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MEMBER BRIEFING

MEDICARE PART D TASK FORCE

MEDICARE PART D POLICY AND TECHNICAL CHANGES PROPOSED RULE— CLARIFICATION AND CLEAN-UP

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On May 25, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule (Proposed Rule) addressing certain policy and technical changes to the Medicare Prescription Drug Benefit program, also known as "Part D." CMS issued a final rule implementing Part D on January 28, 2005. Since that time, CMS has issued a number of interpretive guidances clarifying provisions of the Part D rules.[1] The Proposed Rule would codify the changes articulated in these informal guidances, and proffers several new policy clarifications (that would be effective beginning in 2009) based on CMS' Part D implementation experience. Among these new policies are:

> Definitions related to "cost" (including a new definition of "administrative costs") that are based on the amount the dispensing provider actually receives, rather than the amount the plan sponsor may pay to a contracting intermediary, such as a Pharmacy Benefit Manager;

Codification of existing CMS processes for reconciliation with respect to coordination of benefits;

Revisions to the retiree drug subsidy requirements with respect to timing and actuarial equivalence; and

Coverage of inhaled insulin supplies and improved access to home infusion pharmacies, including a new requirement that home infusion drugs be provided within 24 hours of hospital discharge.

In short, the Proposed Rule is an effort to "clean up" the Part D regulations to codify many practices and policies that are already in effect. CMS is currently reviewing comments received on the new policy provisions articulated in the Proposed Rule and summarized here. A chart identifying select technical corrections set forth in the Proposed Rule is attached.

Proposed Policy Changes – Comments Under Review

1. *Definitions of Costs – Based on the Amount Received by the Dispensing Provider*

In the Proposed Rule, CMS introduces a definition for "administrative costs," and makes various changes to the definitions of "gross covered prescription drug costs" and "negotiated prices." In these provisions, CMS emphasizes that cost will be based on the amount actually received by the dispensing pharmacy/provider, not the amount paid by a plan to any intermediary contracting agent, such as a Pharmacy Benefit Manager. This is a significant

change for the many plan sponsors that negotiate prices for prescriptions with Pharmacy Benefit Managers and calculate their drug costs based on these "locked in" prices—no matter what the dispensing pharmacy/provider actually receives from the Pharmacy Benefit Manager.

Under the Part D statute, CMS is required to exclude "administrative costs" from the calculations of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs.[2] "Administrative costs" have not been previously defined by statute or regulation. Accordingly, the Proposed Rule defines "administrative costs" as the Part D plan sponsor's costs other than those costs incurred to purchase or reimburse the purchase of Part D drugs under the Part D plan. Thus, a Pharmacy Benefit Manager's (or other intermediary contracting organization's) profit or loss resulting from lock-in pricing is an "administrative cost" under Part D.

To further clarify this point, the Proposed Rule revises the definitions of "negotiated prices," "gross covered prescription drug costs," and "allowable risk corridor" to:

> Require that plan sponsors report the amount ultimately received by the pharmacy, dispensing provider or agent (rather than simply the amount the plan may have paid, for example, to an intermediary that does not serve as an agent such as a Pharmacy Benefit Manager).
>
> Include expenditures to other non-pharmacy entities that dispense or receive payment for Part D drugs, such as when a vaccine is administered

in a physician's office or when a plan pays another Part D plan due to reconciliation or pays another third party payer as a result of a coordination of benefits issue.[3]

Under the Proposed Rule, plan sponsors would need to ensure that data reported to CMS, including fields such as the Ingredient Cost, Dispensing Fee, Sales Tax, Gross Drug Cost below the Out of Pocket Threshold, and Gross Drug Cost above the Out of Pocket Threshold, reflect the final amount ultimately received by the pharmacy at the point of sale.[4]

