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September 5, 2006

Memorandum To: All Part D plans

Subject: Medicare Prescription Drug Benefit Manual – Draft of Chapter 5

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Today we are releasing for comment the draft of Chapter 5 of the Medicare Prescription Drug Benefit Manual. The draft of Chapter 5 consolidates previous guidance, questions and answers, and HPMS memoranda. In particular, the revised draft contains information specific to the following areas:

- Part D benefits offered by Part D sponsors
- The establishment of 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.

Comments on the draft of Chapter 5 must be received by CMS no later than 5:00 p.m. EST, Monday, September 18, 2006. Comments must be submitted via e-mail at PartDBenefitImpl@cms.hhs.gov. Please include "Chapter 5" in the subject line of the email.

If you have questions, please contact Vanessa Duran at (410) 786-8697 or Marla Rothouse at (410) 786-8063.

Prescription Drug Benefit Manual

Chapter 5: Benefits and Beneficiary Protections

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Note: This manual is subject to change to both periodic and annual updates and currently reflects CY 2007 guidance.

10 – Benefits and Beneficiary Protections

10.1 – Introduction

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 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.

Other requirements related to beneficiary protections are contained in other chapters of the Prescription Drug Benefit Manual and the Marketing Guidelines, which can be accessed at:

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf>.

10.2 – Definition of Terms

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).

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

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.

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 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.

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.

Or otherwise: Through a government-funded health program.

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

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).

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 brand product that has a generic equivalent but is on a Part D sponsor's formulary at lower cost-sharing than the non-preferred generic equivalent on the sponsor's formulary.

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 nonpreferred 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.

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

20.1 – General

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 (as described in section 20.4), we also make 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, as described in section 20.4.2. 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

A PDP sponsor must offer its prescription drug plans to all Part D eligible beneficiaries residing in those plans’ service areas (please refer to [section 40](#) for more information about prescription drug plan 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

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](#); 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

In 2007, defined standard coverage consists of coverage of covered Part D drugs subject to:

- An [annual deductible](#) of \$265.
- Twenty-five percent coinsurance for costs above the [annual deductible](#) but at or below an [initial coverage limit](#) of \$2400.
- One hundred percent coinsurance for costs above the [initial coverage limit](#) and at or below the [annual out-of-pocket threshold](#) of \$3850.
- Nominal cost-sharing equal to the greater of: (1) 5 percent coinsurance, or (2) a copayment of \$2.15 for a generic drug or a preferred multiple source drug and

\$5.35 for any other drug once an enrollee costs exceed the annual out-of-pocket threshold.

Beginning in 2007, the annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost-sharing after the annual out-of-pocket threshold is met will be adjusted annually. As provided in 42 CFR 423.104(d)(5)(iv), 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. However, CMS will not have Part D program data that can be used in this annual percentage increase until 2008 (for the 2009 contract year benefit parameters). Therefore, until sufficient Part D program data becomes available, the National Health Expenditures (NHE) prescription drug per capita estimates will be used as the basis for updating the benefit parameters. The 2008 and future updates will include an adjustment for any variations between the projected and actual amounts from the prior period. For more information about this methodology, please refer to:

http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/2007_Part_D_Parameter_Update.pdf

Table 2 below summarizes the parameters for defined standard coverage for 2007.

Table 2
Defined Standard Coverage Benefits for 2007

	Cost-Sharing Percentage	Beneficiary Out-of-Pocket Costs	Plan Payment Percentage	Plan Payment
Annual Deductible (\$0-\$265 in spending on covered Part D drugs covered under the plan)	100 percent	\$265	0 percent	\$0
Initial Benefit (>\$265 - ≤\$2400 in spending on covered Part D drugs covered under the plan)	25 percent	\$533.75	75 percent	\$1601.25
No coverage of costs (>\$2400 - ≤\$5451.25 ¹ in spending on covered Part D drugs covered under the plan)	100 percent	\$3051.25	0 percent	\$0
Catastrophic Coverage (after the enrollee has incurred out-of-pocket costs on covered Part D drugs covered by the plan greater than \$3,850; this is generally equivalent to \$5451.25 ¹ in covered spending)	The greater of: (1) 5 percent; or (2) \$2.15 for a generic or preferred multiple source drug/\$5.35 for other drugs.	--	95 percent	--

¹ This figure may, in fact, be higher to the extent that a Part D enrollee is reimbursed for out-of-pocket costs for covered Part D drugs covered under his/her plan by a group health plan, insurance or otherwise, or other third party arrangement.

