Medicare Part D

Medicare Part D and Long Term Care:
Confusion and Complaints Mark Transition to New Drug Coverage

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I. Introduction

The new Medicare prescription drug benefit, known as "Medicare Part D," represents a major change for long term care (LTC) facilities, their residents, and the pharmacies that serve them. Most nursing home residents are Medicare/Medicaid dual eligibles who, prior to January 1, 2006, had outpatient prescription drug coverage under state Medicaid programs, but have had that coverage withdrawn in favor of enrollment in a Part D plan. This mandatory change from a system based primarily on reimbursement under state-dictated fee schedules to a market-based system with numerous managed care plans as payors has been characterized by confusion and complaints regarding the new program and various program implementation policies adopted by the Centers for Medicare and Medicaid Services (CMS).

One major source of confusion has been the success of the program in attracting companies interested in offering the Part D benefit. In many states there are more than forty stand-alone prescription drug plan (PDP) benefit options available, in addition to the Part D plan options offered as part of Medicare Advantage plans, Section 1876 cost-reimbursed plans, and PACE programs. Given the complicated design of the program as established by Congress, the numerous variations in benefit designs and coverage policies that plan sponsors are permitted to make, the many differences under the program for different groups of beneficiaries, and the varying individual situations of each LTC resident, it is hardly surprising that much of the LTC population and those charged with making decisions or caring for them have been bewildered.

CMS has worked to overcome this confusion, but also has come under significant criticism for contributing to it. Aside from the well-publicized error in which CMS incorrectly described an important program detail in the "Medicare & You" booklet mailed to over 40 million Medicare beneficiaries,[1] CMS has struggled with the task of trying to inform potential enrollees of the myriad differences between Part D plans without overwhelming them in so much detail that they cannot make a decision and fail to enroll in any Part D plan. Further, CMS' policy of allowing Part D plan sponsors maximum flexibility in establishing their individual coverage policies has added to the variation between plans and created uncertainty about plan details important to LTC residents.

LTC facilities, pharmacies, and patient advocacy organizations have severely criticized several program implementation decisions by CMS as likely to create significant problems. For example, CMS' determination that LTC pharmacies can receive no reimbursement from a Part D plan unless the pharmacy and the plan have entered into a contract, together with the random auto-assignment of dual eligibles to Part D plans, has created the potential for nursing facilities to have to obtain medications from multiple LTC pharmacies based upon plan/pharmacy contracting relationships. This would represent a major departure from current practice—a change to which nursing facilities have objected on the basis that use of multiple pharmacies would create confusion for facility staff and may lead to adverse consequences for patient care.

Similarly, LTC facilities and pharmacies have expressed both confusion and indignation with respect to CMS' prohibitions on providers "steering" their patients toward particular PDPs, as laid out in the CMS Marketing

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Guidelines for Part D plans. Many of the provider concerns stem from the potential under the program for LTC facilities or pharmacies to effectively end up bearing the cost of drugs provided to LTC residents that had previously been covered by state Medicaid programs, but may now be "non-covered" under a given Part D plan—whether due to the drug being outside the plan's formulary, on-formulary but subject to prior authorization or step therapy requirements, or due to any of several other adjudication edits.

This article addresses in detail these and several other key issues relating to implementation of Part D for LTC residents. But in order to understand those issues, it is necessary to begin with a brief primer on some of the basics of Medicare Part D.

