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TO: All Prescription Drug Plan and Medicare Advantage-Prescription Drug Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

RE: Medicare Prescription Drug Benefit Manual – Chapter 5

DATE: September 20, 2011

CMS is pleased to release updated Chapter 5 of the Medicare Prescription Drug Benefit Manual (Benefits and Beneficiary Protections). The revisions to Chapter 5 reflect changes previously released in the final regulations published in the Federal Register on April 15, 2010 and 2011 and in the Calendar Year 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter released on April 4, 2011.

Specifically, CMS:

- Added the definitions of “Applicable beneficiary,” “Applicable drug,” “Coverage Gap,” and “Non-applicable drugs” to the definition section.
- Updated the description of Standard Prescription Drug Coverage and Alternative Prescription Drug Coverage to address coinsurance in the coverage gap.
- Clarified existing policy with respect to “Free first fill programs” by specifying that, for a new prescription, such programs must apply to both a beneficiary switch from a brand-name medication.
- Stipulated in the section Enhanced Alternative Gap Coverage that sponsors will no longer indicate their level of gap coverage in the Plan Benefit Package (PBP) software, but rather, CMS will quantify each plan’s gap coverage and assign appropriate descriptions.
- Clarified existing policy in the section Restrictions on the Offering of Enhanced Alternative Coverage by MA Organizations to ensure that MA organizations offer at least one option for Part D coverage for supplemental premium at the cost of basic prescription drug coverage and announcing that two questions have been added to the PBP to help ensure this requirement is being met.
- Added a new section Coverage Gap Coinsurance.
- Clarified and updated existing policy regarding dispensing fees to reflect the long-term care dispensing requirements effective January 1, 2013.
- Updated the section Ensuring Meaningful Differences in Approved Bids to reflect that CMS will only approve a bid submitted by a sponsor if its plan benefit package or cost structure is meaningfully different from other plan offerings by the sponsor in the same service area with respect to key characteristics.

- Updated the section Meaningful Differences in Basic Prescription Drug Coverage Options to state that CMS believes that sponsors should only submit one basic offering for a stand-alone prescription drug plan in a service area.
- Updated the section Meaningful Differences in Enhanced Alternative Coverage Options to state that CMS will announce its meaningful differences evaluation methodology via the annual payment notice and call letter.
- Updated the section Transition Period for Sponsors or Parent Organizations with New Acquisitions to reflect a 2 year transition period.
- Updated the section Consolidated Renewal Plan to cover consolidation of two enhanced alternative plans.
- Updated the section PDP Plan Benefit Package (PBP) Renewal and Crosswalk Guidance to include a section Consolidated Plans under a Parent Organization.
- Added a new section Low Enrollment Plans.
- Added a new section Manufacturer Drug Discount Program.
- Updated the sections Costs that Count as Incurred Costs, Costs that do not Count as Incurred Costs, Summary of TrOOP-Eligible and TrOOP-Ineligible Payers, and Pharmacy Waiver/Reduction of Cost-Sharing and Applicability, by addressing discounts paid by manufacturers as part of the Medicare Coverage gap Discount program, costs paid by the Indian Health Service or an Indian tribe or organization, and costs paid by AIDS Drug Assistance Program.
- Clarified the section on Mail-Order Pharmacy Access to state that a pharmacy that makes some, but not all, deliveries by common carrier is not a mail order pharmacy.
- Clarified the section Level Playing Field Between Mail-Order and Retail Pharmacies by stating that the alternative retail/mail order pharmacy rate shall not cause the standard terms and conditions offered to similarly situated pharmacies to vary with respect to the any willing provider pharmacy provisions.
- Revised the section Out-of-Network Pharmacy Access to add an option for sponsors to create an out-of-network benefit structure.
- Clarified the section Public Disclosure of Pharmaceutical Prices for Equivalent Drugs to state that CMS may modify the timing requirement for informing enrollees of any differential between the price of a covered part D drug to an enrollee and the price of the lowest priced generic version if the requirement becomes impracticable to administer.
- Added an Electronic Transactions Standards section to address unique BIN/PCN provisions and Prescriber Identifiers.
- Updated Appendix 1: Adequate Access to Network Home Infusion Pharmacies by State/Territory and Contract Type with 2011 data.

The manual revisions are available at

http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

Any questions regarding this manual chapter may be directed to Lisa Thorpe via e-mail at Lisa.Thorpe@cms.hhs.gov.

Prescription Drug Benefit Manual

Chapter 5: Benefits and Beneficiary Protections

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10 - Benefits and Beneficiary Protections

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

10.1 - Introduction

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

This chapter deals with Part D sponsor requirements with regard to Part D benefits and a number of beneficiary protections for Part D enrollees, including:

- The establishment of prescription drug plan (PDP) service areas;
- Access standards with regard to covered Part D drugs;
- Disclosure to beneficiaries of pricing information for generic versions of covered Part D drugs; and
- Privacy, confidentiality, and accuracy of PDP sponsors' enrollee records.

Except where specifically noted, these requirements apply to all Part D sponsors, including PDPs, MA-PD plans, and cost plans offering Part D coverage. Other requirements related to beneficiary protections are contained in other chapters of the Prescription Drug Benefit Manual, which can be accessed at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

10.2 - Definition of Terms

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Unless otherwise stated in this chapter, the following definitions apply:

Actual cost: The negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of network pharmacy consistent with [42 CFR 423.124\(a\)](#).

Applicable beneficiary: Means an individual who, on the date of dispensing a covered Part D drug--

- (1) Is enrolled in a prescription drug plan or an MA-PD plan;*
- (2) Is not enrolled in a qualified retiree prescription drug plan;*
- (3) Is not entitled to an income-related subsidy under section 1860D-14(a) of the Act;*
- (4) Has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) of the Act during the year;*
- (5) Has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B) of the Act; and*
- (6) Has a claim that--*
 - (i) Is within the coverage gap;*
 - (ii) Straddles the initial coverage period and the coverage gap;*
 - (iii) Straddles the coverage gap and the annual out-of-pocket threshold; or*

(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

Applicable drug: Means a Part D drug that is--

(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

Bioequivalent: The meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Catastrophic coverage: The Part D benefit phase above the annual out-of-pocket threshold described at [42 CFR 423.104\(d\)\(5\)\(iii\)](#) (and in section 20.3.1).

Contracted pharmacy network: Licensed pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Coverage gap: Means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. *For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.*

Employer/Union- Only Group Waiver Plan: For the purpose of this section, Medicare-approved prescription drug plans that qualify for waivers or modifications to their plan offerings consistent with Pub. 100-16, Medicare Managed Care Manual, Chapter 9, Section 10 and Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 12, Section 10.

Generic drug: A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Government-funded health program: Any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following: (1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act; (2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act; (3) The veterans' health care program under Chapter 17 of title 38 of the United

States Code; (4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and (5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan: For purposes of applying the definition of incurred costs in [42 CFR 423.100](#), has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle.

Insurance: A health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following: (1) health insurance coverage (as defined in 42 U.S.C. 300gg-91(b)(1)); (2) a Medicare Advantage (MA) plan (as described under section 1851(a)(2) of the Act); and (3) a PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act). This definition specifically excludes a personal health savings vehicle.

I/T/U pharmacy: A pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care (LTC) facility: A skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy: A pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy: A long-term care pharmacy that is a network pharmacy.

Multiple source drug: A drug defined in section 1927(k)(7)(A)(i) of the Social Security Act.

Network pharmacy: A licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy: A network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Non-applicable drugs: Covered Part D drugs that are not applicable drugs as defined in this section. This includes generic drugs.

Or otherwise: Through a government-funded health program.

Out-of-network (OON) pharmacy: A licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Parent organization: An organization that holds at least the majority of the voting stock in a legal entity that holds a Medicare Prescription Drug Plan (PDP) sponsor contract or a Medicare Advantage (MA) Organization contract.

Part D drug: A drug described in chapter 6, section 10, of this manual.

Person: A natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle: A vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax free basis including any of the following: (1) a Health Savings Account (as defined under section 220 of the Internal Revenue Code); (2) a Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and (3) an Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code). This definition specifically excludes a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002-41 and Internal Revenue Notice 2002-45).

Plan allowance: The amount Part D plans that offer coverage, other than defined standard coverage, may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of [42 CFR 423.124\(b\)](#).

Plan Benefit Package (PBP): A set of benefits for a defined MA or PDP service area. The PBP is submitted by PDP sponsors and MA organizations to CMS for benefit analysis, marketing and beneficiary communication purposes.

Preferred drug: A covered Part D drug on a Part D sponsor's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug on the sponsor's formulary.

Preferred multiple source drug: A drug that is both a preferred drug and a multiple source drug, meaning that one version of that drug is placed on the sponsor's formulary with lower cost sharing than for a non-preferred drug.

Preferred pharmacy: A network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D sponsor.

Retail pharmacy: Any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Rural: A five-digit ZIP Code in which the population density is less than 1,000 individuals per square mile.

Suburban: A five-digit ZIP Code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental drugs: Drugs that would be covered Part D drugs but for the fact that they are specifically excluded as Part D drugs under [42 CFR 423.100](#), and as described in section 20.1 of [chapter 6](#). However, because such drugs must have otherwise qualified as covered Part D drugs

(as defined in section 10.2 of [chapter 6](#)) in order to be covered as a supplemental benefit, and because only prescription drugs are included in the definition of a Part D drug, over-the-counter drugs cannot be supplemental drugs, as discussed in section 10.10 of [chapter 6](#). Supplemental drugs may be included as a supplemental benefit under enhanced alternative coverage, as described in section 20.4.2 of this chapter.

Therapeutically equivalent: Drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

Third party payment arrangement: Any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban: A five-digit ZIP Code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price: The price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

20 - Requirements Related to Qualified Prescription Drug Coverage (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

20.1 - General

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A Part D sponsor must provide enrollees with qualified prescription drug coverage. Qualified prescription drug coverage, which consists of either of the following options, may be provided directly by the Part D sponsor or through arrangements with other entities:

- (1) Standard prescription drug coverage (as described in section 20.3), which includes both defined standard coverage (as described in section 20.3.1) and actuarially equivalent standard coverage (as described in section 20.3.2).
- (2) Alternative prescription drug coverage (as described in section 20.4), which includes both basic alternative coverage (as described in section 20.4.1) and enhanced alternative coverage (as described in section 20.4.2).

For purposes of ensuring that Part D enrollees have a variety of different benefit options in a particular service area, CMS also makes a distinction between qualified prescription drug coverage that is basic prescription drug coverage and qualified prescription drug coverage that provides supplemental benefits (as described in section 20.4.2). Basic prescription drug coverage consists of any of the following:

- (1) Defined standard coverage, as described in section 20.3.1;
- (2) Actuarially equivalent standard coverage, as described in section 20.3.2; or

(3) Basic alternative coverage, as described in section 20.4.1

As described in section 20.4.2, plans may offer an additional type of qualified prescription drug coverage – enhanced alternative coverage – that includes both: (1) basic prescription drug coverage, as described above, and (2) supplemental benefits. Table 1 summarizes the difference between qualified prescription drug coverage and basic prescription drug coverage.

Table 1
Qualified and Basic Prescription Drug Coverage

	Types of Coverage that May be Included
Qualified Prescription Drug Coverage	<ul style="list-style-type: none"> • Defined Standard Coverage • Actuarially Equivalent Standard Coverage • Basic Alternative Coverage • Enhanced Alternative Coverage
Basic Prescription Drug Coverage	<ul style="list-style-type: none"> • Defined Standard Coverage • Actuarially Equivalent Standard Coverage • Basic Alternative Coverage

20.2 - Availability of Prescription Drug Plans

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A PDP sponsor must offer its prescription drug plans to all Part D eligible beneficiaries residing in those plans' service areas (refer to section 40 for more information about PDP service areas). Unlike an MA-PD sponsor, a PDP is not eligible for a capacity limit as described in 42 CFR 422.60(b).

20.3 - Standard Prescription Drug Coverage

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Standard prescription drug coverage includes two distinct types of coverage: (1) defined standard coverage; and (2) actuarially equivalent standard coverage. Both types of standard prescription drug coverage consist of coverage of covered Part D drugs subject to an annual deductible; 25 percent coinsurance (or an actuarially equivalent structure) up to an initial coverage limit; *coinsurance equal to the gap coinsurance percentages (or an actuarially equivalent amount) during the coverage gap*; and catastrophic coverage after an individual incurs out-of-pocket expenses above the annual out-of-pocket threshold. Both defined standard coverage and actuarially equivalent standard coverage include access to negotiated prices, as described in section 20.5.

20.3.1 - Defined Standard Coverage

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Defined standard coverage consists of coverage of covered Part D drugs subject to:

- An annual deductible.
- Twenty-five percent coinsurance for actual costs above the annual deductible but at or below an initial coverage limit.
- *Coinsurance that is equal to the costs of non-applicable and applicable (brand) drugs during the coverage gap multiplied by the gap coinsurance percentages described in section 20.5.*
- Catastrophic coverage with nominal cost-sharing for the remainder of the coverage year once an enrollee's costs exceed the annual out-of-pocket threshold.

The annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost-sharing after the annual out-of-pocket threshold is met are adjusted annually. As provided in [42 CFR 423.104\(d\)\(5\)\(iv\)](#), these amounts will be adjusted relative to the previous year's amounts by the annual percentage increase in average per capita aggregate expenditures for Part D drugs for the 12-month period ending in July of the previous year. The updated benefit parameters for 2012 include an adjustment for any variations between the projected and actual amounts from the prior period. For more information about the methodologies used to update the 2012 benefit parameters, refer to:

<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/AD/list.asp?filtertype=none&datefiltertype=&datefilterinterval=&datafiltertype=1&datafiltervalue=&keyword=&intNumPerPage=10&cmdFilterList=Show+Items>

20.3.2 - Actuarially Equivalent Standard Coverage

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors may also offer actuarially equivalent standard coverage, under which they would substitute certain cost-sharing requirements in defined standard coverage (including tiered structures tied to plan formularies or preferred pharmacies in a plan's network, as described in section 50.9) for:

1. Costs above the annual deductible and up to the initial coverage limit, provided that those alternative cost-sharing requirements are actuarially equivalent to the average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit under defined standard coverage; and/or
2. *Costs for coinsurance during the coverage gap, provided that those alternative cost-sharing requirements are actuarially equivalent to the average expected coinsurance (that is equal to the costs of non-applicable and applicable drugs multiplied by the gap coinsurance percentages described in section 20.5) under defined standard coverage; and/or*
3. Costs in the catastrophic portion of the benefit, provided that those alternative cost-sharing requirements are actuarially equivalent to the average expected cost-sharing

under defined standard coverage described in *the applicable annual Rate Announcement/ Call Letter found at www.cms.gov/PrescriptionDrugCovContra/01_Overview.asp*.

Cost-sharing arrangements under actuarially equivalent standard coverage could include reducing cost-sharing to \$0 for generic or preferred covered Part D drugs, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit and/or to an average expected cost-sharing in the catastrophic portion of the benefit equivalent to the cost-sharing described in *the applicable annual Rate Announcement/Call Letter found at www.cms.gov/PrescriptionDrugCovContra/01_Overview.asp*. Any such cost-sharing arrangements will be reviewed, along with the rest of a plan's benefit design, to ensure that they do not discriminate against certain Part D eligible individuals.

20.4 - Alternative Prescription Drug Coverage

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Alternative prescription drug coverage includes two distinct types of coverage: (1) basic alternative coverage; and (2) enhanced alternative coverage. Both basic alternative coverage and enhanced alternative coverage include access to negotiated prices, as described in section 20.6. In modifying the standard prescription drug coverage design to offer alternative prescription drug coverage, Part D sponsors must use defined standard coverage (and not actuarially equivalent standard coverage) as a fixed point of comparison. In order to receive approval to offer an alternative prescription drug benefit design, a Part D sponsor must:

1. Include a deductible that is no greater than the deductible offered under defined standard coverage.
2. Provide coverage above the annual out-of-pocket threshold that is at least as generous as that provided under defined standard coverage. In other words, Part D sponsors may, at their option, reduce cost-sharing below that required under defined standard coverage.
3. Ensure that the beneficiary premium is at least equal to the beneficiary premium under defined standard coverage.
4. Ensure that, for individuals whose total spending exceeds the initial coverage limit under standard prescription drug coverage, the average Part D sponsor payout is at least equal to that under defined standard coverage.
5. Ensure that the actuarial value of the total or gross coverage is at least equal to that under defined standard coverage.

Sponsors have flexibility to establish benefit designs within the aforementioned parameters that include the following features, which may be particularly useful for increasing utilization of generic drugs. All cost-sharing arrangements will be reviewed, along with the rest of a sponsor's benefit design, to ensure that they do not discriminate against certain Part D eligible individuals.

- **Brand-only deductible:** Sponsors may lower or eliminate cost sharing for generics in the deductible period. Sponsors may not, however, increase the deductible for brands above the defined standard benefit's annual deductible amount in order to compensate for decreasing the cost-sharing for generics before the deductible is met. Sponsors electing a brand-only deductible should note that beneficiary and plan paid amounts for generic drugs will accrue to total drug costs but not toward the brand-only deductible.

“Free first fill” program: Sponsors may establish programs whereby enrollees are offered an incentive in the form of a cost-sharing reduction *if 1) with respect to a new prescription, the enrollee chooses a generic version of, or a preferred brand-name therapeutic alternative to, a medication, over a brand-name drug, and 2) with respect to a refill, the enrollee switches* from a brand-name to the generic version of, or a preferred brand-name therapeutic alternative to, a medication. The goal of such incentive programs is to minimize drug spend and maximize compliance with plan formularies. A sponsor that elects this benefit design must identify these drugs in the Free First Fill supplemental formulary flat file.

20.4.1 - Basic Alternative Coverage

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Basic alternative coverage is alternative prescription drug coverage that is actuarially equivalent to defined standard prescription drug coverage, as described in section 20.3.1. Within the parameters for alternative prescription drug coverage described in section 20.4, a Part D sponsor offering a basic alternative prescription drug benefit design could combine features such as the following to maintain an actuarial value of coverage equal to defined standard prescription drug coverage:

- A reduction in the deductible;
- Changes in cost-sharing (e.g., benefit designs that use tiered copayments or coinsurance) in an actuarially equivalent manner to the 25 percent cost-sharing above the deductible and below the initial coverage limit under defined standard coverage *and in an actuarially equivalent manner to the gap coverage coinsurance (that is equal to the costs of non-applicable and applicable drugs multiplied by the gap coinsurance percentages described in section 20.5) during the coverage gap*; and
- A modification of the initial coverage limit

20.4.2 - Enhanced Alternative Coverage

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

20.4.2.1 - General

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Enhanced alternative coverage refers to alternative prescription drug coverage whose value exceeds that of defined standard coverage. This is only possible if a Part D sponsor offers supplemental benefits in addition to its basic prescription drug benefit. In other words, enhanced

alternative coverage includes both: (1) basic prescription drug coverage, as described in section 20.1; and (2) supplemental benefits.