20.3.2 – Actuarially Equivalent Standard Coverage

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 in the catastrophic portion of the benefit, provided that those alternative cost-sharing requirements are actuarially equivalent to the average expected cost-sharing of the greater of 5 percent coinsurance or \$2.15/\$5.35 copayments under defined standard coverage.

Alternative 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 of the greater of 5 percent coinsurance or \$2.15/\$5.35 copayments in the catastrophic portion of the benefit. Any such alternative 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

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 20.5](#). 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 included under defined standard coverage (the greater of 5 percent coinsurance or \$2.15/\$5.35 copayments).

3. Ensure that the beneficiary premium is at least equal to the beneficiary premium under defined standard coverage.
4. Ensure that, for an individual whose total spending exceeds the initial coverage limit under standard prescription drug coverage, the 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.

20.4.1 – Basic Alternative Coverage

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
- A modification of the initial coverage limit

20.4.2 – Enhanced Alternative Coverage

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” (between the initial coverage limit and the annual out-of-pocket deductible) such that enrollees are liable for less than 100 percent of cost-sharing, 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
- Coverage of drugs that are specifically excluded as Part D drugs under 42 CFR 423.100, 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 (please refer to section 10 of Chapter 6) coverage of over-the-counter drugs could not be offered as part of supplemental benefits. For more information about coverage of over-the-counter products, please refer to section 10.10 of Chapter 6.

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

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.

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

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. Required prescription drug coverage consists of either: (1) basic prescription drug coverage, 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 section 1854(b)(1)(C) of the Act against the otherwise applicable premium. Rebate dollars represent the dollars available for supplemental (and other) benefits when an MA plan's risk-adjusted non-Part D bid is under the risk-adjusted non-drug monthly benchmark amount.

In other words, to the extent that an MA-PD plan chooses to provide enhanced alternative coverage for 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. This requirement ensures that MA organizations offer at

least one option for Part D coverage for a premium at the cost of basic prescription drug coverage.

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

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.

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.

An enrollee in the cost plan may, at his or her option, elect whether 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 – Negotiated Prices

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 (for example, 100 percent cost-sharing in the coverage gap). Negotiated prices will have to take into account negotiated price concessions for covered Part D drugs such as:

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

In addition, negotiated prices must include any applicable dispensing fees (discussed in section 20.6).

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 or coverage gap, in which an enrollee is responsible for 100 percent cost-sharing – for all covered Part D drugs. 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.

20.6 – Dispensing Fees

As discussed in section 20.5, negotiated prices must include any applicable dispensing fees. Provided that Part D sponsors include only those activities allowed under our 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, we note 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 3 below provides a summary of the costs that may be included in dispensing fees, as well as those that may not.

**Table 3
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"> ○ 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 <u>42 CFR 423.153(c)(2)</u> ○ 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 <u>section 10.4 of Chapter 6</u>; ○ Filling the container ○ Physically providing the completed prescription to the Part D enrollee
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	<ul style="list-style-type: none">○ Delivery○ Special packaging○ Overhead associated with maintaining the facility and equipment necessary to operate the pharmacy <ul style="list-style-type: none">● Reasonable pharmacy costs that are appropriate for the typical beneficiary in that pharmacy setting, for example:<ul style="list-style-type: none">○ 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, we believe 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, we believe 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 a 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, we believe that non-LTC facilities in which individuals meeting an institutionalized level of care need reside 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 for via the dispensing fee. However, we note 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
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	<p style="text-align: center;">institutionalized level of care need.</p> <ul style="list-style-type: none"> • The equivalent of all reasonable pharmacy costs discussed above, in the case of pharmacies owned and operated by a Part D sponsor itself, including the salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy.
<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. 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 or distributors to dispensing pharmacies.

30 – Incurred / “True Out-of-Pocket” (TrOOP) Costs

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 4 below provides a summary of those discussions.