II. Medicare Part D: The Basics

Medicare Part D was created under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), signed into law by President Bush in December 2003. The principal goal of the legislation was to make available outpatient prescription drug coverage to Medicare beneficiaries on a voluntary basis, as an optional benefit for an additional premium. Congress designed the benefit to be offered by competing private health insurers that would receive various federal subsidies, adopting a managed care model intended to function similar to the private health insurance market. Beneficiaries with traditional Medicare would receive the benefit by signing up for a PDP offering stand-along prescription drug coverage, whereas beneficiaries of a Medicare Advantage plan, Section 1876 cost-reimbursed plan, or PACE plan would receive the benefit as optional, additional coverage from the same plan sponsor.[2]

The MMA set forth a "standard" benefit design for Part D plans,[3] with allowance for variations by plan sponsors within certain parameters.[4] Most significantly, the MMA allows Part D plans to limit the drugs covered to those listed on a formulary, and to place the drugs on the formulary into different beneficiary cost-sharing tiers, so long as the formulary and tiers meet certain requirements and are approved by CMS. While the details of CMS formulary review are beyond the scope of this article, as a general matter CMS indicated that it would "ensure that beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states and . . . ensure that the formulary design does not discriminate or substantially discourage enrollment by certain groups."[5]

Beneficiary premiums vary from one Part D plan to another, based on the different "bids" that each Part D plan sponsor submitted to CMS for each specific Part D plan offered by that sponsor. For beneficiaries meeting certain income and resource tests, including all dual eligibles, premium subsidies are available to reduce or eliminate the beneficiary premium that would otherwise apply. A dual eligible electing to join a Part D plan with a premium at or below the "low-income benchmark premium amount"[6] calculated by CMS for the given PDP region will have a zero premium. Medicare beneficiaries with income at or below 150% of the federal poverty line and who meet certain asset tests, as well as certain other predefined groups of low-income beneficiaries, are entitled to premium subsidies of anywhere between 25% and 100% of the low-income benchmark premium subsidy amount.[7]

Dual eligibles and other low-income subsidy-eligible beneficiaries also are entitled to the reduction or elimination of various beneficiary cost-sharing requirements. For dual eligible residents of nursing homes, this includes elimination of any deductible, full coverage through the coverage gap,[8] and elimination of any coinsurance or co-payments that would otherwise apply for covered Part D drugs. CMS provides a subsidy to Part D plans to cover

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those amounts. However, dual eligibles and other subsidy-eligible beneficiaries are not entitled to coverage of drugs that would not otherwise be covered under the plan; accordingly, Part D plans will not pay for drugs provided to dual eligibles that are not on the plan's formulary, unless an exception applies.

Part D plans are required to make exceptions to their formularies and cover non-formulary Part D drugs when all of the drugs on the formulary would not be as effective for treatment of the beneficiary, would have adverse effects for the beneficiary, or both. In order to obtain an exception, the beneficiary, the prescribing physician, or a representative appointed by the beneficiary must request an exception, and the prescribing physician must provide a supporting statement (which the plan may require in writing) that such standard has been satisfied. The Part D plan may also require supporting documentation. The plan must respond to the request as expeditiously as the beneficiary's health condition requires, and in no event later than seventy-two hours or, if an expedited response is required, twenty-four hours, after the physician's supporting statement is received. The plan may deny the request if the plan does not believe that the requirements for an exception have been met. If the plan denies the request, a series of appeals are available.[9]

III. Key Issues for Long Term Care[10]

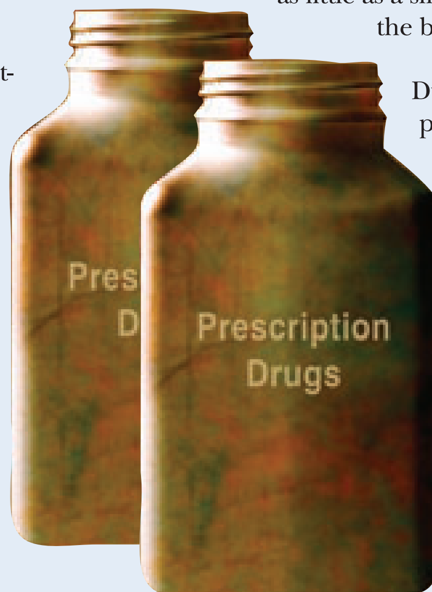
A. Transition Process for Beneficiaries Prescribed Non-Formulary Drugs

In addition to making exceptions to their formularies for coverage of non-formulary drugs, Part D plans are required to have a "transition process" for new enrollees on non-formulary prescriptions or existing enrollees being transitioned from one care setting to another (e.g., discharged from a hospital). This is a particularly important issue for dual eligible residents of nursing facilities, who generally take an average of eight to ten different drugs—many or all of which may not be on the formulary of the Part D plan into which they are auto-enrolled by CMS.