Supplemental benefits consist of:

- Reductions in cost-sharing in the coverage gap such that enrollees are liable for less than *the coinsurance in the gap for defined standard coverage*, and the actuarial value of the benefit provided is increased above the actuarial value of basic prescription drug coverage.
- Reductions in cost-sharing that increase the actuarial value of the benefits provided above the actuarial value of basic prescription drug coverage – for example: (1) a reduction in the deductible; (2) a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible and the initial coverage limit and/or above the annual out-of-pocket threshold; and/or (3) an increase in the initial coverage limit; and/or
- Supplemental drugs.

20.4.2.2 - *Enhanced Alternative Gap Coverage*

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

As part of an enhanced alternative benefit design, Part D sponsors may include coverage of a subset of drugs throughout the coverage gap. Sponsors may elect to *provide additional coverage for*:

1. An entire drug tier;
2. A subset of a drug tier, or
3. A capped dollar amount of drugs within a tier or across the entire benefit (limited gap coverage).

CMS will review the breadth of drugs covered through the gap, be it: (1) an entire drug tier; (2) a subset of a drug tier, or (3) a capped dollar amount of drugs, to ensure that the coverage is sufficient to be labeled either gap coverage or limited gap coverage. CMS reserves the right to label coverage of a subset of all formulary drugs through the gap as something less than gap coverage or limited gap coverage. For example, coverage of only insulin through the coverage gap would not be sufficient to be labeled gap coverage.

In CY 2010, sponsors were required to identify their gap coverage offerings for both generic and brand drugs in the plan benefit package (PBP) software using CMS-defined standardized thresholds for the terms “all,” “many,” “some,” “few,” or “none.” These thresholds represented the proportion of unique Health Plan Management System (HPMS) formulary drug entities (i.e., unique clinical drug component and dosage form) that are covered through the gap for drugs described on the formulary as generic and for drugs described as brand (as specified by the drug type label). Beginning in CY 2011, for 2012 bids, sponsors will no longer indicate their level of gap coverage in the PBP. CMS will quantify each plan’s gap coverage based upon the percentage of formulary drugs (brand, or generic above the standard coverage) covered through

the gap and then will assign appropriate descriptions. The gap coverage level descriptions will reflect additional coverage above the mandated coverage gap coinsurance of non-applicable drugs. Supplemental (excluded) drugs will not be factored into the determination of gap coverage. For example, if a plan covers both generic Part D and supplemental drugs, only the generic drugs as defined in this chapter, will be used in calculating the percentage of formulary drugs covered through the gap. CMS will provide a report in HPMS describing the CMS-assigned gap coverage levels. Gap coverage descriptions for drugs will be communicated to beneficiaries through the SB, other marketing materials, and information dissemination materials.

20.4.3 - Restrictions on the Offering of Enhanced Alternative Coverage by PDP Sponsors

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A PDP sponsor is not permitted to offer a plan that provides enhanced alternative coverage in a particular service area unless it also offers a plan that provides only basic prescription drug coverage, as described in section 20.1, in that same area. This requirement ensures that PDP sponsors offer at least one option for Part D coverage for a premium at the cost of basic prescription drug coverage. For purposes of meeting this requirement, a PDP sponsor is considered to be a PDP parent organization.

20.4.4 - Restrictions on the Offering of Enhanced Alternative Coverage by MA Organizations

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

An MA organization may not offer an MA coordinated care plan, as defined in [42 CFR 422.4](#), in a service area unless that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage for the entire service area. MA plans, by definition, would include private fee-for-service (PFFS) plans. *For purposes of meeting this requirement, an MA organization is considered to be an MA parent organization.*

Required prescription drug coverage consists of either: (1) basic prescription drug coverage (*as described in section 20.1 of this manual*), or (2) enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium for the drug coverage applied under the plan. Such enhanced alternative coverage could be provided without a monthly supplemental beneficiary premium only if a plan applied a credit of rebate dollars available under the plan's Part C bid against the otherwise applicable premium. Rebate dollars represent the dollars available for supplemental (and other) benefits when an MA plan's risk-adjusted Part C bid is under the risk-adjusted Part C monthly benchmark amount. *This requirement ensures that MA organizations offer at least one option for Part D coverage for Part D supplemental premium at the cost of basic prescription drug coverage. Of note, Special Needs Plans (SNPs) cannot satisfy this requirement for non-SNPs in the same service area.*

*If an MA parent organization does not offer basic prescription drug coverage through a basic plan type (defined standard, actuarial equivalent or basic alternative) in a given service area, to the extent that an MA-PD plan chooses to provide enhanced alternative coverage **with** no additional premium through the application of rebate dollars, such enhanced alternative coverage*

would constitute required coverage for the purposes of meeting the requirement that an MA organization offer a plan that includes required prescription drug coverage.

In order to help ensure that this requirement is being met, CMS has added two questions in the PBP software for enhanced alternative plans. Sponsors must indicate that they either have another basic (defined standard, actuarially equivalent or basic alternative) Part D plan or that the enhanced alternative plan being submitted meets this requirement because the sponsor has brought down the supplemental Part D premium to zero using the MA rebate dollars.

20.4.5 - Restrictions on the Offering of Enhanced Alternative Coverage by Cost Plan Sponsors

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A cost plan sponsor that elects to offer Part D coverage may do so only if such coverage is provided as an optional supplemental benefit (under 42 CFR 417.440(b)(2)(ii)) and if the coverage it offers consists of qualified prescription drug coverage. However, a cost plan sponsor may instead elect to offer prescription drug coverage that is not qualified prescription drug coverage, and the requirements of Part D would not apply to this coverage. However, a cost plan sponsor may not offer both a Part D and a non-Part D drug benefit as enrollee options under the same contract.

A cost plan sponsor that elects to offer qualified prescription drug coverage under Part D may offer enhanced alternative coverage as an optional supplemental benefit (under 42 CFR 417.440(b)(2)(ii)), but only if the cost plan sponsor also offers basic prescription drug coverage as an optional supplemental benefit.

If offered by a cost plan sponsor, an enrollee in the cost plan may elect to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage. Individuals enrolling in a Part D plan that is offered as an optional supplemental benefit by a cost plan sponsor may do so according to the requirements for enrollment in a PDP contained in chapter 2. As described in section 10 of chapter 2, such an individual must be a member of the cost plan at the time of the effective date of enrollment in the cost plan's optional supplemental Part D benefit. Individuals enrolled in a cost plan who do not elect Part D coverage offered by the cost plan sponsor may elect Part D coverage offered by a PDP sponsor.

20.5 - Coverage Gap Coinsurance

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Under section 1101(b)(3) of the Health Care and Education Reconciliation Act of 2010 (HCERA), which amended section 3301 of the Patient Protections and Affordable Care Act (PPACA), additional coverage of Part D drugs will be phased into the Part D benefit between 2011 and 2020, so that by 2020 the standard prescription drug benefit will cover 75 percent of the cost of non-applicable drugs in the gap and 25 percent of the cost of applicable (brand) drugs for applicable beneficiaries. Section 1860D-2(b)(2) of the Act was amended to add new paragraphs (C)(i) and (ii) that provide gap coinsurance percentages for future years under the

standard prescription drug benefit. The gap coinsurance percentage for covered Part D drugs that are non-applicable is equal to the following:

<i>Year</i>	<i>Coinsurance Percentage</i>
<i>2011</i>	<i>93 percent</i>
<i>2012 through 2019</i>	<i>Previous year coinsurance percentage decreased by 7 percentage points</i>
<i>2020 and thereafter</i>	<i>25 percent</i>

For applicable (i.e., brand) drugs, the gap coinsurance percentage does not get applied until contract year 2013. The gap coinsurance for applicable (brand) drugs is equal to the following:

<i>Year</i>	<i>Coinsurance Percentage</i>
<i>2013 through 2014</i>	<i>97.5 percent</i>
<i>2015 through 2016</i>	<i>95 percent</i>
<i>2017</i>	<i>90 percent</i>
<i>2018</i>	<i>85 percent</i>
<i>2019</i>	<i>80 percent</i>
<i>2020 and thereafter</i>	<i>75 percent</i>

Part D sponsors offering basic Part D plans will include, as part of the bid, the coverage gap coinsurance for all non-applicable drugs on the plan's formulary, or an actuarially equivalent amount using processes and methods specified under section 1860D-11(c) of the Act. The coverage gap coinsurance applies only to applicable beneficiaries who:

- 1) Are enrolled in a prescription drug plan or an MA-PD plan;*
- 2) Are not enrolled in a qualified retiree prescription drug plan;*
- 3) Are not entitled to the Federal subsidy for low-income individuals under section 1860D-14(a) and in Chapter 13 of this Manual;*
- 4) Have reached or exceeded the initial coverage limit;*
- 5) Have not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold; and*
- 6) Have a claim that –*
 - Is within the coverage gap;*
 - Straddles the initial coverage period and the coverage gap;*
 - Straddles the coverage gap and the annual out-of-pocket threshold; or*
 - Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.*

For alternative plans, the coverage gap begins for the purpose of applying the coverage gap coinsurance based on the plan's initial coverage limit (approved as part of the bid) and ends at the point a beneficiary reaches the catastrophic threshold.

20.6 - *Negotiated Prices*

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors must provide enrollees with access to negotiated prices for covered Part D drugs as part of their qualified prescription drug coverage. This access to negotiated prices must be provided even when no benefits are otherwise payable on behalf of an enrollee due to the application of a deductible or other cost-sharing. Negotiated prices will take into account negotiated price concessions for covered Part D drugs that are passed through to enrollees at the point of sale, such as:

- Discounts;
- Direct or indirect subsidies;
- Rebates; and
- Other direct or indirect remunerations

In addition, negotiated prices must include any applicable dispensing fees (discussed in section 20.7).

Although negotiated prices do not have to be made available for drugs that are not covered Part D drugs, they must be made available throughout the benefit – including in any phase of the benefit, such as the deductible, in which an enrollee is responsible for 100 percent cost-sharing – for all covered Part D drugs. Part D sponsors must ensure that their payment systems are set up to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount *in all phases of the benefit*.

Example: A beneficiary's drug is on a \$10 cost-sharing tier. However, the negotiated price of the drug is \$4. The beneficiary never pays more than \$4.

In addition, uniform negotiated prices must be available to plan enrollees for a particular covered Part D drug when purchased from the same pharmacy. In other words, the negotiated price for a particular covered Part D drug purchased at a particular pharmacy must always be the same regardless of what phase of the Part D benefit an enrollee is in. (To the extent that the negotiated price fluctuates based on fluctuations in Average Wholesale Price (AWP), the actual cost to the beneficiary may vary from purchase to purchase; however the negotiated rate, absent any contractual changes in the reimbursement rate between the pharmacy and the Part D sponsor, will remain constant for that drug.)

20.7 - *Dispensing Fees*

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

As discussed in section 20.6, negotiated prices must include any applicable dispensing fees. Provided that Part D sponsors include only those activities allowed under CMS' definition of dispensing fees in the dispensing fees negotiated with network pharmacies and offer standard

contracting terms and conditions to all similarly situated pharmacies, in accordance with section 50.8.1, CMS notes that Part D sponsors have the flexibility to vary the actual dispensing fee paid to pharmacies. For example, Part D sponsors may need to increase the dispensing fees paid to rural or long-term care pharmacies in order to obtain their participation in networks and meet the pharmacy access standards. Table 2 below provides a summary of the costs that may be included in dispensing fees, as well as those that may not.

Table 2
Costs that May and May Not Be Included in Dispensing Fees

<p>Costs That May be Included in Dispensing Fees</p>	<ul style="list-style-type: none"> • Costs that are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed. • Pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. These pharmacy costs include, but are not limited to: <ul style="list-style-type: none"> ○ <i>The salaries of pharmacists and other pharmacy workers;</i> ○ Any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage; ○ Performing quality assurance activities consistent with 42 CFR 423.153(c)(2); ○ Measurement or mixing of the covered Part D drug, including any labor costs associated with mixing a compounded product that contains at least one Part D drug component, as detailed in section 10.4 of chapter 6; ○ Filling the container; ○ Physically providing the completed prescription to the Part D enrollee; ○ Delivery; ○ Special packaging, <i>e.g., assistive technology packaging; and</i> ○ Overhead associated with maintaining the facility and equipment necessary to operate the pharmacy, <i>including costs associated with the acquisition and maintenance of</i>
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technology.

- Reasonable pharmacy costs that are appropriate for the typical beneficiary in that pharmacy setting, for example:
 - Costs associated with postal or freight shipping (to include air courier) to beneficiaries located in remote and frontier areas with limited or no access to roads. While the typical beneficiary served by a retail pharmacy in most areas of the country would not require postage, freight or other transport costs for delivery of drugs, CMS believes that it is reasonable to assume that the typical beneficiary in remote and frontier areas with limited or no access to roads would require delivery of drugs via postal or freight shipping (to include air courier). Because such a circumstance constitutes a distinct pharmacy setting, CMS believes that the costs associated with postal or freight shipping (to include air courier) to such remotely located beneficiaries would constitute reasonable costs that could be reimbursed as part of the dispensing fee negotiated between a Part D sponsor and a contracted network pharmacy.
 - Costs associated with special packaging and delivery for residents of non-LTC facilities (e.g., assisted living facilities and other forms of congregate residential settings) with the same level of care need as residents of LTC facilities. It is reasonable to assume that the typical enrollee residing in a non-LTC facility setting who meets the same level of care need as a beneficiary in an LTC facility would require the provision of dispensing related services such as unit-dose packaging and home delivery that are provided by LTC pharmacies to the residents of LTC facilities. For this reason, CMS believes that non-LTC facilities in which individuals meeting an institutionalized level of care need constitute a distinct pharmacy setting, and one in which specialized services such as specialized packaging and home delivery would be appropriate for Part D sponsors to reimburse LTC pharmacies via the dispensing fee. However, CMS notes that it would not be appropriate for Part D sponsors to reimburse LTC pharmacies for these specialized services for individuals who do not meet an institutionalized level of care need.
 - *With respect to LTC pharmacies, dispensing fees should take into consideration any incremental costs associated*

	<p><i>with any increased number of dispensing events in a billing cycle due to the dispensing methodology used to minimize the dispensing of unused drugs.</i></p> <ul style="list-style-type: none"> ○ <i>Costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in LTC pharmacies when return for credit and reuse is permitted under State law and is allowed under the contract between the Part D sponsors and the pharmacy.</i>
<p>Costs That May Not be Included in Dispensing Fees</p>	<ul style="list-style-type: none"> ● Administrative costs incurred by the Part D sponsor in the operation of the Part D benefit, including systems costs for interfacing with pharmacies. ● Supplies, equipment, and services associated with administration of covered Part D drugs, including those associated with home infusion therapy of covered Part D drugs or with vaccine administration.¹ With the exception of costs associated with vaccine administration, these costs may also not be paid by Part D sponsors through a separate fee or additional compensation to home infusion pharmacies and other providers. Other than medication therapy management programs, medical or clinical services may not be included in administrative fees. In addition, professional services, including those associated with home infusion, may not be included in supplemental Part D benefits. The costs associated with supplies, equipment, and services for home infusion therapy of covered Part D drugs must be paid by either the enrollee or another payer. ● Reasonable pharmacy costs that are not appropriate for the typical beneficiary in that pharmacy setting, for example: <ul style="list-style-type: none"> ○ Home delivery by retail pharmacies, since the typical retail customer does not require home delivery. While it would be appropriate for Part D sponsors to reimburse LTC, mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies, where the term “delivery” would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale. ○ Costs associated with delivery of drugs from manufacturers

¹ The administration of a Part D-covered vaccine is included in the definition of a “Part D drug,” effective January 1, 2008. Consequently, the Part D program covers vaccine administration costs associated with Part D vaccines. For more information, refer to section 10.14 of [chapter 6](#).

or distributors to dispensing pharmacies.

20.8 - *Ensuring Meaningful Differences in Approved Bids* ***(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)***

20.8.1 - *General* ***(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)***

CMS ensures that plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. Specifically, §423.272(b)(3)(i) stipulates that CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure was substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. Section 423.265(b)(2) also requires that Part D sponsors may submit multiple bids in the same area only if the offerings are substantially different from each other.

While CMS supports the concept of a wide variety of prescription drug coverage choices for Medicare beneficiaries, CMS believes it is necessary to ensure that those choices represent *meaningfully* different options in order to simplify beneficiaries' enrollment decision making process. Ensuring that, *within each service area*, PDP sponsors *offer only plan options that are meaningfully* different will maximize opportunities for beneficiaries to select the most appropriate plan for their needs and reduce beneficiary confusion with respect to choices offered by the same Part D sponsor.

To determine whether there are meaningful differences amongst plans offered by the same sponsor, CMS will evaluate and compare plan offerings in a service area by evaluating plan-specific benefit data (e.g., cost sharing, formulary, and benefits) for each offering. CMS will provide additional information regarding our meaningfully different bid evaluation processes in our annual payment notice and call letter prior to the date of plan bid submissions.

20.8.2 - *Meaningful Differences in Basic Prescription Drug Coverage Options* ***(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)***

To determine whether there *are meaningfully* differences between basic prescription drug coverage options (which includes defined standard, actuarially equivalent standard, and basic alternative benefit designs) offered by the same PDP sponsor in a region, CMS' analysis focuses on whether there are significant differences in proposed *beneficiary out-of-pocket costs* and/or formularies. It is important to note that, even though a sponsor may submit different formularies for different Part D offerings, all submitted formularies must be sufficiently robust to pass CMS' rigorous formulary reviews and checks and be determined not to discourage enrollment by certain types of beneficiaries. Based on CMS' experience and given statutory actuarial equivalency requirements, CMS does not expect that – absent substantial differences in approved formularies – PDP sponsors can demonstrate *meaningful* differences between plans offering basic prescription drug coverage. *Therefore, CMS believes sponsors should submit only one basic offering (where basic offering includes defined standard, actuarial equivalent and basic alternative drug benefit types) for a stand-alone prescription drug plan in a service area.*

20.8.3 - Meaningful Differences in Enhanced Alternative Coverage Options (Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

When evaluating for differentiation among an organization's plan offerings, CMS will scrutinize enhanced benefit designs that add little or no additional value to its basic offering. CMS has found that it is difficult for beneficiaries to distinguish between plan offerings of the same sponsor when cost-sharing and premiums are similar between the enhanced and basic drug plan offering. CMS recognizes that sponsors may have purposefully established plan benefit designs to address different utilization patterns among sub-groups of beneficiaries and in order to segment risk. However, CMS is concerned that some "low-additional-value" enhanced offerings are not understood by beneficiaries in terms of expected value and may not be meaningfully different from the basic offering.

