

Issues for Medicare Beneficiaries in Long-Term Care Settings: An Analysis of the MMA and Proposed Regulations

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for

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Introduction

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act of 2003 or MMA)¹ which creates a new Part D through which Medicare beneficiaries may receive assistance paying for their prescription drugs. Starting in January 2006, voluntary drug coverage will be provided through private insurance companies, either stand-alone prescription drug plans (PDPs) or Medicare Advantage plans with prescription drug coverage (MA-PDs). Individuals with incomes up to 150% of the federal poverty level and with limited resources may be eligible for a low-income subsidy to help defray premiums and other cost-sharing.

In recognition of the potential concerns raised by the MMA for Medicare beneficiaries who live in long-term care settings, Congress authorized the Secretary of HHS to review the current standards of practice for providing pharmacy services to nursing home residents and to report the findings by June 2005, less than six months prior to the time when nursing home residents and other Medicare beneficiaries will begin enrolling in Part D plans.² While nursing home residents will experience many of the same issues in choosing and then enrolling in a Medicare prescription drug plan as other people with Medicare, they will face additional challenges that arise because of their health and economic status and the setting in which they live: they may have fewer drug plan choices than other Medicare beneficiaries; the pharmacies they use may not be included in their drug plan's pharmacy network; and accessing the medications they require and the dosage formats utilized may be difficult for nursing home residents.

This paper considers the implications of the MMA for residents of long-term care facilities. It begins by describing the current situation for people living in long-term care settings, then describes key provisions in the statute, and examines proposed regulations recently issued by the Centers for Medicare & Medicaid Services (CMS), with regard to the ability of nursing home residents to enroll in PDPs or MA-PDs and to access the medications they require under the new drug benefit.

The Current Situation for Beneficiaries in Long-Term Care Settings

Approximately 3 million people resided in a long-term care facility for all or part of the year in 2001.³ As has been well documented, people living in long-term care settings tend to have significant health needs and many have cognitive impairments. Nursing home residents receive, on average, more than six routine prescription drugs per day,⁴ and nearly 75% have cognitive impairments.⁵

Nearly all residents of long-term care facilities have Medicare and therefore will be eligible to enroll in the Part D prescription drug benefit when it takes effect in 2006. An estimated 1.6 million nursing home residents are low-income Medicare beneficiaries dually eligible for both Medicare and Medicaid.⁶ Beginning in 2006, Medicare will begin paying for their prescriptions, rather than Medicaid. Additional numbers of residents will qualify for Part D low-income subsidies if they have incomes up to 150% of the federal poverty level. A smaller share living in nursing homes will not be eligible for low-income assistance.

Smaller numbers of Medicare beneficiaries who reside in institutionalized long-term care settings other than nursing homes also may be affected by the MMA, including residents of intermediate care facilities for individuals with mental retardation (ICFs/MR), another type of long-term care facility, many of whom are also dually eligible for Medicare and Medicaid.⁷ In addition, by October 2002, Medicaid programs in 41 states paid for care for 102,000 residents in assisted living facilities (ALFs).⁸ Those who are placed in ALFs under Medicaid waiver programs must meet the same nursing facility level of care as nursing home residents.⁹

Currently, nursing home residents get their prescriptions from different sources than the general Medicare population. Nearly 80% of all nursing home beds in the country are served by pharmacies that specialize in long-term care services.¹⁰ Such pharmacies specially pack prescription drugs in unit doses to reduce medication errors and provide drugs in a variety of formats.¹¹ They provide 24-hour service and consultant pharmacists to review monthly each resident's drug regimen. Long-term care pharmacies generally provide an open formulary¹² to reflect the needs of the population they serve.¹³

Payments for pharmaceuticals for nursing home residents come from several sources. Residents whose coverage is paid for under Medicare Part A currently have their drug costs paid as part of Medicare's prospective payment to the skilled nursing facility and pay a daily co-insurance amount for their stay after the twentieth day, but they incur no separate charge for prescription drugs. Residents whose Part A coverage has been exhausted and who are dually eligible then have their stay paid for by Medicaid, including their prescription drug costs, which are most commonly paid for separately from the per diem payment to the facility. Residents who are dually eligible for Medicare and Medicaid generally have access to all of the pharmaceuticals they need, though their physicians may need to obtain prior authorization before prescribing some drugs. A smaller share of residents with private coverage pay the costs of their medications out of pocket or from other private sources.