CMS' approach in establishing requirements for these transition processes has been to provide plan sponsors with "maximum flexibility in order to manage their prescription drug benefit offerings,"[11] and as such CMS has not establish any firm requirements for transitional coverage of non-formulary drugs. For example, CMS recommended, but did not require, that Part D plans provide coverage of a temporary supply of a non-formulary medication when a beneficiary first presents a prescription at a pharmacy for the non-formulary drug. Further, if a transitional supply will be covered, plan sponsors "have discretion in deciding the appropriate time frame" for that transitional supply, although "we believe that a temporary 'first fill' supply of 30 days may be reasonable . . . ."[12]

The transition process is required to take into account the unique needs of LTC residents, but here also CMS did not establish any firm requirements. Instead, the agency again stated that "plan sponsors *may* need to provide a temporary 'first fill' supply" and "a transition period of 90 to 180 days *might* be appropriate for residents of nursing facilities on multiple medications . . . ." (Emphasis added).[13]

CMS' transition policy guidance drew criticism from the LTC industry and patient rights advocates, and in response CMS issued additional guidance requiring that a temporary supply must be covered for LTC facility residents while a request for an exception to the formulary is being processed.[14] The rationale for this was that "as a matter of general practice, long-term care residents must receive their medications as ordered without delay," and therefore a plan that failed to provide coverage of an emergency supply or first fill of a non-formulary drug for LTC residents would have a benefit design that tends to discourage enrollment by LTC residents. However, given that an exception request may be denied quickly by a plan, this requirement may effectively require coverage of as little as a single dose of the non-formulary drug unless the beneficiary promptly appeals the denial.



Due to the lack of firm mandates in the CMS policy, concerns remain that the transition policies adopted by Part D plans will provide inadequate coverage of non-formulary medications, with adverse consequences for patient health.

B. Enrollment and Auto-Enrollment

Most Medicare beneficiaries will be entitled to Part D coverage only if they affirmatively enroll in a Part D plan. However, CMS provided that all dual eligibles who had not affirmatively enrolled in a Part D plan on their own

as of December 31, 2005 would be auto-enrolled into a plan by CMS effective January 1, 2006. Per the requirements of the MMA, dual eligible beneficiaries in traditional Medicare, other than those who had affirmatively enrolled in another Part D plan, were to be enrolled into a PDP selected randomly from among those PDPs having a premium at or below the low-income benchmark premium for the given PDP region. Dual eligibles in other Medicare Advantage plans were to be auto-enrolled into a Part D plan offered by that Medicare Advantage plan. CMS sent letters to dual eligibles during the first week of November 2005 indicating the Part D plan into which the beneficiary would be enrolled absent an affirmative enrollment in a different plan prior to December 31.

In order to enroll in a Part D plan, an enrollment application for that plan must be submitted. Plans are permitted to conduct enrollment online via the Internet or over the telephone. The enrollment application must be submitted by the individual or a person having authority under state law to act on that person's behalf (e.g., a legal guardian); accordingly, absent the grant of a power of attorney or the like (assuming the beneficiary has legal capacity to grant same), an LTC facility cannot effect an enrollment for any of its residents. Given that some LTC residents have neither legal capacity nor a legal guardian, they may not be able to enroll in a Part D plan; any such beneficiaries who are dual eligibles will be auto-enrolled by CMS in a plan, and will presumably never leave that plan.

While providers have argued that this creates a significant risk of patients being assigned to inappropriate plans, CMS appears to have taken the view that its formulary exception and transition process requirements are adequate, and consequently any plan will work for any beneficiary.