CMS will evaluate enhanced plans to identify those enhanced plan offerings with meaningful increases in value over basic plan offerings. CMS will announce its meaningful differences evaluation methodology and expectations for plan sponsors via the annual payment notice and call letter. To prepare for negotiations with CMS, Part D sponsors should consult the annual payment notice and call letter when preparing multiple plan bids for the upcoming plan year.

CMS will request that PDP sponsors with plan benefit packages that are not substantially different from each other either withdraw or enhance a bid in order to ensure that all offerings are, in fact, *meaningfully* different. It is CMS' experience, based on this analysis *that* PDP sponsors typically must offer substantive coverage in the coverage gap as a supplemental benefit in order to demonstrate that one enhanced alternative plan design is *meaningfully* different from another.

20.8.4 - Transition Period for Sponsors or Parent Organizations with New Acquisitions (Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

PDP sponsors or parent organizations with new acquisitions *on or after June 7, 2010*, will be afforded a period of **2** years to transition their plan offerings to meet the goal of ensuring that the Part D sponsor's offerings are substantially different from one another. PDP sponsors that have completed a new acquisition will be expected to submit to CMS a plan that details how the **2** year transition will take place.

Example: A PDP sponsor (or its parent organization) completing an acquisition of another PDP sponsor in November 2010 would not be subject to requirements for offering substantially different bids until the 2013 contract year (that is, bids would be due in June 2011 for the 2012 program year; transition would occur during 2011 and 2012; and the Part D sponsor or parent would need to ensure that in June 2012, when it submits its bids for program year 2013, all of its bids are for substantially different plans).

20.9 - PDP Plan Benefit Package (PBP) Renewal and Crosswalk Guidance (Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

The PDP regions are defined by CMS and consist of one or more entire states (refer to Appendix 2 of this chapter for a map of the 34 PDP regions). Each of a PDP sponsor's PBPs must be offered in at least one entire region. A Part D sponsor's PBP cannot be offered in only part of a region. Note that PDP bidding rules require PDP sponsors to submit bids for PBPs that cover only one PDP region at a time. Therefore, HPMS only allows a PDP sponsor's PBPs to cover one region at a time (e.g., a PDP sponsor offering a "national" PDP would, for purposes of bidding, be said to be offering 34 plans – one in each PDP region – and would submit 34 PBPs).

A PDP sponsor may expand the service area of its offerings by submitting additional bids in the PDP regions the sponsor expects to enter in the following contract year, provided the sponsor submits a PDP Service Area Expansion (SAE) application and CMS approves that application and then approves the sponsor's submitted bids for the new region or regions.

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing of its intent to non-renew by the first Monday in June pursuant to 42 CFR 423.507(a)(2)(i). However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with Chapter 3, PDP Eligibility, Enrollment, and Disenrollment Guidance of this manual and CMS non-renewal and service area reduction guidance.)

There are *six* renewal options for PBPs offered by current PDP sponsors: (1) new plan; (2) renewal plan; (3) consolidated renewal plan; (4) renewal plan with a service area expansion (applicable only to "800 series" employer/union-only group waiver plans, or EGWPs); (5) terminated plan (non-renewal); *and (6) consolidated plans under a parent organization.*

20.9.1 - New Plan

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the PDP sponsor must submit enrollment transactions to the MARx system. No beneficiary notice is required in this case.

20.9.2 - Renewal Plan

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor may retain a current PBP for the following contract year. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP identification number for the following contract year. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the sponsor will not submit enrollment transactions for existing members. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) (described in chapter 2 of this manual) which will include any changes to the renewing plan. Based on their review of the ANOC, beneficiaries may elect another plan offered by either the same or another PDP sponsor or MA organization during the Annual Coordinated Election Period.

When renewing a PBP, it is permissible to make the following benefit design changes: (1) from a basic benefit design (meaning a defined standard, actuarially equivalent standard, or basic alternative benefit design) to another basic benefit design; or (2) from an enhanced alternative benefit design to a basic benefit design. As a general matter, CMS will not permit renewal of a PBP through the HPMS Plan Crosswalk when it involves moving enrollees from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

20.9.3 -Consolidated Renewal Plan

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

PDP sponsors are permitted to combine two or more PBPs offered in the current contract year into a single renewal plan so that all enrollees in the combined plans are offered the same benefits under one PBP in the following contract year. When consolidating two existing PBPs into a single renewal PBP, it is permissible for the single renewal PBP to result in a change from:

- (1) a basic benefit design (meaning a defined standard, actuarially equivalent standard, or basic alternative benefit design) to another basic benefit design;
- (2) an enhanced alternative benefit design to a basic benefit design; *or*
- (3) *an enhanced alternative benefit design to another enhanced alternative benefit design.*

Again, as a general matter, CMS will not permit consolidation of two existing PBPs into a single renewal PBP through the HPMS Plan Crosswalk when it involves a change from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

PDP sponsors combining two or more PBPs into a single renewal PBP must designate which of the consolidating plans will be retained in the following contract year after consolidation; that is, the sponsor's designated renewal plan ID must remain the same in order for CMS to consolidate the beneficiary's election by moving him or her into the designated renewal plan ID. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees. Enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions for existing members, though it may need to submit updated 4Rx data (described in chapter 14 *of this manual*) for the enrollees affected by the consolidation to CMS. The PDP sponsor will be responsible for sending a standard ANOC to any enrollees whose current plans are being consolidated into a renewal plan. Based on their review of the ANOC, beneficiaries whose enrollment has been consolidated into a renewal PBP may then elect another plan offered by either the same or another PDP sponsor or MA organization during the Annual Coordinated Election Period.

20.9.4 -Renewal Plan with a Service Area Expansion (800 Series EGWPs only)
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor offering an 800 series EGWP PBP in the current contract year may expand its EGWP service area to include additional PDP regions for the following contract year. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP identification number for the following contract year. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the sponsor will not submit enrollment transactions for existing members. New enrollees must complete an enrollment election. Current enrollees of a renewed 800-series PBP must receive a standard ANOC notifying them of any changes to the renewing plan.

20.9.5 - Terminated Plan (Non-Renewal)
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor may elect to terminate a current PBP for the following contract year. In this situation, the sponsor will not submit disenrollment requests for affected enrollees. To the extent that affected enrollees elect to enroll in a PBP offered by the current or another PBP sponsor, they must complete an enrollment request, and the enrolling sponsor must submit enrollment transactions so that those individuals are enrolled in the PBP *they have* selected. Enrollees of terminated PBPs will be sent a termination notice and will receive a written description of options for obtaining prescription drug coverage in their service area. For more information about non-renewal processes and beneficiary notification requirements, refer to the annual summer HPMS memo providing non-renewal and service area reduction guidance.

20.9.6 - Consolidated Plans Under a Parent Organization
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

For purposes of ensuring compliance with transition requirements following an acquisition or merger under CMS' meaningful differences policy, or to make plan transitions following a novation, a plan sponsor may elect to combine two or more entire PBPs offered under different contracts (the contracts may be offered by the same legal entity or represent different legal entities). PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. A PDP sponsor must complete and submit a request to CMS in accordance with its annual renewal/non-renewal guidance.

Current enrollees of a plan or plans being consolidated across contracts in this manner will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to CMS for those new enrollees. Current enrollees of a consolidated renewal plan must receive a special notification along with a standard ANOC.

20.10 - Low-Enrollment Plans
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

CMS will use its authority under section 1857(c)(2)(B) of the Act, as incorporated by reference for Part D at section 1860D-12(b)(3)(B) and codified in 42 CFR §423.507(b)(1)(iii), to non-renew plans at the benefit-package level that do not have sufficient number of enrollees after a specified length of time to establish that they are viable plan options, because, as a general matter, continuing low enrollment plans is not consistent with the effective and efficient administration of the Medicare program. Consistent with that authority, CMS will be scrutinizing low-enrollment plans during the bid review period and alerting sponsors of low-enrollment plans that CMS expects them to withdraw or consolidate prior to submitting bids for the next calendar year. Before CMS would take any action to non-renew a plan pursuant to 42 CFR §423.507(b)(1)(iii), CMS would take into account all relevant factors.

CMS' scrutiny of low-enrollment plans will not apply to employer stand-alone Part D plans. At this time, a waiver of the minimum enrollment requirements at 42 CFR 423.512(a) (minimum enrollment requirements) for sponsors of employer group applies.

20.11 - Manufacturer Drug Discount Program

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Beginning January 1, 2011, discounts were available to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. Generally, the discount on each applicable drug is 50% of the negotiated price (excluding dispensing fee). An applicable drug is covered under Part D only if the manufacturer has signed agreement with CMS to provide the discount on coverage gap claims for all of its applicable drugs and remains compliant with the terms of the agreement (assuming all other coverage criteria are met). Part D sponsors provide the discounts for applicable drugs in the coverage gap at the point-of-sale. A CMS contractor will coordinate the collection of discount payments from manufacturers and payment to Part D sponsors.

For additional details regarding the policies, and administration of, the Manufacturer Drug Discount program as it evolves, Part D sponsors should consult HPMS.

30 - Incurred/ "True Out-of-Pocket" (TrOOP) Costs

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Not all enrollee out-of-pocket expenditures are considered incurred (or "true-out-of-pocket," or TrOOP, expenditures) for purposes of applicability toward beneficiary spending against the annual out-of-pocket threshold described in section 20.3.1. Sections 30.1 and 30.2 provide further detail on whether certain expenditures are TrOOP-eligible or not, and Table 3 provides a summary of those discussions.

30.1 - Costs that Count as Incurred Costs

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Costs are considered incurred costs and can be added to an enrollee's TrOOP balance if **all** of the following conditions are met:

1. Costs are incurred against any annual deductible, any applicable cost-sharing for costs above the deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the annual out-of-pocket threshold.
2. Costs are incurred with respect to covered Part D drugs that are either included in a PDP or MA-PD plan's formulary or treated as being included in a plan's formulary as a result of a coverage determination, redetermination, or appeal under [chapter 18](#).
3. Costs are:
 - Incurred by the enrollee;
 - Incurred by another person (including charities, if they are not otherwise excluded as TrOOP-eligible payers as provided in section 30.2) on behalf of the enrollee other than costs reimbursed by a group health plan, insurance or otherwise (including a government-funded health program), or another third party payment arrangement;
 - Paid by Medicare on behalf of a low-income individual under the Part D subsidy provisions described in [42 CFR 423.782](#);
 - *Discounts paid by manufacturers as part of the Medicare Coverage Gap Discount program;*
 - Paid on behalf of the enrollee under a qualified State Pharmaceutical Assistance Program (SPAP) described in [42 CFR 423.454](#).
 - *Paid by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); and*
 - *Paid by AIDS Drug Assistant Program (ADAP) under Part B of title XXVI of the Public Health Service Act.*
4. Costs are incurred at a network pharmacy or an out-of-network (OON) pharmacy, consistent with the sponsor's out-of-network access policy (refer to section 60 for more information on out-of-network access requirements).

Following are examples of costs considered incurred costs for purposes of TrOOP calculations:

Example 1: Any differential charged to a beneficiary between a network retail pharmacy's contracted rate and a network mail-order pharmacy's contracted rate for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy, as described in section 50.10.

Example 2: For a covered Part D drug obtained OON consistent with the sponsor's OON policy, any differential charged to the beneficiary between an OON pharmacy's usual and

customary price for the covered Part D drug and the plan allowance for that covered Part D drug.

Example 3: As provided in section 50.4.2 of [chapter 14](#), costs incurred by enrollees by using a discounted cash price, and not their Part D benefit, provided the purchase is for a covered Part D drug; the purchase is made at a network pharmacy; the discounted cash price is lower than the negotiated price offered by the enrollee's Part D plan; the enrollee is in any applicable deductible or coverage gap phase of his or her benefit; and the enrollee submits appropriate documentation to his or her Part D plan to be credited for the purchase.

Example 4: Covered Part D drug cost-sharing waived or reduced by a pharmacy that is not a group health plan, insurance, government-funded health program, or party to a third party payment arrangement with an obligation to pay for covered Part D drugs, as described in section 30.4.

30.2 - Costs that Do Not Count as Incurred Costs

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

The following are not considered incurred costs and cannot be added to an enrollee's TrOOP balance:

1. Costs for non-formulary Part D drugs unless treated by the Part D sponsor as being included in the sponsor's formulary as a result of a coverage determination, redetermination, or appeal as described in [chapter 18](#).
2. Costs for non-Part D drugs, as described in section 20.1 of [chapter 6](#).
3. Costs paid for covered Part D drugs obtained out-of-network when OON access is not consistent with the OON access policy (refer to section 60 for more information on OON access requirements).
4. Costs that are paid for or for which an enrollee is reimbursed by insurance or otherwise, including a government-funded health program.²
5. Costs that are paid for or for which an enrollee is reimbursed by a group health plan.
6. Costs that are paid for or for which an enrollee is reimbursed by another third party payment arrangement.
7. Covered Part D drug cost-sharing waived or reduced by a pharmacy that is also a TrOOP-ineligible payer, as described in section 30.4.

² If an entity providing for or paying the cost of drugs receives a government grant none of which is used to pay for drugs (for example, a low-income housing grant), such an entity is not considered a government-funded health program. If an entity pays for Part D drugs using a mix of private and public funds, the entity is considered a government-funded health program, and all its drug spending is excluded from TrOOP.

Table 3
Costs that Do and Do Not Count Toward TrOOP Expenditures

<p>Costs that Count Toward Incurred / TrOOP Expenditures</p>	<ol style="list-style-type: none"> 1. Costs that are incurred against any annual deductible, any applicable cost-sharing for costs above the deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the annual out-of-pocket threshold; AND 2. Costs that are incurred with respect to covered Part D drugs that are either included in a prescription drug plan or MA-PD plan’s formulary or treated as being included in a plan’s formulary as a result of a coverage determination, redetermination, or appeal under chapter 18; AND 3. Costs that are: <ul style="list-style-type: none"> ○ Incurred by the enrollee; ○ Incurred by another person on behalf of the enrollee other than costs reimbursed by a group health plan, insurance or otherwise (including a government-funded health program), or another third party payment arrangement; ○ Paid by Medicare on behalf of a low-income individual under the Part D subsidy provisions described in 42 CFR 423.782; ○ <i>Discount paid by a manufacturer as part of the Medicare Coverage Gap Discount program;</i> ○ Paid on behalf of the enrollee under a qualified State Pharmaceutical Assistance Program (SPAP) described in 42 CFR 423.454; ○ <i>Paid by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or</i>
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	<ul style="list-style-type: none"> ○ <i>Paid by AIDS Drug Assistance Program (ADAP) under Part B of title XXVI of the Public Health Service Act.</i> <p>4. Costs that are incurred at a network pharmacy or an OON pharmacy, consistent with the sponsor’s OON access policy (refer to section 60 for more information on OON access requirements).</p>
<p>Costs that Do Not Count Toward Incurred / TrOOP Expenditures</p>	<ol style="list-style-type: none"> 1. Costs incurred for non-formulary Part D drugs unless treated by a sponsor as being included in the sponsor’s formulary as a result of a coverage determination, redetermination, or appeal. 2. Costs incurred for non-Part D drugs. 3. Costs paid for covered Part D drugs obtained OON when such OON access is inconsistent with the sponsor’s OON access policy. 4. Costs paid for or reimbursed by insurance. 5. Costs paid for or reimbursed by a government-funded health program. 6. Costs paid for or reimbursed by a group health plan. 7. Costs paid for or reimbursed by another third party payment arrangement. 8. Covered Part D drug cost-sharing waived or reduced by a pharmacy that is also a TrOOP-eligible payer, as described in section 30.4.

30.3 - Summary of TrOOP-Eligible and TrOOP-Ineligible Payers

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D enrollees may have coverage or receive assistance from any of a number of entities that wrap around the benefits available under Part D. As described in sections 30.1 and 30.2 above, this wrap-around assistance or coverage may or may not count as incurred costs. Table 4 below provides plans with information about whether specific entities are “TrOOP-included,” meaning that their wrap-around assistance counts as an incurred cost, or “TrOOP-excluded,” meaning that their wrap-around assistance does not count as an incurred cost.

Table 4
Examples of TrOOP-Excluded and TrOOP-Included Entities

TrOOP-Excluded Entities	TrOOP-Included Entities
<ul style="list-style-type: none"> • Medicaid (even when using State-only funds) • Medicaid 1115 demonstrations • State Children’s Health Insurance Program (SCHIP) • Federally Qualified Health Centers (FQHCs), Rural Health Clinics, and any safety-net facilities including public hospital systems, community hospitals, and local health departments that are considered “government-funded health programs” • Patient assistance programs (PAPs) operating outside the Part D benefit • TRICARE • Federal Employee Health Benefits Program (FEHBP) plans • Black Lung Funds • State programs that do not meet the definition of a qualified SPAP in 42 CFR 423.464. • Health reimbursement arrangements (HRAs) 	<ul style="list-style-type: none"> • State Pharmaceutical Assistance Programs (SPAPs) • Most charities (unless established, maintained, or otherwise controlled by an employer or union) • <i>Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act)</i> • <i>AIDS Drug Assistance Program (ADAP) under Part B of title XXVI of the Public Health Service Act</i> • Health savings accounts (HSAs) • Flexible spending accounts (FSAs) • Medical savings accounts (MSAs)

The term “incurred costs” is only defined with respect to the annual out-of-pocket threshold. Therefore, any coverage that supplements the benefits available under basic prescription drug coverage may be counted toward any applicable deductible even though such drug coverage is excluded from the definition of incurred costs for purposes of TrOOP accounting.

30.4 - Pharmacy Waiver/Reduction of Cost-Sharing and Applicability Toward TrOOP

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Pharmacies are permitted to waive or reduce Part D cost-sharing amounts, provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing for beneficiaries eligible for the low-income subsidy, provided the pharmacy has not advertised that the waivers or reductions of cost-sharing are available. In other words, for low-income subsidy recipients only, pharmacies may provide routine waivers or reductions of cost-sharing amounts and need not ascertain financial need. However, the pharmacies will not be eligible for safe harbor protection if they advertise in any way the availability of waivers or cost reductions.

Waivers or reductions of Part D cost-sharing by pharmacies will generally count toward TrOOP, *as will payments made by AIDS Drug Assistance Program (ADAP) under Part B of Title XXVI of the Public Health Service Act, as well as payments made by the Indian Health Service (IHS), an Indian tribe or tribal organizations, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act).* However, *in all other instances*, to the extent that the party paying for cost-sharing on behalf of a Part D enrollee is a group health plan, insurance, government-funded health program, or party to a third party payment arrangement with an obligation to pay for covered Part D drugs, that party's payment will not count toward TrOOP.

