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FUNDAMENTALS OF MEDICARE PART C

TABLE OF CONTENTS

page

FUNDAMENTALS OF MEDICARE PART C
Margit H. Nahra – Crowell & Moring LLP

I. OVERVIEW OF MEDICARE PART C

A. Origin

Medicare Part C was created by the Balanced Budget Act of 1997. Originally known as Medicare+Choice ("M+C"), it was designed to: (i) offer coverage beyond that provided under Medicare Parts A and B; and (ii) at a lower cost to the Medicare beneficiary. This was to be accomplished through contracts between the federal government (then the Health Care Financing Administration, or "HCFA," now the Centers for Medicare and Medicaid Services, or "CMS") and public or private organizations offering a range of health plan options, including: (i) coordinated care plans ("CCPs") (health maintenance organizations ("HMOs"), provider sponsored organizations ("PSOs"), and preferred provider organizations ("PPOs")); (ii) medical savings account plans ("MSAs"); (iii) private fee-for-service ("PFFS") plans; and (iv) religious fraternal benefit society ("RFBS") plans.

The M+C program suffered from systemic flaws that led to a lack of plan offerings in rural areas, geographic disparities in payment, and a crippling exodus of plans from the M+C program altogether. As a result, the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. 108-173) replaced the M+C program with the Medicare Advantage ("MA") program. The MA program was designed to address the problems encountered under the old M+C program and to implement the new Medicare Part D benefit. CMS issued proposed regulations to implement the MA Program on August 3, 2004 (69 Fed. Reg. 46866). Final regulations were published on January 28, 2005 (70 Fed. Reg. 4588) and were effective as of March 22, 2005.

Thus far, the MA program has been successful in luring plans back to the Medicare managed care market. In December of 2003, when the MMA was enacted, there were only 151 Medicare+Choice plans, down from a high of 346 in 1998. Since 2003, however, the number of Medicare managed care plans (now called Medicare Advantage plans) has more than doubled, to 314 in 2006. These plans cover approximately 5.5 million enrollees (approximately 12% of the Medicare population), and are primarily HMOs, although some other plan types, like PFFS plans, are growing in popularity.

B. Key Concepts Introduced Under the Medicare Advantage Program

The establishment of Medicare Advantage brought a number of changes to Part C as it had existed under the M+C Program. Key concepts introduced by Medicare Advantage include:

- New plan options;
- Local vs. regional PPOs;
- Prescription drug coverage;
- Enrollment lock-in;
- Competitive bidding/benchmark pricing;
- Chronic care initiatives; and
- Expanded state law preemption.

II. TYPES OF MA PLANS (42 C.F.R. § 422.4)

An organization that contracts with CMS under the Medicare Advantage program is a Medicare Advantage Organization ("MA Organization"). A product offered by an MA Organization pursuant to its CMS MA contract(s) is a Medicare Advantage Plan ("MA Plan").

The basic categories of plans that may be offered under Medicare Advantage are the same as those available under the M+C program, i.e., (i) CCPs; (ii) PFFS plans; (iii) MSA plans; and (iv) RFBS plans. However, Medicare Advantage introduced two new types of CCPs: (i) regional PPOs; and (ii) special needs plans ("SNPs").

A. Coordinated Care Plans ("CCPs")

A CCP is a plan that offers a network of providers that meets CMS requirements for access, availability, service area and quality, and consists of providers who have contracted with the MA Organization to deliver the benefit package approved by CMS. Generally, CCP plan enrollees must use the network providers for the provision of covered services or incur higher out of pocket costs for receiving services from providers outside the network.

There are five types of CCPs: (i) HMOs; (ii) PPOs; (iii) PSOs; (iv) SNPs; and (v) RFBS plans.

1. **HMOs:** HMOs typically control utilization by requiring referrals for certain services and by restricting the network of providers from whom beneficiaries may receive

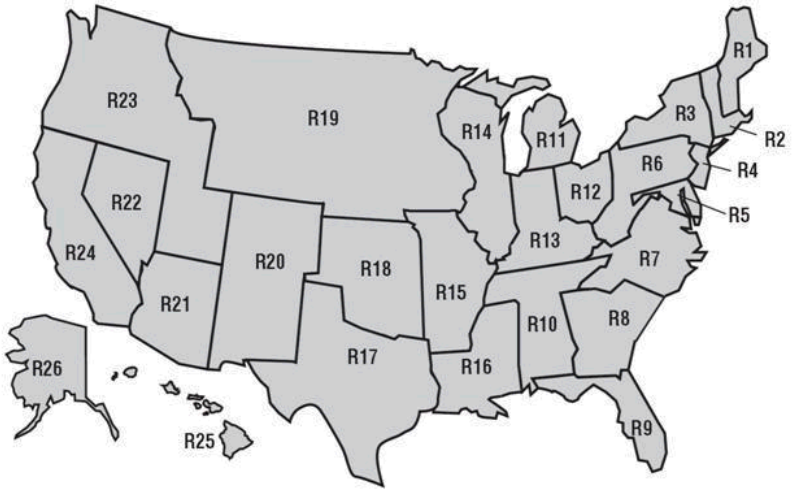
services. HMOs may offer a point-of-services ("POS") benefit permitting beneficiaries to obtain services without complying with normal referral or prior authorization requirements, but beneficiaries generally pay higher cost sharing amounts for such services and the POS coverage may be limited to particular services and/or subject to a financial limit. As of March 2005, HMOs accounted for 80% of CCP contracts and 98% of CCP enrollment.