C. Plan-Pharmacy Contracting Relationships

In the final rule for Part D, CMS determined that an LTC pharmacy could receive reimbursement from a Part D plan only if the pharmacy and the plan had contracted with one another.[15] However, CMS went on to state that it would create a "special enrollment period" (SEP) allowing "beneficiaries entering in, living in, or leaving an institution" to switch to a different PDP—apparently in recognition of the possibility that all Part D plans in a given region might not contract with all LTC pharmacies serving LTC facilities in that region.[16] CMS also stated that it "will require Part D plans to demonstrate that they have contracts with a sufficient number of long-term care pharmacies to ensure convenient access to prescription drugs for institutionalized beneficiaries within the service area."[17]

LONG TERM CARE AND THE LAW

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Among other things, the contracts between Part D plans and LTC pharmacies specify the rates at which the LTC pharmacy will be paid for the drugs it provides to enrollees of the given plan, as negotiated between the plan and the pharmacy. CMS also required that every such contract include the pharmacy's agreement to satisfy ten "performance and service criteria" for LTC pharmacies, obligating the pharmacy to perform specified LTC pharmacy services such as emergency deliveries twenty-four hours a day, seven days per week, provision of "emergency box" medication supplies for facilities, and use of specialized packaging such as unit dose or bingo cards.[18]

Two months after the release of the final rule, CMS released its requirements with respect to convenient access to LTC pharmacies.[19] However, this document did not establish any standard for the number or geographic distribution of LTC pharmacies with which a Part D plan would have to contract, indicating instead that each plan sponsor must "attest that it will ensure that all of its future Part D enrollees who are institutionalized can routinely receive their Part D benefits through the plan's network of pharmacies."[20] On June 30, CMS released its requirements for plan sponsors to submit the lists of LTC pharmacies with which they had contracted; these included a requirement that the plan include the ratio of the number of beds in the plan service area to the number of LTC pharmacies in that service area, but without any detail regarding the geographic distribution of LTC pharmacies in a PDP region or the number of beds that those LTC pharmacies service or have capacity to service.[21] Further, CMS indicated that its review would be "to compare these ratios across plans and identify outliers."[22]

With respect to the SEP, in the final enrollment guidance released by CMS in late August, CMS indicated that the effective date of any SEP switch from one Part D plan to another would not be until the first day of the following month.[23] Particularly for auto-enrolled dual eligibles and new admits to an LTC facility, this has created the potential for periods during which Part D coverage is effectively unavailable for some LTC residents for drugs provided by the LTC pharmacy that generally services that facility's population.

In mid-November 2005, CMS responded to concerns on this issue by "strongly encourag[ing] plans to contract with LTC pharmacies serving all the LTC facilities in which their enrollees might reside as soon as practicable."[24] CMS stated that "[w]hile all plans have met CMS's LTC pharmacy network submission requirements as part of the application approval process . . . we know that continued contracting will be necessary in order for plans to meet the LTC convenient access standard . . . ." CMS played down the significance of the SEP, stating that "neither Part D plans nor providers may rely upon beneficiary special enrollment periods (SEPs) to circumvent the LTC convenient access requirement." Rather, plans must contract with "a sufficient number of pharmacies to ensure that a beneficiary can remain in his or her current plan for as long as he or she resides in a LTC facility in the plan's service area." If the LTC pharmacy serving a given LTC facility in which one of the plan's beneficiary's resides "will not sign a contract," then the plan should contract "with another LTC pharmacy that can serve that facility."

CMS' mid-November release was somewhat shocking, insofar as it indicated that at that late date Part D plans did not have sufficient LTC pharmacy contracts in place to provide LTC pharmacy services to all their LTC enrollees. One might question how CMS could approve Part D plans in September if they had not established that they had satisfied these access requirements when they submitted their pharmacy networks on August 1.