The modified definition of "negotiated prices" requires that beneficiary cost-sharing also be based on the amount actually received by the dispensing pharmacy (or other dispensing provider), rather than the price paid to the Pharmacy Benefit Manager (or other intermediary).[5] Under previous CMS guidance, plan sponsors were permitted to base beneficiary cost-sharing on the lock-in price the sponsor paid a Pharmacy Benefit Manager (or other intermediary) for a Part D drug. The proposed change would begin in contract year 2009.[6]

CMS also modified the definition of "gross covered prescription drug costs" to ensure that a beneficiary's costs are counted both toward total drug spending and the beneficiary's True Out-Of-Pocket Threshold (TrOOP) when the beneficiary pays for a prescription without using the Part D benefit. This may occur, for example, when a beneficiary who is paying 100% of the cost of drugs (*e.g.*, is inside the "donut hole" or paying the Part D deductible) can obtain a

prescription at a lower cost than the Plan Sponsor's negotiated price by using a discount card or receiving a special discount.[7] Beneficiaries must submit appropriate documentation in accord with the established policies of their Part D plans in order to have these costs properly counted.[8]

CMS sought comments on all of these proposed changes.

2. Coordination of Benefits—Codification of Existing Practices

CMS has generally applied special coordination of benefits rules to address complications caused by enrollees' changing Part D plan enrollment, which is subject to a "time lag," when claims are processed in real time.[9] These special rules permit CMS to avoid administratively burdensome claim reversals and readjudications or public release of a payer's negotiated prices. The Proposed Rule codifies these existing operating processes with respect to coordination of benefits:

Plan-to-Plan Reconciliation—The Proposed Rule codifies the use of special prescription drug event submission and reimbursement processes that were developed as a result of the significant lag time for getting correct information to pharmacies during the launch of Part D. These processes prevent the disclosure of proprietary pricing information by masking National Drug Codes (NDC) coding (*i.e.*, precluding the use of claims denials or edits). Because the lag time still exists when, for example, a beneficiary changes plans during a coverage year, these processes are still needed while CMS explores other options.

Reconciliation Process – Under the Proposed Rule, plans must make coordination of benefit payments to other Part D plans based on a CMS-developed reconciliation process. Payments must be based on the covered plan-paid and low-income cost-sharing subsidy amounts reported to the plan by CMS with respect to transferred enrollees and such payments must be made without regard to the plan's formulary or utilization review edits.

Timely Coordination – Under the Proposed Rule, coordination of benefits must be done on a timely basis with third party payers in accordance with CMS-developed reconciliation processes. These processes would be similar to the State-to-Plan Reconciliation Project used in 2006 when the Part D benefit first began and CMS reimbursed many states for payments made on behalf of dual eligible and low-income beneficiaries.[10]

CMS sought comments on the plan-to-plan coordination and CMS-developed reconciliation processes provisions set forth in the Proposed Rule.

3. Retiree Drug Subsidy—Application, Actuarial Equivalence, and Retiree Verification Changes

The Proposed Rule makes three changes related to the Medicare Part D Retiree Drug Subsidy (RDS) for plan sponsors (usually employers) that provide prescription drug coverage to their Medicare-eligible retirees.

First, CMS proposes a practical change for purposes of administrative simplification. The Proposed Rule alters the application deadline for the RDS to give CMS discretion to set the application deadline, for example, to coincide with the end of a month rather than a strict 90 days before the beginning of a plan year (*e.g.*, permitting a September 30th deadline rather than an early October deadline that would be required under the existing 90-day requirement).[11]

CMS also proposes to give non-calendar year plans flexibility to use either current or subsequent year Part D standard prescription drug coverage as the basis for determining whether a plan achieves "actuarial equivalence," as necessary to qualify for the RDS.[12]

Finally, rather than referring to a single specific database to verify that retiree plan sponsors do not claim subsidies for individuals already enrolled in a Part D plan, the Proposed Rule uses a more general reference to permit CMS to use a variety of databases.[13]

CMS sought comments on the proposed changes regarding the RDS.

