not required to utilize the model formulary
  - A Part D formulary must include:
    - At least two drugs in every category or class of drugs (unless only one drug in the category or class)
    - And, for six "classes of clinical concern", all drugs in the category or class.
      - Anti-neoplastic
      - Immunosuppressants when used for organ rejection
      - Anti-retrovirals
      - Anti-depressants
      - Anti-psychotics
      - Anti-convulsants
    - Six-protected class rule had been administrative requirement related to approval of plan formularies
    - Codified in MIPPA with two-prong test for inclusion
    - ACA statutorily protected the six classes until CMS adopted the MIPPA test

Part D

- Regulatory changes
  - January 10, 2014 policy and technical rule makes significant changes to Part D benefit
  - Comment period closes March 6, 2014
  - Major changes proposed
    - New interpretation of "non-interference" clause to permit HHS to oversee negotiations between pharmacies and Part D plans.
    - Revisions to interpretation of protected class rule
      - Anti-depressants, anti-psychotics, immunosuppressants lose protected class status
    - Limitations on number of plans offered by plan sponsors in a region
  - CMS hopes to make the changes effective for plan year 2015
- 2014 Timeline
  - As with MA, Call Letter out in mid-February and finalized April 7.
  - Initial formulary submissions due in May

Conclusion

- 2015 will be a seminal year for Medicare Advantage and Part D
  - ACA payment rates and policies fully in effect
  - Policy and technical rule portends significant changes to both benefits
  - Policies are being developed now for the next plan year
- MA and Part D inextricably wrapped up in political debate over "ObamaCare"