October 1, 2004

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Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue
Room 443-G
Washington, D.C. 20201

Re: General Provision Comments to the Medicare Prescription Drug Benefit and Medicare Advantage Proposed Rules, CMS-4068-P and CMS 4069-P

Dear Administrator McClellan:

The Long Term Care Pharmacy Alliance (LTCPA) appreciates this opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) proposed rules to implement the Medicare Prescription Drug Benefit and establish the Medicare Advantage Program.[1] The LTCPA is an alliance representing the four major national long-term care (LTC) pharmacies, estimated to serve three out of every five nursing home residents and numerous other beneficiaries in institutional settings, through over 500 LTC pharmacies nationwide. In the course of that service, LTCPA and its members have developed a preeminent expertise in providing prescription drugs and related services to this particularly frail and elderly population, virtually all of which will be affected by the proposed regulations and their authorizing statute. Given that experience, we have numerous comments addressing the impact of the proposed regulations on the health and well-being of beneficiaries who are residents of LTC facilities, and a series of proposed solutions to improve the proposed regulations to ensure that medically necessary and appropriate prescription drugs are timely and properly delivered to LTC residents and related populations served by the LTC pharmacy community. We urge CMS to seriously consider the questions we raise in our comments and the solutions we propose.

Our comments are divided into multiple sections. In the first section, we summarize five principles which underlie all of LTCPA's comments on the proposed rules which LTCPA urges CMS to adopt in developing its final rule. These principles can serve as the basis for a set of standards that CMS can use to evaluate the responsiveness of plan bids to the needs of the residents of LTC facilities. In Section II we describe LTC

[1] 69 Fed. Reg. 46632, 46866 (Aug. 3, 2004).

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

pharmacies and the services they provide to LTC residents. We also explain the critical role that LTC pharmacy has come to serve in today's health care system, and the specialized services that LTC pharmacy alone can provide. Section III contains LTCPA's response to CMS' request for comments on whether Prescription Drug Program (PDP) plans should be required or encouraged to contract with LTC pharmacies. Section IV addresses formulary issues, and LTC residents' needs for an open formulary. Section V addresses several critical regulatory changes necessary to ensure proper care for full benefit dual eligibles. Section VI responds to CMS request for input regarding its three options for dispensing fees. Section VII presents a set of questions and comments on Medication Therapy Management Programs (MTMP). Section VIII suggests an expanded definition of "long-term care facility" to include residents of congregate licensed living arrangements for the elderly that "assist with " or "manage" medication administration for their patients. Section IX raises additional issues affecting Part D coverage for LTC residents. Finally, Section X contains a summary of all of LTCPA's recommendations.

EXECUTIVE SUMMARY

Although we address each point in more detail below, we wanted to provide CMS a broad overview of our comments at the outset to assist the Agency in evaluating this analysis and allow CMS the ability to understand how our proposed regulatory changes "fit" with each other. LTCPA, in summary, urges CMS to review the proposed regulations as follows:

1. PDP-LTC Pharmacy Relationship: CMS has correctly understood the critical need to preserve the necessary one-to-one relationship between a nursing home and LTC pharmacy. The proposed regulation, with additional modifications, can strike the right balance by preserving LTC pharmacies' ability to provide drugs to nursing home residents by providing market incentives for LTC pharmacies to join PDP networks, but also allowing LTC pharmacies to provide prescription drugs as out-of-network pharmacies at usual and customary prices, if the circumstances so dictate. Preserving the out-of-network option allows beneficiaries, LTC pharmacies, and PDPs the right mix of economic incentives to permit the LTC pharmacy to negotiate with the PDP an appropriate and fair reimbursement for the additional services it provides beneficiaries. CMS should adopt a system that preserves for all parties the appropriate market-based incentives to negotiate and agree upon appropriate financial terms to allow the suite of necessary specialized services for LTC residents to continue. CMS must permit LTC pharmacies to serve their populations as out-of-network providers in the event that the appropriate financial terms cannot be reached through market-based solutions.

2. Formulary: CMS must revise its formulary requirements, by creating for LTC residents a presumption of coverage for medically necessary drugs (as defined by a beneficiary's physician) so that they can be dispensed and reimbursed without resorting to delays inherent in any appeals process.

3. P&T Committee: CMS solicits public comments on preferred policies for pharmaceutical and therapeutic committees (P&T Committees). Though we propose standards to strengthen P&T Committees in our comments, we do not believe that a formulary should be considered an option for full benefit dual eligibles, particularly those residing in LTC facilities. Nevertheless, it is imperative that CMS require P&T Committees to consider the special needs of LTC residents to the extent that this population is subject to the formularies and utilization controls endorsed by the P&T Committee.

4. Enrollment: LTCPA is concerned that dual eligible beneficiaries will experience a gap in coverage due to the time constraints to implement the Part D program, and the statutory constraint on Medicaid wrap-around. Therefore, we encourage CMS to delay implementation of the program until 2007, and allow Medicaid to continue providing drug coverage to dual eligible beneficiaries during 2006. In addition, we support automatic enrollment of dual eligible beneficiaries in a drug plan that includes the long-term care pharmacy servicing the resident's LTC facility. We also support a special enrollment period for Medicare beneficiaries that enter a LTC facility, modeled after the discount drug card special enrollment period.

5. Dispensing fees: CMS proposes alternative definitions of dispensing fees. LTCPA encourages CMS to include specific dispensing fee costs that are routinely incurred in the LTC setting, and to provide for an inflationary update of the dispensing fee.

6. Medication Therapy Management Program: We urge CMS to provide for a definition of targeted beneficiaries for MTMP services that includes all LTC residents. In addition, MTMP services should be provided by pharmacists with specialized training in geriatric drug therapy. LTC pharmacies should be paid for MTMP services whether or not the pharmacy is in the plan's network.

7. LTC Facility Defined: LTCPA encourages CMS to adopt a broad definition of LTC facility that includes both ICF/MRs and other so-called "waiver" populations in institutional settings being served by Medicaid today.

8. Standards for Plan Bids: CMS will review plan bids to ensure that they are not discriminating against a particular population based on health status. In this process, we encourage CMS to adopt standards that are consistent with the principles of LTCPA in reviewing plan bids to ensure that they are not discriminating against LTC residents. We also encourage CMS to use the model of special needs plans to provide open formularies to LTC residents.

COMMENTS

I. PRINCIPLES UNDERLYING THE COMMENTS OF THE LONG-TERM CARE PHARMACY ALLIANCE

Based on the unique needs of residents of LTC facilities, the regulatory environment in which LTC facilities operate, and protections currently in place for these residents under the existing Medicaid program, LTCPA's comments and recommendations reflect five principles. LTCPA encourages CMS to use these principles to develop a set of standards, such as the standards proposed in our comments, that plan bids must meet in order to be approved. These standards can then be used to evaluate the responsiveness of plans' bids in meeting the prescription drug needs of residents of LTC facilities and to assure that plans do not discriminate against LTC residents.

A. Preserving a one nursing home – one LTC pharmacy relationship is critical to ensuring safety and convenient access for Medicare beneficiaries who are residents of nursing facilities.

B. Nursing facility residents have unique care needs that require immediate access to a wide variety of medications in many different dosages and delivery forms.

C. In addition to prescription drugs, LTC pharmacies provide unique services to nursing facility residents such as clinical consultations, emergency medication access with 24-hour deliveries, specialized packaging, and IV and infusion therapies.

D. For this segment of the Medicare population, access to appropriate medications in a controlled environment is essential to health and safety.

E. There are significant coordination issues associated with transitioning to Part D benefits for institutionalized beneficiaries.

II. LONG TERM CARE PHARMACY AND THE SPECIAL NEEDS OF THE RESIDENTS WE SERVE

Nursing home and other LTC residents today have specialized drug therapy needs far different from the ambulatory Medicare beneficiary. To address those needs, over the past 25 years the LTC pharmacy industry has emerged to serve the unique needs of the nation's most frail elderly persons. We appreciate that CMS, in its proposed rule, has already recognized the fact that LTC pharmacy has responded to those needs through development of a sophisticated delivery system far beyond the scope of what a typical retail pharmacy provides today. Because LTC residents' needs, the services currently being provided by LTC pharmacy, and the resulting cost savings to health care delivery all factor into LTCPA's comments to the proposed rules, we expand upon them below.

LTC Residents Typically Need Greater Drug Therapy: Unlike the typical ambulatory senior, residents in LTC facilities usually are older, in poorer health, and in need of greater care. A 1999 study by Bernabei *et al.* described the typical LTC resident, as follows:

- mean age of residents is 83.1 years;
- 62% of residents were admitted to the LTC facility from an acute care hospital;
- over half of LTC residents had abnormal cognitive function, and only 17% were characterized as independent or required limited assistance in performing the activities of daily living;
- residents typically had three medical conditions, with 45% having four or more and 10% having more than six medical conditions. Typical diseases included cardiovascular clinical conditions (63%), hypertension (31%), coronary artery disease (23%), and congestive heart failure (19%). Significantly, 42% of residents had dementia, and 20% were stroke victims;
- LTC residents were taking an average of 6 drugs, with 45% taking seven or more drugs, and 20% taking more than 10 drugs. Over 50% were on some type of cardiac medication, and approximately 40% were on an analgesic.[2]

More recently, the 2000 National Medication Usage Study of 63,671 nursing home residents revealed an average of 8.07 routine medication orders per resident, with 41% receiving 9 or more routine medications per day.[3] The most commonly used drug classes were antidepressants (45%), analgesics (30%), antipsychotics (24%) and anxiolytics (11%).[4] The frequency of drug usage does not reflect an overuse of medications, but rather the increased efficacy of today's more advanced medicines, and the significant improvements in quality of life that pharmaceuticals can provide to LTC residents who previously had little hope of recuperation from serious illnesses.

LTC Residents Typically Need Different Drug Therapies Than Their Ambulatory Counterparts: Not only are elderly LTC residents on more medications, but they require different medications and different types of medications. More specifically, as a person ages their body processes drugs differently due to their changing metabolism and typical decreases in kidney function.[5] There has been extensive treatment in the literature

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[2] *See* Bernabei, *et al., Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care*; J. 54 Gerontol. A. Biol Sci. Med. Sci. M25 (1999). At the time it was published, the Bernabie *et al.* 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.

[3] *See* D.E. Tobias and M. Sey, *General and Psychotherapeutic Medication Use in 328 Nursing Facilities: A Year 200 National Survey*, 16 Consult. Pharm. 54 (2001).

[4] *Id.*

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

describing the need for a different formulary for the elderly,[6] and companies have published specialized care guidelines documenting exactly how different drugs typically prescribed react (and interact) in these frail elderly people.[7] While these specialized formularies are often not widely known 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.

In addition to differing drug needs, LTC patients also often require specialized drug intake systems. One LTCPA member has estimated from their 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. (A more comprehensive discussion of drug delivery mechanisms and their impact upon formulary issues is included in Appendix 1.) While LTC pharmacy today is equipped to handle and manage these specialized needs, the typical retail or other pharmacy or pharmacy benefit manager is not equipped to address these concerns, or properly manage the significant drug requirements of this specialized elderly population.

LTC Residents Receive Enhanced Drug Services. In light of the significant patient needs noted 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. These services include:

1. Unit Dose and Other Specialized Drug Packaging. This packaging serves two important functions. First, the packaging allows for greater quality control of the drugs and dosages to ensure that medications are taken appropriately and without error. 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. The critical nature 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.[8] The

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[6] *Id.; see also* M. Beers, *Inappropriate Medication Prescribing in Skilled Nursing Facilities,* 117 Arch. of Intern. Med. 684 (1992); A. Stuck, M. Beers, *et al., Inappropriate Medication Use in Community-Residing Older Persons,* 154 Arch. Intern. Med. 2195 (1994); see M. Beers, *Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly,* 157 Arch Intern. Med. 1531 (1997).