Payments made for beneficiary cost-sharing by any entity – including a safety-net pharmacy – that has an obligation to pay for covered Part D drugs on behalf of Part D enrollees, or which voluntarily elects to use public funds, in whole or in part, for that purpose, will not count toward that beneficiary's TrOOP expenditures. Safety-net pharmacies typically include Federal, State, and locally supported community health centers or clinics – many of which are deemed FQHCs – public hospital systems, and local health departments. In some communities, they also include mission-driven teaching hospitals, community hospitals, and ambulatory care clinics. Rural health clinics (RHCs), small rural hospitals, critical access hospitals, clinics that receive Ryan White HIV/AIDS grant funding, and nurse managed clinics are also key components of the safety-net. An estimated 12,000 safety-net providers participate in the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program, which allows them to purchase their prescription drugs at significantly discounted prices. Participation in the 340B Drug Pricing Program can enable safety-net pharmacies to provide prescriptions to their patients at lower-than-market prices.

Disproportionate Share Hospitals (DSH) may also be TrOOP-excluded entities. Receipt of Medicaid or Medicare DSH payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a "government-funded health program." CMS views Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services. However, any program that is operated or funded, in whole or in part, by any government agency, and which uses public funds in whole or in part, to provide to (or pay on behalf of an individual) the costs of Part D drugs is a government-funded health program even if it pays these costs using a mix of private and public funds. An entity that receives DSH funds and uses non-

DSH government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs will meet CMS' definition of a government-funded health program, and any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee's TrOOP balance.

Similarly, participation in the 340B Drug Pricing Program does not in and of itself render a safety-net pharmacy a government-funded health program. However, as with DSH facilities, any use of government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs will render a safety-net pharmacy a government-funded health program such that any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee's TrOOP balance.

However, if an entity can demonstrate to a Part D sponsor that it uses only non-public funds to pay for the cost of Part D drugs, that sponsor may allow for cost-sharing waivers or reductions in cost-sharing paid for by that entity's pharmacies to count toward TrOOP. Part D sponsors remain ultimately accountable for correctly tracking their enrollees' TrOOP expenditures.

If, on the other hand, a pharmacy funds Part D cost-sharing waivers using a mix of private and public funds, the pharmacy is considered a government-funded health program, and all its drug spending is excluded from TrOOP. If a pharmacy is a government-funded health program or other TrOOP-ineligible payer and waives or reduces any applicable Part D enrollee cost-sharing after payment of a claim by the Part D sponsor, that claim must be flagged so that any applicable beneficiary cost-sharing that is waived or reduced by the pharmacy is not added to a beneficiary's TrOOP balance. Currently, there does not exist any capability under the National Council for Prescription Drug Programs (NCPDP) 5.1 transaction set for pharmacies to indicate a pharmacy's waiver or reduction of any applicable beneficiary cost-sharing so that such subsidies are not applied to the beneficiary's TrOOP balance. CMS recommends that Part D sponsors set up manual processes with safety-net pharmacies in their networks in order to accurately maintain beneficiary TrOOP balances.

40 - Prescription Drug Plan Service Areas

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Prescription drug plan regions are areas in which a contracting PDP sponsor must provide access to covered Part D drugs. The service area for a PDP, with the exception of a fallback plan, consists of one or more PDP regions. A PDP sponsor may offer a PDP in more than one region – including in all PDP regions – so long as coverage is provided in all those regions in their entirety. However, the PDP sponsor must submit separate bids for its coverage in each region of its service area.

There are currently 34 PDP regions and 26 MA regions (refer to Appendix 2 and Appendix 3, respectively, for maps of these PDP and MA regions). Each of the five U.S. Territories – American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands – constitutes an additional PDP region. *While* these regional boundaries are currently in effect, CMS may revise both the PDP and MA regions in future years.

50 - Access to Covered Part D Drugs

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Part D sponsors must establish a pharmacy network sufficient to ensure access to covered Part D drugs for their enrollees. As detailed below, Part D sponsors must demonstrate that they provide: (1) convenient access to retail pharmacies for all enrollees; (2) adequate access to home infusion pharmacies for all enrollees; (3) convenient access to LTC pharmacies for enrollees residing in LTC facilities; and (4) convenient access to I/T/U pharmacies for American Indian/Alaska Native (AI/AN) enrollees. Except as indicated in section 50.3 for limited access drugs, covered Part D drugs must be accessible to enrollees through network pharmacies through all phases of the Part D benefit.

Sponsors or their pharmacy benefits manager (PBM) should maintain a contracting log documenting their efforts to provide standard terms and conditions to prospective network pharmacies as well as any contracting negotiations between the sponsor or PBM and prospective network pharmacies. This contracting log will help CMS in its efforts to ensure compliance with pharmacy access requirements, including the any willing pharmacy requirement described in section 50.8.1.

After their initial pharmacy access submissions are approved, Part D sponsors must notify their CMS account manager of any substantive change in their pharmacy network that may impact their ability to maintain a Part D pharmacy network that meets CMS' requirements. Substantive changes to a pharmacy network include, but are not limited to:

- An inability to meet the convenient access standard for retail pharmacies, as described in section 50.1;
- An inability to provide adequate access to home infusion drugs to enrollees within 24 hours of discharge from an acute setting, as described in section 50.4;
- An inability to provide an enrollee residing in an LTC facility convenient access to a network LTC pharmacy that serves the LTC facility, as described in section 50.5.1; or
- Not offering Part D contracts to all I/T/U pharmacies in a Part D sponsor's service area in order to provide convenient access for AI/AN enrollees, as described in section 50.6.

Part D sponsors will be required to provide CMS with data on an annual basis that will allow CMS to determine whether their retail, home infusion, and LTC pharmacy networks continue to meet CMS' pharmacy access standards. For more information about these reporting requirements, refer to:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage

A Part D sponsor must notify CMS when it changes PBMs to manage its pharmacy network mid-year. Specifically, the sponsor must:

- Notify their CMS account manager at least 60 days prior to the effective date of the new contract or the date the new PBM would begin providing services to beneficiaries, whichever is earlier. In instances of a contractual change occurring within less than 60 days, then the Part D sponsor must notify their account manager within 5 days of signing the new contract.
- Ensure the change includes an internal transition period, as any decision to change PBMs during the last quarter of the contract year may cause disruption to beneficiary access and services.
- Make preparations to submit appropriate documentation, upon request, to CMS Central Office at any time after the date the contract takes effect (targeted audit). Such documentation may include but not be limited to:
 - Executed PBM contract
 - Retail pharmacy contract template
 - Mail order pharmacy contract template
 - Home infusion pharmacy contract template
 - LTC pharmacy contract template
 - I/T/U pharmacy contract template
 - Up-to-date Part D pharmacy network listings
 - Up-to-date Part D geo-access reports

50.1 - Retail Pharmacy Access

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors must secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees. CMS convenient access rules require Part D sponsors to establish pharmacy networks in which:

- In urban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live within 2 miles of a retail pharmacy participating in the sponsor's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service areas, on average, live within 5 miles of a retail pharmacy participating in the sponsor's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live within 15 miles of a retail pharmacy participating in the sponsor's network.

The convenient access standards will be applied to different types of Part D sponsors as follows:

- Regional MA-PD and PDP sponsors: Must meet or exceed the convenient access standards across urban, suburban, and rural areas, respectively, in each State in which they operate. To the extent that a regional MA-PD or PDP sponsor operates in a multi-region or national service area, it will be required to meet the convenient access standards in each State in that multi-region or national service area; the sponsor may not meet the convenient access standards by applying those standards across the entire multi-State geographic area it services.
- Local-MA-PD sponsors: Must meet or exceed the convenient access standards across urban, suburban, and rural areas, respectively, in each service area (including multi-county service areas) in which they operate.
- Cost plans: Must meet or exceed the convenient access standards across urban, suburban, and rural areas, respectively, in each geographic area in which they operate.

Part D sponsors may count I/T/U pharmacies and pharmacies operated by FQHCs and RHCs toward the standards for convenient access to retail pharmacies detailed above. However, CMS will review Part D sponsors' pharmacy network submissions to ensure that inclusion of I/T/U, FQHC, and RHC pharmacies in contracted pharmacy networks does not substitute for the inclusion in Part D plan networks of retail pharmacies.

CMS is aware that there may be some areas of the country in which meeting the rural access standard, in particular, will be impossible or impracticable given the lack of pharmacy infrastructure. CMS will consider modifications to the rural access standard in cases in which Part D sponsors can demonstrate that meeting the standard is impossible or impracticable given a lack of infrastructure.

50.2 - Mail-Order Pharmacy Access

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

The inclusion of mail-order pharmacies in Part D plan networks is optional. However, network mail-order pharmacies will not count toward meeting the retail pharmacy access requirements specified in section 50.1. Since network inclusion of mail-order pharmacies is optional, sponsors may designate a subset of formulary drugs (e.g., particular tiers or "maintenance drugs" only) for availability via network mail-order pharmacies. As described in section 50.10, to the extent that a Part D plan offers benefits, including extended supplies of drugs (e.g., 90-day supplies), through network mail-order pharmacies, the plan must ensure that enrollees have reasonable access to the same benefits at network retail pharmacies. *CMS recognizes that some pharmacies may utilize common carriers in order to meet the needs of their patients, such as Part D enrollees residing in LTC facilities or in remote areas. A pharmacy that makes some, but not predominantly all, deliveries by common carrier is not a mail order pharmacy.*

50.3 - Limited Access Drugs and "Specialty" Pharmacies

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Part D sponsors may not limit access to certain Part D drugs to "specialty" pharmacies within their Part D network in such a manner that contravenes the convenient access protections

described in section 50.1. In other words, limited access to a Part D drug may not be based solely on the placement of a Part D drug in a specialty or high-cost tier because this tier placement alone is not indicative of any special requirements associated with such drug.

Part D sponsors may only restrict access to Part D drugs to a subset of their network pharmacies for the following reasons:

1. The FDA has restricted distribution of the drug to certain facilities or physicians; or
2. Appropriate dispensing of the Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.

Additional education or counseling alone does not qualify a drug for limited distribution within the overall pharmacy network.

Part D sponsors may specify, on a drug-by-drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. These drug-by-drug requirements should only apply to special handling and dispensing that may be required for a particular “specialty” drug and not to reimbursement or other standard contracting terms and conditions. Offering pharmacies unreasonably low reimbursement rates for certain “specialty” drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18).

In addition, Part D sponsors may not require network pharmacies to qualify as a “specialty” pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question. The convenient access standards dictate that “specialty” pharmacies be used to supplement network pharmacy access when necessary and not otherwise restrict it.

If a Part D sponsor finds it necessary to restrict access to a Part D drug for either of the two reasons listed above, it must indicate this on the formulary information page in the Formulary Submission module, as well as identifying these drugs in the formulary flat file. Additionally, Part D sponsors must be prepared to provide CMS with documentation substantiating the limited access drug criteria.

50.4 - Home Infusion Pharmacy Access

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

In order to meet the requirements for adequate access to home infusion pharmacies, Part D sponsors must deliver home infusion drugs to enrollees within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge. To ensure Part D sponsors can provide such access, as part of their initial pharmacy access submissions, and through Part D annual reporting requirements (Information Collection Requirements (ICF) OMB 0938-0992), each Part D sponsor must provide a list of all contracted home infusion pharmacies licensed/legally able to serve in all State(s) and/or territories in the service area under each CMS pending contract number. The

pharmacy list must be submitted using the CMS template, which includes NCPDP/National Provider Identifier, pharmacy name, address, and all States and/or territories licensed in/legally able to serve.

CMS conducts an outlier analysis using these home infusion pharmacy network submissions to evaluate the robustness of home infusion pharmacy networks of all active Part D sponsors. As part of the Part D application, initial applicants to the Part D drug benefit program must demonstrate access through submission of their home infusion pharmacy networks, which must be no less robust than these outlier levels for their pending service area(s) as identified in Appendix *I*. CMS will evaluate access for existing sponsors through a modified outlier approach which looks at both the number of pharmacies relative to the established outlier level combined with evidence that the existing sponsor is meeting the 24 hour delivery standard for its enrollees.

Network robustness is assessed within contract types (e.g., PDP, Regional Prospective Payment Organization or RPPO, and MA-PD). Outliers are those contracts that are in the lowest 25th percentile in terms of the number of contracted home infusion pharmacies within a given state. In other words, 75 percent of all similarly-situated Part D sponsors have a more robust home infusion pharmacy network than the outliers in the lowest 25th percentile. For organizations whose service area comprises an entire state, Appendix *I* provides the minimum number of home infusion pharmacies required to surpass the 2010 Reporting Requirement and 2011 Part D Application outlier level. Organizations operating in a service area smaller than an entire state may use the provided ratios of the number of home infusion pharmacies to the number of beneficiaries in the state and apply it to the number of beneficiaries in the organization's service area to calculate the minimum required number of home infusion pharmacies for that particular service area.

CMS does not expect Part D sponsors to provide or pay for supplies, equipment, or the professional services needed for home infusion therapy. Part D sponsors' contracted network pharmacies must be able to:

- Deliver home infused drugs in a form that can be easily administered in a clinically appropriate fashion;
- Provide infusible Part D drugs for both short-term acute care and long-term chronic care therapies;
- Ensure that the professional services and ancillary supplies necessary for the provision of home infusion therapy are in place before dispensing home infusion drugs, consistent with the quality assurance requirement for Part D sponsors described in [42 CFR 423.153\(c\)](#); and
- Provide covered home infusion drugs within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge.

While Part D sponsors remain ultimately responsible for complying with all Part D requirements, they are also permitted to delegate their responsibilities to plan contractors, such as network pharmacies. Part D sponsors may contractually delegate the responsibility for ensuring timely delivery of home infusion drugs to their network pharmacies provided they meet the

requirements of [42 CFR 423.505\(i\)](#) regarding relationships with pharmacies or other providers, related entities, contractors, subcontractors, and first tier and downstream entities.

50.5 - Long-Term Care (LTC) Pharmacy Access

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

As described in section 50.5.1, Part D sponsors must demonstrate that their contracted pharmacy network provides convenient access to LTC pharmacies for enrollees who reside in an LTC facility. Part D sponsors must offer standard LTC pharmacy network contracts to all LTC pharmacies operating in their service area that request such contracts. These standard contracting terms and conditions must include the performance and service criteria for LTC pharmacies specified in section 50.5.2 below.

50.5.1 - Convenient Access to LTC Pharmacies

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Part D sponsors will be required to offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting the performance and service criteria in section 50.5.2 (and relevant State laws governing the practice of pharmacy in the LTC setting), as well as any other standard terms and conditions established by the Part D sponsor for its network LTC pharmacies (NLTCPs). Once a Part D sponsor has negotiated an agreement with an LTC pharmacy, the LTC pharmacy becomes an NLTCP and is eligible to serve the sponsor's enrollees who reside in LTC facilities.

CMS expects that each LTC facility will select one or possibly more than one eligible NLTCP to provide Medicare drug benefits to its residents. A facility can continue to contract exclusively with a single LTC pharmacy if it chooses; however, the features to promote competition described above will likely give each facility access to a broader range of potential LTC pharmacies than was the case before the implementation of the Part D benefit. An NLTCP that serves a particular LTC facility must provide the same services, as delineated in its contract with a Part D sponsor, to all of that sponsor's enrollees who reside in that LTC facility.

Part D sponsors may not rely on OON access to meet the LTC convenient access standard. All of a Part D sponsor's enrollees who reside in an LTC facility must be able to routinely receive their Part D benefits through the plan's network of LTC pharmacies in order for a Part D sponsor to be in compliance with CMS' LTC convenient access standard.

In addition, Part D sponsors may not rely upon beneficiary special enrollment periods (SEPs) to circumvent the LTC convenient access requirement. Although individuals moving into, residing in, or moving out of an institution are entitled to an SEP, and dually eligible individuals are entitled to an ongoing SEP for as long as they are eligible for Medicaid benefits, it is not acceptable for Part D sponsors to rely on this beneficiary option in lieu of contracting with a sufficient number of pharmacies to ensure that a beneficiary can remain in his or her current plan for as long he or she resides in an LTC facility in the Part D sponsor's service area. Ultimately, all beneficiaries – including those who reside in LTC facilities – should have available to them the full array of plans operating in their area.

Part D sponsors must demonstrate that they have a network of contracted LTC pharmacies that provide convenient access to LTC pharmacies for enrollees who reside in LTC facilities. In order to demonstrate convenient access to LTC pharmacies, Part D sponsors must include, as part of their initial pharmacy access submissions, a list of all contracted LTC pharmacies. In addition, Part D sponsors are required to submit an updated list of all contracted LTC pharmacies as part of the annual Part D reporting requirements developed in accordance with 42 CFR 423.514 and OMB 0938-0992.

CMS will evaluate whether Part D sponsors provide convenient access to LTC pharmacies through analysis of these submissions. Specifically, CMS will use these lists to verify that Part D sponsors have contracts in place with LTC pharmacies that serve the LTC facilities where their beneficiaries reside. Part D sponsors should have processes in place to ensure beneficiaries residing in LTC facilities are being served by an LTC network pharmacy.

CMS expects LTC pharmacy contracting activity will be ongoing as Part D sponsors continue to identify LTC facilities and LTC pharmacies, and as they examine their auto-enrollment assignments and incoming enrollments. To the extent that a beneficiary is enrolled in a Part D sponsor's plan that does not have a contract with an LTC pharmacy that can serve the LTC facility in which he or she resides, the appropriate action for a Part D sponsor to take is to contract with the facility's contracted LTC pharmacy or – if that pharmacy will not sign a contract – with another LTC pharmacy that can serve that facility. In some cases, a retroactive contract may be necessary.

50.5.2 - Performance and Service Criteria for Network Long-Term Care Pharmacies (NLTCPs)

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

In order to participate in Part D sponsor LTC pharmacy networks, a pharmacy must be capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting), as well as any other standard terms and conditions established by the Part D sponsor for its network pharmacies. The following minimum performance and service criteria for pharmacies providing LTC services are based on widely used best practices in the market. These performance and service criteria must be incorporated into an addendum to a Part D sponsor's standard network contract for those pharmacies that would like to be designated NLTCPs.

1. **Comprehensive Inventory and Inventory Capacity** – NLTCPs must provide a comprehensive inventory of plan formulary drugs commonly used in the long-term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by Federal and State law for controlled substances. This is not to be interpreted as requiring the pharmacy to have inventory or security measures outside of the normal business setting.
2. **Pharmacy Operations and Prescription Orders** – NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to

routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff are proficient in the NLTCP's processes for ordering and receiving of medications. NLTCPs must be responsible for return for destruction and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.