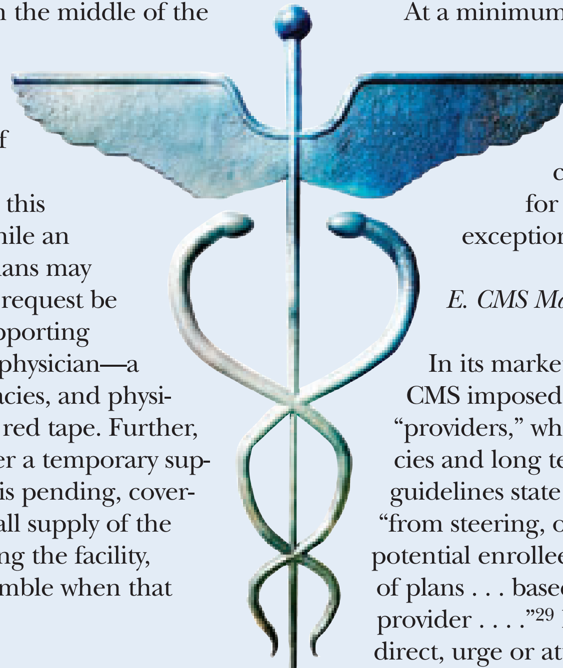
CMS' policy clearly contemplates that LTC facilities may be forced to utilize more than one pharmacy to service their residents—or else utilize only LTC pharmacies that have contracted with all Part D plans in the given area. LTC facilities have repeatedly argued that utilizing multiple pharmacies may create operational problems that might jeopardize patient care. Also, it may not be economically feasible for an LTC pharmacy to provide services to only a few of a facility's residents, while another pharmacy services the rest. As a consequence, at the time of this writing, questions remain regarding whether some Part D enrollees in LTC facilities may not be able to obtain their Part D drugs from a LTC pharmacy.

D. Potential Liability Associated with Non-Covered Medications

Another issue of major concern for LTC facilities relates to potential liability for non-covered medications. Under the Medicare/Medicaid conditions of participation, each nursing facility "must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement [with a third-party LTC pharmacy]."[25] The regulation does not speak to the issue of whether or not a source of payment is available for the given drug or biological, presumably based upon the fact that state Medicaid programs have historically covered such drugs for Medicaid residents.[26] In contrast, Part D plans will have various limitations on their coverage of particular drugs, most notably when the drug is not on the plan's formulary. While CMS has not issued a formal written position on this issue as of the date this article

went to press, some CMS representatives have unofficially stated that nursing facilities will bear responsibility for the cost of non-covered medications provided to their dual eligible residents.

As discussed above, CMS has required Part D plans to cover a temporary supply of non-formulary Part D drugs while an exception request is being adjudicated.[27] This should presumably cover situations where a patient is admitted to a nursing facility with a list of existing prescriptions that must be filled immediately or where a physician orders a medication in the middle of the night and the nurse takes it out of the facility's emergency box supply, without knowing whether it is on the formulary of the given resident's Part D plan. However, because CMS phrased this requirement as applying only while an exception request is pending, plans may require that a formal exception request be filed, including the required supporting statement from the prescribing physician—a step that many facilities, pharmacies, and physicians may consider unnecessary red tape. Further, because the plan need only cover a temporary supply while the exception request is pending, coverage may only apply to a very small supply of the medication—potentially requiring the facility, pharmacy, and physician to scramble when that supply is exhausted.



Aside from drugs being excluded from a plan's formulary, other restrictions on coverage may pose similar issues. For example, plans may deny coverage of a prescription based upon a "refill too soon" adjudication edit when, for example, a refill is ordered twenty-five days after the last thirty-day supply was dispensed. In LTC facilities, however, this may frequently occur due to patients with swallowing problems spitting out pills, or facility staff dropping pills on the floor. Similarly, a prescribing physician may disagree with a Part D plan's denial of "prior authorization" for a particular drug for a particular patient, or the plan's "step therapy" requirements for coverage of a particular drug, and insist that the patient be provided the non-covered medication. A Part D plan could also seek to transition a patient off non-formulary drugs on which the resident is stabilized faster than the attending physician thinks appropriate (e.g., faster than the 90-180 days referenced, but not required, in the CMS guidance). If such circumstances were to arise, would an LTC facility be exposing itself to potential lawsuits if it did not pay for the non-covered medication?