[7] *See, .e.g.,* Omnicare, Inc., *Geriatric Pharmaceutical Care Guidelines, The Omnicare Formulary* (2001). Omnicare is a member of the LTCPA.

[8] *See also* R. Tamblyn, *Medication Use in Seniors: Challenges and Solutions*, 51 Therapy 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 patient outcomes." *Id.* at 276.

specialized drug packaging provided by 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 "24/7" Delivery. LTC pharmacy also provides round the clock availability, either through delivery services, med-carts and emergency carts,[9] 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 they do not have to be transported to a hospital for treatment. It is critical 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 drugs, LTC pharmacy also provides a set of services through Consultant Pharmacists, who are able to review and assist in patient drug care. LTC pharmacists also counsel patients, provide information and recommendations to prescribers and caregivers, review patients' drug regimens, present in-service educational programs, and oversee medication distribution services -- all in addition to providing medication. LTC pharmacists also provide a wide range of other primary care services to seniors, including pain management counseling, pharmacokinetic dosing services, intravenous therapy, nutrition assessment and support, and durable medical equipment assessments and support. In this way, LTC pharmacies assist LTC facilities in preventing medical errors and in ensuring the highest quality of patient care.

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.[10] Given technological and other limitations, appropriate drug reviews are facilitated, particularly on a prospective (rather than retrospective) basis, by having a single dispensing pharmacy for any given patient.[11] Having a single pharmacy from which the patient's medications are dispensed, which has complete knowledge of the medications that a patient is on at any given time, enables more accurate prospective drug regimen review and medication interaction screenings. 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 utilization of prescriptions.

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[9] 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 used when a patient emergency arises.

[10] Tamblyn, *supra* at note 8 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].

[11] 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* at note 11.

The value of these screening services is significant. Bootman *et al.* estimated that Consultant Pharmacist intervention saves $3.6 billion (in 1997 dollars) in avoided drug-related problems.[12] Thus, any attempt to introduce alternative drug delivery systems into LTC facilities must be carefully examined against the backdrop of the savings that already exist as a result of the standards of care that LTC pharmacy already provides to these patients.

Bootman *et al.* explained their finding that 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 the ambulatory setting:

> 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 physiological 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 within the institutional setting.[13]

The Vast Majority of LTC Residents Currently Receive Prescription Drug Benefits under Medicaid. A recently completed Lewin Group study on "Payer -Specific Financial Analysis of Nursing Facilities," published in March, 2002, indicated 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 Expenditures analysis (CMS Office of the Actuary) and the National Health Expenses Chartbook compiled by the Agency for Health Care 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%. Data provided by LTC operators from approximately 3,000 facilities suggest 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, 99% of those residents entering as "private pay" patients become Medicaid eligible. Thus, it is important for CMS to recognize that the vast majority of LTC residents receive Medicaid prescription drug benefits that include access to "medically necessary" prescription drugs. In addition,

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[12] *See* J.L. Bootman, D.L. Harrison, E. Cox, *the Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities*, 157 Arch. Intern. Med. 2089 (1997). Bootman *et al.*'s analysis did not even account for prospective drug regime reviews which are conducted by many LTC staff pharmacists today. *Id.* at 2096.

[13] *Id.* at 2095.

Medicaid provides for a 24 hour appeal determination and 72 hour dispensing, procedures which are less likely to result in adverse health incidents. A reduction in the benefits currently enjoyed by this population has the potential to result in increased adverse health incidents for this population of frail elderly institutionalized beneficiaries.

LTC Facilities are Subject to Federal Nursing Home Act's Statutory and Regulatory Requirements Affecting the Provision of Prescription Drugs. Federal regulations require long-term care facilities to ensure that medication error rates are minimized and that residents do not receive unnecessary drugs.[14] LTC facilities typically contract with LTC pharmacies to provide prescription drugs and services to their residents. These services include consultations with physicians regarding drug regimens, 24 hour, 7 day per week deliveries, specialized packaging, and IV and infusion therapy services. Under this arrangement, beneficiaries receive their medication in a carefully controlled environment where safety can be assured, medication use monitored, and therapies are changed to better reflect the needs of the resident.

LTC Pharmacy is Different from Retail Pharmacy. LTC pharmacy is different from the retail pharmacies that are likely to join PDP plans' networks, or those pharmacies contemplated by the MMA as serving the ambulatory Medicare population that will serve as the backbone of the PDP network.[15] There are three distinctions. First, retail offers other "items" for sale, and thus is not solely dependent upon appropriate drug reimbursement for its revenue. Second, LTC pharmacy's cost structure is higher due to the far greater suite of services it provides. Third, LTC pharmacy is far more dependent on the Medicare population as a customer base than retail pharmacy.

Addressing the structure of their respective facilities first, retail facilities provide a host of other items "for sale" such as food, beverages, candy, household items, and other "drug store" retail products, many of which carry a far higher profit than the prescription drugs sold at 'the back of the store." Thus, retail pharmacies and pharmacy chains have an interest in providing prescription drugs to beneficiaries, if only to attract them into the stores so that other products can be sold. LTC pharmacy, in contrast, has no such "storefront" and has no such products for sale to its customers. Thus, the financial incentives that will attract a retail pharmacy serving ambulatory Medicare beneficiaries to enter into a PDP network, and the negotiating leverage the retail pharmacy may have, is simply not present in the LTC context.

Second, pharmacies that serve institutional sites of care, such as nursing homes, have higher costs of doing business than other pharmacies. In particular, LTC pharmacies have high dispensing and related costs that are different from those of retail pharmacies serving ambulatory individuals in community settings. To quantify this phenomenon, in 2001 LTCPA commissioned the accounting firm of BDO Seidman to conduct a survey of its members' audited dispensing costs, consolidate the financial information, and issue a

[14] 42 C.F.R 483.25(m).

[15] CMS has previously recognized this distinction in its 2002 rulemaking on the ten-proposed discount drug card program. *Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative*, 67 Fed. Reg. 56,617, 56,640 Final Rule, Sept. 4, 2004).

report on the costs of dispensing pharmaceuticals to residents in nursing homes and other LTC sites.

The BDO Seidman survey found (using 2001 audited data) that it costs the major national LTC pharmacy operators (who presumably, through economies of scale, maintain a lower cost structure than the smaller LTC pharmacy companies), on average, approximately $11.37 to dispense a prescription.[16] This figure does not include a return on equity or a profit margin, it simply reflects the costs of operating a LTC pharmacy. In contrast, the National Association of Chain Drug Stores (NACDS) estimated in 2000 that it costs a chain pharmacy, on average, $7.05 to dispense a prescription to a retail customer.[17]

In reviewing the survey results, BDO Seidman found several reasons why the costs of dispensing prescriptions are higher for LTC pharmacies than they are for retail pharmacies. BDO Seidman attributed the higher costs to:

- the dispensing of drugs in specialized packaging systems, such as unit-dose packaging, that reduce the possibility of medication errors and are the standard of care in nursing homes;
- the need for round-the-clock delivery of critical and emergency medications;
- the preparation and dispensing of intravenous medication solutions, a service that retail pharmacies typically do not provide;
- a high percentage of business reimbursed by Medicare and Medicaid, resulting in higher receivables, greater working capital requirements, and a higher percentage of bad debts than generally experienced in the retail setting; and
- the provision of considerable on-site support and consultation to nursing homes and other institutional provider-clients.[18]

Third, beyond the distinct cost structures, retail pharmacies do not depend upon Medicare beneficiaries as a predominant source of revenue. Stated differently, retail pharmacies expect that a broad range of customers will enter their stores, including children, parents, and workers with prescription drug insurance. The flexibility in a retail pharmacy's customer base provides retail pharmacy a significant amount of discretion and leverage in choosing whether or not to enter into a PDP network if the PDP reimbursement is inappropriately low. In contrast, and as described above, the vast majority of LTC pharmacy's customer base are Medicare beneficiaries, and there is virtually no ability for LTC pharmacys to target a different customer base. Thus, by its very definition, LTC pharmacies can be "held hostage" to PDP reimbursement structures, simply for the reason that LTC pharmacy does not have the ability to shift its customer base and marketing efforts. LTCPA urges CMS to take note of this significant market dynamic, which (beyond

[16] *See* BDO Seidman, LLP, *Institutional Pharmacy Dispensing Cost Study* (2002) available at www.ltcpa.org (last visited Sept. 22, 2004).

[17] *Id.*

[18] *Id.*

patient care needs, which also require this same solution) argues for allowing LTC pharmacies the flexibility of serving LTC residents as an out-of-network provider.

III. RELATIONSHIP BETWEEN LTC PHARMACIES AND PRESCRIPTION DRUG PLANS

A. ADDRESSING THE NETWORK STRUCTURE

As our first principle notes, LTCPA believes that a bedrock goal and principle for the regulations should be to preserve and enhance the "one nursing home – one LTC pharmacy" paradigm currently used in today's health care system. Although the preamble to the proposed regulations reflect that CMS understands the importance of this consideration,[19] the proposed regulations themselves do not address the issue of a one nursing home - one LTC pharmacy relationship. Yet, the maintenance of this relationship is critical to providing prescription drugs to nursing home residents in a safe and efficient manner, without such a direct relationship, nursing facilities may not be able to meet pharmacy management standards.

Unfortunately, the MMA and the proposed regulation could put this paradigm at risk because it is virtually certain that Medicare beneficiaries entering nursing homes (and those already in nursing homes who choose a PDP either during the initial enrollment period, auto enrollment, or subsequent open enrollment periods) will be members of a variety of different PDPs. These plans may contract with different pharmacies or use different formularies and different packaging and delivery systems from those previously used by the one LTC pharmacy serving the facility. As a result, every LTC medication nurse will be forced to manage different formularies and multiple packaging and delivery systems from different pharmacies for residents in his/her unit, and adjust to different delivery schedules and drug regime review cycles and processes, creating increased opportunities for medication administration errors. Attending physicians also will be confused by different distribution and administration channels and complexities in having to address multiple and distinct formularies. This creates inefficiency and a large margin for medical error given the many competing demands already placed on nursing home physicians and staff – problems that today's health care marketplace has overcome through the one-on-one relationship typically found in LTC pharmacy.

CMS requests comments on whether it should require or encourage PDP plans to contract with LTC pharmacies or allow LTC pharmacy to provide drugs to beneficiaries as out-of-network providers. LTCPA believes that CMS has struck a reasonable balance by permitting LTC pharmacy to either provide the benefit as an "in-network" or "out of network" provider, as market forces will allow. Without an out-of-network option, we expect plans to treat LTC pharmacy no different than retail pharmacies, which, in turn, would preclude LTC pharmacies from providing the necessary suite of services that beneficiaries currently enjoy and require. By permitting, but not requiring or prohibiting

[19] 69 Fed. Reg. 46648-49.

LTC pharmacies to serve as "in-network" providers, CMS will give LTC pharmacies and PDPs the appropriate negotiating flexibility to reach mutually satisfactory arrangements for providing services to LTC residents.

Allowing LTC pharmacies the ability to serve Medicare beneficiaries as either in-network or out-of-network providers achieves numerous goals. First, it accomplishes the primary goal of preserving the one-to-one nursing home/pharmacy relationship described above. Second, it gives the LTC pharmacy leverage to negotiate a fair reimbursement from the PDPs by giving LTC pharmacies the ability to aggregate a group of LTC resident beneficiaries and more efficiently and effectively allow them to be enrolled in any one (or group) of PDP plans. Third, it allows a PDP the incentive and interest to work with the LTC pharmacy to become a nursing home's "preferred provider." For beneficiaries already in nursing facilities, LTC pharmacy has an incentive to work with LTC residents to educate them for the purposes of having them enroll in the most beneficial network for their needs, and beneficiaries would have an interest in doing so to avoid paying out-of-pocket the differential between the in-network and out-of-network cost. Thus, the option preserves maximum flexibility by each of the market participants – the beneficiary, the pharmacy, and the PDP or MA-PD plan.