4. Access and Coverage -- Home Infusion Pharmacies and Inhaled Insulin

CMS proposes two specific changes related to home infusion pharmacy access and coverage of insulin inhalation products.

The Proposed Rule codifies existing guidance regarding adequate access to home infusion pharmacies and proposes one regulatory change – that Part D plan sponsors ensure covered home infusion drugs are provided within 24 hours

of discharge from an acute setting.[14] Specifically, the Proposed Rule requires that plans contract with a pharmacy network that, at a minimum:

> Is capable of delivering home infused drugs in a form that can be administered in a clinically appropriate fashion,
>
> Is capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies,
>
> Ensures that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing home infusion drugs,[15] and
>
> Provides delivery of home infusion drugs within 24 hours.

CMS views the availability of home infusion therapy as a means to promote early discharge from the hospital and sees it as an urgent form of care. CMS indicates that industry best practices dictate the availability of home infusion drugs upon discharge from a hospital either in time for the patient's next required dose or within 24 hours of discharge. It chose the latter as its proposed standard without further elaboration and invited comments on its choice.[16]

The Proposed Rule also provides that supplies directly associated with delivering inhaled insulin may be covered by Part D, subject to their inclusion in particular Part D plan formularies by Part D plan Pharmacy and Therapeutics (P&T) Committees. Inhaled insulin was approved by the federal Food and Drug Administration (FDA) on January 26, 2006. CMS believes that Congress' intent

was to cover insulin supplies, regardless of delivery form. CMS also indicates that it will narrowly construe those items that will be considered medical supplies and will expect plans to perform utilization management to ensure appropriate use of these supplies. Under this proposed change, for example, insulin chambers (used for inhalation) would be covered, but storage and carrying cases for the chamber would not.[17]

CMS sought comment on the proposed access and coverage changes.

Technical Changes—Cleaning Up the Regulations

In addition to proposing new Part D policy, CMS also makes several technical corrections to the Part D benefit in the Proposed Rule. First, CMS corrects basic typographical and technical errors as set forth in the attached chart. CMS also provides rationale for some of its other technical changes as summarized below.

1. Marketing vs. Assisting in Enrollment/Education

In a response to public comment in the January 28, 2005 Final Rule, CMS used the term "market" in a general sense. Due to CMS' specific definition of the term "market" in its subsequently-issued *Medicare Marketing Guidelines*, some confusion may exist as to what types of outreach are permitted.[18] The Proposed Rule thus sets forth CMS' "consistent policy" that providers and pharmacies that contract with a plan may not "market" to beneficiaries, but may assist in enrollment, including participating in certain provider promotional activities as

permitted under the *Medicare Marketing Guidelines* issued by CMS.[19] Under the Proposed Rule, providers are encouraged to assist beneficiaries in making objective assessments of their needs and of the plans that best meet those needs.[20]

The Proposed Rule also clarifies that providers, provider groups and pharmacies need only accept and display comparative information regarding the Part D plans with which they contract (and need not display information for plans with which they do not do business because this might mislead beneficiaries).[21]

2. Wrap-Around Assistance by Insurance-Like Providers Does Not Count Toward TrOOP

Under the January 28, 2005 Final Rule, waivers or other reductions in cost-sharing by pharmacies count towards a beneficiary's annual TrOOP.[22] The Proposed Rule, however, clarifies that cost-sharing waivers (also called wrap-around assistance) for covered Part D drugs provided by pharmacies (including safety net pharmacies) that <u>also</u> meet the definitions for group health plans, insurance, or government-funded or third party payer arrangements do <u>not</u> count towards a beneficiary's TrOOP. Waivers may only count toward a beneficiary's TrOOP if the pharmacies are not affiliated with these insurance-type entities that have an obligation to pay for covered Part D drugs.[23]

3. Changes to Drug Coverage -- Erectile Dysfunction Drugs and Morbid Obesity Drugs Not Covered; Vaccine Administration Fees Included