2. **PPOs:** PPOs offer a network of providers who have contractually agreed to accept specified reimbursement for covered services and provide reimbursement for all covered services regardless of whether the services are obtained from a network provider. There are two types of PPOs that may be offered as MA Plans: (i) local PPOs; and (ii) regional PPOs.

   a. **Local PPOs:** Local PPOs have service areas that are less than a region and may consist of a county, part of a county, or multiple counties. This is the traditional model of PPO under Part C. However, for 2006-2007, CMS has imposed a moratorium on new local PPO products and on the expansion of existing local PPO service areas in order to encourage MA Organizations to sponsor regional MA PPOs.

   b. **Regional PPOs:** Regional PPOs were introduced into Part C by the MMA to expand managed care options to beneficiaries in rural and underserved areas by requiring broader service areas than local PPOs. A regional PPO must have a service area that covers the entire region, and must offer a uniform benefit package across the region. CMS has established 26 regions for Part C (11 single state and 15 multi-state). Most MA regions are single states (11) or two-state regions (11) but four regions have three states or more and one of these has seven states. (Figure 1)

Figure 1: Medicare Advantage Regions



Note: R = Region Number.

SOURCE: Centers for Medicare and Medicaid Services, December 2004.

c. **Regional PPO Incentives:** The MMA includes a number of incentives designed to encourage MA Organizations to offer regional PPOs, including:

- A two-year moratorium on the offer of new local PPOs and on the expansion of existing local PPOs' into service areas;
- Plan authority to waive deductibles for preventive care and other items and services;
- Uniform deductibles for Parts A and B services;
- For 2006-2007, government risk sharing for Parts A and B benefits;
- Relaxation of state licensure requirements to permit MA Organizations offering MA Plans in multi-state regions that are licensed as risk-bearing entities in at least one state within the region to obtain a temporary waiver of state licensure for the other states within the region so long as they have at least filed an application for licensure in

those other states; and

- A stabilization fund to ensure that plans that enter the market early are not disadvantaged as a result (*see* VII.E below).

3. **PSOs:** PSOs are offered by a provider or affiliated group of providers and provide a substantial proportion of their covered services through the provider or affiliated group of providers.

4. **SNPs:** SNPs either exclusively or disproportionately enroll special needs individuals, i.e., persons who are either:

   - Dually eligible for both Medicare and Medicaid (dual eligibles); or

   - Institutionalized;

   - Suffer from a severe or disabling chronic condition.

   According to CMS, in 2006 there were 276 SNPs authorized to operate. The bulk of these – 226 – were dual eligible plans. Thirty-seven were institutionalized plans, and 13 were chronic care plans. CMS will review proposals for SNPs addressing particular conditions on a case by case basis.

5. **RFBS Plans:** *See* II.D below.

B. Medical Savings Account Plans

Medicare Advantage MSAs combine a high deductible insurance policy with a medical savings account. CMS pays the MSA premium and also makes a deposit to the beneficiary's MSA account. Beneficiaries may use the funds in the MSA to pay for covered services until the annual deductible is reached, after which the plan will pay for 100% of the cost of such services.

C. Private Fee-For-Service Plans

PFFS plans pay providers on a fee-for-service basis according to the plan's rate schedule. Enrollees are not limited to a provider network, though if the plan offers a network and an enrollee obtains services outside of the network, the enrollee's cost sharing may be higher. PFFS plans are not subject to certain Medicare Advantage beneficiary protection or quality assurance requirements, and are not required to offer Part D coverage.

D. Religious Fraternal Benefit Society Plans

RFBS plans are MA Plans offered by a tax-exempt RFB society affiliated with or carrying out the tenets of a church. RFBS plans limit their enrollment exclusively to the members of their sponsoring RFB society, but without regard to health status-related factors. RFBS plans may be structured as any type of MA Plan.

III. ELIGIBILITY & ENROLLMENT (42 C.F.R. § 422B)

A. Eligibility (42 C.F.R. § 422.52)

To be eligible to enroll in an MA Plan, a beneficiary must be eligible for Part A, enrolled in Part B, and not have been medically determined to have end-stage renal disease ("ESRD"), unless the beneficiary seeks to enroll in a SNP that has opted to enroll ESRD individuals. Beneficiaries must also reside within the plan's service area or, if the beneficiary has been enrolled in an MA local plan but moves out of the plan's service area, within a continuation area in which the plan has made arrangements to continue services to enrollees who move out of the plan's service area.

B. Enrollment in Non-MSA MA Plans (42 C.F.R. § 422.62)

Eligible beneficiaries may enroll or disenroll in non-MSA MA Plans during the following four periods:

- The initial coverage election period;
- The annual election period;
- The open enrollment period; and
- A special election period.

This is a change from the M+C enrollment/disenrollment rules, which permitted beneficiaries to enroll in plans any time the plans were open and to disenroll at any time for any reason.

1. **Initial coverage election period:** The initial coverage election period is the first period that a beneficiary may elect Part C coverage, i.e., the period beginning three months before the beneficiary is eligible for both Part A and Part B benefits and continuing until the later of: (i) the last day of the month preceding entitlement to both Part A and Part B; or (ii) after May 15, 2006, the last day of the beneficiary's initial Part B enrollment period.

2. **Annual election period:** Eligible beneficiaries may enroll in or disenroll from an MA Plan each year during the annual election period. The annual election period for 2006 was Nov. 15 to May 15; thereafter, the annual election period will be Nov. 15 to Dec. 31.

3. **Open enrollment period:** The open enrollment period is a period each year during which an eligible individual may make *one* election to: (i) enroll in an MA Plan; or (ii) if already enrolled in an MA Plan, to change his or her enrollment to a different MA Plan or to original Medicare. In making such elections, the beneficiary may not change the nature of his/her prescription drug coverage. Thus, if the beneficiary was enrolled in original Medicare and a PDP, the beneficiary may only change to an MA-PD Plan. Similarly, if the beneficiary was enrolled in original Medicare and was not enrolled in a PDP, the beneficiary may not enroll in an MA-PD Plan or a PDP. MA Plans may elect not to open the plan to new enrollment during the open enrollment period, but must accept disenrollments during this period. The open enrollment period for 2006 was Jan. 1 to June 30; thereafter, the open enrollment period shall be Jan. 1 to March 31.