It appears that CMS' approach on these issues has been to avoid constraining Part D plans with hard and fast mandates, instead allowing the plans flexibility to design policies to accomplish the appropriate result. The consequence of this approach, however, is that LTC facilities or pharmacies have been left to question whether the policies adopted by some Part D plans may be too restrictive, effectively leaving the facilities and/or pharmacies with new liabilities but no corresponding increase in their payment rates.

At a minimum, LTC staff, medical directors, and pharmacies should expect an increased administrative burden in keeping track of different Part D plans' formularies and complying with plan requirements for prior authorization, formulary exceptions, and the like.

E. CMS Marketing Guideline Restrictions

In its marketing guidelines for Part D plans, CMS imposed a number of restrictions on "providers," which it defined to include pharmacies and long term care facilities.[28] The marketing guidelines state that providers are prohibited "from steering, or attempting to steer an undecided potential enrollee toward a plan, or limited number of plans . . . based on the financial interest of the provider . . . ."[29] Further, "[p]roviders also cannot direct, urge or attempt to persuade beneficiaries to enroll in a specific plan."[30] CMS states it is concerned that some providers may gain financially from a beneficiary's selection of one plan over another plan, and this "may result in recommendations that do not address all of the concerns or needs of a potential enrollee."[31] On the other hand, "providers may certainly engage in discussions with beneficiaries when patients seek information or advice from their provider regarding their Medicare options" and "providers are encouraged" to assist a beneficiary in "an objective assessment of the beneficiary's needs and potential plan options that may meet those needs . . . ."[32]

The marketing guidelines also provide that informational materials that explain the benefits of enrollment in a Part D plan or describe the rules that apply to enrollees in a Part D plan and that are prepared by a "benefit/service providing third party" (defined to include pharmacies and nursing homes) must be submitted by a Part D plan to CMS for review. These materials "may not be submitted directly to CMS by the third party [provider]."[33]

Further, lists of Part D plans with which a given provider is affiliated (presumably meaning plans with which the provider has contracted) "that describe Plans in any way (e.g., benefits, formularies, etc.) must be approved by CMS."[34] However, CMS provides no mechanism for providers to make such a submission to obtain CMS approval.

Not surprisingly, the marketing guidelines have created tremendous apprehension and confusion among LTC facilities and pharmacies regarding permissible activities. For example, while the guidelines purport to apply to LTC facilities as parties directly or indirectly contracting with Part D plans, in fact there is no contract between LTC facilities and PDPs. The significant restrictions that the marketing guidelines place on the written materials that providers may distribute have lead some providers to conclude that they are effectively precluded from providing any assistance to their residents, because they do not have the staff available to sit down with the responsible party for every resident. Many providers believe they should be able to compare Part D plans' formularies, prior authorization requirements, and other material features of the Part D plan alternatives available to their residents, and make general recommendations to the residents they serve about the best plans for them. Moreover, many consider any restrictions on their ability to do so inappropriate limitations on their free speech rights.

F. Issues for Assisted Living Facility Residents

In the Part D final rule, CMS defined "long-term care facility" so as not to include assisted living facilities (ALFs). This has two principal consequences for ALF residents.

First, ALF residents are not entitled to exercise an SEP right to switch from one PDP to another at any time, as nursing home residents can. ALF residents are locked into a plan after their enrollment becomes effective until the next annual enrollment period of November 15 – December 31.[35] However, if they move to a nursing home, they will be entitled to the SEP for LTC facility residents.