**Table 4
Costs that Do and Do Not Count Toward TrOOP Expenditures**

<p>Costs that Count Toward Incurred / TrOOP Expenditures</p>	<ul style="list-style-type: none"> • Costs incurred against any applicable enrollee cost-sharing under the plan’s benefit design • Costs incurred for covered Part D drugs • Costs incurred by an enrollee • Costs paid on behalf of an enrollee by another “person” • Costs paid on behalf of an enrollee by a qualified State Pharmaceutical Assistance Program (SPAP) • Costs paid on behalf of an enrollee under the low-income subsidy • Costs incurred at either a network pharmacy or at an out-of-network pharmacy consistent with the plan’s out-of-network access policy • Any differential between a network retail pharmacy’s and a network mail-order pharmacy’s contracted rate for an extended supply of a covered Part D drug paid by an enrollee at a retail pharmacy • Any out-of-network differential paid by the enrollee • Costs for Part D drugs incurred during plan transition processes and in plan-to-plan and state-to-plan reconciliation processes. • Costs incurred by enrollees by using a discounted cash price, and not their Part D benefit, for a covered Part D drug purchased at a network pharmacy in any applicable deductible or coverage gap phase of their benefit (consistent with our Coordination of Benefits Guidance). • Any waiver or reduction of cost-sharing by a pharmacy that is not a TrOOP-excluded entity, consistent with <u>section 1128A(i)(6)(a)</u> of the
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	<p style="text-align: center;"><u>Social Security Act.</u></p> <ul style="list-style-type: none"> •
<p>Costs that Do Not Count Toward Incurred / TrOOP Expenditures</p>	<ul style="list-style-type: none"> • Costs incurred for non-formulary Part D drugs (unless they are treated as being included in the formulary as a result of a coverage determination, redetermination, or appeal) • Costs incurred for excluded Part D drugs • Costs incurred at an out-of-network pharmacy when such access is inconsistent with the plan's out-of-network access policy • Costs paid by insurance • Costs paid by a government-funded health program • Costs paid by a group health plan • Costs paid by another third party payment arrangement • Any waiver or reduction of cost-sharing by a pharmacy that is a TrOOP-excluded entity, consistent with <u>section 1128A(i)(6)(a) of the Social Security Act.</u>

30.1 – Costs that Count as Incurred Costs

The following are considered incurred costs and can be added to an enrollee's TrOOP balance:

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.
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.
3. Costs incurred by the enrollee.
4. Costs incurred by another person on behalf of the enrollee (please note that the definition of "person" includes charities if they are not otherwise excluded as TrOOP-eligible payers as provided in section 30.2).
5. Costs that are paid by the government on behalf of a low-income individual under the Part D subsidy provisions described in 42 CFR 423.782.

6. Costs that are paid on behalf of the enrollee under a qualified State Pharmaceutical Assistance Program (SPAP) described in 42 CFR 423.454.
7. Costs for covered Part D drugs incurred by a TrOOP-eligible party at a network pharmacy or out-of-network, consistent with the plan's out-of-network access policy (please refer to section 60 for more information on out-of-network access requirements).
8. 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.
9. Any differential charged to the beneficiary between an out-of-network (OON) pharmacy's usual and customary price for a covered Part D drug purchased in accordance with the out-of-network rules described in section 60 and the plan allowance for that covered Part D drug.
10. Costs for Part D drugs incurred during plan transition processes and in plan-to-plan and state-to-plan reconciliation processes.
11. As provided in our Coordination of Benefits Guidance, 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 this or her benefit; and the enrollee submits appropriate documentation to his or her Part D plan to be credited for the purchase.
12. Covered Part D drug cost-sharing waived or reduced by a pharmacy consistent with section 1128A(i)(6)(A) of the Act, and as described in section 30.3.

30.2 – Costs that Do Not Count as Incurred Costs

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.
2. Costs for Part D excluded drugs, as described in section 20.1 of Chapter 6.
3. Costs paid out-of-network when such out-of-network access is not consistent with the plan's out-of-network access policy (please refer to section 60 for more information on out-of-network 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.¹
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.

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

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 5 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.

¹ 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 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 5
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 (S-CHIP) • Federally Qualified Health Centers (FQHCs), Rural Health Clinics, and any safety-net facilities that are considered “government-funded health programs” • AIDS Drug Assistance Programs (ADAPs) • I/T/U facilities • 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 <u>42 CFR 423.454</u>. • 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) • Tribal coverage utilizing only non-Federal sources of funding • 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, the fact that coverage that supplements the benefits available under Part D coverage provided by certain entities is excluded from the definition of incurred costs for purposes of TrOOP has no bearing on counting that supplemental coverage against the deductible. Although that wrap-around coverage will not count toward TrOOP, it will count against any applicable enrollee deductible and will therefore not affect an enrollee’s ability to satisfy the deductible and therefore qualify for reduced cost-sharing between the deductible and the initial coverage limit. In addition, TrOOP rules would not preclude an entity from paying for a Part D enrollee’s cost-sharing above the annual out-of-pocket threshold once a beneficiary has accumulated incurred costs in excess of the annual out-of-pocket threshold.

