May 3, 2002

Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue
Room 443-G
Washington, D.C. 20201

Re: Comments on Medicare-Endorsed Prescription Drug Card Assistance Initiative; File Code CMS-4027-P

Dear Ms. Van Hoven:

On behalf of the Long Term Care Pharmacy Alliance ("LTCPA"), we are pleased to submit the following comments in response to the Center for Medicare and Medicaid Services' ("CMS") Proposed Rule entitled "Medicare Program: Medicare-Endorsed Prescription Drug Card Assistance Initiative," published in the March 6, 2002 Federal Register (the "discount card" proposal). 67 Fed. Reg. 10262 (Mar. 6, 2002). We appreciate the opportunity to comment upon the proposed rule and urge CMS to clarify in its final rule that the discount card is not intended for use by residents of long term care institutions. As explained in more detail below, patient care, economy and efficiency all require that a discount card not be used by patients in long term care facilities.

INTRODUCTION

We Appreciate CMS's Recognition That LTC Pharmacy Should be Treated Differently: As CMS is aware, following the President's July 12, 2001 announcement of a discount card initiative, the LTCPA met with several Administration officials about the original proposal, and how the Administration envisioned that it could be applied in the Long Term Care ("LTC") context. In the course of those discussions, Administration officials frankly conceded that they had not had the opportunity to fully consider how the discount card initiative could be implemented by patients residing in LTC facilities. Thus, the LTCPA particularly appreciates CMS's direct solicitation of comments upon the issue of whether and how institutionalized beneficiaries who have access to long term care pharmacies would be affected if they choose to use a Medicare discount card. 62 Fed. Reg. at 10274-1.

As is set out in more detail below, we do not believe that a drug discount card could, or should, be used in Long Term Care facilities such as nursing homes, or in other institutionalized settings in which institution-based pharmacies currently provide drugs. Our comments are divided into four sections. First, we explain who and what LTC pharmacy is and the critical role it plays in today's health care delivery system, so that CMS has a full

www.LTCPA.org
1321 Duke Street, Alexandria, Virginia 22314
Tel: 877.834.7762 Fax: 703.832.0544

understanding of the patient population at issue in these comments and the services that are currently provided to those patients by LTC pharmacy.[1] Following that explanation, Section II explains those numerous reasons that application of a discount card would not work, and should not be allowed, in LTC facilities. Section III restates many of these same ideas in the context of analyzing CMS's goals and objectives, as expressed by it in the proposed rule. Finally, Section IV proposes that CMS explicitly exclude the use of a discount card in LTC facilities.

The Final Rule Should Treat LTC Facilities Like It Does Hospitals: Before addressing our specific comments, we wish to focus CMS on one aspect of its proposed rule, which we believe provide a useful framework for determining whether the discount card should be used by residents of LTC facilities. More specifically, CMS has already recognized that the proposed discount card is "directed at outpatient prescription drugs, not drugs provided during a hospital stay." 67 Fed. Reg. at 10281-2. CMS has already carved out hospitals from its proposal because "hospital stays are covered under Medicare as part of Medicare payments to hospitals." *Id.* While this is generally true, CMS's statement is incomplete, as there are a percentage of hospital patients that do not receive Medicare drug coverage.[2] Because they are not "outpatients," as that term is used in its non-technical sense, however, CMS has excluded those patients who have exhausted their Medicare hospital benefits from eligibility for the discount card.

We understand that CMS "carved out" hospital residents for two separate reasons: (1) the benefits of uniform drug distribution systems in institutional contexts such as reduced medical error rates and prospective and retrospective drug regimen reviews are so significant that they seriously outweigh any price savings benefit provided by the discount card; and (2) the drug card should not be applied to "institutional" settings where patients are otherwise usually eligible for prescription drug benefits (through Medicare Part A, Medicaid, or private insurance). Both statements are not only true of hospitals, but, as expanded upon below, of LTC facilities as well. Thus, the very same rationale for excluding hospitals from the proposed rule also argues for excluding long term care facilities and other "in-patient" settings in the final rule.[3]

---

[1] While these comments address the LTC context, and are not intended to apply to every institutional context, we believe that many of the comments made in this and the remaining sections apply with equal force to all other sectors of institutional care. We urge CMS to seriously evaluate whether any "cost" savings attributable to a discount card will be worth the trade-off in diminished patient care in Assisted Living Facilities, hospices, and in other institutional settings.

[2] Examples of such patients include those who have exceeded their maximum 120-day Medicare stay period (for example, because they experienced additional co-morbidities or other complications during their hospital visit) and who are otherwise uninsured and who are ineligible for Medicaid. Such patients no longer are entitled to any pharmacy benefit, yet would remain excluded from discount card use under the proposed rule.

[3] We understand CMS not to have used the phrase "out patient" in its technical sense, as applying to all beneficiaries other than those in hospitals, but rather in its more general sense. Thus, stated differently, just as hospital residents are "in patients" for purposes of

The unique circumstances involved in the LTC patient population, and the multiple roles that LTC pharmacy is already serving to protect that population both mandate that LTC facility residents be expressly excluded from the final rule. As explained below, introduction of the proposed discount card in the LTC context would create far more harm than good. Thus, just as it has already done for hospitals, we urge CMS to carve out LTC pharmacy from the scope of the discount card rule.