Although LTCPA believes that CMS has struck the correct balance by encouraging, but not requiring, PDPs to contract with LTC pharmacies, the manner by which CMS "encourages" a PDP to contract with a LTC pharmacy is not clear. The regulations must provide an incentive for PDPs to bring LTC pharmacies into their networks. CMS has proposed several standards for pharmacy access, as well as other provisions upon which a plan bid will be measured. LTCPA proposes long-term care standards based on our principles described above that CMS should incorporate into its regulations to ensure that plans do not discriminate against LTC residents. We believe that, in order to meet these standards, plans will be encouraged to contract with LTC pharmacies that can provide pharmaceutical services needed by LTC residents enrolled in their plans.

In circumstances where a plan has not contracted with the LTC pharmacy servicing the institution, the proposed regulatory text does not explicitly permit LTC residents to access the pharmacy as an out-of-network provider. We are concerned that plans, though allowing access to some out-of-network providers, will not necessarily allow patient access to all out-of-work providers. As a result, patient access to the particular pharmacy servicing that facility could be threatened. Therefore, LTCPA believes that the regulatory text should explicitly state that residents will have access to any pharmacy that services that facility.

We are also concerned that the provisions for fallback plans do not specifically require beneficiary access to out-of-network pharmacies, as is required for PDPs and MA-PD plans in Section 423.124. CMS states in Section 423.855 that fallback plans are required to be a PDP sponsor except that it does not have to be a risk-bearing entity. CMS also defines a Fallback Prescription Drug Plan as a plan providing access to negotiated prices, in the same manner as PDPs and MA-PD plans. Nevertheless, CMS does not clarify in Section 423.124 that fallback plans are subject to the same requirements as PDPs and MA-PD plans with regard to out-of network pharmacy access and payment. Therefore, we encourage CMS to make this requirement explicit in the final regulations.

In addition, we encourage CMS to ensure that plans do not have the ability to presumptively include LTC pharmacies in their pharmacy networks based on a pre-existing relationship with the plan sponsor outside of the context of Part D. It is important to note that the Medicare population is unique, and has more extensive pharmaceutical needs that require a broader array of pharmacy services. LTC pharmacies should be able to pro-actively elect to participate in a network providing the Medicare Part D benefit to ensure that the plan and LTC pharmacy have negotiated a mutually beneficial contract.

LTCPA proposes the following revision of Section 423.124:

(a) Out-of-network access to covered part D drugs. A PDP sponsor, MA organization offering an MA-PD plan, *and fallback plans* must assure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when such enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy. *For enrollees residing in a long term care facility, a PDP sponsor, MA organization, or fallback plan must provide the enrollee access to covered Part D drugs dispensed at any out-of-network long term care pharmacy that is contracted to provide pharmacy services to the long-term facility.*

(b) Financial responsibility for out-of-network access to covered Part D drugs.

(1) A Part D enrollee is financially responsible for any deductible or cost-sharing (relative to the plan allowance, as described in Sec. 423.100, for that covered Part D drug).

(2) Any differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance (including any applicable beneficiary cost-sharing) for that covered Part D drug, *except for cost-sharing subject to Section 423.782.*

Recommendations:

- **CMS should encourage, but not require, PDP plans to contract with LTC pharmacies.**
- **CMS also should explicitly preserve, and enhance, the language in proposed section 423.124 to specifically permit LTC residents to access LTC pharmacies as out-of-network providers.**
- **The final rule should explicitly state that fallback plans are subject to the requirements in Section 423.124 for out-of-network pharmacy access and payment.**
- **Plans should not be allowed to presumptively include LTC pharmacies in their pharmacy networks based on pre-existing relationships outside the context of Part D.**

B. Payment of Differential between Out of Network Pharmacy Charge and PDP Plan Allowance, Particularly for Full Benefit Dual Eligibles.

LTCPA also agrees with CMS that, to the extent that it must operate as an out-of-network provider, the pharmacy should receive usual and customary (U&C) reimbursement. Historically, market forces have kept usual and customary fees charged by LTC pharmacies in check and have resulted in market efficiencies in the provision of services. We believe that market competition among LTC pharmacies will ensure the competitiveness of the usual and customary rate through negotiations with the contracted LTC facility, for example as it does currently with Medicare Part A. LTC facilities will seek to negotiate competitive prices for their residents, and will choose the LTC pharmacy that strikes the most effective balance between quality of service and cost.

1. Treatment of the Full Benefit Dual Eligibles

We are concerned that the proposed regulation does not account for the fact that full benefit dual eligible LTC residents and those with low incomes are not responsible for the difference between an out-of-network pharmacy's usual and customary price for a covered Part D drug, and the plan allowance for the covered Part D drug under Section 423.124(b)(2). We believe that CMS must make explicit who will pay the cost differential between the out-of-network pharmacy price and the PDP plan reimbursement for full benefit dual eligibles and others with low incomes. As noted below, we believe the differential should be paid by the plan directly to LTC pharmacy. The CMS payments to PDPs should recognize the differential cost between the usual and customary rate and the plan allowance, and therefore that plans should be directly responsible for covering the usual and customary rate. Otherwise, the most frail elderly, who are often also low-income, will be penalized by paying this higher cost.

The proposed regulation clearly outlines in Section 423.782 the agency's intent to provide coverage of dual eligibles' cost sharing under the new prescription drug benefit. If the final regulations reflect the current policy that enrollees are responsible for the differential cost between the usual and customary rate and the plan allowance, then we strongly encourage CMS to cover this differential for dual eligible and low-income beneficiaries the same as other cost-sharing. Otherwise, LTC pharmacies and/or nursing homes would be put in a situation where they were forced to collect this differential payment from full benefit dual eligible patients with no ability to pay, or from nursing homes who will simply bill the costs back to CMS or Medicaid through their independent reimbursement mechanisms. This would undermine the policy of allowing LTC pharmacies to bill out-of-network at the usual and customary rate to ensure that pharmacies are adequately paid to provide specialized services to LTC residents.

Therefore, we proposed amendments to the proposed regulations that include a new subsection 4:

Section 423.782(a)

(4) Elimination of financial responsibility for the differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance as described in Sections 423.124(b)(1) and (b)(2).
423.124(b)(1) and (b)(2).

We recognize that CMS intends to treat low income beneficiaries differently than full benefit dual eligible beneficiaries, in that low income beneficiaries will remain responsible for a reduced copay. While we recognize that difference, we believe that the low income subsidy for even these beneficiaries should include payment of any cost differentials for prescription drugs. For that reason, we also propose the following amendment:

Section 423.782(b):
(4) Elimination of financial responsibility for the differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance as described in Section 423.124(b)(2).

In addition, and to make explicit that PD sponsors and MA plans must flow through those payments made to them by CMS pursuant to the low income subsidy program, we propose the following new subsection (7) to section 423.120(a), which clarifies that the PD sponsor or MA organization must provide any low income subsidy funding through to the pharmacies.

Section 423.120(a):
(7) A PD sponsor or MA organization is required to pay the pharmacy the full plan allowance, as well as amounts referenced in Section 423.782.

In addition, if CMS chooses to retain the policy that enrollees are responsible for this differential payment, we encourage CMS to retain its position that it count as a beneficiary incurred cost under Section 423.100.

Recommendations:

- **The final rule should reflect that plans will be responsible for paying out-of-network pharmacies the usual and customary price.**

- **CMS should clarify in its final rule that full benefit dual eligibles and other low income beneficiaries residing in long term care facilities have no cost-sharing for covered Part D drugs, whether or not they are on the formulary of the PDP or MA-PD plan.**

2. Prompt Pay

We are concerned that the proposed regulations do not reference or require plans to provide prompt payment to providers under Part D plans. We believe that payment to

pharmacies for prescription drugs dispensed to enrolled Part D beneficiaries should be subject to prompt payment requirements comparable to provisions applicable to carriers under Section 1842(c) of the Social Security Act. Otherwise, plans will have the ability to deny payment of prescription drugs that should be covered by the plan, and force pharmacies to go through a costly appeals process in order to obtain payment. It is important to note that under the existing proposed regulations, pharmacies will not be allowed an expedited review if the drug is dispensed and the grievance is for payment only. Over time, this policy could force LTC pharmacies not to dispense necessary prescription drugs until coverage is approved by the plan, potentially delaying care to patients.

Recommendation:

- **We recommend that CMS provide for prompt payment of pharmacy claims by PDP and MA-PD plans.**

We propose the following addition to Section 423.120(a):

> ***(8) A PDP sponsor or MA organization must meet the requirements set forth at Section 1842(c) of the Social Security Act in providing payment to any pharmacy providing Part D covered drugs to enrolled beneficiaries that are eligible for coverage under the plan as a network or out-of-network provider, including dispensing fees and payment for services such as medication therapy management.***

3. Disclosure of Cost of Generic Equivalent

We strongly support the proposed regulation waiving the requirement that information on differential prices between a covered Part D drug and its generic equivalent be made available to prescription drug plan and MA-PD plan enrollees at the point of sale when prescription drug plan enrollees obtain covered Part D drugs in long-term care pharmacies. We are pleased that CMS understands that LTC pharmacies generally provide drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. We agree that it would be impracticable for LTC pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale.

CMS also requests comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies under Sec. 423.132(a). Not only must timing be considered, but also the recipient of such information. Over half of LTC residents have abnormal cognitive function, making disclosure information confusing and possibly leading to poor treatment decisions by the patient based on the disclosed information.[20] It is imaginable that the information could lead a patient to distrust the physicians, nurses and other caretakers in the facility simply because the patient did not

[20] See Bernabei, paper at note 2.

have the cognitive ability to understand why the information was being provided and what it meant.

Section 423.132(c)(5) gives CMS the discretion to waive the public disclosure requirement in such circumstances as CMS deems compliance to be impracticable. Because of the nature of the sale and delivery processes that LTC pharmacies use, LTCPA requests that CMS waive the requirement for the disclosure of the cost of generic equivalents for LTC pharmacies, rather than set a timeline for which disclosures must be made.

We propose that CMS add to Section 423.132(c)(5):

CMS waives the requirement under paragraph (a) of this section in the case of LTC pharmacies.

Recommendation:

- **CMS should waive the requirement for the disclosure of the cost of generic equivalents for LTC pharmacies.**

IV. FORMULARY ISSUES

As explained above, LTC beneficiaries have a complex set of medication needs distinct from the ambulatory Medicare population. For that reason, restricting LTC residents to the USP's proposed Model Formulary Guidelines or to PDP formularies, in general, is inappropriate. LTC residents should be entitled to a presumption of coverage for all medically necessary covered drugs. Only an open formulary can guarantee this type of coverage.

LTCPA's concerns regarding the inadequacy of the proposed Model Formulary Guidelines for residents of LTC facilities and its preferred policy to address the pharmaceutical needs of LTC residents are summarized below. (A fuller critique of the inadequacies of USP's proposed Model Formulary Guidelines is presented in Appendix 1.[21])

A. Inadequacy of PDP Formularies for Residents of LTC Facilities

Regulations regarding the PDP formularies do not acknowledge the physiological consequences of natural aging, particularly for the most rapidly growing segment of the U.S. population, the frail elderly. These individuals have a high prevalence of chronic conditions that are associated with high health care costs, and place them at increased risk

[21] LTCPA submitted Appendix 1 to USP on September 17, 2004 as part of its comments on USP's draft Model Formulary Guidelines.

of morbidity and mortality. Yet, effective treatment can result in predictable improvements in health status.