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

Under the exception to the anti-kickback statute added by section 101(e) of the MMA, pharmacies are permitted to waive or reduce 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, as set forth in section 1128A(i)(6)(a) of the Act. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing without regard to these standards for beneficiaries enrolled in a Part D plan eligible for the low-income subsidy under section 1860D-14 of the Act, provided the pharmacy has not advertised that the waivers or reductions of cost-sharing are available. Depending on the circumstances, pharmacies that waive or reduce cost-sharing amounts for covered Part D drugs without following the requirements of the pharmacy waiver safe harbor could be subject to civil monetary penalties and exclusion from participating in Federal health care programs, as well as criminal fines and imprisonment under the anti-kickback statute.

Waivers or reductions of Part D cost-sharing by pharmacies will generally count toward TrOOP. However, 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. Thus, 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.

Receipt of Medicaid or Medicare Disproportionate Share Hospital (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." We view Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services, and not akin to government grants and funding that are used, in whole or in part, to provide to (or pay on behalf of) an individual the costs of Part D drugs. That notwithstanding, any program that is operated or funded, in whole or in part, by any government agency, and which uses those 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. To the extent that an entity that receives DSH funds uses non-DSH government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs, it will meet our 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.

If a safety-net 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 such 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 NCPDP 5.1 transaction set for safety-net 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. We recommend 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

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.

On December 6, 2004, we announced the establishment of 34 PDP regions and 26 MA regions (please refer to [Appendix 1](#) and [Appendix 2](#), 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. It is important to note that, while these regional boundaries are in effect for 2007, CMS may revise both the PDP and MA regions in future years.

50 – Access to Covered Part D Drugs

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 long-term care pharmacies for enrollees residing in long-term care pharmacies; and (4) convenient access to I/T/U pharmacies for American Indian/Alaska Native (AI/AN) enrollees.

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 our 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 an enrollee residing in a long-term care facility convenient access to a network long-term care pharmacy that serves the long-term care 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.

In addition, Part D sponsors should notify their Part D account manager if they begin to use a different pharmacy benefits manager (PBM) to manage their pharmacy network.

50.1 – Retail Pharmacy Access

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 plans to establish pharmacy networks in which:

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

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

- Regional MA-PD plans and PDPs: 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 plan or a PDP 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 plan may not meet the convenient access standards by applying those standards across the entire multi-State geographic area it services.

- Local-MA-PD plans: 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 Federal Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) toward the standards for convenient access to retail pharmacies detailed above. However, we 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.

We are 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. We 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

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. 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.

50.3 – Specialty Pharmacy Access

Part D sponsors may not restrict 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. Specifically, Part D sponsors may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Therefore, Part D sponsors may not restrict access based solely on the placement of a Part D drug in a "specialty/high cost" tier because this tier placement alone is not indicative of any special requirements associated with such drug.

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. Requiring pharmacies to accept different reimbursement rates for certain “specialty” drugs is inconsistent with standard industry practice, could result in Part D sponsors setting reimbursement rates below the market rates set in their standard contracts, and could be used to subvert the convenient access standards.

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.

50.4 – Home Infusion Pharmacy Access

Part D sponsors must demonstrate that their contracted pharmacy network provides adequate access to home infusion pharmacies. In order to demonstrate adequate access to home infusion pharmacies, Part D sponsors must include, as part of their initial pharmacy access submissions: (1) a beneficiary to home infusion pharmacy ratio; (2) a list of all contracted home infusion pharmacies, including the States/territories in which they are licensed, for the State(s) or territories that are covered in the service area under each CMS designated contract number; and (3) a narrative that describes how the Part D sponsor will provide adequate access.

CMS will evaluate whether Part D sponsors provide adequate access through analysis of these submissions. When evaluating the home infusion pharmacy ratios, we will compare submitted ratios across Part D sponsors in the same service area and identify outliers. The beneficiary to home infusion pharmacy ratio must provide the following information:

- For local MA-PD plan and cost plan sponsors: The total number of beneficiaries (provided by CMS) in the total service area across all plans in the service area under a CMS designated contract number, relative to the number of home infusion pharmacies contracted by the sponsor that are licensed in the State(s) and/or territory(ies) covered by the total service area.
- For regional MA-PD plan sponsors and PDP sponsors: The total number of beneficiaries (provided by CMS) in each of the State(s) or territory(ies) covered under the CMS designated contract number, relative to the number of home infusion pharmacies contracted by the sponsor that are licensed in the State(s) and/or territory(ies).