Issues Raised by the MMA

Choosing and Enrolling in a Drug Plan

The process of choosing and then enrolling in a drug plan and applying separately for a low-income subsidy could be difficult for many Medicare beneficiaries; for nursing home residents with cognitive and/or physical impairments, it may be even more so. The statute requires that all Part D eligible individuals have a choice of at least two plans, one of which should be a stand-alone PDP for people who want to remain in the traditional Medicare program.¹⁴ However, the statute does not authorize creation of special PDPs to serve nursing home residents. The Medicare Advantage (MA) (formerly Medicare+Choice) program provisions of the law authorize new specialized MA plans with prescription drug coverage that exclusively enroll special needs individuals, including those who are institutionalized, those who are entitled to Medicaid, or those who have severe or disabling chronic conditions.¹⁵ These specialized managed care plans are the only type of plan explicitly authorized by the statute to serve institutionalized individuals.

The statute leaves to the Secretary the details of establishing an enrollment process for Part D plans once an individual chooses a plan in which to enroll,¹⁶ with provisions for dual eligibles

who do not enroll during their initial or special enrollment period. Because Medicaid will no longer cover prescription drug costs for dual eligibles, they will have to enroll separately in a Part D drug plan or will be auto-enrolled at some point after their initial enrollment period ends. If they do not enroll on their own, the Secretary will automatically enroll dual eligibles in a drug plan with a premium at or below the benchmark. If more than one plan offers a low premium, the Secretary will enroll individuals randomly in the available plans.¹⁷ The statute includes no further details about how the auto-enrollment process will work, nor does it provide for auto-enrollment of other residents besides dual eligibles who may not be capable of choosing for themselves. Finally, the MMA does not specify who may receive marketing and enrollment materials or otherwise act on behalf of incapacitated individuals to assist them with enrollment decisions.¹⁸

In response to the statutory requirement that the Secretary establish an enrollment process for Part D plans, the proposed regulations would provide information about available drug plan options to current and potential Part D eligible individuals, and then would require each eligible individual to complete the drug plan's enrollment form.¹⁹ The proposed regulations do not clarify who has authority to act when the eligible individual cannot do so.

The regulations concerning the low-income subsidy allow a personal representative to apply for the subsidy on an individual's behalf.²⁰ A personal representative is defined broadly to include individuals authorized to act on behalf of the applicant; someone acting responsibly on behalf of an incapacitated or incompetent applicant; or someone requested by the applicant to act as his or her representative in the application process.²¹ Of particular concern are residents who have no family member, friend, or other agent recognized under state law to act on their behalf.

The proposed regulations do not clarify how the automatic enrollment process for dually eligible individuals will operate: the entity that will make the auto enrollment decisions, how plans will be chosen, whether special considerations will be accorded institutionalized populations, how individuals will be notified of the plan in which they are enrolled, or how they can exercise their right to decline enrollment.²² The regulations propose that automatic enrollment will occur at the end of the initial enrollment period, which is on May 15, 2006.²³ Because dual eligibles will lose their drug coverage through Medicaid on January 1, this situation may create gaps in their drug coverage.

Ensuring Access to Part D Covered Drugs and to Network Pharmacies

General concerns about whether Medicare beneficiaries will have access to a wide array of medications in the dosages they require are augmented for residents of long-term care facilities. The MMA ensures access to drugs covered under the new Part D and convenient access to network pharmacies.²⁴ The drugs that are covered and the pharmacies that are included will be among the key factors used by Medicare beneficiaries to evaluate their plan options and to determine in which plan they should enroll.