Drug selection in the frail elderly must take into account the physiologic, pharmacokinetic, and pharmacodynamic aberrations that occur as a natural consequence of aging, which are often compounded by pathophysiologic consequences of chronic conditions. However, people older than 80 years of age are often excluded from interventional trials, contributing to the paucity of high quality clinical evidence supporting the safe and effective use of medications in the elderly. Medications within a particular therapeutic category may be considered generally comparable in studies comparing two different groups of patients. But these studies are usually conducted on otherwise relatively healthy young elderly. These medications often differ substantially on one or more critical factors relevant to selecting appropriate medications in the frail elderly.

LTC residents must have access to a wider range of medications given their limitations in swallowing, physiologic susceptibility to adverse drug effects, and multiplicity of concurrent underlying conditions complicating optimal drug selection.[22] For some chronic conditions, patients are at high risk of destabilization when drug therapy is interrupted or changed in the absence of a clinically valid reason. In these situations, efforts to contain costs on medications by periodically switching patients to different preferred brands can result in loss of control of the condition, hospitalizations, and other adverse outcomes.

In the preamble to the proposed regulations, CMS appropriately raises the issue of nursing home residents' need for special formulary considerations.[23] However, the MMA does not address formularies for LTC residents and directs PDP sponsors to establish coverage determination processes modeled after the Medicare+Choice process.[24] From the prospective of LTC pharmacy, USP's draft Model Formulary Guidelines exclude categories of drugs needed by LTC residents, places other drugs in danger of not being covered, and fails to accommodate the range of dosage forms that residents of LTC facilities require. We are concerned that PDPs and MA-PD plans will rely heavily on the USP Model Formulary Guidelines and have very limited formularies. This will reduce access for institutionalized, frail elderly beneficiaries.

We understand that CMS must base the regulation on existing statute, including the definition of a "covered Part D drug," which excludes benzodiazepines, barbiturates, over-the-counter drugs, and medications for unintended weight loss. We will be seeking legislative change in the future to amend Section 423.100 to cover these medications for the frail elderly, and invite CMS to support this effort.

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[22] T. Higashi, *et al*., The Quality of Pharmacologic Care for Vulnerable Older Patients. 40 Ann. Intern. Med. 714 (2004).

[23] 69 Fed. Reg. 46661.

[24] Section 1852(g).

Recommendation:

- **CMS should work closely with state Medicaid programs to ensure, in the short-term, that benzodiazapines and barbiturates, over-the-counter drugs, and medications used for intended weight loss will continue to be covered.**

- **CMS should consider for approval PDPs that wish to cover benzodiazapines and barbiturates, over-the-counter drugs, and medications used for unintended weight loss.**

A number of drugs are in danger of not being covered in the two drugs per category schema called for in the regulation, including: biotech injectables and infusables; anticoagulants; anticonvulsants; non-sedating antihistamines; rapid-acting and basal insulins; selective serotonin reuptake inhibitors and selective norepinephrine and serotonin reuptake inhibitors; calcium channel blockers; atypical antipsychotics;selective serotonin reuptake inhibitors and selective norepinephrine and serotonin reuptake inhibitors; calcium channel blockers; atypical antipsychotics;thropoietin; HMG-COA Reductase Inhibitors (statins); Cox-2 Inhibitors; proton pump inhibitors; antibacterials; beta-adrenergic receptor antagonists (beta-blockers); and new drugs (new molecular entities, new indications, and new dosage formulations).[25]

The proposed regulations also do not accommodate the range of dosage forms that residents of LTC facilities require. In addition, the guidelines do not address the range of drug delivery systems that are critical to treating the institutionalized frail elderly including: tablets and capsules; time release medications; topical patches; injectable and intravenous medications; and dosage forms administered via various delivery systems in the ophthalmic, optic and inhalants classes.

In the nursing home environment, half to two-thirds of residents have some form of dysphagia, which can have a dramatic impact on nutritional status.[26] LTC residents at risk for developing dysphagia include those who have had a stroke, Parkinson's Disease, Huntington's Corea , Multiple Sclerosis, cancer of the head, neck or esophagus, residents with dementia, and residents who are on medications that cause sedation, impair cognition, or decrease production of saliva.[27] LTC facilities must take steps to avoid the complications and consequences of dysphagia, which include aspiration pneumonia, choking, chronic malnutrition, decreased quality of life, and unintended weight loss.[28]

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[25] *See* Appendix 1 for a fuller critique and citation of relevant scientific literature supporting LTCPA's critique.

[26] *See* Becky Dorner & Associates, *It's Tough to Swallow; Dysphagia Causes and Treatments*, National Association Directors of Nursing Administration in Long Term Care Magazine.

[27] *Id.*

[28] *See* C. Shanley, and G. O'Loughlin, *Dysphagia Among Nursing Home Residents: An Assessment and Management Protocol*. 8 J. Gerontol. Nurs. 35 (2000).

Issues of dysphagia lead to the placement of feeding tubes to ensure adequate nutrition for these residents. Liquid or crushable oral medication or injectable dosage forms are critical in ensuring appropriate drug therapy. If the appropriate dosage forms are not available to our most frail patients, managing their serious illnesses such as congestive heart failure, hypertension, diabetes, or even infection will be impossible. If LTC residents do not have access to these dosage forms under formularies established by PDP plans, in all likelihood they will be transferred to a hospital, a more expensive health care alternative, to receive these medications.

Given the concerns expressed above and further described in Appendix 1, LTCPA believes that restricting LTC residents to drug categories and classifications in the USP proposed Model Formulary Guidelines or to PDP formularies, in general, is inappropriate and contrary to the health and well-being of LTC residents.

B. Potential Gaps in Coverage of Medically Necessary Non-Formulary Drugs

We are concerned that the proposed regulations do not specifically address coverage of non-formulary drugs for dual eligible LTC facility residents. We understand that CMS provides for an exceptions and appeals process for an enrollee, allowing the authorized representative, or prescribing physician to request coverage of a covered Part D drug that is not on a sponsor's formulary. Nevertheless, we are concerned that the timeframes for this process are not realistic for nursing home patients. Drugs which are medically necessary to treat the enrollee's disease or medical condition must be provided in as timely a manner to LTC residents as they are under current Medicaid policies.

For example, if a nursing home resident requires a certain drug in order to be stabilized, the nursing home resident will get that drug in one of two ways under the current regulations. In one circumstance, the physician would place an order for the prescription from the LTC pharmacy, and the LTC pharmacy would bill the PDP or MA-PD plan after dispensing. Under the current regulations, no expedited process would be available to the LTC pharmacy for payment of the drug by the plan because the drug was already dispensed. If the coverage appeal is denied, the LTC pharmacy would have no recourse except to bill the resident and/or facility. It is not clear whether the federal government would be responsible for the cost of the drug for dual eligibles.

Over time, the potential financial hardship experienced by the LTC pharmacy could force the pharmacy to require a coverage determination before dispensing. In this circumstance, a LTC resident requiring a non-formulary drug in order to be stabilized could be forced into a hospital for treatment, while waiting for a coverage decision from the plan. The LTC pharmacy would request coverage from the plan upon receiving the prescription, and the plan would automatically deny coverage because the drug is not on its formulary. Then the LTC facility would be forced to either cover the cost of the drug and take the potential financial loss in order to dispense the drug to the patient in a timely manner, or send the patient to a hospital where Medicare Part A would cover the treatment. As a result, the cost to the federal government for treating the patient in an

acute care setting would be more than it would have been to maintain the patient in the LTC facility. And most of all, patient access to necessary treatment would be delayed.

There are several issues raised by these examples. First, are PDP sponsors and/or MA-PD plans required in any way to cover non-formulary drugs for LTC residents, particularly those with dual eligible status? Second, is an expedited process going to be available to LTC pharmacies seeking payment for the provision of non-formulary drugs? Third, who bears the cost of the non-formulary drug; the LTC pharmacy, the LTC facility, the resident, the plan, or the federal government? CMS must directly address these issues in order to ensure that LTC residents retain access to the high quality services provided by LTC pharmacies.

C. Providing Notice to Beneficiaries of Formulary Changes Does Not Ensure Access to Medically Necessary Drugs

Section 423.128(d)(2)(iii) provides current and prospective Part D enrollees with at least 30 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a covered Part D drug on its prescription drug plan's or MA-PD plan's formulary. We are concerned that this timing is not consistent with other federal program standards. More importantly, the notice requirement does not address the issue of how LTC residents will maintain their access to medically necessary drugs.

D. Only Open Formularies Can Address the Pharmaceutical Needs of LTC Residents

As discussed above, restricting LTC residents to the USP's proposed Model Formulary Guidelines or to PDP formularies, in general, is inappropriate. CMS' proposed notice requirements also do not adequately address the issue of LTC residents' continued access to medically necessary drugs. We believe that LTC residents should be entitled to a presumption of coverage for all medically necessary covered drugs prescribed by a physician and dispensed by LTC pharmacies. To the extent that the drugs are not within the plan's formulary, they should be provided by the LTC pharmacy to the beneficiary and billed to the patient's plan.

1. Preferred Policy

Access to non-formulary drugs should be preserved irrespective of whether the LTC pharmacy has joined in the PDP network. For example, if a nursing home resident is enrolled in PDP A, and the LTC pharmacy serving the beneficiary's nursing home is in-network in PDP A, then any drugs on PDP A's formulary will be covered at the negotiated reimbursement between the LTC pharmacy and the PDP according to the provisions of the MMA. However, to the extent a drug is not on the PDP formulary, CMS' regulations should explicitly allow the LTC pharmacy to dispense the drugs to the beneficiary on an out-of-network basis, with regular out-of-network rules applying, even though the pharmacy is in-network with the PDP.

In summary, LTC pharmacies will always be treated as out-of-network when billing for an enrollee's non-formulary drug. The plan would be responsible for reimbursing the LTC pharmacy at the usual and customary rate for all non-formulary drugs. CMS would reimburse the plan for such costs on a monthly basis in the same manner that the agency subsidizes plans for other cost-sharing for low-income and dual eligible beneficiaries.

2. Formularies Will Ultimately Lead to Higher Costs for LTC

The costs associated with this policy for Medicare and its associated health plans, PDPs and MA-PD plans will surely be more than offset by Medicare savings due to decreased hospitalizations, adverse drug reactions, and over-utilization of drugs caused by these events. First, it would avoid the appeals process for non-formulary drugs that would otherwise delay access to medication therapy needed to maintain or stabilize a LTC resident's condition. Such delays would inevitably lead to discharge into costlier acute care settings or life-threatening delays in treatment.

An open formulary would avoid the serious costs of missed doses, inconsistency in treatment due to switching medications, gaps in coverage, and/or delays in drug treatment. Subjecting LTC residents to a formulary will either cause patients to be subjected to these unsafe practices when the prescribed medication is not on the plan's formulary, or will leave the LTC pharmacy or LTC facility with the cost of care for residents whose medications do not fit a plan's formulary. The latter situation is not a sustainable business model for any health care provider, and ultimately will threaten patient quality of care.

Boockvar *et al*. studied adverse drug events associated with changes in drug dose, frequency, and administration to residents of four nursing homes in the New York City metropolitan area when they were admitted to one of two tertiary care academic medical centers.[29] These residents experienced alterations in previously prescribed medications including: increases or decreases in daily dose; route of administration changes; changes from routine to as-needed administrations and vice versa; substitution of medication; and discontinuation of medications. All of these changes are likely to occur if residents of LTC facilities transition abruptly to new medications or experience dosage form changes because their previous prescribed medications are not on a PDP plan's formulary or there is no provision for the previously used dosage form or route of administration. Boockvar *et al*. found an overall risk of adverse drug events per drug of 4.4%. Extrapolating these findings to residents of long term-care facilities, who take an average of 6 drugs, we could project from 4.4% to 26.4% total incidence of adverse drug events that could be associated with abrupt changes in prescription drug use among residents of LTC

[29] K. Boockvar, E. Fishman, C. Kyriacou, A. Monias, S. Favi, and T. Cortes, *Adverse Events Due to Discontinuations in Drug Use and Dose Changes in Patients Transferred Between Acute and Lont-term Care Facillities*, 164 Arch. Intern. Med. 545 (Mar. 2004). Consistent with the Bernabei *et al*. data cited earlier, Brockyar *et al*. note that the mean number of medications prescribed in the nursing home before the residents transitioned to the hospital setting was 6.1. *Id.*

facilities. For the 20% of residents taking 10 or more drugs, there is a potential 40.4% total incidence of adverse drug events. When this projected incidence is applied to the population of residents of LTC facilities, the magnitude of risk is staggering. LTC residents cannot be expected to transition literally overnight from a payment system that generally provided for relatively open formularies, to a system in which the drugs and drug dosage forms they were using may no longer be available to them.