3. **Special Packaging** – NLTCPs must have the capacity to provide specific drugs in units of use packaging, bingo cards, cassettes, unit dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to, or arrangements with, a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.
4. **IV Medications** – NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.
5. **Compounding/Alternative Forms of Drug Composition** – NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.
6. **Pharmacist On-call Service** – NLTCPs must provide on-call, 24-hour-per-day/7-day-a-week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.
7. **Delivery Service** – NLTCPs must provide for delivery of medications to the LTC facility up to 7 days each week (up to 3 times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCPs must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP delivery of medication to carts is a part of routine “dispensing.”

8. **Emergency Boxes** – NLTCPs must provide “emergency” supply of medications as required by the facility in compliance with State requirements.
9. **Emergency Log Books** – NLTCPs must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident’s medication order and drug administration.
10. **Miscellaneous Reports, Forms and Prescription Ordering Supplies** – NLTCPs must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.

To qualify as an LTC pharmacy for a Part D sponsor’s LTC pharmacy network, a pharmacy must currently have the capacity – either by itself or through subcontracts with other entities – to meet all these performance and service criteria, even if an LTC facility that pharmacy serves does not need a particular service subsumed under those performance and service criteria. Pharmacies subcontracting with other entities to meet the performance and service criteria must ensure that they comply with all relevant Part D requirements, including all performance and service criteria for the provision of LTC pharmacy services. However, it will ultimately be up to LTC facilities and their contracted LTC pharmacy(ies) to determine which of these specific items or services a nursing facility needs. In other words, an LTC pharmacy must be capable of meeting all the aforementioned performance and service criteria at the time it contracts with a Part D sponsor, but it will not be required to provide all those services to LTC facilities if those facilities do not have a need for those certain services.

These performance and service criteria are not intended to be exclusive or exhaustive. Rather, they are intended to be minimum requirements for becoming an NLTCP. While payment terms for LTC pharmaceutical and dispensing services are subject to negotiations between the Part D sponsor and its NLTCPs, CMS notes that payment to LTC pharmacies under Part D may only cover drug ingredient costs and dispensing fees as defined in section 20.6. Specialized services provided in the administration of drugs after they are dispensed and delivered from the LTC pharmacy are specifically not covered by the Part D benefit.

50.5.3 - Other LTC Contracting Terms and Conditions and Uniformity of Benefits

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Outside of the minimum performance and service criteria, Part D sponsors and pharmacies may propose a number of contracting terms and conditions. With rare exceptions, CMS does not generally involve itself in determining whether standard contracting terms and conditions are “reasonable and relevant,” since these are fact-specific questions that are best left between negotiating parties. Thus, for example, CMS generally does not opine on contracting terms and conditions associated with compensation, billing, and business practices provided such terms and conditions are consistent with explicit Part D statutory and regulatory requirements.

LTC pharmacies may propose other terms and conditions in their negotiations with Part D sponsors as additional beneficiary protections. Such additional terms and conditions may be problematic because they explicitly conflict with statutory and/or regulatory requirements for the Part D program. Some of these proposed contracting terms and conditions not only conflict with CMS rules, but could even be harmful to beneficiaries. Following are several examples of such terms and conditions. While these examples are not exhaustive – and others may exist with similar effects – ultimately, all contracting terms and conditions must comply with Part D rules and requirements in order to protect the interests of beneficiaries and safeguard the integrity of the Medicare prescription drug program.

Example 1: Requirements for a longer transition period than the plan has provided for in its transition process submission to CMS.

As described in section 30.4.4.2 of [chapter 6](#), all plans must offer a temporary supply of non-formulary drugs of at least 31 days with multiple refills during a 90-day transition period in the LTC setting. Some pharmacies may wish to extend that transition period to up to 180 days. However, given uniform benefits requirements under the statute and CMS' regulations, plans cannot agree to a differential transition policy for some of their LTC enrollees. Transition policies must be applied uniformly to all similarly situated enrollees. Moreover, extending a transition period for some plan enrollees has cost implications for plans that may ultimately drive up costs to both beneficiaries and the Medicare program.

Example 2: Waivers of prior authorization or other utilization management edits for LTC facility residents.

Plans must determine whether a particular drug is a Part D drug and, in addition, must establish cost-effect utilization management programs. Waivers of prior authorization management edits or other utilization management edits for some plan enrollees run counter to these program requirements. In addition, given uniform benefits requirements under the statute and CMS' regulations, plans cannot apply prior authorization or other utilization management edits differentially to a subset of their LTC enrollment.

Example 3: Waivers of certain DUR requirements for LTC facility residents.

Plans must optimize drug regimens, which requires an up-front and thorough review of enrollee drug files in order to ensure their safety (e.g., by preventing drug-drug interactions). In addition – and as stated above – uniform benefits requirements under the statute and CMS' regulations mean that plans cannot apply DUR edits differentially to a subset of their LTC enrollees. All plan benefits must be applied uniformly to all similarly situated enrollees.

Part D sponsors may be out of compliance with uniform benefits requirements to the extent that they agree to particular contracting terms and conditions that have the net result of creating a non-uniform benefit for plan enrollees residing in LTC facilities serviced by network LTC pharmacies whose contracts with Part D sponsors may not include these same provisions. Plan benefits must also be applied uniformly across all enrollees (both those who reside in the

community and those residing in LTC facilities) when there is no justification for applying different rules to enrollees residing in LTC facilities. However, there are instances in which it is appropriate or legally required under CMS' Part D guidance for Part D sponsors to establish standards that differentiate between enrollees residing in LTC facilities and ambulatory patients.

For example, it is perfectly acceptable for Part D sponsors to adopt alternative standards applicable only in the LTC setting when clinically justified, legally required, or otherwise justified based on characteristics unique to beneficiaries residing in LTC facilities, such as extended transition periods for enrollees residing in LTC facilities or prior authorization or other utilization management requirements (for example, those that distinguish between Part B and Part D covered drugs given that some drugs covered for use in the home under Part B are not covered by Part B in LTC settings). However, Part D sponsors cannot agree to differential benefits which would result in a non-uniform benefit among enrollees in LTC facilities, such as an extended transition period, certain utilization management edits, or different drug utilization review protocols that are limited to those LTC enrollees who obtain their Part D drugs from a specific LTC pharmacy. Plan benefits must be applied uniformly to all similarly situated enrollees, meaning that all enrollees residing in LTC facilities must be subject to the same rules.

50.5.4 - Access to LTC Pharmacies for Enrollees Residing in Institutions for Mental Disease (IMDs), Intermediate Care Facilities for the Mentally Retarded (ICFs/MR), and LTC Hospitals **(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)**

To the extent that an ICF/MR or IMD designated by a State as an institution has, as an inpatient, any institutionalized individuals – which means any full benefit dual eligible individual for whom payment is made under Medicaid throughout a month, as provided in section 1902(q)(1)(B) of the Act – it falls within CMS' regulatory definition of the term “LTC facility.” There exists a statutory Federal financial participation exclusion under Medicaid affecting residents of IMDs between the ages of 22 and 64. However, the IMD exception to the definition of “medical assistance” under section 1902(q)(1)(B) of the Act does not apply to individuals who are age 65 and older. Thus, all elderly full-benefit dual eligibles who are inpatients in an IMD designated by the State as an institution for a full month are considered institutionalized individuals for that month. Long-term care hospitals are also medical institutions and are considered LTC facilities if they have as inpatients any institutionalized individuals.

CMS also clarifies that as medical institutions, hospitals (including long-term care hospitals) that receive payments under section 1902(q)(1)(B) of the Act can meet the definition of an LTC facility. As discussed in section 20.2.1 of [chapter 6](#), to the extent that inpatients in these hospitals exhaust their Part A inpatient days benefit, and payment is no longer available under Part A or Part B for drugs that would otherwise meet the definition of a Part D drug, such drugs are Part D drugs.

This means that Part D sponsors must ensure that they provide convenient access to network LTC pharmacies for:

- All of their enrollees residing in a long-term care hospital or in an IMD or ICF/MR designated by the State as an institution, and in which any institutionalized individuals

reside (although living in an institution that does not meet the definition of an LTC facility does not preclude an individual from enrolling in Part D).

- All of their enrollees who are inpatients in a hospital that is a “medical institution” under 1902(q)(1)(B) of the Act – and therefore would meet the Part D definition of an LTC facility – and whose Part A benefits have been exhausted.

Part D sponsors will not be compliant with CMS’ LTC convenient access standard if they do not provide access to covered Part D drugs via an LTC pharmacy in their network for all of their enrollees who reside in LTC facilities.

Many ICFs/MR, IMDs, and LTC hospitals utilize in-house pharmacies and, particularly in the case of ICFs/MR and IMDs, such pharmacies are State run and operated. In some States, licensing laws preclude facilities from obtaining prescription drugs and LTC services for their residents from anyone but the facility’s in-house pharmacy. States may not be able to agree to certain standard clauses in some LTC standard contracts because of constitutional and legal restraints on States. Part D sponsors should be prepared to readily negotiate with States to address these issues. To the extent that Part D sponsor contracting efforts involve communication with State run and operated pharmacies, CMS encourages Part D sponsors to coordinate their efforts through a single point of contact at the State level. Refer to the following Web site for lists of State contacts for IMDs and ICFs/MR:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/11_PartDContacts.asp#TopOfPage

50.5.5 - Post-Consumption Billing

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

CMS interprets the term “post-consumption” billing as billing that is performed after a drug is dispensed and consumed by an enrollee, usually at the end of the month or the beginning of the next month. While post-consumption billing is not typical in retail pharmacy, certain LTC pharmacies utilize post-consumption billing procedures. A significant advantage of this type of billing is reduction in waste because only those drugs actually consumed by an individual are billed. Post-consumption billing arrangements are permissible under the Part D program and should be accommodated by sponsors, assuming they are managed in a manner that is compatible with all other Part D requirements (i.e., for a formulary drug used for a medically accepted indication) and in a manner that provides for an accurate calculation of TrOOP expenditures (for example, via a single claim, Point-of-Sale transaction, HIPAA compliant format (i.e., *v. NCPDP 5.1 or v.D.0*)).

Network pharmacies are responsible for verifying that drugs dispensed to the beneficiary are covered under the beneficiary’s Part D plan. Because network pharmacies utilizing post-consumption billing will not submit the first claim to a Part D plan until after the drug has been dispensed, the pharmacy must employ another mechanism for verifying coverage in advance of dispensing.

50.6 - I/T/U Pharmacy Access

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

To the extent that any I/T/U pharmacies are present in their service areas, Part D sponsors must demonstrate that their contracted pharmacy network provides convenient access to I/T/U pharmacies. Part D sponsors must offer standard pharmacy network contracts to all I/T/U pharmacies operating in their service area. These standard contracting terms and conditions must conform to a model addendum developed by CMS, in collaboration with various stakeholders, that accounts for the operational differences between I/T/U and retail pharmacies. Upon request, sponsors must provide CMS with documentation to demonstrate that they have offered all I/T/U pharmacies in their service area a conforming contract; such documentation may be proof of FAX or U.S. postage or other carrier's receipt of delivery. Refer to the following Web site for a copy of the model I/T/U pharmacy contracting addendum:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/10_RxContracting_SpecialGuidance.asp#TopOfPage

In order to demonstrate convenient access to I/T/U pharmacies, Part D sponsors must include, as part of their initial pharmacy access submissions, a list of all I/T/U pharmacies in their service areas. This information must be submitted at the county level and CMS-designated contract level and include contracting status with each of the I/T/U pharmacies listed. CMS will review this list to ensure that sponsors are providing convenient access to I/T/U pharmacies in their service areas.

50.7 - Waiver of Pharmacy Access Requirements

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

As detailed below, CMS will waive pharmacy access standards under two circumstances: (1) for MA-PD plans and cost plans offering Part D coverage that operate and own their own pharmacies, provided they demonstrate convenient access using an alternative standard; and (2) for private fee-for-service (PFFS) plans offering Part D coverage that provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies and do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.

50.7.1 - Waiver of Retail Pharmacy Access Requirements for MA-PD Plans and Cost Plans with Plan-Owned and Operated Pharmacies

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

MA-PD plans or cost plans that provide access (other than via mail order) to qualified prescription drug coverage through retail pharmacies owned and operated by the MA organization that offers the plan or the cost plan will not be required to meet the retail pharmacy access standards in section 50.1. However, in order for the pharmacy access standards to be waived, the MA-PD plan or cost plan in question must have a pharmacy network that, per CMS' determination, provides comparable pharmacy access to its enrollees as provided under 42 CFR 422.112 or 42 CFR 417.416(e), as appropriate.

This waiver is automatically granted when the MA-PD plan or cost plan provides Part D drugs **predominantly** through plan-owned and operated retail pharmacies (i.e., more than 50 percent of prescriptions are provided through owned and operated retail pharmacies). While this waiver of the convenient retail access standards is automatically granted to plans that meet this criteria,

MA-PD and cost plans using this waiver must initially submit information to CMS about the number of prescriptions filled at plan-owned retail pharmacies and at contracted pharmacies, and the percentage of prescriptions provided through plan-owned retail pharmacies during the last complete year prior to the contract year when the waiver applies. Part D sponsors that have been granted this waiver will be required to provide CMS with data on an annual basis on prescriptions filled at plan-owned and operated retail pharmacies. For more information about these reporting requirements, refer to:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.aspx#TopOfPage

50.7.2 - Waiver of Pharmacy Access Requirements for Private Fee-for-Service Plans

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Private fee-for-service (PFFS) plans offering Part D coverage will not be subject to the pharmacy access requirements in sections 50.1, 50.4, 50.5, and 50.6, provided they:

- Provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies; and
- Do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.

Given these two provisions, PFFS plans offering Part D coverage must provide access to pharmacies in one of the following ways:

1. PFFS plans offering Part D coverage that meet the retail pharmacy convenient access standards described in section 50.1, the home infusion pharmacy adequate access standard described in section 50.4, the long-term care pharmacy convenient access standard described in section 50.5, and the I/T/U pharmacy convenient access standard described in section 50.6 will only have to provide access to non-network pharmacies consistent with CMS' out-of-network access policy as described in section 60. In other words, they will be treated in the same way as all other Part D plans vis-à-vis the access requirements in sections 50.1, 50.4, 50.5, and 50.6.
2. PFFS plans offering Part D coverage will not have to meet the retail pharmacy convenient access standards described in section 50.1, the home infusion adequate access standard described in section 50.4, the long-term care pharmacy convenient access standard described in section 50.5, and the I/T/U pharmacy convenient access standard described in section 50.6— either because they do not contract with any network of pharmacies, or because they contract with a limited network that does not meet the relevant regulatory access requirements – if they provide access to covered Part D drugs at all pharmacies without charging beneficiaries any additional cost-sharing (relative to the cost-sharing applicable at any network pharmacies the plan may have). Access at non-network pharmacies would be provided by reimbursing the pharmacy its usual and customary (U&C) price, minus any applicable beneficiary cost-sharing.

In effect, PFFS plans offering Part D coverage have the following options:

- Create a network that meets CMS' regulatory access standards and limits access to out-of-network providers consistent with CMS' regulatory provisions regarding out-of-network access;
- Create a network that does not meet CMS' regulatory access standards and provides access to all non-network pharmacies by not charging additional cost-sharing for drugs obtained at non-network pharmacies; or
- Not create a network at all but provide access to all pharmacies at the same cost-sharing.

PFFS sponsors choosing to have either no contracted pharmacy network or a limited pharmacy network that does not meet CMS' pharmacy access requirements must ensure that their enrollees are able to access their benefits at all non-network pharmacies without paying any more cost-sharing than they would under their approved Part D benefit structure.

When accessing their drugs at non-network pharmacies in non-emergent situations, enrollees of PFFS plans that have received waivers of the pharmacy access standards will pay only their required cost-sharing at the point of sale. Moreover, such claims should be adjudicated electronically whenever pharmacies support electronic billing. In other words, PFFS sponsors with pharmacy access waivers should not routinely rely on billing practices that require an enrollee to pay U&C price upfront and then submit a paper claim to the sponsor for reimbursement.

CMS notes that sponsors are required to accurately track TrOOP and gross covered drug spend amounts in order to correctly position an enrollee in the benefit. As indicated in [chapter 14 of this manual](#), plans are required to process claims in real-time and track TrOOP in real-time. Consistent with those requirements, sponsors – including PFFS sponsors –receiving waivers of the pharmacy access standards – must establish policies and procedures appropriately restricting the use of paper claims only to situations in which online claims processing is not available at the point of sale in order to promote accurate TrOOP accounting, to minimize administrative costs to Part D sponsors and the Medicare program, as well as opportunities for fraudulent duplicate claims reimbursement. Therefore, PFFS sponsors choosing to obtain a waiver rather than meet CMS' pharmacy access requirements must arrange for automated, online billing at non-network pharmacies (similar to the way in which CMS's point-of-sale contractor has allowed for online billing by non-contracted pharmacies).

50.8 - Pharmacy Network Contracting Requirements

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

In establishing its contracted pharmacy network, a Part D sponsor must meet certain requirements with respect to any willing pharmacy and insurance risk, as described in sections 50.8.1 and 50.8.2 below.

50.8.1 - Any Willing Pharmacy Requirement (Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

“Any willing pharmacy” refers to the requirement that Part D sponsors permit the participation in their Part D plan networks of any pharmacy – including non-retail pharmacies such as mail-order pharmacies – that is willing to accept the sponsor’s standard contracting terms and conditions. These standard contracting terms and conditions must be reasonable and relevant. However, whether a Part D sponsor has permitted a pharmacy an opportunity to participate in its network, or whether a pharmacy can meet or has met contract terms in compliance with the law and CMS’ regulations at 42 CFR 423.120(a)(8)(i) are fact-specific questions that are generally best left between the parties.

It is unlikely that a Part D sponsor could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies – for example, rural and long-term care pharmacies. Standard terms and conditions, particularly for reimbursement terms, may vary to accommodate geographic areas or types of pharmacies, and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. Thus, for example, provided a Part D sponsor offers all mail-order pharmacies in a particular area with the same standard terms and conditions, it may offer separate standard terms and conditions to mail-order pharmacies than it does to retail pharmacies. With standard terms and conditions as a “floor” of minimum requirements that all similarly situated pharmacies must abide by, Part D sponsors may modify some of their standard terms and conditions to encourage participation by particular pharmacies.

The any willing pharmacy requirement is waived for certain MA-PD plans or cost plans that provide access (other than via mail order) to qualified prescription drug coverage through retail pharmacies owned and operated by the MA organization that offers the plan or the cost plan. In order to obtain this waiver of the any willing pharmacy requirement, an MA organization or cost plan sponsor must generally demonstrate at the plan level that at least 98 percent of enrollee prescriptions have been filled through pharmacies that are owned and operated by the plan sponsor in order to be granted the waiver.