I. LTC PHARMACY AND ITS ROLE IN PATIENT CARE

To understand why the discount card proposal is not appropriate in the LTC and "institutional" context, it is critical to understand the unique role that LTC pharmacy plays in the delivery of drugs to LTC residents. LTC patients have a unique set of drug needs far different from the typical ambulatory Medicare beneficiary to whom the discount card proposal is directed. LTC pharmacy has responded to those needs through development of a sophisticated delivery system far beyond the scope of what retail pharmacy provides. LTC resident needs, requirements, the services currently being provided by LTC pharmacy, the resulting cost saving to the health care delivery, and the minimal number of LTC patients who would be eligible for, and could retain, a discount card, all argue in favor of limiting the use of the discount card in LTC institutions.

LTC Residents Typically Need Greater Drug Therapy: Unlike the typical ambulatory Medicare beneficiary, patients in LTC facilities usually are older, in poorer health, and in need of greater care. The typical LTC resident has the following characteristics:[4]

- mean age of 83.1 years;
- usually being admitted to the LTC facility directly from an acute care hospital (62% of residents);
- more than not likely to have impaired or abnormal cognitive function; only 17% of LTC residents were characterized as independent or required limited assistance in performing the activities of daily living;
- typically having three medical conditions, with 45% of residents having four or more conditions and 10% of residents having more than six medical conditions.[5] Typical diseases included cardiovascular

---

receiving drug therapy, so are nursing home residents, who also receive drugs as "in patients" residing in nursing homes.

[4] Bernabei, R. *et al., Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care*; J. Gerontol. A. Biol Sci. Med. Sci. 54:M25-33 (1999). At the time it was published, the Bernabie study and the SAGE database were the only published statistics specific to long-term care structured to capture specific processes of care provided in LTC facilities. *Id.* at M29.

[5] In the Coalition's experience, LTC residents often have a higher number of illnesses, and a recent HCFA-sponsored analysis has suggested that the actual number many be 7.8 medical conditions. *See* Bodenheimer, J., *Long Term Care for Elderly People, The On-Lok Model,* 341 N. Eng. J. Med. 1324, 1326 (1999) (noting that 1995 data suggest that the average patient was

clinical conditions (63%), hypertension (31%), coronary artery disease (23%), and congestive heart failure (19%). Significantly, 42% of residents have dementia, and 20% were stroke victims;

- typically on prescriptions for 6 drugs, with 45% taking seven or more drugs, and 20% taking more than 10 drugs. Over 50% of residents are taking cardiac medication, and approximately 40% are taking analgesics.

The frequency of drug usage does not reflect an overuse of medications, but rather the serious medical conditions faced by residents requiring long term care, the increased efficacy of today's more advanced medicines, and significant improvements in quality of life that pharmaceuticals can provide to LTC residents who previously had little hope of recuperation from serious illnesses. The reality, however, is that LTC residents are among the nation's most ill, among the least able to manage their own prescription drug needs, and the most dependent upon a functioning and efficient drug delivery system to meet their prescription demands.

<u>LTC Residents Typically Need Different Drug Therapy:</u> Not only are elderly LTC residents on more medications, but they require different specialized medications. More specifically, as a person ages their body processes drugs differently (a function of changing metabolism and typical decreases in kidney function).[6] Extensive literature has documented the need for specific elder drug formularies,[7] and companies have published specialized care guidelines documenting exactly how different drugs typically prescribed react (and interact) in elderly people.[8] While these specialized formularies are often not widely understood or applied outside that segment of the medical community involved in geriatric treatment, the specifics of geriatric care are extremely important in avoiding adverse drug affects and inappropriate treatment.

---

80 years old, have 7.8 medical conditions, and had impairments impeding performance of 2 to 3 activities of daily living). .

[6] Fouts, M. Hanlon, J., Pieper, C., Perfetto, E. and Feinberg, J., *Identification of Elderly Nursing Facility Residents at High Risk for Drug-Related Problems,* 12 The Consultant Pharmacists 1103 (Oct. 1997).

[7] *Id.; see also* Beers, M., *Inappropriate Medication Prescribing in Skilled Nursing Facilities,* 117 Annals of Internal Med. 684 (1992); Stuck, A., Beers, M. *et al., Inappropriate Medication Use in Community-Residing Older Persons,* 154 Arch. Intern. Med. 2195 (Oct. 10, 1994); Beers, M. *Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly,* 157 Arch Intern. Med. 1531 (July 28, 1997); Zhan, C., *et al., Potentially Inappropriate Medication Use in the Community-Dwelling Elderly,* 286 JAMA 2823 (December 12, 2001) (documenting similar problems in community dwelling facilities based upon 1996 Medical Expenditure Panel Survey).