4. **Special election period:** A special election period is a period outside of the normal enrollment or election periods during which a beneficiary who is enrolled in an MA Plan may disenroll from the plan and enroll in a different MA Plan or in original Medicare due to special circumstances. The circumstances triggering a special election period include:

    a. The individual has moved out of the original plan's service or continuation area or is otherwise no longer eligible for coverage under the original plan;

    b. CMS has terminated or issued notice that it is going to terminate the MA Plan in which the individual is currently enrolled;

    c. The individual demonstrates that the original plan materially violated its CMS contract with respect to the individual or materially misrepresented the plan in marketing the plan; or

d. The individual meets other exceptional requirements provided by CMS.

C. MA MSA Plan Enrollment (42 C.F.R. § 422.62(d))

Individuals may enroll in MA MSA Plans only during the initial or annual election periods, and may only disenroll from MA MSA Plans during the annual election period or a special election period

IV. MA COVERED BENEFITS (42 C.F.R. § 422D)

A. Basic Benefits (42 C.F.R. §§ 422.2, 422.100-101)

At a minimum, MA Plans must offer a "basic benefits" package, which is defined to include all Medicare-covered benefits (other than hospice care) that are available to individuals residing in the plan's service area.

B. Supplemental Benefits (42 C.F.R. § 422.102)

Supplemental benefits are health care services that are in addition to the basic benefit package and not covered by Medicare.

1. Mandatory supplemental benefits are benefits which an MA Organization may require enrollee to purchase as part of an MA Plan. They may include additional health care services or a reduction in cost sharing for benefits under the Medicare fee-for-service program, and must be imposed on all enrollees in the MA Plan. They are subject to CMS approval and are paid for through premiums, cost sharing, and/or application of the beneficiary rebate rule (*see* VII.B.2 below).

2. Optional supplemental benefits are benefits which may be purchased at the option of the enrollee. They must be offered to all enrollees in the MA Plan without regard to health status and are paid for through premiums or cost sharing.

C. Prescription Drug Benefits (42 C.F.R. § 422.4(c))

1. CCPs *must* offer at least one MA plan throughout the plan's service area offering Part D benefits, either through an MA plan offering Part D benefits (an "MA-PD" plan), or through a stand-alone Part D prescription drug plan (a "PDP"). Note, however, that if a beneficiary enrolls in a CCP that does not offer Part D benefits, the

enrollee *may not* enroll in a PDP.

2. SNPs *must* offer Part D coverage in addition to the basic benefit package.

3. MSAs are *prohibited* from offering prescription drug coverage other than that required under Parts A and B.

4. PFFS plans *may* offer Part D coverage at the plan's option.

5. RFBs *must* offer Part D coverage, depending on what type of plan they are structured as.

D. Negotiated Benefits for Employer-Sponsored MA Plans (42 C.F.R. § 422.106)

MA Organizations may also contract with employers who sponsor MA Plans to offer benefits not offered to the general Medicare population, such as payment of some or all of the MA basic and supplemental premiums or cost sharing amounts.

E. Application of Local Medical Review Policies (42 C.F.R. §§ 422.101(b)(4)-(5))

If an MA Plan's service area covers a geographic area encompassing more than one local coverage policy area, the MA Plan may elect to apply the Local Medical Review Policy ("LMRP") that is most beneficial to enrollees uniformly across the plan's entire service area, provided that in doing so, a regional PPO MA Plan must apply the LMRPs of a single local coverage policy area.

V. Quality Improvement Programs (42 C.F.R. § 422 Subpart D)

All CCPs other than PFFS plans must provide an on-going quality improvement program that encompasses a chronic care improvement program and quality improvement projects, each of which must meet statutory and regulatory requirements, and which encourages provider participation in the program. The quality improvement programs of CCPs other than regional PPO plans must also include written policies and procedures reflecting current standards of medical practice, mechanisms for detecting over- and underutilization of services, performance measurement and reporting to CMS, and the provision of quality and outcome data to CMS to permit beneficiaries to make meaningful comparisons among plans.

A. Chronic care improvement programs (42 C.F.R. § 422.152)

All CCPs other than PFFS plans must develop an on-going chronic care improvement program to improve the care of beneficiaries with chronic conditions such as congestive heart failure, complex diabetes and chronic obstructive pulmonary disease. Such programs must include (i) methods for identifying MA enrollees with multiple or severe conditions who would benefit from participation in such a program; and (ii) mechanisms for monitoring enrollees participating in such a program.

B. Quality improvement projects (42 C.F.R. § 422.152)

CCPs other than PFFS plans must also conduct quality improvement projects that measure performance, include system interventions such as the development of clinical practice guidelines, improve performance and follow-up on system interventions.

VI. GRIEVANCES & APPEALS (42 C.F.R. § 422M)

Consistent with the general presumption of federal preemption of state regulation under the MMA (*see* IX.A below), the MA implementing regulations set forth a uniform federal grievance process, including the notice and appeals procedures promulgated by CMS after settlement of *Grijalva v. Shalala*, 119 S.Ct. 1573 (1999), at 42 C.F.R. §§ 422.460 *et seq*. Enrollee rights under these procedures include the right to:

- File general complaints, or grievances, with the applicable MA Organization;
- File complaints regarding quality of care issues with the applicable MA Organization, the applicable Quality Improvement Organization, or both;
- Appeal an adverse coverage or payment determination to the applicable MA Organization.

Note that there are distinct processes for each of these. Enrollees may also seek expedited consideration of certain grievances or appeals, and may request reconsideration of adverse appeal determinations, including reconsideration by an independent, outside entity of adverse determinations that are affirmed by the applicable MA Organization and a hearing before an administrative law judge (ALJ) where the amount in controversy exceeds a specified threshold.

VII. MA PAYMENT METHODOLOGY (42 C.F.R. §§ 422F-G)

The MA Program introduced the concept of competitive bidding as a means of encouraging plans to keep their costs down in order to reduce beneficiary financial liability and offer additional benefits.