Recommendation:

- **Beneficiaries residing in LTC facilities should have a presumption of access to all medically necessary drugs, regardless of a plan's formulary, and the LTC pharmacy should be permitted to dispense the drugs to these beneficiaries on an out-of-network basis, even if otherwise in-network for the beneficiary's PDP or MA-PD plan.**

Therefore, we propose the following revision to the regulations at 423.120(b)(2) to add:

> ***Beneficiaries residing in long term care facilities are entitled to a presumption of coverage for medically necessary drugs, and may receive such drugs that are not on the formulary of the prescription drug plan of the MA-PD plan in which the beneficiary is enrolled from a long term care pharmacy on an out-of-network basis as set forth in section 423.124(b), notwithstanding that the beneficiary is enrolled in the prescription drug plan or MA-PD plan and/or their dispensing long-term care pharmacy is enrolled in such a plan's network.***

E. Dual Eligible Beneficiaries Should Be Held Harmless

Without access to an open formulary, CMS risks substantial discrimination against dual eligible beneficiaries, who formerly received prescription drug benefits under Medicaid. CMS has not addressed the discrepancy between the benefits that dual eligibles have under Medicaid, and the potential benefits available to them under Part D.

Though State Medicaid programs are allowed to have formularies, federal statute limits the exclusion of drugs.[30] Under this policy, Medicaid is limited in terms of the drugs the State may exclude from coverage as follows:

> (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) ***only if***, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act[154] but is a medically accepted indication, based on information from the appropriate

[30] Section 1927(d)(4)(C) of the Social Security Act.

> compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.
>
> (D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).[31]

As stated in this provision, State Medicaid programs are required to ensure that drugs excluded from formularies can be covered subject to prior authorization under Section 1927(d)(5). Federal statute mandates that prior authorization requests be decided upon within 24 hours, a 72-hour supply of medicine must be available in emergencies, and that the State must have in place a mechanism for the appeal of denial.[32] This standard ensures that Medicaid beneficiaries have access to drugs that are not on a State Medicaid plan formulary, and is particularly important for institutionalized beneficiaries with broad drug needs.

It is important to note that Medicaid beneficiaries are accustomed to the Medicaid standard for prescription coverage, and will experience the proposed Medicare Part D grievance and appeals processes proposed by CMS as a diminished benefit in comparison to Medicaid. Dual eligibles should be held harmless, by providing access to an open formulary for their Part D prescription drug benefit.

We also are concerned about the transition period between Medicaid coverage for dual eligible residents of LTC facilities and the start of coverage under Medicare Part D benefits. In some states, Medicaid covers all medications including prescription drugs, over-the-counter medications, and infused drugs. Under MMA, however, states cannot pay for drugs defined by the MMA as covered Part D drugs through their Medicaid program, and states' ability to provide coverage with state funds may be limited. In addition, the MMA does not provide clarity on how existing Medicaid coverage for over-the-counter and infused drugs will be coordinated with Medicare Part D.

Recommendation:

- **Full benefit dual eligible beneficiaries residing in LTC facilities should have a presumption of access to all medically necessary drugs, regardless of a plan's formulary.**

In addition to our recommendation on beneficiaries residing in LTC facilities, we propose to add the following revision to the regulations at 423.120(b)(2):

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[31] *Id.* [emphasis added].

[32] *Id.* at Section 1927 (d)(5)(A).

Full benefit dual eligible beneficiaries residing in LTC facilities should have a presumption of access to all medically necessary drugs, regardless of a plan's formulary.

F. Preferred Policies for Pharmaceutical and Therapeutic Committee Standards

Though we fundamentally support a strong and independent P&T Committee, we realize that the P&T Committee will not be capable of balancing the needs of LTC patients with the needs of the general Medicare population. As discussed above, to do so would require open formularies for all beneficiaries. By providing full benefit dual eligibles and residents of LTC facilities with an open formulary, we believe that the P&T Committee will be better able to function in the best interest of all Medicare beneficiaries.

Nevertheless, we understand that the majority of Medicare beneficiaries will be subject to plan formularies. Therefore, we encourage policies in the final regulation that ensure that plan formularies place a priority on clinical concerns, as opposed to strictly cost concerns. Our recommendations are based on the premise that residents of LTC facilities and full benefit dual eligible beneficiaries will have access to open formularies, and therefore P&T Committee decisions regarding formularies will not affect LTC residents. It is important to note that CMS does not include a provision in its proposed regulations that would require the P&T Committee to be accountable for considering the needs of special populations with unique health needs, such as those residing in long-term care facilities. CMS clearly states that plan formularies may not discriminate based on health status, but we believe their position could be strengthened.

Therefore we propose adding the following to Section 423.120(b)(1):

(vi. taken into consideration the special needs of frail elderly and institutionalized beneficiaries.)

CMS solicits public comment with respect to the appropriateness of strengthening the statutory requirement in section 1860D-4(b)(3)(A)(ii) of the Act by requiring, in its final regulations, that more than just one pharmacist and one physician on the P&T committee be independent and free of conflict. We believe that at least two-thirds of the committee should be comprised of independent pharmacists and physicians. In addition, we believe that these independent committee members should be experts regarding the care of elderly or disabled individuals.

Therefore we propose the following revisions to Section 423.120(b)(1):

(ii) *at least two-thirds of the committee members should be* practicing physicians and practicing pharmacists who are independent and free of conflict with respect to the PDP sponsor and prescription drug plan, or MA

organization and MA-PD plan, and who are experts regarding the care of elderly or disabled individuals.

We also are concerned that CMS does not clarify the decision-making process for the P&T committee in the regulation. If a simple majority vote is the standard for a binding decision, non-physicians and non-pharmacists that lack a clinical perspective could have a disproportionate share of influence in the decisions of the committee. Therefore, we recommend that CMS ensure that this balance be maintained by requiring a super-majority or unanimous vote of the P&T Committee to ensure that independent committee members have a meaningful vote.

We agree with CMS that decisions of the P&T Committee should be binding on plans and encourage CMS to retain this policy in its final rule. Otherwise, the role of the P&T Committee could be undermined by the plan, resulting in policies that threaten patient access to a sufficient number of medications in the formulary.

CMS also states in its proposed regulations that "it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs.)" We agree with CMS and encourage a provision in the final regulations that explicitly requires P&T Committee oversight of utilization controls.

Recommendations:

- **Require that the P&T Committee consider the special pharmacy needs of the frail elderly and institutionalized beneficiaries.**
- **Increase the number of independent physicians and pharmacists to at least two-thirds of the members of the Committee.**
- **Provide for specific qualifications for geriatric pharmacy expertise for physicians and pharmacists on the Committee.**
- **Require a super-majority or unanimous vote.**
- **Maintain requirement that the P&T Committee's decision be binding on the plan and require P&T Committee oversight of utilization controls.**

V. ENROLLMENT OF FULL BENEFIT DUAL ELIGIBLE RESIDENTS OF LTC FACILITIES

A. Delay the Part D Benefit for Full Benefit Dual Eligibles until 2007.

CMS does not fully address the potential six-month gap in coverage for full benefit dual eligible beneficiaries between January 1, 2006 when the Part D benefit first goes

into effect, and June 1, 2006, when automatic enrollment occurs. The financial burden of caring for full benefit dual eligibles during this time period, with no federal support, would be significant. LTCPA understands that CMS may have plans to auto-enroll full benefit dual eligibles prior to January 1, 2006. However, this is an extremely ambitious timeline and the risks of not achieving complete auto-enrollment of dual eligibles by January 1, 2006 are great. Rather than risk even small gaps in coverage for full benefit dual eligibles, LTCPA respectfully recommends that CMS postpone the implementation of the Part D prescription drug benefit for full benefit dual eligibles until January 1, 2007.

Recommendation:

- **In order to avoid gaps in coverage for full benefit dual eligibles between January 1, 2006 and June 1, 2006, CMS should postpone the implementation of the Part D prescription drug benefit for dual eligibles until January 1, 2007.**

B. Automatic Enrollment

CMS has requested comments on the most appropriate method of performing automatic assignment of full benefit dual eligibles and the appropriate entity to do so. As discussed earlier, it is vital that the one nursing home-one LTC pharmacy relationship be maintained to ensure a high standard of care for nursing home residents. LTC pharmacies should be allowed to remain as out-of-network pharmacies for purposes of billing PDPs and MA-PD plans on behalf of an enrollee. Nevertheless, if a LTC pharmacy has chosen to become an in-network provider for a plan, we believe that the auto-enrollment policy should ensure that nursing home residents have access to the LTC pharmacy's contracted plan, rather than to a plethora of plans for which the LTC pharmacy may not be in-network. Otherwise, a LTC pharmacy in a particular plan network would be forced to provide services to an enrollee as an out-of-network plan, which would undermine the market negotiations between an LTC pharmacy and PDP plans and preclude the enrollee from receiving the potential benefits of the contracted relationship. Automatic enrollment of beneficiaries into plans that have included the LTC pharmacy in-network would bring overall efficiencies to the process.

Therefore, we propose the following revision to Section 423.34(d)(2):

For full benefit dual eligible residents of a long-term care facility that contracts with a long-term care pharmacy, random automatic enrollment will be limited to PDPs that include the long-term care facility's contracted pharmacy in the plan's network, unless the long-term care pharmacy is not in any PDP network in which case residents are automatically enrolled in the same manner as noninstitutionalized individuals.

We believe that the policy described above is consistent with the statute's requirement for "random" enrollment by using a stratified random sample of plans that include the LTC pharmacy in their networks. It is also consistent with CMS precedent in automatically enrolling State Pharmaceutical Assistance Program (SPAP) members in drug discount cards.

Though CMS was able to authorize states to enroll beneficiaries in a discount drug card program chosen by the state (as opposed to random enrollment), the Agency explicitly encouraged SPAPs to inform individuals in a long-term care facility of long-term care special-endorsed cards available to them.[33] Based on this precedent, we believe that the resources exist for CMS to distinguish Part D plans available to LTC residents within the context of random enrollment, as described in the proposed language above. This policy would ease a LTC resident's transition into the Part D benefit, and would encourage contractual relationships between LTC pharmacies and plans.

Recommendation:

- **CMS should auto-enroll dual eligibles in PDPs whose network includes the LTC pharmacy serving that facility, if any.**

C. Special Enrollment Periods

Under the drug discount card program, a move to a nursing home was considered a change in residence allowing the enrollee to choose a new discount card plan with no penalty.[34] The proposed regulation does not specifically address this issue as it applies to LTC pharmacies under Part D. We are concerned that without a comparable special enrollment period for the Part D benefit, there would be considerable delay (until the next open enrollment period) in allowing the beneficiary to move to a PDP plan for which the LTC pharmacy serving that LTC facility is "in-network." In turn, this would cause the beneficiary (or CMS, in the case of full benefit dual eligibles) to incur a higher cost to the extent there is a differential between the PDP's covered plan cost and the U&C cost.

We believe that LTC residents will have an incentive to join the PDP plan that includes the LTC pharmacy in-network to avoid paying the differential between the usual and customary price, and the plan allowance. Impairing the ability of a timely change into that PDP plan would undermine the ability of an LTC pharmacy to negotiate to be in the network of a PDP or MA-PD plan. A special enrollment period comparable to the discount card program would increase choices for Medicare beneficiaries seeking the best plan for their needs, and allow the beneficiary (or, in the case of full benefit dual eligibles) to avoid additional costs until the next open enrollment period.