[8] *See, .e.g.,* Geriatric Pharmaceutical Care Guidelines, The Omnicare Formulary (2001), published by Omnicare, Inc. Omnicare is a member of the LTCPA. In contrast to formularies like the Omnicare guidelines, PBMs and retail pharmacy have little no experience in designing or maintaining geriatric formularies.

While geriatric formularies are likely necessary for most Medicare beneficiaries, LTC patients also often require specialized drug intake systems. One LTCPA member has estimated from its Minimum Data Set records of over 400,000 LTC residents that 9.3% of LTC patients cannot swallow and must be tube fed, and an additional 20.5% of residents have difficulty swallowing and must take their medications through capsules, liquids, injectables, or through pills that can be crushed. While LTC pharmacy today is equipped to handle and manage these specialized needs, the typical retail or other pharmacy or pharmacy benefit manager cannot address these concerns, or properly manage the significant drug requirements of this specialized elderly population.

LTC Residents Require Enhanced Drug Services Not Contemplated by the Discount Card Proposal: In light of the significant patient needs outlined above, both standards of care and federal and state regulations have evolved to provide LTC residents with an enhanced set of services related to their prescription drugs not provided by retail pharmacy.[9] These services include:

1. Unit dose and other specialized drug packaging. This packaging, or similar "bingo cards" or "bubble wraps," ensures that each patient receive drugs in a dedicated and uniquely labeled card, with one pill per "unit." In addition to ensuring product integrity, the packaging serves two other important functions. First, the packaging allows for greater control of the drugs and dosages to ensure that medications are taken appropriately and without error. Nurses delivering the drugs to patients are able to monitor when a pill or other drug has been provided to the patient, and know, just by looking at the card, how many doses the patient has been given.

Second, the unit dose system provides a uniform and easily managed process for drug delivery through the central distribution point of the LTC nurse, who will actually deliver the drugs to the patient on any given day. Nurses no longer have to place pills into little paper cups to distribute to the patient. Rather, they are able to avoid the multiplicity of drug delivery errors inherent in such an outdated system by relying upon the unit dose system dedicated to each LTC resident. The importance of this uniform distribution system throughout the facility cannot be overemphasized – LTC facility nurses face a significant challenge in distributing multiple drugs to dozens of patients each day, where patients consume an average of 6 medications apiece.[10] The specialized drug packaging provided by

---

[9] *See* 42 U.S.C. § 1819(b)(4)(A) and 1919(b)(4)(A); 42 C.F.R. § 483.60 (all mandating specific requirements for LTC facilities, including providing necessary drugs, preventing unnecessary drugs, and minimizing medication errors) and 483.75 (authorizing contracts with third parties to provide such services). These regulations have been further implemented and clarified through the Guidance to Surveyors (F425, F428), republished in Nursing Home Procedures and Interpretive Guidelines, A Resource for the Consultant Pharmacist, ASCP (1999)

[10] *See also* Tamblyn, R., Medication Use in Seniors: Challenges and Solutions, 51 Therapie 296 (1996). Tamblyn aptly notes that [h]ealth care system policy and practice can have a substantial impact on the drug utilization among seniors." *Id.* at 275. "Although regulatory changes are made in [governmental] drug plan policies to control costs, there is virtually no information on the impact of drug policy interventions on drug utilization patterns and

LTC pharmacy today is a critical system in helping to reduce patient risks of receiving the wrong drugs, or the inappropriate dosages, from a nurse making delivery rounds.

2. Around the Clock Delivery. LTC pharmacy also provides "around the clock" availability, either through delivery services, med-carts and emergency carts,[11] all of which assist in getting patients necessary medications in a timely manner. This service is particularly important in having intravenous medications available for LTC residents, so that patients do not have to be transported to a hospital for emergency treatment. It is important for CMS to recognize the enormous cost savings to the health care system just from this single service.

3. Consultant Pharmacist Services. In addition to providing the drugs, LTC pharmacy also provides a set of services through consultant pharmacists, who are able to review and assist in patient drug care. These services include, among others, retrospective drug regimen reviews, as required by law, 42 C.F.R. 483.60(c), and prospective drug screenings to monitor for medical appropriateness of the prescribed drugs and for inappropriate drug interactions.[12]

Critical for the provision of these important services is the need for the dispensing pharmacy and its consultant pharmacists to have a complete and accurate understanding of the patient's medical conditions, and, more importantly, current drug utilization.[13] Given current technological and other limitations, the only way in which appropriate drug reviews can be conducted, particularly on a prospective (rather than retrospective) basis is for there to be a single dispensing pharmacy for any given patient.[14] Stated differently, the prerequisite to prospective drug regimen review and medication interaction screenings is that there be a single pharmacy from which the patient's medications are dispensed, and which has complete knowledge of the medications that a patient is on at any given time. Without that single source, there is no way for the pharmacy or pharmacist to know the actual drug intake that the patient is consuming, or to monitor for contraindications, inappropriate drug interactions, drug abuse, or inappropriate prescription utilization.