A. Bid Submission by MA Organizations (42 C.F.R. §§ 422.254-.256)

MA Organizations must annually submit to CMS a monthly aggregate bid amount for each MA Plan to be offered by the organization in the following year. Such bids must be actuarially sound and reflect the plan's estimate of the cost of: (i) original Medicare (i.e., Parts A and B) coverage; (ii) basic Part D coverage (if any); and (iii) supplemental benefits coverage (if any), as well as administrative and other costs. CMS will evaluate the reasonableness of each element of a bid, and may negotiate with the MA Organization regarding the proportions of the bid attributable to each category of coverage and the reasonableness of the assumptions reflected in the bid.

B. Monthly Payments to MA Plans (42 C.F.R. § 422.258)

CMS will administratively set geographically-based benchmarks representing the maximum amount that CMS will pay, against which bids will be compared in order to determine the amount of CMS' monthly payment to the MA Organization and the amount of beneficiary cost sharing and premiums, if any. Plans will submit bids for providing required Parts A and B benefits. The benchmark will be calculated by updating the previous year's capitation rate by the annual increase in the minimum percentage increase.

1. If a bid is equal to the benchmark amount, CMS will pay the MA Organization the benchmark amount.

2. If a bid is less than the benchmark amount, CMS will pay the bid amount plus 75% of the difference between the bid and the benchmark in the form of a beneficiary rebate. The remaining 25% of the average per capita savings will be retained by the federal government. Plans must use such rebates to provide additional mandatory supplemental benefits to enrollees and/or to reduce beneficiary cost sharing or premium payments.

3. If a bid is more than the benchmark amount, CMS will pay the benchmark amount and the plan must charge beneficiaries a premium equal to the difference between the benchmark and bid amounts.

C. Premiums (42 C.F.R. § 422.262)

MA Plans are permitted to impose separate premiums for supplemental benefits and for Part D coverage. In the case of a plan that is required to charge a premium because its bid was higher than the benchmark, the basic benefits premium, Part D premium and supplemental benefit premium will be consolidated into a single premium.

D. Payment Adjustments Based on Risk and Other Factors (42 C.F.R. §§ 422.308-.310)

CMS will adjust plan payments for a variety of beneficiary risk factors, including age, gender, disability status, institutional status, health status and other factors the agency deems appropriate to ensure the actuarial equivalence of bids. Adjustments may also be made to account for factors such as services subject to a national coverage determination, legislative changes in benefits, intra-service area variations, and the number of actual enrollees in the plan (if different from the projected number used by CMS in determining the amount of a monthly plan payment). The risk adjustment factors are based on risk data submitted by the plans for services during the previous twelve-month period.

Note that the MMA provides for further adjustment to risk-adjusted payments to ensure that the risk adjustments are budget neutral and do not result in overall plan payments being reduced. However, under the Deficit Reduction Act of 2006, Pub. L. No. 109-171 (2006), the budget neutrality adjustments will be phased-out over the next five years.

E. Regional Stabilization Fund (42 C.F.R. § 422.458(f))

The MMA provided for the establishment of a regional stabilization fund to provide additional payments to regional plans that service previously unserved areas or that continue to service certain regions. The statute set aside $10 billion dollars to be used between 2007 and 2013 to increase plan payments and encourage plan reentry and retention in such areas, and additional amounts will be added to the fund from a portion of any average per capita monthly savings amounts. (Beneficiaries receive 75% of average per capita savings in the form of a rebate. The federal government retains the remaining 25% of the average per capita savings and one-half of the amount retained by the federal government is available to the stabilization fund.)

Note that the future of the fund had been in question during conference negotiations over the Deficit Reduction Act. Stronger than anticipated plan participation gave rise to arguments that the fund was not needed, and indeed, the Senate version of the bill contained a provision eliminating the

fund. However, the statute as enacted retained the fund.

F. Essential Hospital Payments (42 C.F.R. § 112(c))

If an MA regional PPO has tried to contract with a hospital deemed essential to the PPO's ability to meet MA network access requirements and the parties are unable to agree on reimbursement terms, the PPO may apply to CMS to have the hospital designated as an "essential hospital" eligible for additional payments from CMS. Such designation is conditioned upon, among other things, the PPO demonstrating that it made a good faith effort to contract with the hospital and that there are no competing Medicare participating hospitals to which beneficiaries could be transferred for inpatient care. In addition, the hospital must demonstrate that its actual cost of providing services to the PPO's enrollees would be greater than the rates the PPO has agreed to pay. If CMS determines that the parties have established all necessary conditions for an essential hospital designation, the hospital will be deemed to be part of the PPO's network and CMS will pay the hospital the hospital's reasonable costs for providing inpatient hospital services, reduced by the amount that the services would cost under the inpatient prospective payment system ("PPS"). The MMA provided for $25 million per year to be made available for such payments, which are to be made based on the order in which claims are received.

VIII. STATE LAW ISSUES (42 C.F.R. § 422I)

A. Preemption (42 C.F.R. § 422.402)

In enacting the MMA, Congress wanted to move away from deference to state regulation and towards a presumption of preemption. Thus, the MMA expanded the preemption of state laws with respect to MA Plans, such that only state laws governing licensure and solvency apply to MA Plans; all other state laws applicable to health plans are preempted. CMS has cautioned against states attempting to end-run the preemption by characterizing all health plan requirements as licensure requirements, and has informally advised that they will apply the general principle that requirements designed to regulate plan conduct once the plan is doing business will be deemed to be preempted.

B. Premium Taxes (42 C.F.R. § 422.404)

The MMA also prohibits the imposition of premium or other taxes on payments made by CMS on behalf of MA enrollees or on payments made by a beneficiary, or a third party on a beneficiary's behalf, to an MA Plan.

IX. ADDITIONAL KEY ISSUES FOR MA ORGANIZATIONS

A. Increased Record Retention Requirements (42 C.F.R. § 422.504(e)(4))

The MA implementing regulations extended the previous six-year record retention requirement applicable to M+C organizations in order to conform to the statute of limitations for discovery of False Claims Act violations. Accordingly, MA Organizations must retain records for 10 years from the end of the final contract period or the completion of a government audit, whichever is later.