Recommendation:

- **Admission into a LTC facility should qualify as a "triggering event" for special enrollment into a PDP plan whose network includes the LTC pharmacy serving that facility, if any.**

Therefore, we propose the following revision to Section 423.36(c)(7):

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[33] *See* http://www.cms.hhs.gov/discountdrugs/autoenrol.pdf.

[34] Section 1860D-3(C)(1)(c)(3).

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered. ***Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a long-term care facility) or enrollment in or disenrollment from a plan under part C through which the individual was enrolled in an endorsed program to be an exceptional circumstance.***

VI. DISPENSING FEES

A. Discussion of CMS Proposed Options

CMS proposes three alternative definitions of the term "dispensing fee" for which the Agency seeks comments. We appreciate the Agency's recognition in the preamble to the proposed rule of our concern about reimbursement for services that are currently provided to LTC facility residents.[35] We are concerned that contracts between Medicare plans and network pharmacies will not necessarily fully address the costs of services that must be provided to LTC residents. In addition, we are concerned that LTC pharmacies billing plans as out-of-network pharmacies will not be able to bill the plan for dispensing fees at all.

As proposed by CMS, Option 1 appears to be targeted at the level of service provided in a retail pharmacy, whereas Options 2 and 3 incorporate the costs of dispensing for more complex drug treatment regimens. The BDO Seidman study, explained above, explains the varying dispensing costs incurred by LTC pharmacies, and we hope it provides CMS with clarification on the costs for LTC pharmacies of dispensing to enable the Agency to specifically address the LTC population.

As noted above, LTC pharmacies must be reimbursed for at least the following additional dispensing fee costs that it routinely incurs for LTC residents:

- specialized packaging systems, such as unit-dose packaging, that reduce the possibility of medication errors and are the standard of care in nursing homes;
- round-the-clock delivery of critical and emergency medications to meet LTC regulatory requirements;
- the preparation and dispensing of intravenous medication solutions and other alternative delivery modes (such as powders and others), a service that retail pharmacies typically do not provide;
- on-site support and consultation to nursing homes and other institutional provider-clients.[36]

[35] 69 Fed. Reg. 46657-58.

[36] *See* BDO Seidman, *supra* at note 18.

LTC pharmacies, in order to be responsive to the needs of nursing home residents, are often called upon to make unscheduled deliveries of urgently-needed medications. We believe that by including the cost of this additional service within the definitions of option 3, PDPs will be able to appropriately compensate for this service, which falls outside of the routine dispensing and delivery function.

Recommendation:

- **CMS should provide for separate dispensing fees based on the complexity of dispensing the drug. LTCPA recommends specifically that a separate dispensing fee be added to that proposed in Option 1 for long-term care pharmacies that incorporates the costs of specialized packaging, around-the-clock service and delivery, emergency services, services and supplies associated with infusion therapy, and other considerations deemed appropriate by the Secretary.**

To accomplish this, we propose three new sections in the final regulations:

Section 423.xxx (a) Dispensing fees
(1). Dispensing fees described in Section 423.308 under the definition of gross covered prescription drug costs and described in Section 423.100 under the definition of negotiated prices are required to be actually paid to a pharmacy (or other intermediary) as described by the plan in its bid.
(2). Plan bids will be evaluated to ensure that dispensing fees are scaled to capture the complexity of dispensing a prescription drug to an enrolled beneficiary.
(3). Where provided, dispensing fees should incorporate the costs of emergency services, services and supplies associated with infusion therapy, and other considerations deemed appropriate by the Secretary.

Section 423.xxx (b) Delivery fees
(1) Delivery fees shall also be included as being described in Section 423.308 under the definition of a gross covered prescription drug costs and described in Section 423.100 under the definition of negotiated prices and are required to be actually paid to a pharmacy (or other intermediary) as described by the plan in its bid.
(2) Plan bids will be evaluated to ensure that delivery fees are scaled to capture the complexity of dispensing a prescription drug to an enrolled beneficiary in a long-term care facility.
(3) Where provided, delivery fees should incorporate the costs of around-the-clock service and delivery, emergency services, and other considerations deemed appropriate by the Secretary.

Section 423.xxx (c) Packaging fees
(1) Packaging fees shall also be included as being described in Section 423.308 under the definition of a gross covered prescription drug costs and described in Section 423.100 under the definition of negotiated prices and

are required to be actually paid to a pharmacy (or other intermediary) as described by the plan in its bid.
(2) Plan bids will be evaluated to ensure that packaging fees are scaled to capture the complexity of dispensing a prescription drug to an enrolled beneficiary residing in a long-term care facility.
(3) Where provided, packaging fees should incorporate the costs of specialized packaging, and other considerations deemed appropriate by the Secretary.

B. Payment Methodology

The preamble to the proposed rules notes that dispensing fees (and, in our proposal, packaging and delivery fees) are to be paid from PDP plans' administrative costs rather than through a separate budget item. That payment methodology allows for wide variation in the plans' fee schedules for dispensing fees for LTC residents as well as potential problems when dispensing fees are provided for plan beneficiaries by an LTC pharmacy that is out-of-network. LTCPA suggests that CMS establish a standard fee schedule for dispensing fees for LTC residents, (at least as a model against which PDP plan bids will be measured), and require those fees to be paid by PDP plans via contracting arrangements with LTC pharmacies that are in-network or directly to LTC pharmacies that are out-of-network. By establishing a standard fee schedule and payment mechanism, CMS will assure the provision of prompt and continuous MTMP services for residents of LTC facilities. We also propose that CMS provide for a yearly inflationary update to the proposed standards' fee schedule.

VII. MEDICATION THERAPY MANAGEMENT PROGRAM (MTMP)

LTCPA appreciates CMS interest in seeking comments on requirements and/or guidelines for Medication Therapy Management Programs (MTMP), and believes it can be most helpful by confining its comments to MTMP for the populations it serves - residents of LTC facilities and related populations served by the LTC pharmacy community. [37] Both the statutory language and CMS proposed regulations call for MTMP to be provided to "targeted beneficiaries," yet it is unclear whether residents of LTC facilities and related populations meet the definition of targeted beneficiaries. The proposed regulations also do not provide for the content of MTMP for LTC residents, how PDP plans' provision of MTMP will be integrated with the services and standards currently in use by consultant pharmacists, or to what extent LTC pharmacies would be reimbursed for MTMP.

A. LTC Residents as Targeted Beneficiaries

[37] The American Society for Clinical Pharmacists has written an issue paper on "Medication Therapy Management Services for Ambulatory Medicare Beneficiaries" which presents a set of goals for MTMP and describes types of MTMP services for ambulatory adults.

CMS provides a definition of "targeted beneficiaries" in Section 423.153(d)(2)(i-iii) that should apply to residents of LTC facilities. (*See* Section VIII for LTCPA's proposed definition of "long-term care facility") As noted in the profile presented in Section II, LTC residents have multiple chronic diseases, will be taking multiple Part D drugs, and are likely to incur high annual costs for covered Part D drugs. However, CMS has not defined the number or type of diseases that constitute "multiple" chronic diseases, nor has it defined the number of prescription drugs that will constitute "multiple" Part D drugs. Moreover, without knowing the "predetermined level that CMS determines" that will constitute the benchmark against which to measure costs exceeding that amount, it is impossible to categorize LTC residents as targeted beneficiaries with certainty. Instead, LTCPA urges CMS to explicitly include residents of LTC facilities as targeted beneficiaries for MTMP.

By explicitly including residents of LTC facilities within the definition of targeted beneficiaries, CMS will be able to more closely evaluate PDP plans' bids and monitor their MTMP services for the population of institutionalized frail elderly. Defining LTC residents as targeted beneficiaries also helps to assure consistent national standards of MTMP provision across PDP plans and geographic areas. In regulations implementing the Omnibus Budget Reconciliation Act of 1990, CMS required Drug Regimen Reviews by nursing facilities. Providing MTMP for residents of LTC facilities furthers Congress' intent to carefully monitor prescription drugs and their effects for this population.

Explicitly including residents of LTC facilities as targeted beneficiaries also removes incentives for plans to exclude this population of frail elderly from MTMP services that it must support with administrative costs. PDP sponsors and MA organizations also will be more accountable for their expenditures on MTMP and the quality of the services they provide.

Recommendation:

- **CMS should add to Section 423.153(d)(2)(iv) *or are residents of LTC facilities* and require PDP sponsors and MA plans offering MA-PD to disclose to CMS and others, upon request, the amount and portion of fees they expend for MTMP services to residents of LTC facilities.**

B. MTMP to be Provided to LTC Residents by Pharmacists with Specialized Training or Expertise in Geriatric Drug Therapy in a LTC Facility

The proposed regulations state that MTMP "may be furnished by a pharmacist." At the Open Door Forum on the quality components of MMA, CMS noted that it does not view pharmacists as the only appropriate provider of MTMP services. However, LTCPA believes that MTMP services for LTC residents must be furnished by a pharmacist with specialized training or expertise in geriatric drug therapy in a LTC facility setting. As noted in Sections II and IV, and Appendix I, the physiological consequences of aging,

particularly in the frail elderly, the multitude of chronic disease conditions, and the relatively large number of prescription drugs used by LTC residents necessitates MTMP provided by pharmacists skilled in complex drug management. In order to fulfill the mandate that MTMP assure that drugs are "appropriately used to optimize therapeutic outcomes" and reduce the risk of adverse drug events and adverse drug interactions, the skills of specially trained or experienced geriatric pharmacists are needed.

Recommendation:

- **CMS should amend Section 423.153(d)(1)(iii) to specify that MTMP for residents of LTC facilities must be provided by pharmacists with specialized training or expertise in geriatric drug therapy in a LTC facility.**

C. Services to be Provided in MTMP to LTC Residents

At its Open Door Forum on quality issues related to MMA, CMS provided the following examples of MTMP: patient health status assessments; brownbag reviews; collaborative drug therapy management; special packaging; and formulating, monitoring, and adjusting prescription drug treatment plans. Section 423.153(d)(1)(iv) states that MTMP "[m]ay distinguish between services in ambulatory and institutional settings." LTCPA, therefore, proposes that CMS make this distinction for PDP and MA-PD plans and describe MTMP services within LTC settings. These services will have to be integrated within existing services provided by pharmacists in LTC facilities. For example, LTC pharmacies already provide special packaging, and drug regimen reviews are provided by consultant pharmacists in LTC facilities.

Federal regulations require nursing homes to provide for the conduct of a monthly drug regimen review by a pharmacist. An independent consulting pharmacist or a consultant pharmacist employed by the provider pharmacy will often provide services that support the nursing facility's efforts to meet monthly drug regimen review requirements. In addition, consultant pharmacists assist nursing facilities in the development of policies and procedures, ensure the accountability of controlled substances and provide in-service training to nursing facility staff. Nursing homes, with the exception of New Jersey facilities, typically contract with consultant pharmacists to provide certain pharmaceutical services to residents.

However, additional clinical services would be appropriate for MTMP in the LTC facility setting, including: evaluation and management of particular drugs, such as warfarin; consultation on pressure sore care; and consultation on proper strategies to minimize adverse drug effects for residents with Parkinson's disease or Alzheimer's disease. Section 107(b) of the MMA mandates that CMS conduct a study of current standards of practice for pharmacy services for Medicare beneficiaries residing in long-term care facilities. This study, which will be completed in mid 2005, will provide valuable information to CMS on its design of MTMP for LTC residents.