---

patient outcomes." *Id.* at 276. It is exactly such an analysis that the LTCPA suggests CMS need undertake before applying the discount card proposal to LTC patients.

[11] Med-carts and emergency carts are pre-positioned medicines provided to the LTC facility for emergency uses. Typically several thousand dollars of drugs are stored in such carts, which are only called upon when patient emergencies arise.

[12] Dashner, M., Brownstein, S., Cameron, K., Feinberg, J., *Fleetwood Phase II Tests A New Model of Long-term Care Pharmacy,* 15 The Consultant Pharmacist 989 (Oct. 2000). The Fleetwood Phase II project also documented the benefits of early pharmacist intervention on identification of high risk patients, interaction with the prescribing doctor, and development of care plans.

[13] Tamblyn, supra, at 275 (noting that risk of inappropriate drug prescriptions could be reduced 20 to 30 percent by ensuring that primary physicians and pharmacists have "better access to information about all drugs prescribed to patients") (emphasis added).

[14] While current law only requires retrospective drug regimen reviews, the advantages of prospective drug screening are documented in the literature. *See, e.g.,* Dashner*, supra.*

The value of these screening services is significant. In 1997, Dr. J. Lyle Bootman estimated that for every dollar of drugs spent in LTC facilities, another $1.33 of additional health care costs was generated by drug-related medical errors. Bootman, J.L, Harrison, D.L. Cox, E., *The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities,* 157 Arch. Intern. Med. 2089 ((Oct. 13, 1997). However, Dr. Bootman was able to estimate that consultant pharmacist intervention saves **$3.6 billion** (in 1997 dollars) in avoided drug related problems. Dr. Bootman's analysis did not even account for prospective drug regimen reviews which are conducted by many LTC pharmacies today. *Id.* at 2096.

Dr. Bootman also addressed why drug related problems in the LTC context ($4.6 billion with consultant pharmacists, as opposed to $8.2 billion without their services) were a third higher than those he had previously found in ambulatory patients:

> First, nursing facility residents consume, on average, a greater number of prescription medications, thus increasing the potential for [drug related problems, or] DRPs. Additionally, in contrast to their ambulatory counterparts, nursing facility residents are placed at higher risk of DRPs because of the psychological effects of aging that alter the ability to metabolize certain drug products. Finally, another factor leading to the greater cost of drug-related morbidity and mortality is that once a DRP has occurred in the nursing home patient, there is a greater intensity of care required to treat the DRP. This could be the result of a more severe reaction experienced by the frail elderly or the higher costs of care that occur within the institutional setting.

Id. at 2095. Thus, to the extent that CMS considers changing drug delivery systems into LTC facilities, it must carefully examine the savings it expects to achieve against the savings that already exist as a result of the standards of care that LTC pharmacy provides to LTC patients.[15]

<u>LTC Residents' Eligibility Will Constantly Shift, Causing Confusion and Unnecessary Administrative Burdens:</u> CMS should not only evaluate the unique medical needs of LTC pharmacy, but should also consider the pool of current LTC residents that would be eligible for a discount card, and the trade-off between any cost savings for that small class of LTC residents against the risk of confusion that card availability would engender. The vast majority of LTC residents currently receive some type of prescription drug benefit, and would never be eligible for use of the proposed discount card in the first instance. The Lewin Group has recently completed a study on "Payer -Specific Financial Analysis of Nursing Facilities," March 2002, indicating that 66% of LTC residents are Medicaid beneficiaries, 12% are Medicare beneficiaries (receiving specific Medicare pharmacy benefits, for example, within their "first 100 days")and the remaining 22% receive insurance benefits or are "private pay" patients. These findings are consistent with both the National Health

---

[15] CMS should also re-evaluate its cost impact and financial analyses to properly reflect true drug consumption costs in the LTC community. While CMS estimates that typical Medicare beneficiary drug consumption to be $1,351 in 2004, 67 Fed. Reg. at 10280, the Coalition anticipates such spending by LTC residents to be approximately $4,700.

Expenditures analysis (CMS Office of the Actuary) and the National Health Expenses Chartbook compiled by the Agency for HealthCare Research and Quality. The National Health Expenses Chartbook also indicates that between 1987 and 1996 the number of LTC residents receiving prescription drugs outside of a Medicare or Medicaid benefit declined from 33.1% to 24.4%. Recent private company data confirms this trend, and the LTCPA expects that it will continue into the future.