Some pharmacies, particularly independent pharmacies, work with agents or Pharmacy Services Administration Organizations (PSAO) for purposes of negotiating and/or signing contracts with Part D sponsors. Such agents negotiate and/or sign contracts with health plans and PBMs on behalf of participating pharmacies to streamline the contracting process. To the extent that such agents are authorized to act on behalf of a participating pharmacy for purposes of negotiating and/or signing pharmacy network contracts, there is no distinction between a pharmacy and its agent for purposes of the any willing pharmacy requirement. In other words, the any willing pharmacy requirement at 42 CFR 423.120(b)(8)(i) extends to an agent authorized to negotiate and/or sign contracts on behalf of a pharmacy, as long as it is in compliance with all Federal and State laws. A Part D sponsor will be in violation of this requirement if it refuses to offer a standard contract to an agent acting on behalf of a participating pharmacy for purposes of negotiating and/or signing contracts. However, Part D sponsors that currently have independent contracts with pharmacies belonging to a PSAO are only required to offer standard terms and

conditions to those pharmacies under the PSAO with no preexisting contract with the Part D sponsor.

50.8.2 - Insurance Risk

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A Part D sponsor may not require a network pharmacy to accept insurance risk as a condition of participation in its pharmacy network. Insurance risk in relation to a network pharmacy refers to risk of the type commonly assumed only by insurers licensed by a State, but not including payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions, or elements potentially in the control of the pharmacy (for example, labor costs, and productivity).

More specifically, subcapitation of pharmacies is not allowed in Part D sponsor administration of the Part D benefit. If the only contract Part D sponsors offered a pharmacy were a capitated arrangement, this practice would equate to requiring a pharmacy to accept risk. Second, and more importantly, subcapitated arrangements are inconsistent with the four payment mechanisms CMS is required to use to pay plans. Part D plans must be able to report costs to CMS that distinguish beneficiary liabilities (e.g., for TrOOP accounting and accumulation); low-income cost-sharing subsidy payments made at the individual beneficiary level by plans to pharmacies; costs that are considered supplemental benefits at the individual beneficiary level (supplemental drugs and supplemental cost-sharing); and allocation of plan costs above and below the out-of-pocket threshold at the individual beneficiary level and that subject the plan to different levels of risk-sharing depending on which phase of the drug benefit the beneficiary is in. If the plan's providers do not process and submit meaningful claims, this data is not available to compute these payment streams as mandated by law. Finally, subcapitated payments to certain pharmacies (e.g., home infusion, long-term care, and other non-retail pharmacies) could include payment for services (e.g., clinical professional services and extensive fees for administering drugs to patients) that are not allowed under the Part D benefit.

50.9 - Differential Cost-Sharing for Preferred Pharmacies

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Despite the “any willing pharmacy” requirement (discussed in section 50.8.1), Part D sponsors – with the exception of those offering defined standard coverage, since cost-sharing cannot be altered under defined standard coverage – are permitted to reduce cost-sharing differentially for network pharmacies. In other words, Part D sponsors may vary cost-sharing not only based on type of covered Part D drug or formulary tier, but also on a particular pharmacy’s status within their pharmacy network (i.e., Part D sponsors may establish distinctions between “preferred” and “non-preferred” pharmacies within their pharmacy networks).

While these within-network distinctions are allowed, such tiered cost-sharing arrangements must in no way increase CMS payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions can only be included in Part D sponsors’ benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D sponsor

network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage).

In other words, sponsors cannot designate certain network pharmacies as preferred without designating its other network pharmacies as non-preferred. A pharmacy can only be designated as preferred if it offers enrollees a lower level of cost-sharing than a non-preferred pharmacy. This means that the differences in cost-sharing must be based on the designated cost-sharing levels, and not on the actual cost to the enrollee, as illustrated in the examples below.

Example 1: A sponsor with a benefit design based on coinsurance could offer 20% coinsurance at preferred pharmacies and 25% coinsurance at non-preferred pharmacies.

Example 2: A sponsor with a benefit design based on copayments could offer a \$20 copayment at preferred pharmacies and a \$25 copayment at non-preferred pharmacies.

CMS will permit plans to refer to non-preferred pharmacies as “other network pharmacies” instead of “non-preferred pharmacies” in their marketing materials and other beneficiary communications.

Differential cost-sharing in the context of preferred and non-preferred pharmacies does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in 42 CFR 423.782.

A Part D sponsor may not establish a differential between cost-sharing at preferred versus non-preferred pharmacies that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan – even if it otherwise meets the retail access standards detailed in section 50.1. A pharmacy network that effectively limits access in portions of a Part D sponsor’s service areas in this manner would be discriminatory and disallowed as provided in 42 CFR 423.272.

50.10 - Level Playing Field Between Mail-Order and Retail Pharmacies

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors that include mail-order pharmacies in their networks must permit enrollees to receive benefits, which may include an extended supply of covered Part D drugs (for example, a 90-day supply), through a network retail pharmacy rather than a network mail-order pharmacy, if they so choose. However, a sponsor may require that enrollees choosing to receive benefits, including an extended day supply of covered Part D drugs, at a network retail pharmacy rather than a network mail-order pharmacy be responsible for any higher cost-sharing associated with obtaining those benefits at a network retail pharmacy.

If a sponsor does choose to charge the beneficiary the higher cost-sharing associated with obtaining the drug through a retail pharmacy, any increase in cost sharing must be limited to the “differential in charge” to the sponsor in terms of any difference between higher contract rates at a network retail pharmacy as opposed to a network mail-order pharmacy for that benefit. Sponsors may therefore require an enrollee to pay higher cost-sharing up to an amount equal to the mail-order cost-sharing plus any differential in contracted rates between retail and mail-

order, but plans may charge beneficiaries a lower cost sharing at retail if they so choose. This differential in charge-based cost-sharing should be viewed as a ceiling on cost-sharing and not a floor. In addition, Part D sponsors must ensure that the availability of benefits (including extended day supplies) at retail rather than mail-order pharmacies does not increase costs to the government. Enrollee cost-sharing for an extended-day supply at retail must never exceed what the enrollee would have paid at the same retail pharmacy had the enrollee had his or her prescription filled in multiple 1 month supply increments at retail pharmacy rates.

Sponsors electing to offer extended supplies of covered Part D drugs must make available to retail pharmacies, on request, an “Extended Supply Addendum” to their standard contracting terms and conditions for retail pharmacies. The addendum may allow retail pharmacies to offer an extended supply of drugs to any enrollee at the same negotiated price, reimbursement rate (including dispensing fee, if any), and cost-sharing as their network mail-order pharmacy or pharmacies. CMS refers to this rate as the network mail-order pharmacy rate.

Alternatively, Part D sponsors electing to offer extended supplies of covered Part D drugs may through their addendum allow retail pharmacies to dispense an extended supply of drugs for a higher contracted reimbursement rate (including dispensing fee, if any) than their network mail-order pharmacy rate. At the sponsor’s election, any differential in charge between the network mail-order pharmacy rate and the higher contracted reimbursement rate for the extended supply dispensed at the retail pharmacy may be reflected in higher cost-sharing paid by the beneficiary. CMS refers to this rate as the alternative retail/mail-order pharmacy rate. Any such higher contracted reimbursement rate shall not increase costs to the government and in no event shall *the standard terms and conditions offered to similarly situated pharmacies with respect to CMS’ any willing pharmacy provisions vary.*

Below are two examples of contracting scenarios designed to illustrate the calculation of a “difference in charge.”

Example 1: Network Mail Order Pharmacy Rate

Suppose that a network pharmacy’s contracted retail rate is AWP-12% plus a \$2 dispensing fee, and the plan’s retail cost-sharing requires 25% to be paid by the beneficiary. Further suppose that the plan’s contracted mail-order rate is AWP-22%, with no dispensing fee and that the plan’s mail-order cost sharing requires 20% to be paid by the beneficiary. If the sponsor offers a 90-day supply at network mail-order pharmacies, any retail pharmacy must be allowed to fill a 90-day prescription under the same terms and conditions as the mail-order pharmacy provided it agrees to accept the network mail-order pharmacy rate for that 90-day prescription – AWP – 22% (no dispensing fee) with 20% cost sharing paid by the beneficiary.

AWP = \$100			
Retail Rate		Network Mail Order Rate	
AWP – 12%	\$88	AWP – 22%	\$78
Dispensing Fee	\$2	Dispensing Fee	\$0
Total	\$90	Total	\$78

Retail beneficiary cost sharing paid to pharmacy (25%)	\$22.50		Mail order beneficiary cost sharing paid to pharmacy (20%)	\$15.60
Plan payment to pharmacy	\$67.50		Plan payment to pharmacy	\$62.40

Example 2: Alternative Retail / Mail Order Pharmacy Rate

A Part D sponsor may establish an alternative retail/mail-order pharmacy rate for an extended supply for retail pharmacies that cannot or will not match the network mail-order pharmacy rate for the extended supply prescription. Suppose under this scenario, the retail pharmacy could not match the network mail-order pharmacy rate for a 90-day prescription (see example 1), but would accept an alternative retail/mail-order pharmacy rate of AWP -19% (plus \$2.00 dispensing fee). In this case, the sponsor could allow a retail pharmacy to fill the 90-day prescription at the alternative retail/mail-order pharmacy rate. The sponsor also may charge the beneficiary the difference in charge between the network mail-order pharmacy rate for that 90-day prescription and the alternative retail/mail-order pharmacy rate for a 90-day prescription. In this example, the retail pharmacy would be reimbursed AWP -19% plus \$2.00 and the beneficiary would have to pay 3% of AWP plus \$2.00, which would be added to the 20% cost sharing calculated on AWP – 22%. (As stated earlier, this difference in charge-based cost-sharing would be a ceiling, but not a floor – in other words, the cost-sharing paid at retail could not exceed the amount described in the previous sentence, but it could be lower than such amount.)

AWP = \$100				
Network Mail Order Rate			Alternative Retail / Mail Order Pharmacy Rate	
AWP – 22%	\$78		AWP – 19%	\$81
Dispensing Fee	\$0		Dispensing Fee	\$2
Total	\$78		Total	\$83
Beneficiary cost sharing paid to pharmacy (20%)	\$15.60		Beneficiary cost sharing based on mail order rate (20%)	\$15.60
			Difference in charge	\$5
			Total beneficiary payment to pharmacy	\$20.60
Plan payment to pharmacy	\$62.40		Plan payment to pharmacy	\$62.40

NOTE: These examples are not intended to provide guidance on specific prices or contract rates that plans should or should not consider in contracting with pharmacies.

Part D sponsors offering benefits, including extended-day supplies of covered Part D drugs, at network mail-order pharmacies must offer retail pharmacies a reasonable opportunity to provide those same benefits. Part D plans must therefore contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day

supply benefits at retail that are available at mail-order. CMS will review the adequacy of initial pharmacy network submissions and may require that plans address any network access issues as part of this review. CMS may conduct additional reviews of a Part D sponsor's pharmacy network and may require remedial action by Part D sponsors based upon such factors as enrollee complaints that their access to benefits at network retail pharmacies is being unreasonably denied. Part D sponsors will be required to provide CMS with data on an annual basis on the number of retail pharmacies in their networks contracted to provide extended day supply benefits. For more information about these reporting requirements, refer to: http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage

50.11 - Use of Identification Card for Accessing Negotiated Prices (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors must issue (and reissue, as appropriate) a card or other technology for enrollees to use in accessing negotiated prices for covered part D drugs. CMS has developed standards related to a standardized format for a plan identification card for this purpose. These standards were developed after consultation with the NCPDP and are summarized in our Marketing Guidelines, which can be accessed at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

50.12 - Pharmacy Access During a Federal Disaster or Other Public Health Emergency Declaration (Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

If a Presidential major disaster or emergency declaration is issued or the Secretary declares a public health emergency, and the underlying circumstances are reasonably expected to result in a disruption in access to covered Part D drugs, CMS expects sponsors to lift their "refill-too-soon" edits. Part D sponsors may exercise some operational discretion as to how these edits are lifted during a disaster or emergency as long as access to Part D drugs is provided at the point-of-sale. For instance, Part D sponsors could implement an edit that is readily resolvable at the point-of-sale through the use of a pharmacist override code. CMS also expects Part D sponsors to allow an affected enrollee to obtain the maximum extended day supply, if requested and available at the time of refill.

CMS expects that Part D sponsors will continue to lift these edits until the termination of a public health emergency or the end of a declared disaster or emergency. In the case of a public health emergency, it terminates when it no longer exists or upon the expiration of the 90-day period beginning from the initial declaration, whichever occurs first. For major disasters declared by the President, Part D sponsors should pay particular attention to the closure of disaster incident periods listed in the Disaster Federal Register Notice section on Federal Emergency Management Agency's (FEMA's) Web site <http://www.fema.gov/news/disasters.fema>, noting that in circumstances in which the incident period has not officially closed 30 days from the initial Presidential declaration. Part D sponsors may consider extending the implementation of the edits but are not required to do so. However, if sponsors choose to remove the edits, they need to work closely with enrollees who indicate that they are still displaced or otherwise impacted by the disaster or emergency.

In the absence of a Presidential major disaster or emergency declaration or a public health emergency, Part D sponsors may consider lifting the edits -- for instance, in advance of an impending disaster -- if they determine it is appropriate to do so to ensure pharmacy access. However, at all times, and especially in disaster and/or public health emergency situations, Part D sponsors must ensure, consistent with this chapter, that their enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine.

50.13 - Drug Shortages

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

This section describes the expectations of Part D sponsors when shortages impact the offering of drug products on plan formularies. By “shortages”, CMS is referring to those drug products that have been identified on the FDA Drug Shortage Webpage:

<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>

When establishing policies and procedures to address shortages, Part D sponsors should not adopt a one-size-fits-all approach. Drug shortages may occur for differing reasons and impact Part D sponsor application of its formulary in different ways. Therefore, when a drug shortage occurs, Part D sponsors should begin by considering the type of drug involved, condition(s) being treated by the drug, expected length of the drug shortage, and which enrollees are impacted. Based on this information, Part D sponsors can work with their enrollees and providers to find appropriate therapeutic alternatives. The Part D sponsor will need to evaluate the availability (or unavailability) of therapeutically equivalent drug products. Different scenarios to be addressed include:

- A single-source formulary brand drug product is temporarily unavailable—no therapeutically equivalent products are available;
- A multiple-source formulary brand drug product is temporarily unavailable—only therapeutically equivalent generic products are available;
- A multiple-source formulary generic drug product is temporarily unavailable (all makers)—only therapeutically equivalent brand product is available; or
- A multiple-source formulary drug product is temporarily unavailable—no brand or generic therapeutically equivalent product is available.

In order to minimize unnecessary changes in therapy resulting from temporary shortages of multiple-source formulary drug products, CMS expects Part D sponsors to provide access to therapeutically equivalent non-formulary drug products, or therapeutically equivalent formulary drug products that otherwise require prior authorization or step therapy, for those enrollees currently taking the drug product subject to a shortage. When applicable, Part D sponsors should allow pharmacies to utilize a value of “8” in field 408-D8 (Dispense as Written/Product Selection Code) of the NCPDP v5.1 Telecommunication Standard to specify that an equivalent

brand product is being dispensed due to the unavailability of any generic formulary products. The Part D sponsor is not required to charge the same cost-sharing that applies to the unavailable formulary product and may charge the applicable non-formulary or brand cost-sharing that would otherwise apply to the substituted therapeutically equivalent product.

Under these circumstances, CMS does not consider access to therapeutically equivalent non-formulary drug products, or therapeutically equivalent formulary drug products that otherwise require prior authorization or step therapy, to be formulary exceptions and, therefore, access to such drug products may be limited to the duration of the shortage. In the event that the shortage becomes a market withdrawal, Part D sponsors must follow notice requirements consistent with 42 CFR 423.120(b)(5) if the Part D sponsor intends to discontinue coverage of the therapeutically equivalent product. This policy does not preclude a beneficiary from seeking a non-formulary or tiering exception to obtain access to a non-formulary drug product or formulary drug product otherwise requiring prior authorization or step therapy.

50.14 - Waivers for Plans in the Territories (Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

To ensure access to coverage in the territories, section 1860D-42(a) of the Act grants CMS the authority to waive access requirements to secure access to qualified prescription drug coverage for Part D eligible individuals residing in the territories. The regulations for the MMA under 42CFR 423.859(c) allow access to coverage in the territories to be waived or modified either through an Applicant's request or at CMS' own determination. Under that authority, CMS has waived the convenient access requirements for a plan's Part D contracted retail, home infusion and long-term care network in the Pacific territories.

60 - Out-of-Network Access (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

60.1 - Out-of-Network Pharmacy Access (Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors must ensure that their enrollees have adequate access to covered Part D drugs dispensed at OON pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine. The coverage rules applicable to covered Part D drugs dispensed at OON pharmacies may generally mirror those applicable to covered Part D drugs dispensed at network pharmacies, to the extent that the OON pharmacy has the ability to effectuate those coverage rules. However, Part D sponsors must develop policies and procedures governing reasonable rules for appropriately limiting OON access (for example, quantity limits, purchase of maintenance medications via mail-order for extended out-of-area travel, or plan notification or authorization processes). Following are various scenarios under which CMS would expect that OON pharmacy access be guaranteed to enrollees.

Example 1: An enrollee is traveling outside his or her Part D plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy.

Example 2: An enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service.

Example 3: An enrollee must fill a prescription for a covered Part D drug in a timely manner, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail-order pharmacies.

Example 4: An enrollee is provided covered Part D drugs dispensed by an OON institution-based pharmacy while he or she is a patient in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting, *and as a result cannot get his or her medications filled at a network pharmacy.*

Example 5: During any Federal disaster declaration or other public health emergency declaration in which Part D enrollees are evacuated or otherwise displaced from their place of residence and cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. In addition, in circumstances in which normal distribution channels are unavailable, Part D sponsors are expected to liberally apply their OON policies to facilitate access to medications.

If a Part D sponsor offers coverage other than defined standard coverage, it may require enrollees to not only be responsible for any cost-sharing, including a deductible, that would have otherwise applied if a covered Part D drug had been purchased at a network pharmacy, but also any differential between an OON pharmacy's (or provider's) U&C price and the plan allowance.

Given the cost-sharing requirements for defined standard coverage, under which the cost-sharing between the deductible and initial coverage limit must always be 25 percent of the actual cost of a drug at the point of sale (see section 20.3.1), Part D sponsors offering defined standard coverage may not charge enrollees the OON differential described above. Instead, Part D sponsors offering defined standard coverage must simply require their enrollees to pay any deductible or cost-sharing, relative to the OON pharmacy's (or provider's) U&C price. The Part D sponsor will pay the difference between the OON pharmacy's (or provider's) U&C price and the enrollee's cost-sharing.