Access to Medications

In discussing access to covered Part D drugs, the MMA gives discretion to each drug plan to develop its own formulary. It contains no requirements for providing greater access to drugs used by nursing home residents and other vulnerable populations.²⁵ The definition of a Part D drug raises potential questions for nursing home residents whose care is paid for under Medicare Part A, as the definition excludes payment for a drug that, as prescribed and dispensed or administered, may be paid for under Medicare Part A or Part B.²⁶

The proposed regulations request comments about the development of formularies and use of other cost management tools by drug plans. Specifically, the agency requests comments concerning special treatment that should be accorded to nursing home residents and other special populations, including access to “... an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees...”²⁷ The preamble discusses an array of mechanisms that a drug plan may use to produce cost-savings both for the plan and for Medicare. The agency expresses concern that these mechanisms, including prior authorization, tiered cost-sharing and step therapies, may have a negative financial impact on vulnerable populations who need a broader array of drugs than provided in the formulary. The agency seeks suggestions on how to balance the needs of these populations with the ability of plans to use cost-saving mechanisms in designing their formularies.²⁸

The impact on nursing home residents from a limited formulary could be handled through a drug plan’s exceptions process,²⁹ through which beneficiaries could seek coverage for a non-formulary drug or a reduction in cost sharing for a non-preferred drug. However, residents of long-term care facilities could experience difficulty going through the exceptions process, especially if they have no one to act on their behalf or to assist them in gathering the medical and other evidence that is required. In addition, the beneficiary could wait up to a month for the plan to review an initial exceptions request and then to review a redetermination request. This time period could be extended if the resident had to appeal to the independent review entity and then to an administrative law judge.³⁰

Access to Network Pharmacies

In directing the Secretary to establish rules for convenient access to pharmacies, Congress gave the Secretary discretion to include particular standards for pharmacy access for long-term care facility residents.³¹ However, the MMA does not define what qualifies as either a long-term care facility or a long-term care pharmacy that serves residents. In the preamble to the proposed regulations, the agency seeks comments on whether to exercise its statutory discretion and require Part D drug plans to include long-term care pharmacies in their network, or whether they should “strongly encourage” plan sponsors to take such action.³²

The proposed regulations include a definition of long-term care pharmacy,³³ but do not set standards for their inclusion in a plan's pharmacy network.³⁴ Concern is expressed in the preamble that if drug plans are required to include long-term care pharmacies in their network,

they may have to negotiate preferential contracting terms relative to other pharmacies, since such pharmacies may want additional reimbursement for the services they provide.

The preamble states that rules concerning access to out-of-network pharmacies will be used to assure access to long-term care pharmacies if those pharmacies are not part of a plan's network.³⁵ However, the proposed regulations do not identify the situations to which the out-of-network provisions apply, including the situation concerning residents of long-term care facilities.³⁶ Thus, there is no regulatory requirement that plans allow residents to use long-term care pharmacies under the out-of-network protection as stated in the preamble, and no legal assurance that drug plans will interpret the regulatory provision as stated.

Elimination of Co-insurance for Dual Eligibles

The MMA provides a significant protection for nursing home residents by eliminating all co-insurance for an individual who is eligible for full Medicaid benefits (a “full-benefit dual eligible”) and who is institutionalized, i.e., who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month.³⁷ Non-institutionalized dual eligible individuals must pay nominal co-insurance amounts.³⁸ According to the MMA, Medicare will subsidize 100% of the premium payment for Part D plans for dual eligibles to the extent the premium of the plan they choose is set at or below the benchmark set for plan premiums. Someone who chooses a plan with a higher premium must pay the difference between the subsidized and actual premium amount.³⁹ While the MMA clearly prohibits Medicaid from paying cost-sharing obligations for low-income individuals,⁴⁰ the statute does not define “cost sharing.” Thus, it is not clear whether the elimination of the co-insurance includes elimination of any amounts a resident has to pay towards the premium of a drug plan that exceeds the premium benchmark.

The proposed regulations also do not clarify what assistance will be available to help dually eligible individuals pay the premium differential if they enroll in a drug plan whose premium exceeds the premium benchmark amount. The regulations follow the statute and preclude Medicaid from covering “any cost-sharing obligations under Part D relating to covered Part D drugs.”⁴¹ They do not include a definition of cost-sharing.