Even within the population of so-called "private pay" patients the trend is to "spend down" or otherwise change status to become Medicaid beneficiaries within a short period of time. While the LTCPA is unaware of published statistics on this issue, it has reviewed statistics collected by a group of LTC operators from approximately 3000 facilities suggesting that within six months of entering a LTC facility, approximately 80% of private pay patients become Medicaid eligible and that by the end of a year within an LTC facility, 99% of those residents entering as "private pay" patients become Medicaid eligible. Thus, it is important for CMS to recognize that the potential class of LTC residents even eligible for the proposed discount card is small, and significantly shrinks as patients remain in the LTC facility.[16]

LTC Residents Already Benefit from Some of the Lowest Drug Prices Negotiated in the Health Care Market: Finally, CMS should recognize that the larger LTC pharmacies represented in the Coalition are among the most efficient drug purchasers relative to other drug purchasers in today's health care system. As such, the Coalition members are able to pass the savings from their bulk purchasing on to those "private pay" patients that would be eligible for the proposed discount card in the first instance. Stated differently, the LTCPA members today already behave like the "pharmacy benefit managers" or "bulk purchasers" described in the proposed rule who are able to aggregate purchasing power to obtain from manufacturers lower drug prices. 67 Fed. Reg. at 10263. Thus, any potential "savings" or "volume discounts" projected by CMS as a benefit of the proposed discount card already exist for the LTC patient population.

II. THE PROPOSED DISCOUNT CARD WILL NOT WORK IN THE LTC CONTEXT

The proposed discount card will cause far more harm than good if allowed to apply to LTC residents.[17] Because the discount card networks will inevitably be unable to achieve

---

[16] In light of patients' almost inevitable ineligibility, the LTCPA has not been surprised that neither LTC facilities or LTC residents have sought to use the available private discount cards or state-sponsored discount cards available in the health care market today.

[17] The LTCPA supports CMS's proposal not to require LTC pharmacies to join a discount card network and not to require discount card networks to account for LTC residents in meeting their geographic coverage obligations. 67 Fed. Reg. at 10274. CMS should therefore expect that LTC pharmacies are unlikely to join in the discount card pharmacy networks that will be assembled once the final rule is promulgated. This expectation is more than reasonable in light of the multiple disincentives and negative impacts upon patient care that a discount card proposal would bring.

nationwide (or even partial) coverage of LTC residents using LTC pharmacies, those few LTC residents who could actually use the card during the initial period of their residency in the facility would have to obtain drugs through retail pharmacies or PBMs, both of which are neither equipped or capable of delivering the suite of services to LTC residents that LTC pharmacy today provides. As expanded upon below, the result will be an increase in medication error rates, a reduction in prospective drug interaction screenings, a drop in the provision of emergency pharmacy services such as IVs, bureaucratic inefficiencies for both network providers and LTC facilities, and the possible increase in drug abuse and theft. Thus, CMS should exclude LTC residents from the scope of the discount card rule.

A. The Discount Card Would Lead to An Increase In Medical Errors: Most LTC facilities in the United States do not contain in-house pharmacies. As a result, facilities typically contract with a specialized LTC pharmacy to provide both drugs and consultant pharmacist services for the facility. The vast majority of facilities contract with a single pharmacy (subject to applicable freedom of choice requirements[18]) in order to ensure uniform drug distribution systems and to maximize the quality of services that pharmacies provide. While to be sure there are financial and administrative benefits to the LTC facility in having a single pharmacy dispense medications for the facility's residents, the primary reason that LTC facilities have chosen to contract with a single pharmacy is the development of a uniform distribution system within the LTC facility to ensure that appropriate medications in correct dosages have been prescribed and medication errors are avoided. *See, e.g.,* 42 C.R.F. § 483.25(l) (requiring LTC facilities to ensure that patients drug regimens are reviewed to avoid unnecessary drugs), § 483.25(m)(requiring LTC facilities to ensure that "[r]esidents are free of any significant medical errors").[19] As a result of these systems, the LTC facility is able to use the LTC pharmacy's specialized packaging and delivery services to meet its regulatory goals.

The introduction of a Medicare discount card into LTC facilities, however, would eliminate many of the benefits that the uniform distribution system provides, and result in an increase in medical error rates due to mistakes in drug delivery. Starting from the most obvious impact, LTC residents holding a discount card would inevitably seek to purchase their drugs from sources outside the standard LTC facility provider. Those medications would come into the nursing home in a variety of different packaging, including plastic vials (rather than

[18] *See* Region V Program Letter 94-20 (noting that statutory freedom of choice provisions do "not give unbridled freedom of choice to the nursing home resident to choose a pharmacy. We believe the statute places the responsibility to accurately administer drugs on the facility, and with that responsibility goes the right to define certain uniform standards for labeling, sorting, processing and administering of drugs. These uniform standards are essential in assuring that the patient is protected from medication errors."

[19] Although this regulation only applies to LTC facilities serving residents receiving Medicare or Medicaid benefits, the LTCPA believes that the overwhelming majority of LTC facilities in the United States serve a mix of both Medicare/Medicaid patients and private pay patients, thus bringing them within the scope of the regulations. Even if the regulations did not technically apply to a LTC facility, however, CMS as a matter of policy should evaluate the discount card's application in the LTC setting against the policies articulated in the federal regulations.

unit dose or "bingo card" sheets). While nursing staff would continue to provide effective and efficient service, experience dictates that distribution errors would increase due to the variety of drug packaging systems that would be used, with adverse (if not fatal) results for patients. Because CMS has not chosen to mandate that traditional retail pharmacies and PBMs be required to utilize the unit dose delivery systems when providing drugs to LTC residents, inevitable delivery and medical errors would occur as Patient A received the drugs in Patient B's vial, and so forth.[20]

In contrast, today's LTC pharmacies are able to provide drugs in unit dose packaging, with individual labeling for each patients. LTC nurses understand this individualized packaging, know how to distribute drugs to patients using it, and can easily and quickly account for the drugs that have actually been provided using the system. Were that system to break down, nurses could easily begin to give patients each others' drugs, or give multiple doses, or incorrect doses, of the drug to a patient.