B. Legal Compliance (42 C.F.R. § 422.504(h)(1))

MA Organizations must contractually agree to comply with applicable laws and regulations, including, but not limited to, federal fraud and abuse laws and the HIPAA administrative simplification rules.

C. Compliance Initiatives (42 C.F.R. § 422.503)

1. **Mandatory fraud and abuse compliance requirements:** The MMA imposed stringent requirements on Part D plans with respect to the detection and prevention of fraud, waste and abuse. *See* 42 C.F.R. § 423.504. These requirements also apply to MA-PD Plans pursuant to 42 C.F.R. § 422.503(b)(4)(vi)(H).

2. **Required investigation of suspected violations:** The MA implementing regulations as originally proposed required that MA Plans disclose to CMS any suspected violations of law, regulation or other wrongdoing. 69 Fed. Reg. 46908 (2004). The final MA regulations dropped the mandatory self-reporting requirement, but do require that if an MA Plan discovers evidence of misconduct related to payment or the delivery of services, the plan must conduct a timely, reasonable inquiry into that conduct and take appropriate corrective measures in response. (42 C.F.R. § 422.503(b)(4)(vi)(G))

X. Sources of Law and Agency Guidance

1. Social Security Act, 42 U.S.C. §§ 1395w-21 – 28

2. Implementing regulations, 42 C.F.R. Parts 417 and 422

3. Additional guidance is available through the CMS web site, particularly the Medicare Managed Care Manual at http://www.cms.hhs.gov/HealthPlansGenInfo.

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FUNDAMENTALS OF MEDICARE PART D
TABLE OF CONTENTS

page

FUNDAMENTALS OF MEDICARE PART D

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I. OVERVIEW OF MEDICARE PART D

Medicare Part D was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173). It was designed to improve access to and the affordability of prescription drugs for Medicare eligible beneficiaries. Under the MMA, Part D also replaces Medicaid as the primary source of drug coverage for low-income and disabled people covered under both Medicare and Medicaid ("dual eligibles").

The program relies on private plans to provide coverage and to bear some of the financial risk for drug costs. Federal subsidies covering the bulk of the risk for certain populations are provided to encourage plan participation.

The Medicare Part D drug benefit took effect on January 1, 2006. In the program's initial year, some 22.5 million beneficiaries enrolled in the 2,743 Part D plans offered nationwide, including 10.4 million beneficiaries enrolled in stand-alone Part D prescription drug plans ("PDPs"), 5.5 million beneficiaries enrolled in Medicare Advantage prescription drug plans ("MA-PDs"), and 6.6 million dual eligibles assigned to a variety of available plan models.

II. PART D PLANS

A. Plan Models (42 C.F.R. § 423.4)

There are two basic types of Part D plans:

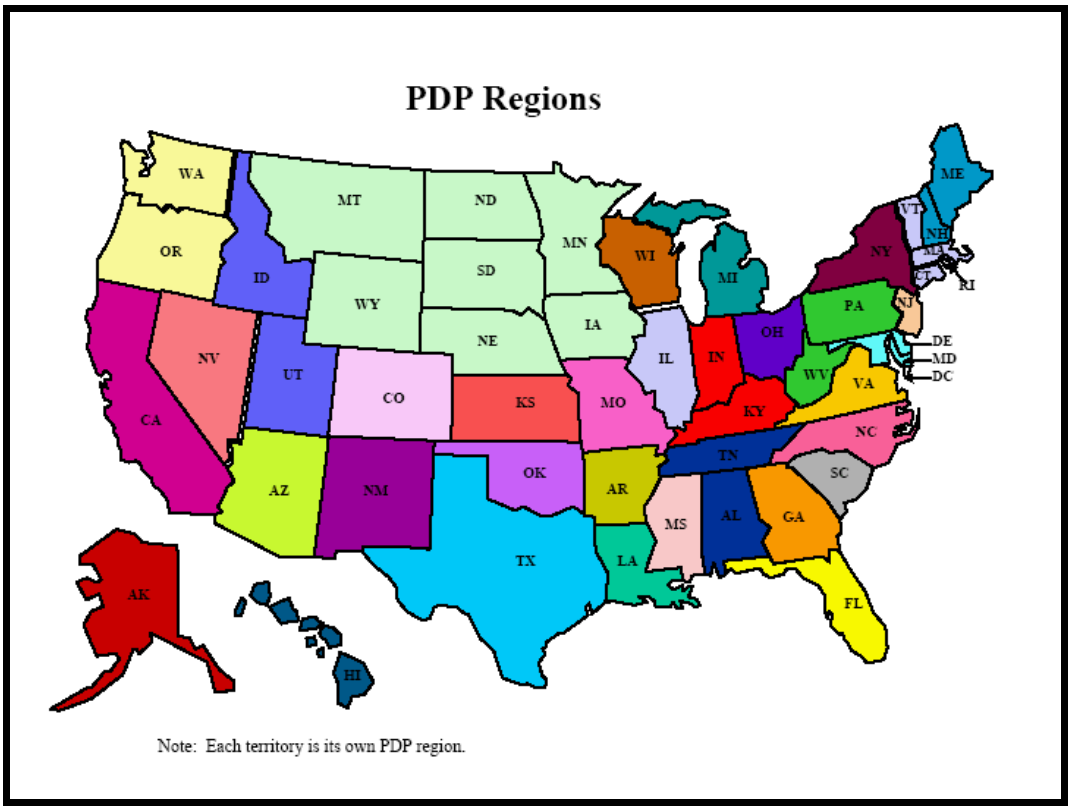
- Stand-alone prescription drug plans ("PDPs"); and
- Medicare Advantage Prescription Drug Plans ("MA-PDs").

PACE and Medicare cost plans may also offer Part D benefits.