While we do 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. In addition, Part D sponsors must require that contracted network pharmacies that deliver home infusion drugs ensure that the professional services and ancillary supplies necessary for the provision of home infusion therapy are in place before dispensing home infusion drugs. Obtaining these assurances is a minimum quality assurance requirement for Part D sponsors as provided in 42 CFR 423.153(c).

Home infusion pharmacy networks must also include contracted pharmacies capable of providing infusible Part D drugs for both short-term acute care (e.g., IV antibiotics) and long-term chronic care (e.g., alpha one anti-trypsin protease inhibitors) therapies. While the same network pharmacy does not necessarily need to be capable of providing the full range of infusible Part D drugs, a Part D sponsor's home infusion network, in the aggregate, must have a sufficient number of pharmacies capable of providing the full range of home infusion Part D drugs to ensure enrollees have adequate access to medically necessary home infusion therapies when needed.

50.5 – Long-Term Care (LTC) Pharmacy Access

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 a 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

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 (NLTCP) pharmacies. 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.

We expect 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 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 out-of-network (OON) access to meet the convenient access standard. All of a Part D sponsor's enrollees who reside in a LTC facility must be able to routinely receive their Part D benefits through the plan's network of pharmacies in order for a Part D sponsor to be in compliance with our 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 a 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 a 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: (1) a nursing home bed to LTC pharmacy ratio; (2) a list of all contracted LTC pharmacies; and (3) a narrative that describes how the Part D sponsor will provide convenient access.

CMS will evaluate whether Part D sponsors provide convenient access to LTC pharmacies through analysis of these submissions. When evaluating the LTC ratios, we will compare submitted ratios across Part D sponsors in the same service area and identify outliers. The nursing home bed to LTC pharmacy ratio must provide the following information:

- For local MA-PD plan and cost plan sponsors: The number of nursing home beds (provided by CMS) in the total service area across all plans in the service area under a CMS designated contract number, relative to the number of LTC pharmacies contracted by the sponsor and licensed in the State(s) and/or territory(ies) covered by the total service area.
- For regional MA-PD plan sponsors and PDP sponsors: The number of nursing home beds (provided by CMS) in each of the State(s) or territory(ies) covered under the CMS designated contract number, relative to the number of pharmacies contracted by the sponsor and licensed in the State(s) and/or territory(ies).

We expect 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 a 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 LTC Pharmacies (NLTCs)

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 NLTCs.

1. ***Comprehensive Inventory and Inventory Capacity*** – NLTCs must provide a comprehensive inventory of plan formulary drugs commonly used in the long-term care setting. In addition, NLTCs 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*** – NLTCs 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 NLTC 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 NLTC 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 NLTC must provide written copies of the NLTC's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCs are also required to provide ongoing in-service training to assure that LTC facility staff are proficient in the NLTC's processes for ordering and receiving of medications. NLTCs 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*** – NLTCs must have the capacity to provide specific drugs in Unit 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 seven days each week (up to three 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 a long-term care 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 a 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 long-term care 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, a 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 certain of those services.

These performance and service criteria are not intended to be exclusive or exhaustive. Rather, they are intended to be minimum requirements for becoming a NLTCP. While payment terms for LTC pharmaceutical and dispensing services are subject to negotiations between the Part D sponsor and its NLTCPs, we note 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

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 condition are “reasonable and relevant,” since these are fact-specific questions that are best left between negotiating parties. Thus, for example, we generally do 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 30.4.6 of Chapter 6, in 2007, all plans must offer a temporary supply of non-formulary drugs of at least 30 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 our regulations, plans cannot agree to a differential transition policy for some of their enrollees. Transition policies must be applied uniformly to all 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 our regulations, plans cannot apply prior authorization or other utilization management edits differentially to a subset of their enrollment.

Example 3: Waivers of certain drug utilization review (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 our regulations mean that plans cannot apply DUR edits differentially to a subset of their enrollees. All plan benefits must be applied uniformly to all 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 our 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 IMDs, ICFs/MR, and LTC Hospitals

To the extent that an intermediate care facility for the mentally retarded (ICF/MR) or institute for mental disease (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 our regulatory definition of the term “LTC facility” at 42 CFR 423.100. 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. Once inpatients in LTC hospitals have exhausted their Part A inpatient days benefit, Part D becomes the primary payer for all drugs that cannot be billed to Part B, as discussed in section 20.2.1 of Chapter 6.