Furthermore, under the proposed rules, a drug plan can require individuals who use out-of-network pharmacies to pay the difference between the out-of-network pharmacy's usual and customary price and the drug plan's price, in addition to the usual co-insurance.⁴² Thus, nursing home residents may have to pay this differential amount if the pharmacy they are required to use is not part of the plan's network. Requiring beneficiaries to pay the difference between the plan-negotiated drug price and the non-network pharmacy price could erode cost-sharing protections for dual eligibles.

Other Issues

The agency seeks guidance concerning its definition of a long-term care facility.⁴³ As proposed, the definition is limited to a skilled nursing facility (SNF) as defined in Section 1819(a) of the Social Security Act, pertaining to Medicare coverage, or a nursing facility (NF) as defined in

Section 1919(a) of the Act, pertaining to Medicaid coverage.⁴⁴ The limited definition results from the agency's understanding that only SNFs and NFs are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies.⁴⁵ The agency seeks comments on whether to include in the definition intermediate care facilities for the mentally retarded or related conditions (ICFs/MR). CMS includes for consideration the extent to which ICFs/MR and other types of facilities rely on long-term care pharmacies to provide drugs and related services to their residents. This same rationale applies to dual eligible residents of ALFs, who often require the same level of care as residents of nursing facilities, and who may be required to obtain their prescriptions through long-term care pharmacies.

One provision in the proposed regulations may have adverse consequences for some of the poorest Medicare beneficiaries. The MMA excludes from the definition of a Part D covered drug any drug for which Medicare Part A or Part B would pay, as prescribed and dispensed. The regulations stipulate that coverage will be excluded for individuals who have only either Part A or Part B and, for whatever reason, have chosen not to enroll in both parts.⁴⁶ The stated rationale is that everyone who is eligible for premium-free Part A can enroll in Part B, and everyone eligible for Part B only can *buy in* to Part A.⁴⁷ This rationale does not take into account the inability of those SSI recipients for whom the state buys into Part B but not Part A to pay the full Part A premium.⁴⁸ Thus, they would be left without any drug coverage when hospitalized or in a Part A covered SNF stay or receiving hospice care, since Medicaid will no longer cover the cost of their medications, and Part D will not cover drugs that would have been paid for under Part A had the individuals been enrolled in that part of Medicare.

Practical Examples of the Issues Raised for Nursing Home Residents

Some of the potential implications of the proposed regulations for nursing home residents are illustrated in the following examples:

- Mrs. C, an 83-year old dually eligible nursing home resident, does not enroll in a prescription drug plan during the initial enrollment period. As per the proposed regulations, she is automatically enrolled in a plan chosen randomly for her at the end of the initial enrollment period in May 2006.⁴⁹ The MMA and the proposed regulations require Medicaid to stop covering drugs for dual eligibles after December 31, 2005. Thus, Mrs. C has no source of payment for the medicines she needs from January until she is enrolled in a plan.
- The nursing home in which she lives requires Mrs. C to get all of her prescriptions from a specific long-term care pharmacy, but the pharmacy is not included in the pharmacy network for the drug plan in which she was automatically enrolled. The plan says that rules concerning use of out-of-network pharmacies do not specifically require the plan to pay for drugs received from the long-term care pharmacy, so they will not cover any drugs supplied by that pharmacy.
- The plan in which Mrs. C was enrolled also does not include on its formulary some of the drugs or dosage forms she uses. Mrs. C's physician requests an exception to cover insulin in the dosage format she requires. However, while waiting for the plan's decision, Mrs. C is hospitalized as a result of a diabetic episode stemming from receiving improper amounts of insulin.
- Mr. D, a 37-year old man with quadriplegia resulting from a traumatic brain injury, moved from a nursing home to an assisted living facility under his state's Medicaid waiver program. When he was in the nursing home, he did not have to pay any co-insurance for his prescriptions because he was dually eligible for Medicare and Medicaid and living in an institution. However, after he moved he had to start paying co-insurance because the assisted living facility is not included in the definition of what constitutes a long-term care facility.

Options to Address Key Issues Raised by the MMA and Proposed Regulations

Steps could be taken to ensure that residents of long-term care facilities have access to prescription drug plans, both PDPs and MA-PDs, which provide them with the medications they require and access to the pharmacies they utilize. Some of the issues raised could be addressed by regulation; others by a change in law.