In either case, enrollees will likely be required to pay more for a covered Part D drug purchased OON than one purchased at a network pharmacy. However, as explained in section 30.1, any OON differential that an enrollee is required to pay for purchases made consistent with a Part D sponsor's OON access policy will count toward his or her TrOOP balance. CMS will pay the OON differential, as applicable, for appropriate OON purchases of covered Part D drugs for individuals receiving the low-income subsidy.

Sponsors may not routinely allow more than a month's supply of medication to be dispensed at an OON pharmacy. In creating their out-of-network benefit structure, sponsors may choose one of the following options:

- The plan's network cost-sharing;
- The plan's network cost-sharing plus the differential between the OON billed charge and their network allowable charge (applicable to all benefit structures except defined standard prescription drug coverage);
- The plan's network cost-sharing with a limited days supply (this limited days supply must be greater than or equal to 10 days); *or*
- *The plan's network cost-sharing plus the differential between the OON billed charge and network allowable, with a limited days supply.*

Plans may override the 1 month limit on a case-by-case basis when warranted by extraordinary circumstances.

CMS expects that enrollees obtaining covered Part D drugs at an OON pharmacy consistent with a Part D sponsor's OON access policy may be required to pay the OON pharmacy's U&C price at the point-of-sale, submit a paper claim to the sponsor, and wait for reimbursement from the sponsor as described above.

60.2 - Access to Vaccines

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D vaccines may be dispensed and administered in different settings (e.g., by pharmacists in pharmacies, by physicians in physician offices) depending on factors such as State laws regarding the administration of vaccines and product administration complexity. While access to Part D vaccines via a network pharmacy is likely the best method for improving enrollees' access to Part D vaccines, Part D sponsors must ensure that enrollees have adequate access to Part D vaccines in physician offices when those Part D vaccines are appropriately dispensed and administered in physician offices. Such access is considered OON access because sponsor networks are defined as pharmacy networks only.

CMS recognizes, however, that the process of upfront payment by an enrollee and subsequent reimbursement by his or her Part D plan described for OON purchases in section 60.1 may be less feasible in the case of enrollees who require OON access to a vaccine in a physician's office. As new vaccines come on the market with indications for use in the Medicare population, network Part D vaccine access will become more critical. To address this issue, CMS offers a range of in-network and facilitated OON approaches, described in sections 60.2.1 and 60.2.2 below, for improving access to Part D vaccines appropriately administered and dispensed by a physician without requiring upfront beneficiary payment and subsequent reimbursement by Part D sponsors. Part D sponsors are not limited to these approaches and are encouraged to pursue the implementation of any cost-effective, real-time billing option at the time of vaccine administration. Additionally, Part D sponsors may consider adopting alternative approaches, depending upon the vaccine and its respective cost, storage requirements, and complexity of administration. Sponsors electing to implement one or more of the options discussed below must still meet their obligation to generally provide OON access when appropriate – including through upfront payment by an enrollee and subsequent reimbursement by his or her Part D plan.

The administration of a Part D-covered vaccine is included in the definition of a “Part D drug,” effective January 1, 2008. Consequently, the Part D program covers vaccine administration costs associated with Part D vaccines. For more information, refer to section 10.14 of [chapter 6](#).

60.2.1 - In Network Vaccine Distribution Approaches

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

While CMS is in no way limiting Part D sponsors to any specific approach to ensuring access to Part D vaccines, CMS believes that an in-network, real time solution is the best method to improve vaccine access. In addition to the in-network options listed below, Part D sponsors could reduce the burden of copayment collection by establishing a benefit design with zero cost-sharing on vaccines.

1. In Network Retail Pharmacy Access

Enrollees could obtain a prescription from the physician and bring it to their local network retail pharmacy for filling. In some States, it might be possible for the vaccine administration to be provided by the pharmacist. Forty-eight States currently allow pharmacists to provide some type of vaccinations. Where it is safe to dispense these vaccines in the pharmacy, Part D sponsors could explore utilization of their network pharmacists as a provider of adult Medicare Part D vaccines. Pediatric vaccines should continue to be provided by physicians, however.

2. In Network Pharmacy Distribution

A Part D sponsor’s network pharmacy could provide vaccines directly to physician offices. Under this scenario, the physician could call or fax in a prescription, or the beneficiary could mail a prescription for the vaccine to the pharmacy. The pharmacy would fill the prescription for the vaccine, deliver or ship to the physician’s office, and bill the Part D sponsor for the vaccine. This model resembles the competitive acquisition program being implemented by Medicare Part B in that the drug is shipped to the physician but the physician never purchases or is reimbursed for the drug.

60.2.2 - Facilitated OON Access Approaches

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

While the following options are OON arrangements between physicians and Part D sponsors, CMS expects that these and similar options will reduce the need for up-front beneficiary payment by facilitating other forms of payment arrangements between physicians and Part D sponsors, increasing access beyond the current regulatory OON requirements and avoiding the incurring of significant OON costs by beneficiaries or CMS as part of the low-income subsidy.

1. Model Vaccine Notice for Physicians (Paper Claim Enhancement)

Under this option, Part D sponsors would provide all enrollees with a vaccine-specific notice that the enrollees could bring to their physicians. This notice would provide information

necessary for a physician to contact the enrollee's Part D plan to receive authorization of coverage for a particular vaccine, reimbursement rates, enrollee cost-sharing to be collected by the physician, and billing instructions. If the Part D sponsor authorizes payment, the physician would then bill the Part D sponsor using the physician standard claim form or ASC X12 electronic format (which Part D sponsors must accept) and would receive payment directly from the Part D sponsor. Alternatively, physicians could access this information directly by calling the sponsor's prior authorization line.

2. Web-Assisted Electronic Physician Billing

Using a commercially-developed Web-based system based on the real-time NCPDP standard, physicians could electronically request OON reimbursement from Part D sponsors on behalf of beneficiaries for vaccines dispensed and administered in the physician's office. The physician would agree to accept Part D sponsor payment as payment in full as a condition of using the system.

60.3 - Vaccine Administration

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

60.3.1 - Vaccine Administration Cost-Sharing Considerations

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Since the vaccine administration fee is a component of a vaccine's negotiated price, any cost-sharing applied to a vaccine should be applied relative to the negotiated price of the vaccine and its related component costs. If a sponsor structures its vaccine cost-sharing as coinsurance, including 100 percent cost-sharing in any applicable deductible or coverage gap, the coinsurance should be applied relative to the entire negotiated price (including the vaccine administration fee). Similarly, if a sponsor structures its vaccine cost-sharing as a copayment, the copayment should be applied relative to the entire negotiated price. In other words, a sponsor should not charge separate copayments for the vaccine ingredient cost and its related component costs, respectively (i.e., the vaccine administration fee and dispensing fee, if applicable), since CMS views the vaccine and its administration as intrinsically linked. Similarly, low income subsidy eligible individuals with copayments set by statute (see section 1860D-14(a)(1)(D) of the Social Security Act) will pay only one copayment for a vaccine and all related charges. Thus, for example, a low income subsidy eligible individual entitled to \$1.05/\$3.10 copayments in 2008 would pay only \$3.10 for both the vaccine and its administration (and any applicable dispensing fee) even if the components are billed separately.³

³ In cases involving defined standard coverage and out-of-network vaccine administration, cost-sharing for a vaccine is based on the usual and customary price for both the vaccine ingredient cost and vaccine administration fee. This is because, given the cost-sharing requirements for defined standard coverage – under which the cost-sharing between the deductible and initial coverage limit must always be 25 percent of the actual cost of a drug at the point of sale – Part D sponsors offering defined standard coverage may not charge enrollees any out-of-network differential. However, sponsors offering other benefit designs (e.g., actuarially equivalent standard coverage, basic alternative coverage, or enhanced alternative coverage), may require enrollees being administered a vaccine out-of-network (e.g., in a physician's office) to be responsible for any cost-sharing that would have otherwise applied had the drug been purchased at a network pharmacy, and also any differential between the provider's usual and customary

60.3.2 - Separate Billing of the Vaccine and Vaccine Administration (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Although CMS prefers that all Part D vaccines be billed on one claim for both the vaccine and its administration, CMS recognizes there are circumstances that might require vaccine administration to be billed and reimbursed separately from the vaccine. For example, a Part D vaccine might have very specific storage conditions that would impede most physicians' offices from maintaining a ready inventory for their patients. It might be more efficient for the physician to have a pharmacy dispense and deliver the vaccine for administration. The pharmacy will submit the vaccine ingredient cost and dispensing fee to the Part D sponsor for reimbursement and the physician will bill the beneficiary for the administration. Part D sponsors should establish processes necessary to separately reimburse the pharmacy for the vaccine ingredient cost/dispensing fee and the beneficiary for physician's administration charge.

CMS has concerns about separate billing of Part D vaccines and vaccine administration fees because it provides an opportunity for both inappropriate and duplicate billing of administration fees. Separate billing is more challenging for Part D sponsors to process and track, and there is greater potential for programmatic fraud and abuse when the vaccine and its administration are not linked at time of reimbursement. Consequently, CMS strongly encourages Part D sponsors to link billing of a vaccine and its administration wherever possible. Where this is not possible, and separate billing occurs, CMS expects Part D sponsors to closely scrutinize the separate claims to ensure the beneficiary has received reimbursement for both elements and that the sponsor has neither over- nor underpaid for both the vaccine and the vaccine administration fee. CMS plans on monitoring Part D sponsors to ensure that when separate billing does occur, there is a reasonable correlation of prescription drug event (PDE) records for vaccines dispensed to PDE records for vaccine administration.

60.3.3 - Claims Processing Considerations (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors will implement a process that helps ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) vaccine billing requirements. Under the Tax Relief and Healthcare Act of 2006 (TRHCA), a "covered Part D drug" is defined to include the vaccine and the administration of the vaccine. For purposes of billing for vaccines, Part D vaccine administration therefore is unique. As defined by statute, the "drug" incorporates both the vaccine and its administration. Consequently, billing of the Part D drug vaccine must be conducted using the NCPDP 5.1 standard for both the vaccine and its administration. When the administration is performed by the pharmacy or facilitated by the pharmacy through an established relationship with physician or immunizer, the administration will be included in one standardized field in the billing transaction as part of the vaccine prescription request to the Part D sponsor.⁴ In other words, the pharmacy should submit the vaccine and its administration, if

price for the vaccine and vaccine administration fee and the plan allowance for the vaccine and vaccine administration (see section 60.1).

⁴ Relative to the establishment of relationships between pharmacies and immunizers, the parties must ensure that such arrangements do not violate the physician self-referral ("Stark")

they are involved with the administration, as a single claim and not as two separate claims. NCPDP has issued formal guidance regarding the standardized field to be used for vaccine administration in the billing transaction.

When administration is billed separately from the dispensing of the vaccine, Part D sponsors or their subcontracted PBM should review existing claims for the presence of a vaccine charge. Should no vaccine charge be present in their claims history, the Part D sponsor should work with the beneficiary to ensure the beneficiary did not forget to submit a paper receipt for the vaccine and that appropriate reimbursement has been paid. For example, a sponsor could generate a letter to an enrollee whenever it receives a claim for a vaccine but does not receive a claim for vaccine administration within a certain time period.

A new, unique vaccine administration field has been added to the PDE elements for Part D sponsor submission of vaccine administration. This specific vaccine administration field allows a one-to-one claim to PDE relationship. For instance, if a sponsor receives a single claim from a network pharmacy inclusive of the vaccine and its administration it will need to attribute the vaccine ingredient cost, dispensing fee (if applicable), and administration to the appropriate fields of the PDE for submission to CMS. If separate billing by a pharmacy for the dispensing of the vaccine and by a physician for its administration occurs, the sponsor will submit one PDE based on the pharmacy claim inclusive of the vaccine and dispensing fee and a separate PDE based on the out-of-network claim from the beneficiary inclusive of the vaccine administration costs attributable to physician's administration. For this second separate PDE, the vaccine ingredient National Drug Code (NDC) would still be identified, but the vaccine ingredient cost and dispensing fee would be set to zero dollars. The format will be published on www.csscooperations.com.

60.3.4 - Vaccine Administration Access

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors will allow any provider so authorized by State law to administer a Part D vaccine. Where it is safe to dispense and administer vaccines in a pharmacy, sponsors could explore utilization of their network pharmacists as providers of adult Medicare Part D vaccines (pediatric vaccines should continue to be provided by physicians). Out-of-network vaccines administered in a physician's office or by other non-network providers may be covered under the out-of-network access rules detailed in section 60.2, where a Part D enrollee may self-pay for the vaccine cost and its administration and submit a paper claim for reimbursement to his or her Part D sponsor.

70 - Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors must ensure that their network pharmacies inform enrollees of any differential between the price of a covered Part D drug to an enrollee and the price of the lowest priced generic version of that drug that is an AB-rated alternative, therapeutically equivalent and

prohibition (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), or any other applicable Federal or State law or regulation.

bioequivalent, on the plan's formulary, and available at that pharmacy. This information must be provided:

- At the time the plan enrollee purchases the drug, if the enrollee purchases that drug at a pharmacy; or
- At the time of delivery of that drug, in the case of drugs purchased by mail order.

CMS may modify the timing requirement (i.e., at the time of purchase or delivery) when CMS determines the requirement to be impossible or impracticable to administer.

However, disclosure of this information will not be necessary if the particular covered Part D drug purchased by an enrollee was the lowest-priced generic version of that drug available at a particular pharmacy.

The requirement that information on lowest-priced generic drug equivalents be provided to enrollees for covered Part D drugs purchased by Part D plan enrollees is not applicable when those covered Part D drugs are purchased at:

- Any pharmacy, when the individual is enrolled in an MA private fee-for-service plan that offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies, and does not charge additional cost-sharing for access to covered Part D drugs dispensed at all pharmacies;
- Out-of-network pharmacies;
- I/T/U network pharmacies;
- Network pharmacies located in any of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands); *and*
- *A long-term care pharmacy.*

80 - Privacy, Confidentiality, and Accuracy of Enrollee Records (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

To the extent that a PDP offered by a PDP sponsor maintains medical records or other health information regarding Part D enrollees, the PDP sponsor must meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations offering MA plans must currently meet under 42 CFR 422.118. These requirements do not apply to PACE organizations and cost plans offering qualified prescription drug coverage, since these plans are subject to similar requirements under 42 CFR 460.200(e) and 460.210, and 42 CFR 417.486, respectively.

Specifically, PDP sponsors must:

- Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;
- Ensure that medical information is released only in accordance with applicable Federal and State law;
- Maintain the records and information in an accurate and timely manner; and
- Ensure timely access by enrollees to records and information pertaining to them.

PDP sponsors are covered entities under the HIPAA Privacy Rule because they meet the definition of “health plan” at 45 CFR 160.103. The Department of Health and Human Services Office for Civil Rights (OCR) is responsible for administering and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints, to conduct compliance reviews, and to impose civil money penalties for HIPAA Privacy Rule violations. Thus, any violations by a PDP sponsor for its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a Web site with frequently asked questions and other compliance guidance at: <http://hhs.gov/ocr/hipaa>

Part D sponsors, including both PDP sponsors and MA organizations, must effectively secure all beneficiary information, whether in paper or electronic format. This includes ensuring that data files are not saved on public or private computers when accessing corporate e-mail through the Internet, ensuring staff are properly trained to safeguard information, and ensuring electronic systems are properly programmed for beneficiary mailings to avoid inadvertent disclosures of individually identifiable health information. All sponsors should either perform an internal risk assessment or engage an industry-recognized security expert to conduct an external risk assessment of the organization to identify and address security vulnerabilities. Weaknesses or gaps in Part D sponsors’ security programs should be quickly remedied. Sponsors should annually train staff on responsibilities and consequences of failing to secure sensitive beneficiary information. Compliance with the HIPAA Security and Privacy rules must be documented and kept current in response to environmental or operational changes affecting the security and privacy of the electronic protected health information. In addition to HIPAA requirements, sponsors should notify CMS immediately upon discovery of any security breach compromising beneficiary personally identifiable information.

90 - Electronic Transaction Standards
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102, which sets forth the HIPAA administrative simplification standards for health care claims.

A Part D sponsor must also require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in section 50.11 is presented or on file

at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

90.1 - Unique Benefit Identification Number (BIN)/Processor Control Number (PCN) Provisions

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

For Part D claims with a dispensing date of January 1, 2012 and later, and submitted in, National Council for Prescription Drug Programs (NCPDP) version D.O format, a Part D sponsor must assign and exclusively use a unique:

- Part D cardholder identification number (RxID) for each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries (other fields such as person code may not be used to differentiate enrollees), and*
- Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in its Medicare Part D line of business, unless non-exclusive use is expressly allowed by CMS and industry standard coding.⁵*

Part D sponsors that do not support industry standard coding may only process Part D- covered drug claims under the Part D unique BIN/PCN and must reject all other claims. (See section 90.1.2 below). The intent of the unique BIN/PCN provisions is to ensure: (1) that pharmacies can routinely identify situations in which they are billing a Part D claim; and (2) that payers secondary to Part D can properly coordinate benefits on Part D claims. These goals cannot reliably be met if Part D claims cannot be distinguished from other types of pharmacy claims through unique routing and beneficiary identifiers.

Industry standard coding provides a mechanism whereby, in limited circumstances, both non-Part D Drugs and Part D drugs not covered by the plan may be submitted to and processed under a Part D BIN/PCN. The industry standard coding requires Part D plans to clearly indicate on the paid response whether the drug is a non-Part D Drug covered by a Part D plan benefit structure or a Part D drug not covered by the Part D plan but processed under the Part D BIN/PCN.

It should be noted that in order to use Part D routing identifiers, an organization must sponsor a Part D plan. Thus, stand-alone Medicare Advantage plans should not use Part D routing identifiers.

With respect to which level of the sponsor's or the sponsor's subcontractor's organization the unique routing identifier ("BIN" or "BIN/PCN" combination) should be assigned, the BIN or BIN/PCN combination should uniquely identify the Part D line of business and correspond to a payer sheet applicable solely to Part D processing requirements. This means that the BIN or BIN/PCN combination must be exclusively used for Part D claims processing, and must be supported by a payer sheet, regardless of whether the routing identifiers uniquely identify the

⁵ *E.g., NCPDP Recommendations for Effective 4Rx Usage in Medicare Part D Processing, Version 1.0, July 2011, NCPDP.*

processor, the sponsor's parent organization, or a subset of the sponsor's business. Thus, one BIN or BIN/PCN combination could represent multiple sponsors, as long as only Part D claims are submitted to and processed under that identifier

90.1.1 - Alternate Identifiers/Crosswalking/Mapping **(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)**

Sponsors may not utilize the unique Part D identifiers "behind the scenes" in adjudicating claims while providing different 4Rx data (the BIN, PCN, Group, and Cardholder ID identifiers) to CMS through the MARx system enrollment-related transaction and on PDEs. The 4Rx data submitted to CMS following enrollment, which supports the online real-time eligibility queries ("EI transactions"), must be the same data that pharmacies submit on claims and that the processor uses to adjudicate claims and prepare PDEs. This way, the plan sponsor, its claims processor, the pharmacy, the TrOOP facilitator, and any subsequent payers that wrap around the Part D benefit can all accurately identify and manage Part D claims.