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 a LTC facility does not preclude an individual from enrolling in Part D). Part D sponsors will not be compliant with our LTC convenient access standard if they do not provide access to covered Part D drugs via a 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, we encourage Part D sponsors to coordinate their efforts through a single point of contact at the State level. Please refer to the following website for lists of State contacts for IMDs and ICFs/MR:

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

50.6 – I/T/U Pharmacy Access

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. Please refer to the following website 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

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

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 our 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 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. CMS account managers annually will assess continued eligibility for this waiver through its program compliance monitoring.

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

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 our 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 our regulatory access standards and limits access to out-of-network providers consistent with our regulatory provisions regarding out-of-network access;
- Create a network that does not meet our 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.

50.8 – Pharmacy Network Contracting Requirements

In establishing its contracted pharmacy network, a Part D sponsor must meet certain requirements with regarding 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

“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 our regulations at [42 CFR 423.120\(b\)\(8\)\(i\)](#) are fact-specific questions that are 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 demonstrate at the plan level that at least 98 percent of enrollee prescriptions are 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 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.

50.8.2 – Insurance Risk

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 drug to patients) that are not allowed under the Part D benefit.

50.9 – Differential Cost-Sharing for Preferred Pharmacies

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. In other words, 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 sponsor’ 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). 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 423.265](#).

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

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, 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 will be responsible for any higher cost-sharing associated with obtaining those benefits at a network retail pharmacy.

Any increase in cost sharing for benefits, including an extended-day supply, obtained at a network retail pharmacy will be limited to the “differential in charge” to the Part D plan 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. Part D plans 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 30-day supply increments at retail pharmacy rates.

Part D sponsors must therefore include in their contracts with retail pharmacies offering benefits available through network mail-order pharmacies (including extended day supplies of covered Part D drugs) a provision that will allow those 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. We refer to this rate as the network mail-order pharmacy rate.

Additionally, Part D sponsors may 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, but 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 would have to be reflected in higher cost-sharing paid by the beneficiary. We refer 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 higher contracted reimbursement rate vary between pharmacies in the network.

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 a 90-day prescription for retail pharmacies that cannot or will not match the network mail-order pharmacy rate for a 90-day prescription. Suppose under this scenario, the retail pharmacy could not match the network mail-order pharmacy rate (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 retail pharmacy could fill the 90-day prescription at the alternative retail/mail-order pharmacy rate and would 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%.

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. In addition, 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.

50.11 – Use of Identification Card for Accessing Negotiated Prices

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. We have developed standards related to a standardized format for a plan identification card for this purpose. These standards were developed after consultation with the National Council for Prescription Drug Programs (NCPDP) and are summarized in our Marketing Guidelines, which can be accessed at:

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf>

60 – Out-of-Network Pharmacy Access

60.1 – Out-of-Network Pharmacy Access

Part D sponsors must ensure that their enrollees have adequate access to covered Part D drugs dispensed at out-of-network (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 we 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.

Example 5: During any State or 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 had been purchased at a network pharmacy, but also any differential between an OON pharmacy's (or provider's) usual and customary (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.

We expect that enrollees obtaining covered Part D drugs at an OON pharmacy consistent with a Part D sponsor's OON access policy will 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 – Physician Office Access to Vaccines

Part D vaccines that are appropriately dispensed and administered in a physician's office must be covered under Part D sponsors' out-of-network access policies because Part D plan networks are defined as pharmacy networks only. Therefore, 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.

The process of upfront payment by an enrollee and subsequent reimbursement by his or

her Part D plan described for OON pharmacy 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. We offer 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 several approaches, depending upon the vaccine and its respective cost, storage requirements, and complexity of administration. These options are not meant to override the Part D sponsors' obligations to provide OON access – including through upfront payment by an enrollee and subsequent reimbursement by his or her Part D plan – when necessary.

60.2.1 – In Network Vaccine Distribution Approaches

While we are in no way limiting Part D sponsors to any specific approach, we believe 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 copay 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-four 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 (CAP) 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

While the following options are OON arrangements between physicians and Part D sponsors, we expect 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.

70 – Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

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 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; or
- In the enrollee's written explanation of benefits (EOB), in the case of a drug

provided by a long-term care (LTC) network pharmacy.