Access to Prescription Drug Plans and Long-Term Care Pharmacies

Under the statute and proposed rules, nursing home residents who want a prescription drug plan that is tailored to their specific requirements may need to enroll in a Medicare Advantage care plan that specializes in care for nursing home residents. This approach could be problematic for several reasons. First, specialized MA plans will not be available in all areas throughout the country and today only a small percentage of long-term care residents are MA enrollees.

Second, the “special” function of these MA plans, to offer specialized treatment through coordination of services for the target population,⁵⁰ may already be provided by the skilled nursing facilities.⁵¹ Third, this approach does not provide an explicit option for those who choose to remain in traditional Medicare and enroll in a stand-alone PDP.

Congress could authorize special stand-alone prescription drug plans as well as special MA plans, although this approach may be difficult to implement. Because residents of long-term care facilities utilize more prescriptions than many other beneficiaries, potential sponsors may be hesitant to enter the market. Congress allowed CMS to waive certain requirements of the drug discount card program to induce sponsors to offer special discount cards for long-term care residents.⁵² As a result, CMS waived the requirement that special long-term care discount cards offer negotiated prices to their enrollees, and allowed them to serve solely as a conduit for the low-income assistance available under the discount card program.⁵³

Another approach would be to require, in the final regulations, that all drug plans whose service areas include a long-term care facility should negotiate with long-term care pharmacies to include them in their networks, provide open formularies that include the prescriptions and dosage methodologies required by residents, and incorporate the language from the preamble into the regulations to clarify when an enrollee may use an out-of-network pharmacy, and at what cost (for non dual eligibles). If the regulations do not require plans to include long-term care pharmacies in their networks, they could prohibit drug plan sponsors that do not include any long-term care pharmacies in their network from charging long-term care facility residents an extra fee for utilizing a long-term care pharmacy.

Application and Enrollment in a Part D Plan and in the Low-income Subsidy Program

The proposed regulatory definition of a personal representative who can apply for the low-income subsidy may set too broad a standard for both situations without further guidance and limitations. In going beyond the usual agents – individuals authorized to act under state law or by the beneficiary⁵⁴ – to include a person who acts responsibly on behalf of the individual, the definition may increase the potential for someone to take advantage of the resident. In adopting clear standards about who can act for a resident, the final regulations could define what it means to “act responsibly” for the individual, both in terms of choosing and applying for a plan, and in applying for the low-income subsidy; identify situations where potential conflicts of interest may arise, such as where the person has some connection to a PDP or MA-PD; incorporate state agency laws;⁵⁵ and establish remedies, including a special enrollment period, when the person “acting responsibly” enrolls the resident in a plan that does not further her interest or does not adequately meet her drug needs.

Nursing home ombudsmen act on behalf of nursing home residents in every state, and in some jurisdictions also help people who live in assisted living facilities. While ombudsmen already have a relationship with residents, and could stand in a natural position to help with Part D enrollment, they may not have the expertise or resources to assist residents in applying for drug plans and the low-income subsidy. Congress could authorize ombudsmen to act on behalf of residents and allocate additional resources to fund these activities.

To clarify the auto-enrollment process for dual eligibles who do not enroll in a drug plan during their initial enrollment period, the final regulations should identify what entity has the obligation to enroll such individuals. The regulations could also waive the requirement that individuals be randomly assigned to a Part D plan, allowing dual eligible nursing home residents to be enrolled in the plan that may be most likely to provide access to the drugs and pharmacies they use; and clarify how residents and others will be notified of their enrollment in the assigned plan.

Protections for Low-income Individuals

Dually eligible nursing home residents by definition are eligible for the elimination of all co-insurance accorded to institutionalized individuals. However, dually eligible residents of assisted living facilities who have the same nursing needs may not be so protected. Congress could clarify that to the extent that state licensure requirements authorize an assisted living facility to provide the requisite medical care to meet the definition of a medical institution,⁵⁶ and to the extent that an assisted living facility has requisite staff to meet a resident's medical needs, dually eligible residents of assisted living facilities should be entitled to the elimination of all coinsurance that Congress accorded to dually eligible nursing home residents.