Recommendation:

- **CMS should convene an expert panel of pharmacists with specialized training or expertise in geriatric drug therapy in LTC and other related institutional settings to review the findings of CMS' Section 107(b) study and establish a set of activities that will constitute MTMP for LTC residents that will be well-integrated into the services currently provided by pharmacists in LTC facilities.**

D. Provide for PDP Plans to Pay LTC Pharmacies that are Either In-Network or Out-of-Network for MTMP That They Provide to LTC Residents.

The preamble to the proposed rules notes that MTMP is to be paid from PDP plans' administrative costs rather than through a separate budget item. That payment methodology allows for wide variation in the plans' fee schedules for MTMP for LTC residents as well as potential problems when MTMP is provided for plan beneficiaries by an LTC pharmacy that is out-of-network. LTCPA suggests that CMS establish a standard fee schedule for MTMP for LTC residents, (at least as a model against which PDP plan bids will be measured), and require those fees to be paid by PDP plans via contracting arrangements with LTC pharmacies that are in-network or directly to LTC pharmacies that are out-of-network. By establishing a standard fee schedule and payment mechanism, CMS will assure the provision of prompt and continuous MTMP services for residents of LTC facilities. We also propose that CMS adopt a yearly inflationary update to the standard fee schedule.

Recommendation:

- **CMS should establish a standard fee schedule for MTMP for LTC residents and require PDP plans to pay these fees in their contract arrangements with LTC pharmacies that are in-network and directly to LTC pharmacies that are out-of-network.**

VIII. EXPANDED DEFINITION OF "LONG-TERM CARE FACILITY"

A. Definition of "Long-Term Care Facility"

CMS states in its proposed rulemaking that the Agency would consider expanding the definition of "long-term care facility" to the extent that these facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities. We understand that it is difficult to predict situations in which this exclusive contracting relationship exists, and are pleased that the Agency has recognized the issue in the preamble to the proposed regulations. There are several settings in which this situation exists, including group homes for the developmentally disabled and assisted living facilities. There are also situations in which the beneficiary could be cared for in an institutional setting were it not for the existence of 1915(c) waivers, 1115

waivers or other Medicaid waivers. These waivers generally allow for less restrictive care settings under the terms of the waiver. Long-term care is moving steadily away from an institution-only model and CMS should consider alternative definitions that more accurately reflect the current model of long-term care. While assisted living facilities do not generally fit the regulatory framework that makes their identification easy, we believe CMS should, in those states in which Medicaid provides for assisted living care, allow assisted living residents to qualify as residents of long-term care facilities. LTCPA offers the following definition of "long-term care facility" to accommodate other types of facilities that exclusively contract with LTC pharmacies.

Recommendation:

- **CMS should expand the definition of "long-term care facility" to include residents of congregate licensed living arrangements for the elderly that "assist with" or "manage" medication administration for its residents. These facilities include intermediate care facilities for the mentally retarded and hospice, as well as assisted living facilities and any facilities recognized by State law as eligible for payment under Sections 1915(c), 1616(e), and 1115. In addition, where they can be identified, the definition should be extended to group homes for the developmentally disabled and other forms of congregate living arrangements regulated by the states.**

IX. ADDITIONAL ISSUES

A. CMS Lacks Data on Institutionalized Beneficiaries for Potential PDPs' Bids

LTCPA is concerned that CMS lacks adequate databases on institutionalized beneficiaries and their prescription drug costs for PDP sponsors to use in developing their bids. CMS proposes to make four data sets available to facilitate bid preparation by potential PDP sponsors for the provision of Part D prescription drug coverage. In a September 10, 2004 Special Open Door Forum, CMS described each of these data sets as well as their limitations. The overall quality and/or appropriateness of each data set for accurately providing information on the needs of LTC residents is questionable, at best.

First, information on institutionalized Medicare beneficiaries is imputed for the Cost and Use file of the Medicare Current Beneficiary Survey (MCBS), the first of four data sets to be made available to bidders. The MCBS is limited because it does not collect information on drug expenses for institutionalized beneficiaries. These data also are limited because they will be based on data from 2001 and will not reflect current demographics of LTC residents, incidence of institutionalization, or the costs and use of new drugs prescribed for Medicare beneficiaries within the past three years. Moreover, the data are not representative below the national level and will not even accurately reflect institutionalized Medicare beneficiaries in the subset of states that account for the vast majority of LTC residents. CMS also notes that there are a number of states for which there are no geographic sampling areas used in the MCBS.

Second, two of the three other data sets are constructed using information from the MCBS. The Distributions of Total Claims Costs and the Medicare 5% Claims Data both contain imputed drug use on institutionalized beneficiaries. The Continuance Tables are the distributions of drug expenses in selected dollar intervals for fee-for-service Medicare beneficiaries at projected 2006 expense levels. These tables were developed from Distributions of Total Claims Costs for all beneficiaries, and will contain data on community and institutionalized beneficiaries with CMS imputed daily-institutionalized drug expenses. The Medicare 5% Claims Data contains information on Medicare beneficiaries in hospice and skilled nursing facilities, however, prescription drug data from the MCBS will be imputed to each beneficiary in the 5% sample file. Since drug use on institutionalized beneficiaries was not collected in the MCBS, but imputed, the potential inaccurate portrayal of prescription drug costs for institutionalized individuals becomes a part of the Medicare 5% Claims data, also. In addition, CMS advises cautious use of this data set for state-level estimates.

Finally, the Geographic Prescription Drug Utilization Index reflects per capita drug utilization measures from a set of federal retirees age 65 and older in a single benefit plan and contains no adjustments for demographics or morbidity in either the expenditures, prescriptions filled, or days supplied indices. As such, it is not useful for estimating prescription drug costs for institutionalized individuals.

In response to a question regarding CMS' own assessment of the quality of their data on institutionalized beneficiaries, CMS expressed a great deal of caution, and suggested that bidders use their own proprietary data on institutionalized beneficiaries to supplement CMS' information on institutionalized individuals.

This posture presents problems. If bidders do not have proprietary data, they are reliant on CMS' admittedly flawed data on institutionalized beneficiaries. And, for those bidders with proprietary data, CMS will have no objective way to evaluate the accuracy of the assumptions that the plans make on the prescription drug costs of institutionalized beneficiaries. Either way, standard, accurate estimates of the prescription drug costs of institutionalized beneficiaries will not be publicly available. Planning for prescription drug coverage for institutionalized beneficiaries, including residents of LTC facilities, in such an information void just does not make sense.

B. Part B and Part D Coordination of Benefits

The MMA requires CMS to conduct a study making recommendations for transitioning coverage of Part B drugs to Part D. Though CMS does not address this issue in its proposed regulations, we would like to express support for the concept. At this time, it is a complex adjudication process to distinguish drugs covered under Part B from those that are not covered at all. Also, depending on how they are administered, some Part D covered drugs may be payable under Part B. A policy providing coverage of drugs under one system would eliminate much confusion for providers, and allow for a more seamless system for beneficiaries trying to determine their cost-sharing obligations.

C. Plan Bid Submission Consistent with Federal Statute

The U.S. Congress enacted the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) on December 22, 1987. As part of this legislation, Congress requires skilled nursing facilities to provide, directly or under arrangements with others, "pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident."[38]

The U.S. Congress subsequently enacted the Omnibus Reconciliation Act of 1990 (OBRA '90) on November 5, 1990. Many provisions included in Section 4401 of OBRA '90 directly affect Medicaid pharmacy programs and Medicaid pharmacy providers. The framers of OBRA '90 incorporated into the Medicaid statute the OBRA '87 language requiring pharmaceutical services in nursing facilities in an effort to ensure quality care in nursing facilities and reduce medical costs within State Medicaid programs.[39] While nursing facilities are responsible for programs mandated by OBRA '90, pharmacies often provide certain services that assist the nursing home in meeting the statutes' requirements.

CMS has not proposed standards for bid submissions requiring that plans provide for coverage of services to residents of LTC facilities that are required by OBRA 1987 under the Medicare statute, and under OBRA '90 under the Medicaid statute. We do not believe that Congress intended that Part D plans be exempt from providing the same services required under Medicare Part A or Medicaid to nursing facility residents. Therefore, we strongly recommend that CMS require plans to incorporate the costs of paying for such services into their bid submissions, and that plans state clearly how they intend to pay qualified pharmacists for providing such services.

We propose the following revision to Section 423.265(c)(1):

(1) Included costs. The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits, *as well as costs of services required by Section 1819(b)(4)(A)(iii) and Section 1919(b)(4)(A)(iii) in nursing facilities and other pharmacy services required under OBRA 1990.*

D. Special Needs Plans

CMS notes in the preamble to the Title II regulations that, currently, MA plans may not selectively limit enrollment to a subgroup, for example, institutionalized individuals (except for areas in which an organization is permitted to limit enrollment to retirees obtaining their employer/union coverage through an MA plan, as permitted through waivers authorized under section 1857(i)(1) of the Act). CMS then proposes to establish

[38] § 1819(b)(4)(A)(iii) of the Social Security Act

[39] § 1919(b)(4)(A)(iii) of the Social Security Act

specialized MA plans allowing MA plans to exclusively enroll special needs individuals in MA plans that have targeted clinical programs for these individuals.

We encourage CMS to explore ways to use this model to allow plans to provide open formularies to institutionalized beneficiaries, and to ensure patient access to specialized pharmacy services through LTC pharmacies. Such action would require CMS to establish an adequate risk adjustment for the special needs plan, otherwise patients could be put at risk if the plan is unable to provide payment for special pharmacy services required for institutionalized patients.

We also believe that special needs plans should meet the requirements of Section 423.124. In addition, we request that CMS ensure that any plans targeting institutionalized beneficiaries work closely with LTC pharmacies to ensure that specialized services are being provided, and that plans be accountable for reimbursing LTC pharmacies for those services (such as dispensing fees and medication therapy management as described above).

E. Claims Processing Issues and Electronic Prescribing

LTCPA also offers the following comments on the claims processing issues and electronic prescribing provisions of the proposed rule:

§ 423.34: As we expect that CMS will want to create special conditions of participation for enrollees residing in long-term care facilities, whether related to formularies or cost sharing, the claims processing system needs to be able to identify, in real time, and online, the residential status of Medicare beneficiaries enrolled in the Part D benefit. This will be important in determining to what extent the long-term care resident is, or is not, subject to the exceptions within the program for long-term care residents.

§ 423.104: Coordination of benefits may be a complicated process, with multiple federal plans responsible for primary coverage based on the type of service provided. For example, Medicare beneficiaries may have claims where the primary payer is Medicare Part B, Part A, or other payer. In addition, there needs to be a common method by which plans calculate true out-of-pocket costs (TrOOP). We recommend that CMS commission the National Council for Prescription Drug Programs (NCPDP) to develop common business practices in order to facilitate proper benefit coordination on a unified platform.

§ 423.124: We are aware that the NCPDP's definition of "Usual and Customary" differs from the definition in the proposed regulation. Although we are not aware to what extent the difference in definition is meaningful, we have relied on the definition in the proposed regulation in our comments to the proposed regulation. We are also aware that the NCPDP does not recognize the terms "in-network" and "out-of-network" provider and, instead, uses the terms "participating provider" and "non-participating provider." Again, we are not aware the relevance of any difference, but

we have relied on the CMS definition within the proposed regulation in our comments.

§ 423.159: In testimony to the National Center on Vital Health Statistics (NCVHS), the NCPDP recommended that participation be encouraged from the long-term care industry to address the special needs of this sector as it applies standards and, where needed, to suggest extension of the standards. The LTCPA endorses this recommendation and stands ready to participate in that process.

X. Conclusion

In summary, we provide the following list of recommendations to assist CMS.