Second, Part D plans are not required to pay for specialized packaging and delivery for drugs provided to ALF residents—i.e., they may be required to obtain their drugs from retail pharmacies, unless LTC pharmacies are willing to provide those services at retail pharmacy rates. CMS has stated that it "recommends" that Part D plans pay for those services with respect to ALF residents "requiring an institutionalized level of care" (not defined), but Part D plans are not required to do so.[36]

Accordingly, as with the issues noted above, CMS has opted to give Part D plans flexibility, rather than establishing a set requirement. As a consequence, determining whether deliveries and specialized packaging will be available from an LTC pharmacy for drugs covered by a given Part D plan is one more variation among Part D plans that potential Part D enrollees should take into account.

IV. Conclusion

Many significant issues remain with respect to the transition of LTC residents to Medicare Part D. CMS' implementation of the program has been severely criticized on a number of grounds by various interested parties. Time will tell how valid these concerns are, and what changes may be needed to correct the associated problems.

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End Notes

1 The booklet incorrectly stated that dual eligibles would not pay a premium under any PDP in their PDP region. In fact, dual eligibles will pay a premium if they choose a plan with a premium above the "low income benchmark premium amount" for the given PDP region. The CMS release on this error is available on the CMS website at www.cms.hhs.gov/partnerships/tools/materials/publications/erratas/noe100305.pdf (accessed Nov. 15, 2005).

2 Each of these alternative benefit options is defined by CMS as a "Part D plan," *see* 42 C.F.R. § 423.4, and that term is used accordingly in this article.

3 The standard Part D benefit design set forth in the MMA, referred to as "defined standard coverage" by CMS, has the following features: (1) a $250 deductible; (2) coverage of 75% of the cost of covered Part D drugs (i.e., 25% beneficiary coinsurance) for the cost of covered Part D drugs in excess of the $250 deductible, up to an initial coverage limit of $2,250; (3) no coverage (i.e., 100% beneficiary coinsurance, a/k/a the "coverage gap" or "doughnut hole") until the beneficiary has $3,600 in incurred costs (a/k/a "true out-of-pocket" costs or "TrOOP") for covered Part D drugs, which equates to $5,100 in total drug expenditures; and (4) after

the $3,600 TrOOP limit has been hit, coverage of the full cost of covered Part D drugs, subject only to a beneficiary co-payment of $2 for generic drugs or preferred multiple source drugs and $5 for branded drugs, or, if more, 5% beneficiary coinsurance ("catastrophic coverage").

4 For example, plan sponsors are allowed to replace the 25% coinsurance with tiered beneficiary cost-sharing (e.g., $10 for a generic drug, $25 for a preferred branded drug, and $50 for a non-preferred branded drug), eliminate the $250 deductible, and under a CMS demonstration program provide benefits in the "coverage gap" or "doughnut hole," in each case so long as the overall benefit meets certain tests for actuarial equivalency—i.e., if the benefit is made richer in one respect it must be weakened in some other respect. CMS defines Part D plans with these types of modifications as offering "basic alternative coverage." In addition to this "standard" or "basic" Part D benefit, Part D plans may also offer "enhanced alternative coverage" that provides supplemental benefits for an additional premium. The supplemental benefits may consist of added coverage through the deductible and/or coverage gap, reduction of coinsurance/co-payments that would otherwise apply, and/or coverage of certain drugs otherwise excluded from coverage under defined standard coverage.

5 "Medicare Modernization Act Final Guidelines—Formularies" at p. 6, *available at* www.cms.hhs.gov/pdps/FormularyGuidance.pdf (accessed Nov. 13, 2005). *See generally* that document for the details of CMS' review of Part D plan formularies.

6 This is essentially a weighted average of the premiums for Part D plans in the region, other than premiums attributable to supplemental benefits. *See* 42 C.F.R. § 423.780(b)(2) for specifics. The benchmark rates for each PDP region are *available at* www.cms.hhs.gov/healthplans/rates/rates-archive/PartD2006.zip.