The final regulations also could clarify whether dually eligible individuals will be responsible for paying the premium differential if they enroll in a drug plan whose premium exceeds the premium benchmark amount. The final regulations could include a definition of "cost-sharing" applicable to the prohibition against Medicaid payment for any cost-sharing obligations under Part D relating to covered Part D drugs.

To protect individuals for whom the state purchases only Medicare Part B and not Part A, the final regulations could provide for Part D coverage of drugs that otherwise would have been covered under Part A for dually eligible individuals who do not have Part A because their state only buys in to Part B.

Definition of a Long-Term Care Facility

In response to the question concerning the definition of what constitutes a long-term care facility, the definition could be expanded in the final regulations to include residents of ICFs/MR and those residents of ALFs who are placed in their facility pursuant to a Medicaid waiver.

Conclusion

The Medicare Modernization Act of 2003 and the proposed implementing regulations recognize that Medicare beneficiaries who reside in long-term care settings have needs that may be different from other beneficiaries. Steps could be taken to improve the ability of these beneficiaries to access the medications they require, the pharmacies they utilize, and the assistance that could help them make an informed choice about their Part D prescription drug plan. Most of these changes could be made by regulation, such as requiring PDPs to contract with pharmacies that specialize in serving populations in long-term care settings. However, more extensive changes, such as authorizing special stand-alone PDPs to serve beneficiaries in nursing homes, would require a change in the law.

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- ¹ Pub. L. 108-173 (Dec. 8, 2003).
- ² Medicare Modernization Act § 107(b).
- ³ CMS Compendium 2001, “Characteristics of Nursing Home Residents,” at 54. Available at <http://www.cms.hhs.gov/medicaid/survey-cert/datacomp.asp> (Site last visited August 25, 2004.)
- ⁴ Dan Mendelson, Rajeev Ramchand, Richard Abramson and Anne Tumlinson, “Prescription Drugs in Nursing Homes: Managing Costs and Quality in a Complex Environment,” NHPF Issues Brief No. 784 (November 12, 2002), www.nhpf.org (Site visited September 9, 2004).
- ⁵ CMS Compendium, *supra*.
- ⁶ Andy Schneider, “Dual Eligibles in Nursing Facilities and Medicare Drug Coverage,” (Kaiser Commission on Medicaid and the Uninsured, November 13, 2003).
- ⁷ ICFs/MR are institutionalized environments that offer treatment for people with mental retardation, many of whom have other chronic conditions. Ellen O’Brien, Risa Elias, *Medicaid and Long-Term Care* (Kaiser Commission on Medicaid and the Uninsured, May 2004).
- ⁸ Robert Mollica, National Academy of for State Health Policy, State Assisted Living Policy, Executive Summary (Dec. 2002), <http://www.nashp.org/Files/ltc_15_AL_2002.pdf. (Last visited August 25, 2004). According to the American Association of Homes and Services for the Aging, about 910,000 people reside in assisted living facilities. <http://www2.aahsa.org/Docu,emt/Display.asp?MsgID+1-@-SU4302003145346.eml&SC=> (visited Sept. 8, 2004).
- ⁹ 42 U.S.C. § 1396a(a)(10)(ii)(VI). Indeed, ALF industry experts have stated that ALF residents have care needs similar to those nursing home residents. Paul R. Willging, Ph.D. (“Expert Opinion,” SNALF, Apr. 22, 2002), <http://www.snalf.com/mysnalf/featured_artucle.cfm?cntntID=4754.
- ¹⁰ *Id.*
- ¹¹ For example, residents may need liquid dosages or medications that can be crushed, or they may need injectable dosage forms for intravenous therapies. Certain drugs may be less effective for residents because of their frailty and multiple chronic conditions. Further, because of their age and co-morbidities, residents may experience more adverse consequences as a result of having to change to a medication on a plan’s formulary.
- ¹² An open formulary provides access to all medically necessary drugs.
- ¹³ Booz Allen Hamilton, “Formulary Structure Environmental Scan for the United States Pharmacopeia,” (July 16, 2004), <http://www.usp.org>
- ¹⁴ Social Security Act § 1860D-3(a).
- ¹⁵ Social Security Act § 1859(b)(6)(B). Medicare Advantage plans include health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), or preferred provider organizations (PPOs).
- ¹⁶ Social Security Act § 1860D-1(b)(1)(A).
- ¹⁷ Social Security Act § 1860D-1(b)(1)(C).
- ¹⁸ The statutory requirement that individuals apply separately for the low-income subsidy could be a significant burden for nursing home residents. Because subsidy applications are made through either the state Medicaid agency or through Social Security, Social Security Act § 1860D-14(a)(3)(B), CMS has not proposed regulations to implement the process and it is not discussed in this paper.
- ¹⁹ Proposed 42 C.F.R. 423.34(b), 423.48.
- ²⁰ Proposed 42 C.F.R. 423.774(d).
- ²¹ Proposed 42 C.F.R. 423.772.
- ²² Proposed 42 C.F.R. 423.34(d).
- ²³ Proposed 42 C.F.R. 423.36(a)(1).
- ²⁴ Social Security Act § 1860D-4(b).
- ²⁵ Social Security Act § 1860D-4(b)(3).
- ²⁶ Social Security Act § 1860D-2(e)(2).
- ²⁷ 69 Fed. Reg. at 46661.
- ²⁸ *Id.*
- ²⁹ The MMA requires all Part D plans to establish an exceptions process. Social Security Act §1860D-4(h).
- ³⁰ Proposed 42 C.F.R. 423.578.
- ³¹ Social Security Act § 1860D-4(b)(1)(C)(iv).
- ³² 69 Fed. Reg. at 46656-46657.