The Proposed Rule clarifies that as of January 1, 2007, erectile dysfunction drugs will not be covered by Part D when used to treat sexual or erectile dysfunction, though other FDA-approved uses are covered. This change was required by statute (thus requiring no actual regulatory change) and well-publicized by CMS prior to issuance of the Proposed Rule.[24] Part D plans, however, may still offer erectile dysfunction drugs as part of enhanced alternative coverage. CMS also clarifies that weight loss drugs, even when used for morbid obesity, are not covered by Part D.[25]

CMS also intends to include a reference to vaccine administration in the definition of Part D drugs after January 1, 2008 to reflect statutory changes made by the Tax Relief and Health Care Act of 2006.[26]

4. Retiree Drug Subsidies and Revisions to the Actuarial Equivalence Test

Under Part D, in order for an employer (or other plan sponsor) to claim the RDS, the plan sponsor must offer a plan that is actuarially equivalent to Medicare's standard prescription drug coverage and attest to this fact.[27] Actuarial equivalence may be demonstrated through a "gross test" or a "net test."[28] With respect to actuarial equivalence of employer-sponsored retiree prescription drug plans, the Proposed Rule:

> Clarifies previous guidance by codifying CMS' position that a plan must actually provide employer-sponsored supplementary drug coverage to its retirees that elect Part D in order to do a Medicare supplementary adjustment under the "net test" option of the actuarial equivalent test.[29]

In accord with previous guidance, gives plans the option of aggregating a subset of the benefit options offered by the plan to specific groups of retirees for the actuarial equivalent "net test" as an alternative to aggregating all benefit options or evaluating each option individually. The plan sponsor may not claim the subsidy for those benefit options excluded from the net value calculation under the test, however.[30]

Clarifies that no attestation must be submitted when a plan sponsor makes a potentially material change to a plan, but still meets the actuarial equivalent test after the change and has added no new benefit options. This is an exception to the requirement that plans submit an attestation no later than 90 days before the implementation of a material change to coverage. [31]

5. Institutes for Mental Disease and Hospitals as Long Term Care Facilities

In the discussion of the definition of "long term care facility" in the Preamble to the January 28, 2005 Final Rule, CMS inadvertently left out references to institutes for mental disease (IMDs), which caused some "confusion."[32] The Proposed Rule clarifies that the term "long term care facility" includes any medical institute that has an institutionalized patient, that is, a full benefit, dual eligible individual for whom payment is made for IMD services under Medicaid throughout a month. As such, IMDs are in fact covered under the definition of "long term care facility." Hospitals are also included in the definition when their patients exhaust Part A inpatient day benefits such that payment is no

longer available under Part A or Part B for drugs that would otherwise meet the definition of a Part D drug. Part D plan sponsors must ensure that they provide convenient access to network long term care pharmacies for their enrollees in these IMD and hospital settings (which may include using a hospital's in-house pharmacy as a plan-contracted pharmacy).[33]

6. States Cannot Provide Medicaid Coverage for Any Covered Part D Drugs

The Proposed Rule makes clear that only drugs specifically excluded from Part D may be covered by Medicaid. For full benefit, dual eligible beneficiaries, federal financial participation in Medicaid is not available for drugs that would otherwise be Part D covered drugs except for the fact that they are not on a plan formulary. In other words, states cannot provide medical assistance for covered Part D drugs simply because they are not on a plan formulary.[34]

Conclusion

In the Proposed Rule, CMS seeks to clean up inaccurate and/or confusing provisions from its January 28, 2005 Final Rule, incorporating, in most instances, informal guidance that it has issued in the interim. If finalized, Part D plans will need to ensure they have the systems in place to incorporate the proposed requirements regarding the definition of "costs" used in the reporting and reinsurance and risk-sharing calculations, the coordination of benefits reconciliation processes, and the requirements for home infusion pharmacy services, among others.