As of January 1, 2012, CMS does not permit the use of alternate identifiers on the inbound claim that are subsequently crosswalked or otherwise mapped to the identifiers on record with CMS and/or then converted into PDEs. When alternate identifiers have previously been utilized prior to the implementation of this policy change, there may be initial disruption the first time a pharmacy claim is submitted using the old identifiers, and it will be denied. However, the correct identifiers should be readily available through the use of an EI query or claim reject responses processes as defined by industry standard. Once the proper identifiers have been submitted, subsequent claims should not reject for invalid BIN/PCN/Group or Member ID.

CMS recognizes that some plans and processors do not use all 4 data elements of 4Rx (BIN/PCN/GROUP/Cardholder ID) or may only use a portion of the characters for matching purposes and as such expects that sponsors consult the industry standard on how to communicate to CMS when certain data elements or values within a data element are not used.

90.1.2 - Sponsors that do not Support Industry Standard Coding to Distinguish non-Part D-Covered Drugs **(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)**

If a sponsor does not support industry standard coding as described above in this section, the sponsors must not use the Part D BIN or RxBIN and Part D processor control number (RxPCN) for the following type claims:

- **Part B Claims**

The Part D routing identifiers cannot be used to process Part B claims at point of sale when the sponsor is a Medicare Advantage Organization or an MA-PD. Processing a Part B claim as if it were a Part D claim will cause the pharmacy to pass the Part B claim to any secondary payer or subsequent payers that coordinate benefits with Part D. This may result in these other payers providing benefits that they are not authorized to provide.

- **Co-Administration of Part D and Secondary Payer Benefits**

Unique Part D routing identifiers may only be used to process co-administered primary Part D and secondary payer benefits, such as when a sponsor contracts with both CMS for primary Medicare Part D benefits and with an SPAP for secondary coverage, as long as the sponsor is reasonably certain that no other payers are liable to coordinate benefits on Part D claims. (In the absence of independent knowledge of any such other payers, the sponsor may rely upon the CMS Coordination of Benefits (COB) files for this information). In this situation, the pharmacy would correctly treat the claim as a Part D claim, and no subsequent payer would be at risk of inappropriate coordination of benefits. However, the sponsor takes on additional risk in segregating and reporting the components of the one transaction properly to the two respective payers, as well as ensuring that the transaction is HIPAA compliant.

- ***Discount Card Transactions***

The unique Part D routing numbers cannot be used to process discount card or other transactions that extend Part D negotiated prices to non-covered drugs (Part D or otherwise). Such use could lead pharmacies to misidentify such claims and apply Part D rules, terms and conditions to non-Part D claims.

90.2 - Prescriber Identifiers

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Sponsors must report on PDE records one of the following four prescriber identifiers:

- *NPI,*
- *DEA number*
- *UPIN*
- *State license number*

Beginning January 1, 2012, sponsors must ensure these identifiers are active and valid.

Sponsors may not reject a pharmacy claim solely on the basis of an invalid prescriber identifier in order to not impede Medicare beneficiary access to needed medications unless the issue can be resolved at point of sale. In other words, sponsors may not reject a pharmacy claim at point of sale without prompt follow-up to ensure that the claim has been resubmitted with a corrected and valid prescriber identifier, or new information has been otherwise received to correct the sponsor's information. If this is not possible, pharmacies can fill prescriptions and sponsors can pay the associated drug claims with an unvalidated prescriber ID at the point of sale. However, sponsors are then responsible for verifying and reporting a valid prescriber ID on the PDE record, and, whichever type of identifier is reported on the PDE, the identifier must be valid. Therefore, if an active and valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire a valid ID of one of the four acceptable types before the PDE is submitted to CMS.

Follow-up may require review of the prescription, contact with the prescriber, use of the multiple sources of state and federal data on providers, or the purchase of prescriber ID validation services from a commercial vendor. Among the available state and federal sources are individual state licensing board data on licensing and sanctions, Drug Enforcement Agency registrant files, the Social Security Administration death file, OIG and state Medicaid program excluded provider lists, and the CMS National Plan & Provider Enumeration System (NPPES) database. Periodically updated files are available from these databases, in some cases directly from these agencies, or otherwise through the Department of Commerce's National Technical Information Service (NTIS). In addition to these resources, CMS understands that multiple commercial firms compile databases and offer services for validation of prescriber identifiers, so an alternative approach would be for sponsors to purchase prescriber identifier validation services from commercial vendors who already have access to these sources of data and are currently providing these services to pharmacy, health plan, and pharmaceutical manufacturer clients. Thus, sponsors have the option to either build their own systems or contract with commercial vendors for prescriber ID validation services.

Although the requirement for validation of prescriber identifiers is imposed on Part D sponsors, CMS expects that network pharmacies may either contractually agree to provide some of these services themselves, or will fully support any retrospective review of the prescription and other records necessary to identify the prescriber and obtain a valid identifier. Contractual negotiations between sponsors/their agents and network pharmacies should address the terms and conditions as to responsibilities for these processes and any penalties for failure to perform. However, any requirement for a pharmacy to acquire and utilize its own automated validation capability should be a result of mutual agreement between the parties, since such a requirement may be impractical for many smaller pharmacy organizations. Also, CMS would expect that pharmacies will have the opportunity to correct any invalid data before payment for a claim is reversed whether or not the applicable contract delegates any sponsor duties.

90.2.1 - Foreign Prescribers

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Certain border states permit prescriptions from foreign (e.g., non-U.S. or U.S. territory licensed) prescribers under their applicable pharmacy laws.

The only exception to the guidance in section 90.2 of this manual is that the identifier of a foreign prescriber cannot practically be validated. Therefore, sponsors should use the license number assigned by the foreign jurisdiction and report it on the PDE without validation against any official database, if the Part D claim was submitted in a state that recognizes prescriptions from foreign-located prescribers. By license number, CMS means the one assigned by an appropriate licensing board in the foreign jurisdiction in which the prescriber practices/resides on the claim with the State license qualifier.

90.2.2 - Beneficiary Requests for Reimbursement

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Beginning 2012, a valid prescriber identifier must be reported on the PDE record of non-standard format claims, such as requests for reimbursement ("paper" claims) submitted by

Medicare beneficiaries. Sponsors may require members to furnish the prescriber's name and address or phone number, or the pharmacy information, to assist the sponsor in obtaining the prescriber ID. Once the prescriber or pharmacy contact information is acquired, the sponsor must process the request for reimbursement and the sponsor, or the pharmacy (if doing so is in accordance with its contract terms), must follow up retrospectively to acquire a valid ID. Follow-up may entail a review of the prescription, prescriber contact, use of state or federal data on providers, or purchase of prescriber ID validation services from a commercial vendor.

Payment to the beneficiary cannot be made dependent upon the sponsor's acquisition of the prescriber ID, itself. Sponsors may withhold reimbursement to the beneficiary only if there is a reason to suspect fraud or if there are coverage issues. In the absence of fraud, if the sponsor is unable to retrospectively acquire a valid prescriber ID, the sponsor may not seek recovery of the Part D payment from the beneficiary.

90.2.3 - National Provider Identifiers (NPIs)

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

CMS will begin validating the format of all prescriber identifiers on PDEs that are coded as an NPI and will exclude from payment reconciliation PDEs with invalid NPIs. CMS will also be assessing each sponsor's performance regarding NPI use and validity and will be notifying plan sponsors of their performance level. While section 90.2 of this manual has specifically addressed prescriber identifiers, CMS reminds both Medicare Advantage organizations and Part D sponsors that they are also required to obtain valid provider NPIs on claims. NPIs may be deactivated for reasons such as provider death or fraud related to identity theft and other forms of fraud. The NPPES database is updated monthly to reflect these changes. Therefore, in addition to verifying the reported NPI is valid, sponsors must also periodically confirm the identifiers are active. In those instances when the NPI is found to have been deactivated, sponsors must follow up with the provider to determine the reason for the deactivation.

90.2.4 - Controlled Substances

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

In 2012, sponsors are required to confirm the validity of DEA numbers on Schedule II-V drug claims or map NPIs on these claims to the prescriber's DEA numbers. In addition, sponsors will be required to confirm that the controlled substance prescribed is consistent with the prescriber's DEA Schedule registration. As noted in section 90.2 of this manual, sources of state and federal data on providers are available to support sponsor efforts in this regard in addition to prescriber identifier validation services from commercial vendors. Sponsors should understand that this requirement supports (and does not supersede or alter) existing pharmacy obligations relative to DEA registrants under the Controlled Substances Act and DEA rules.

Appendix 1: Adequate Access to Network Home Infusion Pharmacies by State/Territory and Contract Type

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

State	MA-PD		PDP & RPPO	
	Number of HI Pharmacies Needed to Meet Adequate Access for Full-State Service Areas	Eligible Beneficiaries to HI Pharmacy (Beneficiaries: HI Pharmacy)	Number of HI Pharmacies Needed to Meet Adequate Access	Eligible Beneficiaries to HI Pharmacy (Beneficiaries: HI Pharmacy)
AK	2	59,500:1	2	59,500:1
AL	13	67,500:1	13	67,500:1
AR	7	84,500:1	7	84,500:1
AZ	10	96,000:1	8	108,000:1
CA	60	80,000:1	49	97,500:1
CO	9	72,000:1	9	72,000:1
CT	7	91,500:1	7	91,500:1
DC	2	75,000:1	2	75,000:1
DE	2	140,000:1	2	140,000:1
FL	24	139,000:1	25	133,500:1
GA	14	88,500:1	13	95,500:1
HI	2	193,500:1	2	193,500:1
IA	8	72,500:1	6	101,000:1
ID	3	106,500:1	3	106,500:1
IL	17	111,000:1	15	126,500:1
IN	12	87,500:1	12	87,500:1
KS	8	59,500:1	8	59,500:1
KY	18	43,000:1	18	43,000:1
LA	5	163,500:1	6	131,000:1
MA	12	92,500:1	11	102,000:1
MD	9	93,000:1	9	93,000:1
ME	3	126,500:1	3	126,500:1
MI	27	63,000:1	27	63,000:1
MN	10	83,000:1	9	93,500:1
MO	11	96,500:1	11	96,500:1
MS	4	159,000:1	4	159,000:1
MT	6	32,000:1	6	32,000:1
NC	21	73,500:1	19	80,000:1
ND	2	106,500:1	2	106,500:1
NE	9	34,000:1	8	39,000:1
NH	2	204,500:1	2	204,500:1
NJ	8	183,000:1	8	183,000:1
NM	5	73,500:1	5	73,500:1

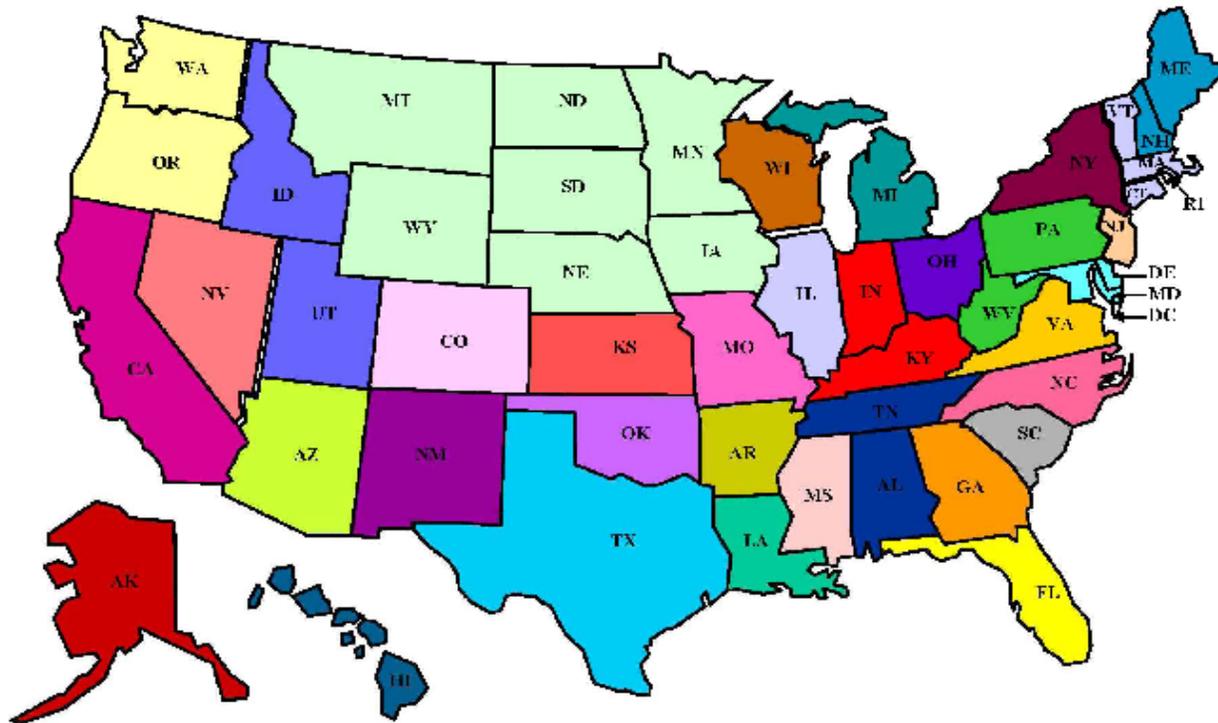
State	MA-PD		PDP & RPPO	
	Number of HI Pharmacies Needed to Meet Adequate Access for Full-State Service Areas	Eligible Beneficiaries to HI Pharmacy (Beneficiaries: HI Pharmacy)	Number of HI Pharmacies Needed to Meet Adequate Access	Eligible Beneficiaries to HI Pharmacy (Beneficiaries: HI Pharmacy)
NV	10	36,500:1	10	36,500:1
NY	25	120,500:1	25	120,500:1
OH	18	108,000:1	18	108,000:1
OK	7	96,000:1	7	96,000:1
OR	5	145,500:1	5	145,500:1
PA	27	85,500:1	27	85,500:1
RI	4	59,500:1	4	59,500:1
SC	9	89,500:1	7	119,500:1
SD	2	131,500:1	2	131,500:1
TN	21	52,500:1	19	57,000:1
TX	40	75,500:1	34	90,000:1
UT	3	131,500:1	3	131,500:1
VA	14	83,000:1	13	89,500:1
VT	2	104,500:1	2	104,500:1
WA	12	82,000:1	12	82,000:1
WI	7	145,500:1	7	145,500:1
WV	6	74,500:1	4	124,500:1
WY	3	38,000:1	2	76,000:1
Territory	MA-PD		PDP & RPPO	
	Number of HI Pharmacies Needed to Meet Adequate Access for Full-Territory Service Areas*	Eligible Beneficiaries to HI Pharmacy (Beneficiaries: HI Pharmacy)	Number of HI Pharmacies Needed to Meet Adequate Access*	Eligible Beneficiaries to HI Pharmacy (Beneficiaries: HI Pharmacy)
AS	<i>No defined minimum</i>		1	3500:1
GU	<i>No defined minimum</i>		2	11,500:1
MP	No defined minimum		No defined minimum	
PR	3	315,500:1	2	630,500:1
VI	2	15,000:1	2	15,000:1

NOTE: Number of pharmacies listed above is based on the Beneficiary Data Count File (release date January 4, 2011) used for the CY2011 Reporting Requirements & CY2012 Part D Applications. The number of pharmacies needed to meet adequate access may change annually based on beneficiary counts.

Appendix 2: PDP Regions

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Appendix 2

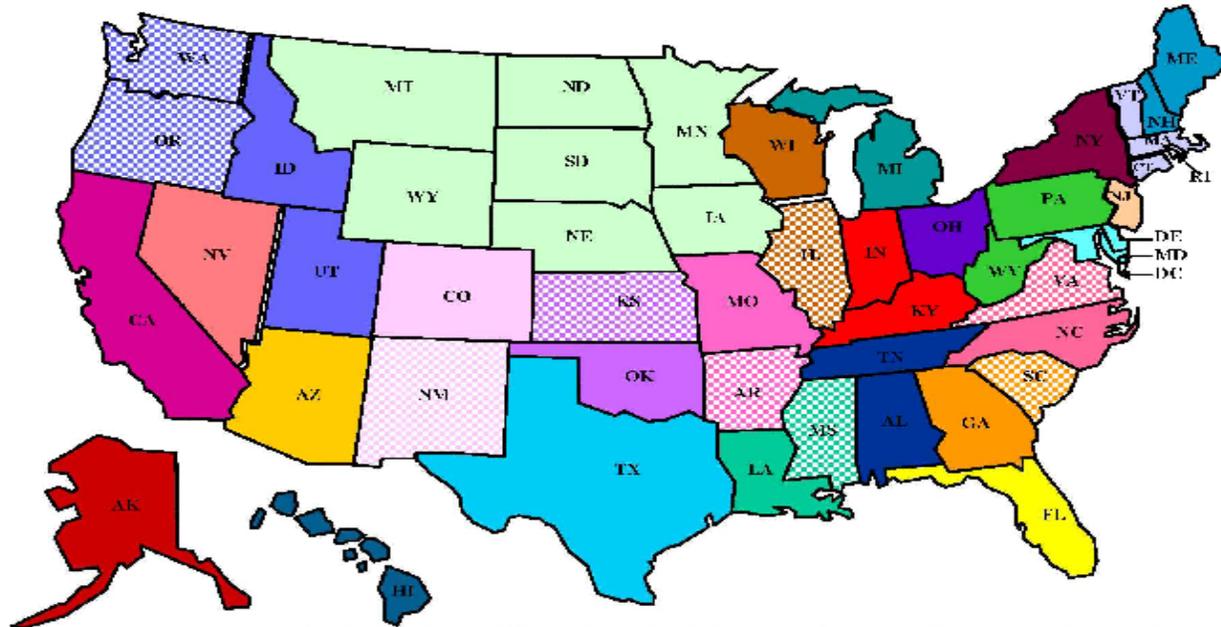


Note: Each territory is its own PDP region.

Appendix 3: MA Regions

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Appendix 3



Note: An MA region is one color. A difference in shading indicates that there are multiple PDP regions nested within the MA region. No change indicates that the MA and PDP regions are the same. For example, Wisconsin and Illinois are in one MA region; they are each a separate PDP region. Each territory is its own PDP region.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R14PDB	09/30/2011	Chapter 5 - Benefits and Beneficiary Protections	09/30/2011	N/A
R5PDB	12/18/2009	Chapter 5 - Benefits and Beneficiary Protections	01/01/2010	N/A
R1PDB	07/03/2008	Initial release of chapter	07/03/2008	N/A