The discount card concept may also inadvertently cause increased medical errors for other reasons as well. In locations where more than one discount card "provider network" is available, LTC patients have an incentive to "shop the networks" for drugs that might not be available in their primary network, but would be available in another.[21] This, in turn, will further diffract the distribution mechanisms in today's LTC facilities, and run even greater risks of increasing errors when the drugs are actually delivered to LTC residents. Similarly, the networks may obtain discounts on drugs in a therapeutic class that are medically inappropriate for the elderly,[22] therefore indirectly motivating the increased prescription of those drugs by well intentioned by unsophisticated doctors seeking to encourage drug utilization by prescribing the "less expensive" drugs available to their patients. While CMS surely does not intend these results, they are the likely outcomes of the proposed discount card, particularly if used in the LTC facility.

In sum, the discount card simply does not belong in the LTC, or other "institutional," context. Virtually all LTC patients today receive their medications in unit dose packaging (as is typically required by state pharmacy boards for LTC residents), through a uniform distribution network in the LTC facility. Application of the discount card concept would result in the "double whammy" of breaking down the uniform distribution process within

---

[20] The strong correlation between the number of medications prescribed and the risk of drug-related illness has been well documented. *See,* Tamblyn*, supra* at 272-73 ("The number of medications and the complexity of the daily regimen of administration are both negatively associated with patient compliance and may increase the likelihood of unintended errors in medication administration."

[21] This scenario is highly likely given the proliferation of private discount card by the drug manufacturers themselves. Further, State Medicaid experience with restrictive formularies suggests that certain networks would reflect a preference (or bias) towards particular manufacturers branded drugs. For example, Florida's recent imposition of a Medicaid restricted formulary demonstrated an overwhelming preference for Pfizer branded drugs, to the exclusion of any other manufacturer.

[22] *See* Beers, *supra.*

www.LTCPA.org
1321 Duke Street, Alexandria, Virginia 22314
Tel: 877.834.7762 Fax: 703.832.0544

the facility, and by increasing the possibility that the patient would be more prone to medical errors by taking the inappropriate drugs (or incorrect dosages). The benefits of a uniform unit dose distribution system on the LTC environment are well understood. By tearing down that system for the sake of a ten or fifteen percent discount off of a small number of drugs, CMS will unintentionally create a greater cost through increased medical errors.

B. The Discount Card Would Impede Effective Drug Interaction Screening: Assuming that a patient in an LTC facility could exercise the necessary judgment and had the necessary mobility to use a discount card, the purchase of some drugs using a discount card from a retail or PBM network pharmacy while purchasing other drugs from existing LTC pharmacies, would destroy the ability of any consultant pharmacist (whether in or out of the discount card network) to conduct a comprehensive drug screening. Prospective drug reviews could not be conducted because no pharmacist would be able to definitely know whether the information in that pharmacy database contained all, or only some, of the drugs the patient was receiving at the time the drug was dispensed.[23]

At present, the LTC pharmacy is able to consolidate patient information into a single patient record that is stored at the pharmacy. In turn, this information allows the consultant pharmacist working at the pharmacy to conduct a prospective drug interaction screening before medications are dispensed (electronic checks on patient records also occur). If the discount card were added, however, the pharmacist would have no way to know which (or how many) pharmacies were providing drugs to the patient, much less which drugs subject to the "discount card" were coming from one pharmacy as opposed to another, or which drugs were coming from pharmacies outside the discount card network.[24]

While prospective drug interaction screening is not directly mandated by existing CMS regulation, it is a well recognized tool used by consultant pharmacists today to prevent medical errors and inappropriate drug use. Particularly in the LTC resident population, where the average resident takes six or more drugs at any time, drug interaction is of far greater concern than in the general Medicare population. As such, application of the drug discount card to this institutional population would be "penny wise but pound foolish."

[23] This is not to say that retrospective drug regimen review could not be performed, as required by current regulation. 42 C.F.R. § 483.60. However, the benefits of prospective, rather than retrospective, review would be lost.

[24] CMS's view that drug regiment review would be enhanced for the non-institutional beneficiary by the use of a discount card is itself questionable. Because the proposed rule requires that only one drug per therapeutic class be available for a discount in any network, discount card holders have no incentive to purchase that non-"discounted" drug from the same pharmacy. In turn, pharmacists have no ability to know what drugs are being purchased by the beneficiary from other pharmacies or networks. The only way that CMS can ensure that proper drug regimen review is performed for patients holding "discount cards" would be for CMS to mandate that discount card holder purchase all their drugs from a single pharmacy. The discount card proposed rule, of course, contains no such requirement (nor could it in light of the other provider network requirements that CMS has already proposed).