B. PDP Regions (42 C.F.R. § 423.112)

The service area for a prescription drug plan shall consist of one or more PDP regions, as defined by CMS. To the extent practicable, the PDP regions were established to be the same as the MA regions. However, smaller PDP regions were defined as deemed necessary by CMS to improve access to Part D benefits. Thus, there are 34 PDP regions, as compared to 26 MA regions. Prescription drug plan service areas must cover an entire PDP region, but regional or national plans may offer coverage in multiple or all PDP regions.

Beneficiaries must enroll in a PDP plan that serves the geographic region in which he or she resides.



C. Qualified Plan Sponsors (42 C.F.R. § 423.500)

1. Qualification requirements

With some exceptions, CMS must enter into plan sponsorship contracts with all qualified entities that meet applicable standards for actuarial value and plan design. Part D plan sponsors must be licensed as risk-bearing entities in each state in which they offer Part D coverage. Entities that are not so licensed can receive a waiver from CMS under procedures similar to those for provider-sponsored organizations under MA. Certain grounds for approval are deemed to be met in the case of states that do not have a licensing process for PDP sponsors. CMS has also established solvency and capital adequacy standards; un-licensed PDP sponsors must be certified for compliance with these standards. CMS may periodically review and revise regulatory requirements but may not implement significant changes other than at the beginning of a calendar year.

2. Plan design

Plan sponsors must have in place, directly or through arrangements: (i) a cost-effective drug utilization management program (with incentives to

reduce costs, such as through use of generics); (ii) quality assurance systems to reduce medical errors and adverse drug interactions; and (iii) a program to control fraud, abuse, and waste. Plans also must have a medication therapy management program, which may be furnished by a pharmacist, and must be designed to assure covered drugs are appropriate used by enrollees with chronic diseases taking multiple drugs, and are likely to incur annual drug costs that exceed a level specified by CMS. The program must developed in cooperation with pharmacists and physicians and may distinguish between services in ambulatory and institutional settings.

3. Any Willing Pharmacy (42 C.F.R. §§ 423.120(a)(8), 423.505(b)(18))

Part D plan sponsors must allow any pharmacy that agrees to the plan's standard terms and conditions to participate in the plan's network. Furthermore, plan sponsors must have a standard contract with "reasonable and relevant terms and conditions of participation" that any pharmacy can access.

D. Fallback plans (42 C.F.R. § 423, Subpart Q)

The MMA requires that each Part D eligible individual have at least two qualifying Part D plans to choose from in the PDP region in which they reside. At least one of the qualifying plans must be a PDP. If CMS determines that eligible individuals do not have the choice of at least two plans within their region, the agency is authorized to designate the underserved area as a "fallback" area and to permit entities that are not licensed as risk-bearing entities to sponsor plans in that area. To date, CMS has not designated any PDP regions as fallback areas.

E. Limited Risk Plans (42 C.F.R. § 423.272(c))

A limited risk plan is a prescription drug plan that provides standard Part D coverage but assumes only a modified risk level. CMS may only approve limited risk plans if necessary to meet minimum plan access requirements.

III. ELIGIBILITY AND ENROLLMENT

A. Eligibility

In general, any individual who is entitled to Medicare Part A and/or enrolled in Part B as of the effective date of coverage of the Part D plan and permanently resides in the service area of a PDP is eligible for Part D.

B. Enrollment Periods

There are three periods during which an individual may enroll or disenroll from a PDP:

- **Initial enrollment period ("IEP"):** The seven-month period consisting of the three months before, the month of, and the three months after the individual becomes eligible for Medicare Part B.

- **Annual coordinated election period ("AEP"):** Nov. 15- Dec. 31. Beneficiaries are allowed to change plans annually, so long as they maintain continuous drug coverage.

- **Special enrollment periods ("SEPs"):** Provided for involuntary loss of eligibility due to a move, loss of dual-eligible status, substantial and material contract violations by plan sponsor, plan termination or non-renewal, involuntary loss of creditable coverage, governmental error, or exceptional conditions.

These periods are coordinated with the corresponding MA periods so as to accommodate enrollment in MA-PDs. Plans may not refuse enrollment to any beneficiary except for capacity limitations.

C. Enrollment of Dual Eligibles

Full-benefit dual eligibles who do not select a plan during the open-election period are enrolled by default in a plan with a premium at or below the low-income benchmark set by CMS. If more than one plan is available in the relevant service area, enrollment occurs on a random basis. Individuals may decline or change default enrollments.

IV. PART D BENEFIT

Part D plans must offer either a statutorily-defined standard benefit ("defined standard coverage"), alternative coverage that is actuarially equivalent in value ("alternative coverage"), or alternative coverage that offers benefits beyond the defined standard coverage ("enhanced alternative coverage"). Plans must provide enrollees access to negotiated prices regardless of whether benefits are payable due to the deductible or coverage limit. Beneficiaries pay a monthly premium, which varies by plan, and a yearly deductible, which is capped at $250 for 2006. Part D coverage is also subject to beneficiary cost-sharing, such as co-payments and coinsurance.

A. The Standard Benefit

The foundation of Part D is the standard benefit. Since beneficiary premiums and government subsidies for Part D plans are determined based on a bidding process, the law establishes a standard benefit that serves as a minimum benefit and allows for comparisons across plans offered by various sponsors. Coverage is subject to an initial cap of $2,250 per year, after which the beneficiary is responsible for 100% of the negotiated cost of covered drugs until an annual out-of-pocket limit is reached (the "donut hole"), thereby triggering catastrophic coverage of 95% of applicable costs.

1. Annual deductible

The standard drug package has an annual deductible of $250 for 2006. For subsequent years, the deductible amount will be indexed to the annual growth in average per capita spending by Medicare beneficiaries for Part D drugs and rounded to the nearest $5; amounts for 2007 will increase by 7% over 2006 levels. Plans providing basic coverage may apply a lower, but not higher, deductible within the overall actuarial equivalent requirements.