Disclosure of this information will not be necessary, however, 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; and
- 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).

80 – Privacy, Confidentiality, and Accuracy of Enrollee Records

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:

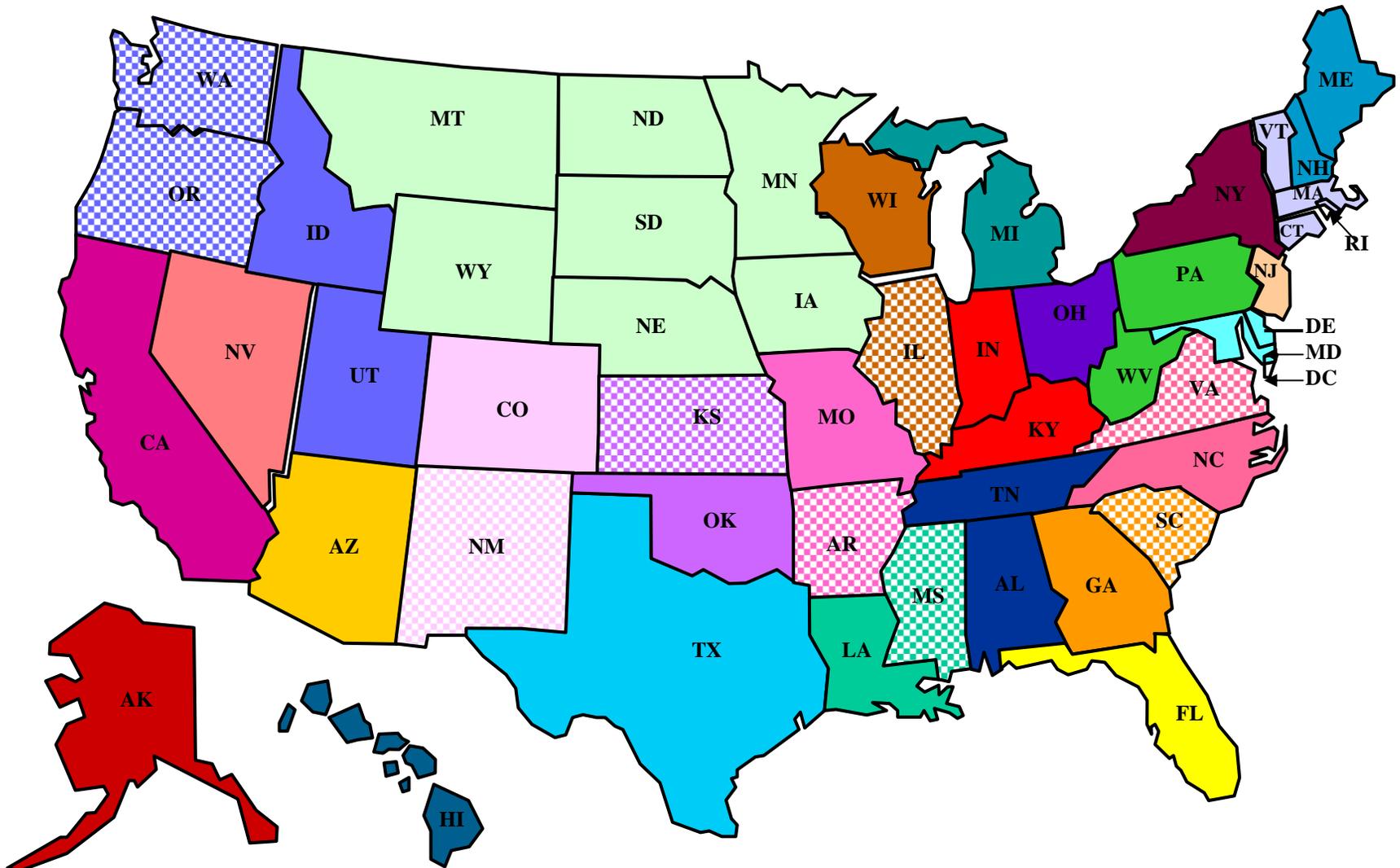
- Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;
- Ensure that medical information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

PDPs are covered entities under the HIPAA Privacy Rule because they meet the definition of “health plan,” as defined in 45 CFR 160.103. The HHS Office for Civil Rights (OCR) is responsible for implementing 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 website with frequently asked questions and other compliance guidance at <http://hhs.gov/ocr/hipaa>