7 *See* 42 C.F.R. Subpart P and the CMS documents *available at* www.cms.hhs.gov/medicarereform/lir.asp for additional information on low-income subsidies.

8 *See supra* note 3 for a description of the "coverage gap."

9 *See* 42 C.F.R. §§ 423, Subpart M for the regulations relating to exception requests, particularly § 423.578.

10 It should be noted that CMS is continually issuing additional subregulatory guidance with respect to the Part D program, some of which may have addressed some of the issues discussed in this article after it went to press.

11 "Information for Part D Sponsors on Requirements for a Transition Process, March 16, 2005," at p. 1, *available at* www.cms.hhs.gov/pdps/transition_process.pdf (accessed Nov. 13, 2005).

12 *Id.* at p. 2.

13 *Id.* at p. 3.

14 CMS Q&A response under link entitled "Clarification—Emergency Fill for LTC Residents," *available at* www.cms.hhs.gov/pdps/qafirstfillforltcresidents-final.pdf (accessed Nov. 13, 2005).

15 70 Fed.Reg. 4194, 4251 (Jan. 28, 2005).

16 *Id.*

17 *Id.*

18 *See* "Long Term Care Guidance, March 16, 2005," available as part of the document *at* www.cms.hhs.gov/pdps/LTCcoverletter110805final.pdf (accessed Nov. 15, 2005).

19 *Id.*

20 *Id.*

21 August 1, 2005 Submission of Pharmacy Access Analysis—June 30, 2005, at pp. 47-53, *available at* www.cms.gov/pdps/Aug1PharmAccess.asp (accessed November 15, 2005).

22 *Id.* at p. 48.

23 "PDP Guidance: Eligibility, Enrollment and Disenrollment," at p. 16, *available at* www.cms.hhs.gov/pdps/PDP_enrollmentguidance+exhibits_FINAL_8-29-05.pdf (accessed Nov. 13, 2005)

24 *See* "Long-Term Care (LTC) Convenient Access Standard Statement," *available at* www.cms.hhs.gov/pdps/LTCcoverletter110805final.pdf (accessed Nov. 15, 2005).

25 42 C.F.R. § 483.60.

26 It should be noted, however, that various states have adopted "preferred drug lists" for their Medicaid programs, which can result in denial of payment for drugs not on the preferred list unless the state grants prior authorization for coverage of the drug. States vary in their requirements for granting such prior authorization. The author does not mean to suggest that liability for non-covered medications due to preferred drug lists or otherwise has not been an issue for nursing facilities prior to the implementation of Part D, but rather that Part D creates the potential for this to become a larger issue than in the past—particularly in light of the fact that there will be multiple different formularies, instead of a single preferred drug list.

27 *See* discussion under Section III.A. and document referenced *supra* note 14.

28 Final Marketing Guidelines (as revised Nov. 1, 2005), at p. 130, *available at* www.cms.hhs.gov/pdps/marketingguidelinesupdate11-1-05.pdf (accessed Nov. 13, 2005).

29 *Id.* at p. 131.

30 *Id.*

31 *Id.*

32 *Id.*

33 *Id.* at p. 122.

34 *Id.* at p. 132.

35 Due to something of a quirk in the enrollment rules, however, an ALF resident who enrolls in a plan may make a single change to another plan prior to May 15, 2006. *See* CMS enrollment guidance, *supra* note 23, at p. 8.

36 CMS Q&A #5116, *available at* questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=5116&p_created=1119907478&p_sid=Hr6qeBUh&p_lva=&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jvd19jbnQ9NTEmcF9wcm9kcz0mcF9jYXRzPTAmcF9wdj0mcF9jdj0mcF9zZWFyY2hfdHlwZT1hbnN3ZXJzLnNlYXJjaF9ubCZwX3BhZ2U9MSZwX3NlYXJjaF90ZXh0PWFzc2lzdGVkIGxpdmluZw**&p_li=&p_topview=1 (accessed Nov. 14, 2005).