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- ³³ A long-term care pharmacy is defined as a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents. Proposed 42 C.F.R. 423.100.
- ³⁴ Proposed 42 C.F.R. Section 423.100. CMS interprets the statutory access standards as applying only to retail pharmacies, so that non-retail pharmacies such as those that are institution-based do not "count" when determining whether the access standards are met. See 69 Fed. Reg. at 46656.
- ³⁵ 69 Fed. Reg. at 46656-46657, 46662.
- ³⁶ Proposed 42 C.F.R. 423.124(a) requires all drug plans to assure access to non-network pharmacies when the enrollee cannot reasonably be expected to obtain their drugs at a network pharmacy.
- ³⁷ Social Security Act § 1860D-14(a)(1)(D), citing Section 1902(q)(1)(B) of the Social Security Act.
- ³⁸ Social Security Act § 1860D-14(a)(3)(B)(v).
- ³⁹ Social Security Act § 1860D-14(a)(1)(A).
- ⁴⁰ 42 U.S.C. § 1395(d). Note that the MMA eliminates co-insurance payments for drugs for dually eligible residents but not for residents who are otherwise eligible for the low income subsidy.
- ⁴¹ Proposed 42 C.F.R. 423.906.
- ⁴² Proposed 42 C.F.R. 423.124(b).
- ⁴³ Proposed 42 C.F.R. 423.100.
- ⁴⁴ Proposed 42 C.F.R. 423.100.
- ⁴⁵ 69 Federal Register at 46648-49.
- ⁴⁶ Proposed 42 C.F.R. 423.100.
- ⁴⁷ 69 Fed. Reg. at 36647.
- ⁴⁸ CMS recently announced that the monthly Part A premium will be \$375 in 2005. 69 Fed. Reg. 54673 (Sept. 9, 2004).
- ⁴⁹ Proposed 42 C.F.R. 423.34(d).
- ⁵⁰ 69 Fed. Reg. 46866, 46873 (Aug. 3, 2004).
- ⁵¹ SNFs and NFs are required to provide all of the services a resident needs. 42 U.S.C. 1395i-3(b), 1396r(b).
- ⁵² Social Security Act § 1860D-31(g)(5)(A).
- ⁵³ 42 C.F.R. 403.816 (b),(c).
- ⁵⁴ See, proposed 42 C.F.R. 423.560 defining who can file an appeal on behalf of an incapacitated or incompetent beneficiary.
- ⁵⁵ All but 14 states have provisions that preclude or limit the ability of nursing homes and their workers from serving as health care agents. See, www.abanet.org/aging/update.html.
- ⁵⁶ 42 CFR 435.1009.



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