2. Beneficiary coinsurance/copayments

The standard drug package has beneficiary coinsurance of 25% for spending above the deductible and up to the initial coverage limit ($250 to $2,250 in 2006). Plans providing basic coverage may require different coinsurance or copayments that are actuarially consistent with an average cost-sharing of 25%. Once the annual out-of-pocket limit is reached ($3,600 in 2006), enrollees pay the greater of $2 for generics/$5 for brand drugs, or 5% for coinsurance.

3. Annual out-of-pocket limit

The annual limit on beneficiary out-of-pocket expenditures is $3,600 in 2006. Deductible, cost-sharing, and costs above the annual coverage limit count towards the out-of-pocket limit unless they are paid by a third party (except a state pharmaceutical assistance program, another individual such as a family member, or as a low-income subsidy for drug benefits provided under the MMA). Costs for non-formulary drugs (or drugs not treated a formulary drugs) do not count toward the annual out-of-pocket limit.

4. Catastrophic coverage

Once the annual out-of-pocket limit is reached, Part D catastrophic coverage applies. This coverage pays for 95% of the cost of covered drugs; the enrollee is responsible for only a 5% coinsurance amount.

B. Alternative Benefit Designs

Part D plans have the option of offering alternative coverage with actuarial value equal to defined standard coverage, subject to certain requirements. For example, alternative coverage may include a tiered co-payment structure in lieu of the 25% coinsurance for drug costs between the $250 deductible and the $2,250 initial coverage limit.

C. Enhanced Alternative Coverage

Enhanced alternative coverage is alternative coverage with an actuarial value greater than defined standard coverage. For example, enhanced alternative coverage may offer of one or more of the following:

- Coverage of certain drugs that are excluded from the definition of Part D drugs;
- Reduction or elimination of deductibles or copays applicable under defined standard coverage; or
- Coverage of drugs in all or part of the donut hole.

D. Incurred Costs and TrOOP Limit (42 CFR § 423.100)

Only specific beneficiary costs for Part D drugs are considered "incurred" for purposes of the annual "true-out-of-pocket" ("TrOOP") limit.

1. Out-of-pocket ("incurred") drugs costs are defined in the Part D implementing regulations as payments for deductible, cost-sharing amounts, or costs not paid because of the initial coverage limit, and that are paid by: (i) the enrollee; (ii) another person on behalf of the enrollee; (iii) a state pharmaceutical assistance program; or (iv) the low-income cost-sharing subsidy provisions of the MMA.

2. Out-of-pocket costs do not include costs for which the enrollee, or the person paying on behalf of the enrollee, is reimbursed through a group health plan, through a third party payment arrangement, or through certain other plans.

3. The Part D implementing regulations further expand the term "incurred costs" to include:

- Any differential the enrollee must pay between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for obtaining an extended supply of a covered Part D drug from a retail pharmacy; and

- Any differential the enrollee must pay between an out-of-network pharmacy's usual and customary price for a drug purchased in accordance with the out-of-network pharmacy's usual and customary price for a drug purchased in accordance with the out-of-network access rules and the plan allowance for the drug.

4. A variety of entities, including charities and manufacturer patient assistance programs (but not group health plans or other third party payment arrangements) are permitted to cover deductible, cost-sharing amounts, or other prescription drug costs and have the amount of the payments count toward TrOOP. However, any arrangement in which a charitable organization pays a Medicare beneficiary's Part D cost-sharing obligations must comply with all applicable fraud and abuse laws, including the anti-kickback statute, as well as the civil monetary penalty provision prohibiting inducements to beneficiaries. 70 Fed. Reg. 4239. The HHS OIG has issued several advisory opinions regarding such programs.

V. DRUG COVERAGE UNDER PART D (42 C.F.R. § 423.100)

A. Covered Drugs

Items covered under Part D include prescription drugs, biological products and insulin (including medical supplies associated with injection) that are covered under Medicaid, and vaccines licensed under Section 351 of the Public Health Service Act. This includes coverage for any use of a covered outpatient drug for a medically-accepted indication, as defined under Medicaid.

B. Drugs Excluded from Coverage

Excluded from coverage under Part D are drugs for which payment is available under Medicare Part A or B, and drugs in categories that may be excluded under Medicaid (i.e., weight loss or gain, fertility, cosmetic or hair growth, cough or cold relief, vitamins and minerals, non-prescription drugs, barbiturates, and benzodiazepines), except for smoking cessation agents.

Drugs not meeting the Medicare definition of reasonable and necessary, or not prescribed according to plan or Part D requirements, can be excluded from coverage by plans, but such determinations are subject to appeal.

C. Relationship Between Part B and Part D Coverage

Medicare Part B covers drugs that are:

- Not usually self-administered;
- Furnished as part of a physician service; and
- Other selected drugs, such as those requiring administration using a piece of covered durable medical equipment ("DME").

By contrast, Medicare Part D covers drugs that are:

- Approved by the FDA;
- Used for a medically-accepted indication; and
- Which are not covered under Part B (or Part A).

Despite CMS' attempts to distinguish the two sources of coverage, there are a number of grey areas, especially with respect to Part B drugs that may be self-administered using DME. Enrollees seeking to fill prescriptions for such drugs often experience considerable delays as their pharmacists and plans attempt to sort out coverage. To address this problem, CMS has issued guidance indicating that plans may rely on physician information included with the prescription (such as diagnosis or location of administration) to the same extent that the plans rely on similar information obtained from the physician through prior authorization forms.

VI. FORMULARIES

CMS established minimum requirements for Part D formularies -- the list of drugs covered by an individual plan — to help ensure that Part D plans do not offer formularies that discriminate against certain types of beneficiaries.

A. Formulary Rules (42 C.F.R. § 423.120(b))

Plans may have a formulary—including tiered cost sharing—so long as the formulary meets the following standards:

- Formularies must be developed by a pharmacy and therapeutic (P&T) committee; a majority of the P&T committee must be practicing physicians or pharmacists;

and the committee must have at least one practicing physician and one practicing pharmacist independent and free of conflict with respect to the sponsor and plan, both with expertise in the case of elderly or disabled.