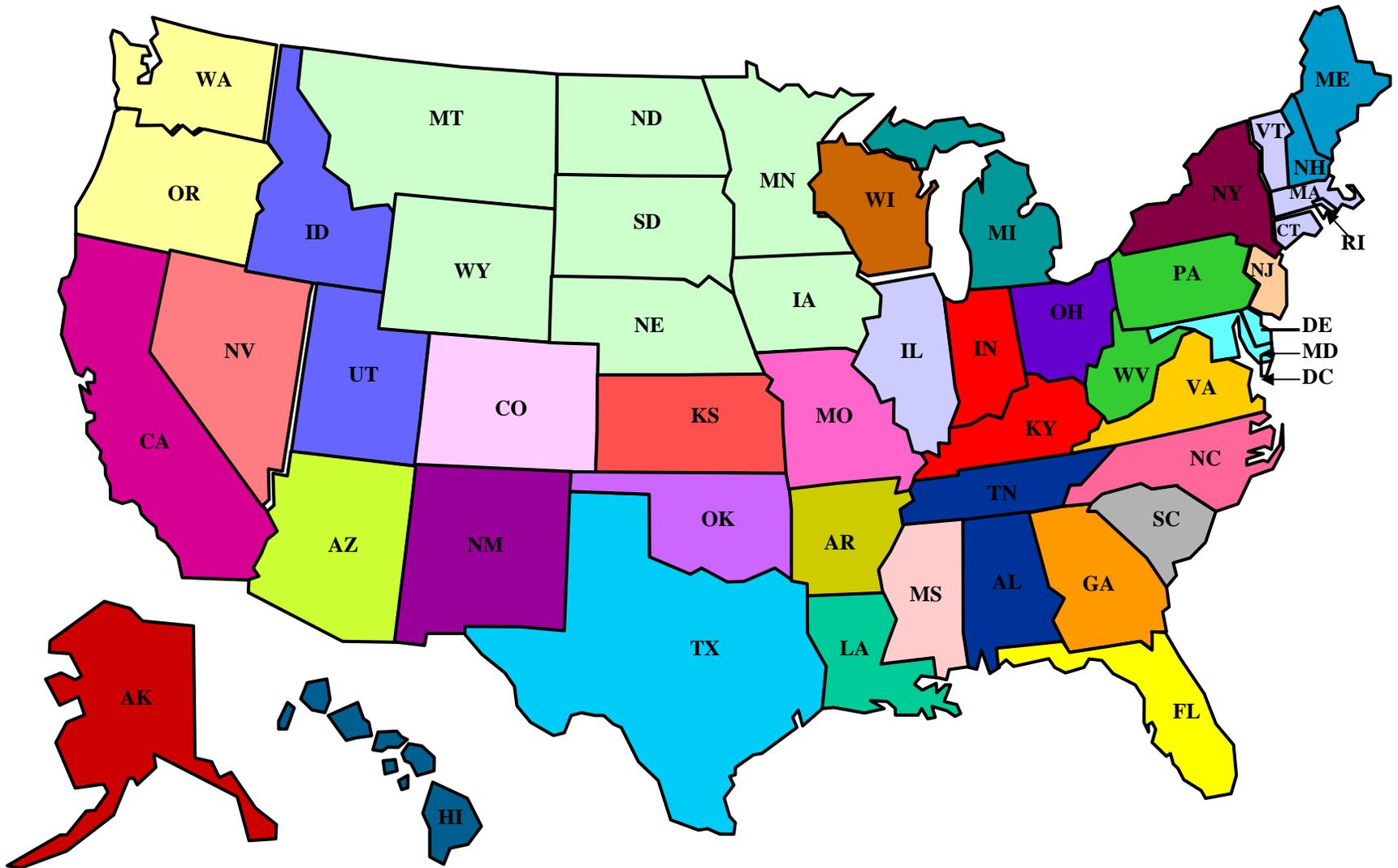
Part D sponsors, including both PDP sponsors and MA organizations, must effectively secure all beneficiary information, whether in paper or electronic format. This includes ensuring that data files are not saved on public or private computers when accessing corporate e-mail through the Internet, ensuring staff are properly trained to safeguard information, and ensuring electronic systems are properly programmed for beneficiary mailings. 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. Organizations 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 of the electronic protected health information. In addition, plans should notify CMS immediately upon discovery of any security breach compromising beneficiary personally identifiable information.

MA and PDP Regions



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.

PDP Regions



Note: Each territory is its own PDP region.