Select Proposed Technical Changes to the Medicare Prescription Drug Benefit
July 2007

Regulation	Correction	Type of Correction
42 C.F.R. § 423.56(b)(6)	Cross-reference should be to 42 C.F.R. § 403.305, not § 423.205	Typographical error
42 C.F.R. § 423.100	Clarifies that pharmacies in a contracted pharmacy network must be licensed	Inadvertent omission
42 C.F.R. §§ 423.120(a)(2), 423.464(f)(1)(vii)	Changes reference from "rural health centers" to "rural health clinics"	Technical error
42 C.F.R. § 423.293(a)	Clarifies (through revised cross-reference) that SSA § 1854(d) (requiring plans to permit payment of both basic and supplementary premiums on a monthly basis) applies to Part D (Prescription Drug plans) as well as Part C (Medicare Advantage plans)	Technical error
42 C.F.R. § 423.350(b)	Changes reference from "notice of the adverse determination" (relevant only for fee-for-service plans) to "notice of final payment for [risk adjustment, reinsurance, low-income cost-sharing subsidies, or risk-sharing payments]" (for Part D)	Technical error
42 C.F.R. § 423.410(d)	Revises regulation to permit "substantially" rather than fully complete applications to be submitted for special waivers under 42 C.F.R. § 423.410(d), in accord with statutory requirements	Technical error

42 C.F.R. § 423.458(d)(2)(ii)	Adds reference to SSA § 1894, reflecting fact that PACE[35] operates under the Medicare and Medicaid statutes	Inadvertent omission
42 C.F.R. § 423.262(f)(1)	Clarifies that Part D plans must coordinate benefits with other Part D plans (not just with group health plans)	Technical error
42 C.F.R. § 423.504	Changes reference from 42 C.F.R. § 423.265(a)(1) to § 423.265 (to include broader list of information related to bid submission)	Incorrect citation
42 C.F.R. § 423.505(h)(1)	Revises citation to False Claims Act to read 31 U.S.C § 3729 et seq.	Incorrect citation
42 C.F.R. § 423.509(a)(9)	Revises citation to marketing requirements to refer to 42 C.F.R. § 423.50	Incorrect citation
42 C.F.R. § 423.560	Revises definition of “appointed representative” to clarify that representatives may file a grievance for enrollees; revises definition of “projected value”	Inadvertent omission; technical error
42 C.F.R. § 423.570(d)(3)	Revises regulation to require that a Part D sponsor send an enrollee written notice of the denial of a request to expedite a coverage determination within 3 calendar days	Inadvertent omission
42 C.F.R. § 423.584(b)	Revises regulation to apply procedures applicable to standard redeterminations to expedited redeterminations	Inadvertent omission
42 C.F.R. § 423.610(c)(2)	Revises numbering	Typographical error

	scheme	
42 C.F.R. § 423.780(b)	Revises regulation to include methodology for determining low-income benchmark premium when there are multiple Medicare Advantage Prescription Drug (MA-PD) plans but only one Prescription Drug Plan (PDP) sponsor in a region; clarifies that in multiple PDP sponsor regions, the MA-PDs included in the weighted average are coordinated care plans	Technical error
42 C.F.R. § 423.780(e)	Revises regulation to reflect statutory requirement for use of sliding scale calculation for late enrollment penalty subsidy for "other" low income subsidy individuals	Inadvertent omission
42 C.F.R. § 423.910(b)(1)	Changes reference from "quarterly" to "monthly"	Typographical error

[1] *See, e.g.*, CMS, Medicare Marketing Guidelines for: Medicare Advantage Plans (MAs); Medicare Advantage Prescription Drug Plans (MA-PDs); Prescription Drug Plans (PDPs); 1876 Cost Plans (last updated 2006) (hereinafter "Medicare Marketing Guidelines"), *available at* http://www.cms.hhs.gov/PrescriptionDrugCovContra/Dowloads/FinalMarketingGuidelines.pdf; CMS, Question & Answer 5115 (2005), *available at* http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=gIVVcxhi; CMS, Question & Answer 7682 (2006), *available at* http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=F*VR*Ygi; CMS, Guidance on the Actuarial Equivalence Standard for the Retiree Drug Subsidy (2005), *available at* http://www.cms.hhs.gov/employerretireeedrugssubsid/Downloads/ActrlEquvlncStdforRDS.pdf.