C. The Discount Card Would Impede Emergency Drug Services, Timely Delivery, Reliability of Delivery and Accountability in the Name of Price Cutting, Thus Costing Patients More, Rather than Less: LTC pharmacy today not only provides patients with specialized packaging and uniform distribution for their required medical needs, but also assumes responsibility for other patient drug needs. For example, because they already have established delivery routes and schedules for LTC resident drugs on a facility-by-facility basis, LTC pharmacies are also able to deliver emergency IVs or other "on demand" medications for administration to the patient in the LTC facility. The benefits of this delivery system accrue not only to the patient (who will receive needed medications faster and in a more comfortable environment), but to the health care system in general. If LTC pharmacies were not able to deliver IVs, for example, a needy patient would have to be transported to a hospital for emergency treatment, rather than remaining in the LTC facility. While a hospital stay may not cost the patient any more (as presumably it would be encompassed by Medicare Part A coverage), the costs to the health care system in general are significant.

Retail and PBM networks cannot, and will not, in most instances be able to prepare and deliver these "STAT" medications. To the extent that LTC residents eligible for a discount card chose to use the card, rather than to contract with an LTC pharmacy for service, they would not have these emergency services available to them. As a result, these patients would need to be moved (oftentimes back) to hospitals for any IVs or other emergency drug treatments. The costs to patients, and to the health care system in general, again far outweigh the benefits that a card would provide.

The proposed rule would also negatively impact the current delivery of drugs to LTC facilities. Even assuming that LTC pharmacies could afford to maintain their delivery frequency and timeliness, PBMs and retail pharmacies participating in provider networks would not be able to match the current service levels. As a result, LTC facilities would begin receiving deliveries at different times, further impeding the efficient and timely delivery of drugs that occurs in LTC institutions today. Simply stated, timely deliveries, reliable delivery, and accountability would thus each suffer from the division of pharmacy providers to the LTC institutions.

D. The Discount Card Would Create Massive Bureaucratic Inefficiencies: Unjustifiable bureaucratic inefficiencies would also result if CMS permits the discount card to be used in LTC facilities. As noted above, the vast majority of LTC patients are and will remain ineligible for a discount card, either because they are already Medicaid beneficiaries, they currently have Medicare Part A prescription drug coverage (within their so-called "first 100 days"), or are otherwise receiving some type of insurance. Given the rapid frequency with which the LTC population moves from one reimbursement status, and the "spend down" rate at which even those without prescription drug coverage inevitably become Medicaid beneficiaries, the benefits of providing discount cards to LTC residents is dubious at best.

Two separate deleterious results are likely to occur. First, with the publicity that the proposed discount card program has already received and that which it will receive once CMS actually implements its plans, it is virtually certain that LTC residents will be confused. The Coalition fully expects current Medicaid beneficiaries to attempt to obtain a card, and to

become frustrated when they are told that they are ineligible. Those few Medicare patients that are eligible, however, will be all the more frustrated when they obtain a card, and then soon lose eligibility as they change status.

Second, a bureaucratic nightmare will be created, as discount card networks will be forced to track eligibility status for LTC residents. Particularly given the frequency of LTC facility residents going in and out of hospitals, and the quick changes in their eligibility status for Medicare drug benefits (not to mention their inevitable status change to Medicaid beneficiaries), the costs of tracking eligibility for this small class of potential discount card users are going to be far greater than any savings that could be achieved. The increased costs will be born by the networks, who will inevitably pass these costs on to non-institutional discount card holders – the primary intended beneficiaries of the proposed rule. Ambulatory Medicare beneficiaries should not be burdened with the additional administrative costs of trying to fit the discount card into institutional care. Stated differently, CMS has claimed that Section 1102 of the Medicare Act, requiring CMS to ensure the "efficient administration" of the program, provides it a statutory basis for the discount card program. Efficient administration, however, dictates that CMS avoid burdening the proposed discount card program with these additional and unjustifiable costs and burdens.

E. The Discount Card Will Create Other Unintended Consequences if Permitted in LTC Facilities: There are a variety of other unintended consequences that will flow from the discount card's application to LTC facilities. For example, it is unclear what would occur to unused drugs purchased through a discount card program, particularly in those states which have implemented return and reuse requirements for unit dose packaging dispensed in LTC facilities. Similarly, by opening up the unified distribution systems currently existing in many LTC facilities, the discount card proposal increases the number of persons and steps involved in the drug distribution process for LTC residents, and increases the risk of theft or drug tampering.

III. CMS'S STATED POLICY OBJECTIVES WILL BE DEFEATED, NOT ADVANCED, IF THE DISCOUNT CARD IS APPLIED TO LTC FACILITIES

Application of the proposed discount card in LTC facilities will also undermine, rather than advance, many of the policy objectives articulated by CMS in the proposed rule. An analysis of those objectives in the context of the LTC facility reveals that many of CMS's goals will not be met.