- The formulary must include drugs within each therapeutic category and class; decisions must be based on the strength of scientific evidence and standards of practice; and must take into account whether the formulary drug has therapeutic advantage in terms of safety and efficacy. A PDP sponsor may not change categories and classes other than at the beginning of each plan year, except as CMS permits to account for new therapeutic use and newly covered Part D drugs.

- The P&T committee must have procedures to educate providers and enrollees concerning the formulary and appropriate notice must be given to enrollees and physicians before a drug is removed from the formulary or the tier status of a drug is changed.

- The United States Pharmacopeia, in consultation with PBMs and others, developed a model list of categories and classes to be used by plans and revises the list periodically. Plans using the model list cannot be found by CMS to have a design of categories and classes intended to discourage enrollment by certain beneficiaries.

- Formulary requirements may be met by a PDP sponsor directly or through arrangements with another entity.

B. Access to Non-Preferred or Non-Formulary Drugs

Enrollees may request an "exception" to a plan's tiered cost sharing structure or formulary restrictions. Such exceptions requests must be supported by a physician's statement establishing that: (i) in the case of a request for a tiering exception, the non-preferred drug or applicable dosing restrictions are ineffective for treating the enrollee's condition or could adversely affect the drug's effectiveness or patient compliance; or (ii) in the case of a request for a non-formulary drug exception, that the requested drug is medically necessary and the formulary alternatives would be ineffective for the enrollee's condition, could adversely effect the enrollee, or both.

VII. GRIEVANCES AND APPEALS (42 C.F.R. § 423, Subpart M)

A. Grievances and Appeals Generally

CMS has established a process for Part D beneficiary grievances and appeals that is very similar to, but not the same as, the process established for Part C. As under Part C, under Part D, beneficiaries have the right to:

- File general complaints, or grievances, with the plan sponsor;
- File complaints regarding quality of care issues with the plan sponsor, the applicable Quality Improvement Organization, or both; and
- Request a redetermination of an adverse coverage or payment determination.

B. Time Frames

Note that the applicable time frames for effectuating plan decisions is shorter than those applicable to decisions under Part C. Under Part D, plans must notify enrollees of initial coverage determinations as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request for the determination. In the case of requests for an expedited determination, the plan must notify the enrollee within 24 hours of receiving the request for a determination.

C. Appeals Process

Under Part C, an unfavorable redetermination decision is automatically sent by the plan to the independent review entity ("IRE"). By contrast, under Part D, the enrollee must generally affirmatively request independent review within 60 days of the date of the redetermination decision. The IRE must render a decision within seven days of receiving the request for review or, in the case of requests for expedited review, within 72 hours of receiving such a request. Unfavorable IRE determinations may be appealed by either party to an administrative law judge ("ALJ"), and ALJ determinations that are unfavorable to the beneficiary may be appealed by the beneficiary (but not by the plan sponsor) to the Medicare Advisory Council ("MAC").

VIII. ADDITIONAL KEY ISSUES FOR PART D PLANS

A. Impact of Part D on Medigap:

- No new Medigap prescription drug coverage may be sold after January 1, 2006;

- Part D eligible beneficiaries with existing Medigap drug coverage may retain such coverage only if they do not enroll in Part D; and

- Part D eligible beneficiaries with existing Medigap drug coverage who wish to enroll in Part D may retain their Medigap coverage without drug coverage.

B. Employer Options With Respect to Retiree Drug Benefits Under Part D

Under Part D, employers considering whether to offer drug benefits to their retirees may:

- Purchase coverage for their retirees from a Part D plan;

- Offer retiree drug coverage themselves and apply for a tax-exempt subsidy from the federal government ("the Retiree Drug Subsidy")

  - Subsidy for 2006 is 28% of claims costs between $250 and $5000.

- Offer benefits as a supplement to Part D coverage obtained by retirees on their own;

- Rely on Part D benefits for retiree drug coverage and decline to offer, or discontinue offering, drug coverage from the employer.

C. Compliance Initiatives (42 C.F.R. § 423.504(b)(4))

1. Compliance plan

Like MA Organizations, Part D plan sponsors must have in place a compliance plan that incorporates the HHS OIG's standard elements for effective compliance plans (i.e., designation of a compliance officer and committee, effective compliance training and education, effective lines of communication for reporting compliance concerns, enforcement of compliance standards through well-published disciplinary guidelines, procedures for effective internal monitoring and auditing, and procedures for prompt response to detected offenses).

2. Comprehensive fraud, waste and abuse plan

The Part D implementing regulations additionally require Part D plan sponsors to implement a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse that include procedures for voluntary self-reporting to appropriate governmental authorities of any potential fraud or misconduct related to the Part D

program. CMS's standards for such plans are addressed in Chapter 9 of the Medicare Prescription Drug Manual. That chapter describes Part D functions and activities considered by CMS to present a high risk of fraud, waste and abuse and details specific recommendations (noted in the chapter as steps that plan sponsors "should" implement) and statutory and regulatory requirements (noted in the chapter as steps that plan sponsors "must" implement) for addressing such risks. Such recommendations and requirements include extensive certification and reporting obligations, pre- and post-employment screening obligations, and training and education obligations, all applicable not only to Part D plan sponsors, but also to their subcontractors and downstream entities.

3. MEDICs

CMS has also contracted with private organizations, called Medicare Drug Integrity Contractors ("MEDICs"), to assist CMS in the management of CMS's efforts to audit and oversee Part D compliance and otherwise combat fraud, waste and abuse. MEDIC functions include the investigation of suspected Part D misconduct and the development of potential Part D fraud, waste and abuse cases for referral to law enforcement agencies.

IX. Sources of Law and Agency Guidance

- Social Security Act, 42 U.S.C. §§ 1395w-21 – 28
- Implementing regulations, 42 C.F.R. Part 423
- Additional guidance related to various aspects of Part D, including individual chapters of the Medicare Prescription Drug Manual, continue to be published and generally may be found at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/