[2] *See* Social Security Act §§ 1860D-15(b)(2) & (3), 1860D-15(e)(1)(B).

[3] *See* Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed. Reg. 29,403, 29,409 (May 25, 2007) (to be codified at 42 C.F.R. pt. 423) at 29,407 (with respect to definition of "negotiated prices"), 29,409-10 (with respect to definitions of "gross covered prescription drug costs," and "allowable risk corridor").

[4] *See id*. at 29,409.

[5] *See id.* at 29,407.

[6] *See id*. at 29,407. CMS also acknowledges that, despite the language in the definition of "negotiated prices," Part D sponsors in practice may not be able to apply discounts, rebates or other price concessions at the point of sale, meaning that no price concessions can be passed through to beneficiaries. Despite this acknowledgement, CMS still did not change the provision of the definition of negotiated prices regarding the pass-through of such price concessions. *Id.*

[7] *Id*. at 29,410.

[8] *Id*. *See also* CMS, Question & Answer 7942 (2006); CMS, Question & Answer 7944 (2006), *available at* http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=gIVVcxhi.

[9] *Id*. at 29,411-12.

[10] *See Id.* at 29,412.

[11] *Id.* at 29,414.

[12] *Id.* at 29,415. Under Part D, in order for an employer/plan sponsor to claim the RDS, the plan sponsor must offer a plan that is actuarially equivalent to Medicare's standard prescription drug coverage, and attest to this fact. *See* Social Security Act, §1860D-22(a)(2)(A).

[13] Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed. Reg. at 29,415

[14] Existing guidance can be found at http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/HomeInfusionReminder_03.10.06.pdf.

[15] Plans are not required to provide or pay for the supplies, equipment or professional services needed for home infusion therapy. *See Id.*

[16] *See* Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed. Reg. at 29,408-09.

[17] *See Id*. at 29,405-06.

[18] "Marketing" is defined under the *Medicare Marketing Guidelines* as "steering, or attempting to steer, an undecided potential enrollee towards a plan, or limited number of plans, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities." Medicare Marketing Guidelines at 8.

[19] *See Id.*

[20] *See* Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed. Reg. at 29,404.

[21] *Id.*

[22] *See* Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4240 (January 28, 2005) (to be codified at 42 C.F.R. pts. 400, 403, 411, 417, and 423).

[23] *See* Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed. Reg. at 29,407-08.

[24] *See Id.* at 29,405; *see also* CMS, Question & Answer 7682 (2006), *available at* http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std.alp.php?p_sid=F*VR*Ygi. Media exposure and CMS' outreach programs also emphasized this change in policy.

[25] *See* Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed. Reg. at 29,405.

[26] *Id*. *See also* Social Security Act §1860D-2(e)(1)(B).

[27] Social Security Act §1860D-22(a)(2)(A).

[28] *See* 42 C.F.R. §423.884(d)(5) (2006).

[29] *See* CMS, Guidance on the Actuarial Equivalence Standard for the Retiree Drug Subsidy (2005), *available at* http://www.cms.hhs.gov/employerretireeedrugssubsid/Downloads/ActrlEquvlncStdforRDS.pdf.

[30] *Id.*

[31] *See* Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed Reg. at 29,415. *See also* Social Security Act §1860D-22(a)(2)(A); 42 C.F.R. §423.884(d)(6)(ii) (2006).

[32] *See* http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/IMDICFPharmacyGuidance.pdf.

[33] *See* Policy and Technical Changes to the Medicare Prescription Drug Benefit, 72 Fed. Reg. at 29,406-07.

[34] *See Id.* at 29,416.

[35] Program of All Inclusive Care for the Elderly. (PACE).