Objective 1: Increase education to private market methods. 67 Fed. Reg. at 10263, 10265: Most LTC residents do not purchase their prescriptions through the private market and will not benefit from any education about such private market conditions while they are in long term care facilities. Further, given that a significant portion of long term care residents suffer from impaired mental faculties, including a percentage that are diagnosed as suffering from dementia, it is more likely than not that this patient population is not appropriate to target for education through media and marketing tools. To the extent that the information will exist on web-sites, 67 Fed. Reg. at 10286, LTC residents do not have computers, or know how to use them. Even if the patient population were appropriate, however, LTC patients purchase their prescriptions through a highly regulated institutional setting rather than through the "private market." Thus, this policy goal is not advanced by applying the discount card to LTC residents.

Objective 2: Access to Tools for Management, including Drug Regimen Review. 67 Fed. Reg. at 10264. As noted above, LTC residents already benefit from prospective and retrospective drug regimen review, typically by the same pharmacy that dispenses all their prescriptions in the first instance. As explained above, introduction of the discount card in this fragile patient population will likely result in the opposite of what CMS seeks; rather than enhance drug utilization screening, it will diffuse the sources of drugs from with LTC residents will be motivated to purchase drugs, thus impeding proper and comprehensive drug screening.

Objective 3: Publicize information: As explained above, the percentage of LTC residents suffering from dementia likely diminishes any real gains that would be achieved by publicizing information to the LTC patient population. However, publicizing information about prices and formularies is likely inappropriate for LTC residents, who take far more than average the number of drugs, and already benefit from geriatric formularies created and used by LTC pharmacy. CMS's efforts to publicize information within the LTC resident community will likely increase confusion, rather than enhance understanding, about prescription drugs.

Objective 4: Enhance participation in drug programs, and increase leverage on prices. 67 Fed. Reg. at 10264. There is no enhancement in participation of LTC residents, or improvement in their access to drugs, and they already have the best access of any patient population in the country. Further, LTC pharmacy today is among the most efficient purchasers of prescription drugs, as they not only aggregate patients within specified regions, but generally are able to aggregate buying power across the country to maximize their leverage in reducing purchase prices from manufacturers. These lower prices, in turn, are passed on to those "private pay" LTC residents that might be subject to the proposed discount card in the first instance. It would indeed be ironic, but highly possible, for CMS's media and public relations efforts to result in LTC residents choosing network plans who charged higher prices than LTC pharmacy charges today.

Objective 5: Quality of services. 67 Fed. Reg. at 10264. It is not clear how access to a card would enhance quality of services, other than provide the pharmacy benefit services already mentioned. However, LTC residents using the discount card would experience a reduction, not enhancement, of services that they now routinely receive from their LTC facilities. Of course, we recognize that CMS is not proposing that LTC patients "drop out" of the LTC process, but we point out that there is no policy objective achieved in the quality of services arena by a proposed discount card that fails to carve out LTC pharmacy from its scope. In fact, as noted above, due to diffraction of the current uniform delivery mechanisms, the discount card likely does harm, rather than good, in the LTC context.

Objectives 6 and 7: Endorsing cards and program and increasing access to such programs. 67 Fed. Reg. at 10264. There are numerous private "discount cards" currently available in the marketplace, and even more prescription drug programs such as today provided by LTC pharmacy to LTC residents that do not style themselves as "discount card programs" yet achieve many of the same goals of reduced prices through aggregate purchasing, enhanced services, and increasing information about prescription drugs to the elderly. Thus, to the extent that increasing access to a discount card has value, those objectives are already met by LTC pharmacy in its routine provision of prescription drugs to LTC residents.

In sum, we believe that CMS will defeat, rather than advance, its stated policy objectives in the event the discount card is applied to long term care facilities.

IV. THE SOLUTION – EXCLUDE LONG TERM CARE FACILITIES AND OTHER INSTITUTIONAL FACILITIES FROM THE DISCOUNT CARD PROGRAM.

For the reasons set forth above, the LTCPA urges CMS to exclude long term care facilities from the scope of the proposed discount card program. Many of CMS's goals are already being met for LTC residents in institutions, and other benefits and services that are beyond the scope of the proposed discount card plan would be harmed if the discount card could be used by the small percentage of LTC residents that might even benefit from the card.

We appreciate the opportunity to comment upon the proposed discount card, and we look forward to working with CMS on this and other proposed prescription drug benefits that the Agency may be contemplating or proposing in the future. Of course, we would welcome the opportunity to answer any questions CMS has about the above comments, or any other aspect of LTC pharmacy, and urge CMS to contact Mr. Stephen Northrup, Executive Director of the Alliance, at 202.257.5482 with any questions it may have.

Sincerely,

Stephen Northrup
Executive Director
Long Term Care Pharmacy Alliance

cc: LTCPA Members (w/o attachments)

www.LTCPA.org
1321 Duke Street, Alexandria, Virginia 22314
Tel: 877.834.7762 Fax: 703.832.0544