PDP-LTC Pharmacy Relationship:

- CMS should encourage, but not require, PDP plans to contract with LTC pharmacies.
- CMS also should explicitly preserve, and enhance, the language in proposed section 423.124 to specifically permit LTC residents to access LTC pharmacies as out-of-network providers.
- The final rule should explicitly state that fallback plans are subject to the requirements in Section 423.124 for out-of-network pharmacy access and payment.
- CMS should clarify in its final rule that full benefit dual eligibles and other low income beneficiaries have no cost-sharing for covered Part D drugs, whether or not they are on the formulary of the PDP or MA-PD plan.
- CMS should provide for prompt payment of pharmacy claims by PDP and MA-PD plans.
- Plans should not be allowed to presumptively include LTC pharmacies in their pharmacy networks based on pre-existing relationships outside the context of Part D.

Disclosure of Generic Equivalents:

- CMS should waive the requirement for the disclosure of the cost of generic equivalents for LTC pharmacies.

Formulary:

- CMS should work closely with state Medicaid programs to ensure, in the short-term, that benzodiazapines and barbiturates, over-the-counter drugs, and medications used for intended weight loss will continue to be covered.

- CMS should consider for approval PDPs that wish to cover benzodiazapines and barbiturates, over-the-counter drugs, and medications used for unintended weight loss.

- Beneficiaries residing in LTC facilities should have a presumption of access to all medically necessary drugs, regardless of a plan's formulary, and the LTC pharmacy should be permitted to dispense the drugs to these beneficiaries on an out-of-network basis, even if otherwise in-network for the beneficiary's PDP or MA-PD plan.

- Full benefit dual eligible beneficiaries residing in LTC facilities should have a presumption of access to all medically necessary drugs, regardless of a plan formulary, and be able to access those drugs through an out-of-network pharmacy arrangement.

P & T Committee:

- CMS should require that the P&T Committee consider the special pharmacy needs of the frail elderly and institutionalized beneficiaries.

- CMS should increase the number of independent physicians and pharmacists to at least two-thirds of the members of the P&T Committee.

- CMS should provide for specific qualifications for geriatric pharmacy expertise for physicians and pharmacists on the P&T Committee.

- CMS should require a super-majority or unanimous vote for the P&T Committee.

- CMS should maintain the requirement that the P&T Committee's decision be binding on the plan and require P&T Committee oversight of utilization controls.

Enrollment:

- In order to avoid gaps in coverage for full benefit dual eligibles between January 1, 2006 and June 1, 2006, CMS should postpone the implementation of the Part D prescription drug benefit for dual eligibles until January 1, 2007.

- CMS should auto-enroll dual eligibles in PDPs whose network includes the LTC pharmacy serving that facility, if any.

- Admission into a LTC facility should qualify as a "triggering event" for special enrollment into a PDP plan whose network includes the LTC pharmacy serving that facility, if any.

Dispensing Fees:

- CMS should provide for separate dispensing fees based on the complexity of dispensing the drug. LTCPA recommends specifically that a separate dispensing fee be added to that proposed in Option 1 for long-term care pharmacies which incorporates the costs of emergency services, services and supplies associated with infusion therapy, and other considerations deemed appropriate by the Secretary.

- CMS should provide for delivery fees that should incorporate the costs of around-the-clock service and delivery, emergency services, and other considerations deemed appropriate by the Secretary.

- CMS should provide for packaging fees that include the costs of specialized packaging and other considerations deemed appropriate by the Secretary.

Medication Therapy Management Program:

- CMS should add to Section 423.153(d)(2)(iv) "or are residents of LTC facilities" and require PDP sponsors and MA organizations offering MA-PD plans to disclose to CMS and others, upon request, the amount and portion of fees they expend for MTMP services to residents of LTC facilities.

- CMS should amend Section 423.153(d)(1)(iii) to specify that MTMP for residents of LTC facilities must be provided by pharmacists with specialized training or expertise in geriatric drug therapy in a LTC facility.

- CMS should establish a standard fee schedule for MTMP for LTC residents and require PDP plans to pay these fees in their contract arrangements with LTC pharmacies that are in-network and directly to LTC pharmacies that are out-of-network.

- CMS should convene an expert panel of pharmacists with specialized training or expertise in geriatric drug therapy in LTC and other related institutional settings to review the findings of CMS' Section 107(b) study and establish a set of activities that will constitute MTMP for LTC residents that will be well-integrated into the services currently provided by pharmacists in LTC facilities.

- CMS should establish a standard fee schedule for MTMP for LTC residents and require PDP plans to pay these fees in their contract arrangements with LTC pharmacies that are in-network and directly to LTC pharmacies that are out-of-network.

LTC Facility Defined:

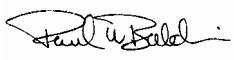
- CMS should expand the definition of "long-term care facility" to include residents of congregate licensed living arrangements for the elderly that "assist with" or "manage" medication administration for its residents. These facilities include intermediate care facilities for the mentally retarded and hospice, as well as assisted living facilities and any facilities recognized by State law as eligible for payment under Sections 1915(c), 1616(e), and 1115.

Standards for Bid Plans:

- CMS should require plans to incorporate the costs of paying for such services required under OBRA 1987 and 1990 into their bid submissions, and that plans state clearly how they intend to pay qualified pharmacists for providing such services.

We appreciate this opportunity to provide comments to CMS, and seek to express our sincere appreciation to CMS for its diligent work during this implementation process. We hope that our comments will lead to sound policies that ensure the safety and well-being of LTC residents.

Sincerely,



Paul Baldwin
Executive Director

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

APPENDIX 1

FORMULARY ISSUES

LTC beneficiaries have a complex set of medication needs that are distinct from those of the ambulatory Medicare population. For that reason, restricting LTC residents to the USP's proposed Model Formulary Guidelines or to PDP formularies, in general, is inappropriate. LTC residents should be entitled to a presumption of coverage for all medically necessary covered drugs. Only an open formulary can guarantee this type of coverage for residents of LTC facilities.

A. Inadequacy of PDP Formularies for Residents of LTC Facilities

1. The regulations regarding DPD formularies do not acknowledge the physiological consequences of aging. The proposed regulations do not acknowledge the physiological consequences of natural aging, particularly for the most rapidly growing segment of the U.S. population, the frail elderly. Only about 25% of this group resides in nursing facilities. The remainder resides in assisted living, their own homes, or other living arrangements. These individuals have:

- A high prevalence of chronic conditions
- Conditions associated with high health care costs
- Increasing morbidity and mortality
- Conditions for which evidence supports effective treatment, irrespective of the age of the patient, that will result in predictable improvements in health status
- Conditions with a high risk for treatment failure[40]

The elderly undergo many physiologic consequence of natural aging that combine to produce changes in the body's handling of medications (pharmacokinetics) and the response to medications (pharmacodynamics). Age-related changes as well as concurrent disease result in increased variability in drug absorption in the elderly. For example:

- Lipid-soluble drugs may show an increased volume of distribution and water-soluble drugs may show a decreased volume of distribution related to changes in body composition.
- Creatinine clearance declines on average 10% per decade after age 20, resulting in impaired renal elimination.
- Serum creatinine is a poor predictor of renal function in the old elderly due to decreased muscle mass and immobility.
- Drugs metabolized exclusively by Phase II mechanisms (glucuronidation, sulfation) are preferred in the elderly.

[40] Barbara Zarowitz, *Public Comment on the Draft Medicare Formulary Model Guidelines on Behalf of Omnicare* (2004), U.S. Pharmacoepia.

- The potential for significant drug interactions, particularly resulting from hepatic enzyme inhibition in elderly patients on multiple medications must be considered carefully.
- There are pharmacodynamic changes in the elderly due to changes in receptor responsiveness (number, affinity, and signal transduction mechanisms) as well as homeostatic regulation.[41]

Two examples illustrate these changes:

Example 1: impaired cholinergic transmission associated with a decreased number of muscarinic acetylcholine receptors = increased sensitivity to anticholinergics resulting in a significant source of adverse drug effects.[42]

Example 2: baroreceptor reflex responsiveness decreases with age = postural hypotension with nitroglycerin, dihydropyridine calcium channel blockers, peripheral alpha blockers, phenothiazine antipsychotics.[43]

Drug selection in the frail elderly must take into account the physiologic, pharmacokinetic, and pharmacodynamic aberrations that occur as a natural consequence of aging, which are often compounded by pathophysiologic consequences of chronic conditions. Yet, people older than 80 years of age are often excluded from interventional trials, contributing to the paucity of high quality clinical evidence supporting the safe and effective use of medications in the elderly. Medications within a particular therapeutic category may be considered generally comparable in studies comparing two different groups of patients. But these studies are usually conducted on otherwise relatively healthy young elderly. These medications often differ substantially on one or more critical factors relevant to selecting appropriate medications in the elderly.[44]

2. Nursing home residents must have access to a wider range of medications given their limitations in swallowing, physiologic susceptibility to adverse drug effects, and multiplicity of concurrent underlying conditions complicating optimal drug selection.[45] Because of the number of chronic conditions, superimposed upon the natural consequences of aging, formularies in elderly people must include:

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[41] *Id.*. at 2.

[42] *Id.* at 3.

[43] *Id.*

[44] *Id.* at 3-4.

[45] See T. Higashi, *et al,. The Quality of Pharmacologic Care for Vulnerable Older Patients,* 40 Ann. Intern. Med. 714 (2004).

- drugs with oral, crushable, and, where applicable, intravenous/injectable dosage forms, to accommodate the significant percentage of frail elderly who have difficulty swallowing and who receive medications and nutrition through feeding tubes.
- drugs with low anticholinergic activity are preferred to decrease the potential for drug-related falls and CNS side effects.
- drugs, which are not metabolized by phase I reactions and those without toxicity or limitation in patients with severe impairment in renal function are advantageous.
- multiple drug choices for common chronic conditions so that medication needs can be tailored to minimize side effects, based on underlying patient factors.
- the rationale and supporting evidence for recommendations of drugs to be added to formularies.[46]

For some chronic conditions, patients are at high risk of destabilization when drug therapy is interrupted or changed in the absence of a clinically valid reason. Examples include:

- Antiepileptic drugs in the treatment of seizure disorders
- Atypical antipyschotics in the treatment of schizophrenia
- Antidepressants in the treatment of depression or bipolar disorders
- Antiviral medications in the treatment of HIV/AIDS
- Beta blockers in the treatment of congestive heart failure
- Analgesics in the face of optimal pain control
- Benzodiazepines for treatment of anxiety[47]

In these situations, efforts to contain costs on medications by periodically switching patients to different preferred brands can result in loss of control of the condition, hospitalizations, and other adverse outcomes.

3. USP's draft Model Formulary Guidelines do not accommodate the unique needs of the frail elderly nor do they allow immediate access to a wide variety of medications. In the preamble to the proposed regulations, CMS appropriately raises the issue of nursing home residents' need for special formulary considerations.[48] However, the MMA does not address formularies for LTC residents and directs PDP sponsors to establish coverage determination processes modeled after the Medicare+Choice process.[49] From the prospective of LTC pharmacy, USP's draft Model Formulary Guidelines exclude categories of drugs needed by LTC residents, endangers other drugs from being covered, and fails to accommodate the range of dosage forms needed by LTC residents. We are concerned that PDPs and MA-PD plans will rely heavily on the USP Model Formulary

[46] Zarowitz, *supra* at note 42, at 5.

[47] *Id.* at 6.

[48] 69 Fed. Reg. 46661.

[49] Section 1852(g).

Guidelines and have very limited formularies. This will reduce access for institutionalized, frail elderly beneficiaries.

4. The MMA statute excludes whole categories of drugs needed by residents of LTC facilities.

a. *Benzodiazepines and Barbiturates*

Benzodiazepine medications are hypnotic-anxiolytics used to treat anxiety, insomnia, muscle spasm and seizures. Within the benzodiazepine class of medications there is great variation in drug characteristics such as half-life and duration of effect in the body, blood-brain barrier penetration, metabolic pathways and their associated consequences. Approximately 10% of nursing home residents receive anxiolytics, most commonly benzodiazepines.[50] Benzodiazepines are the 13th leading class of medications in the United States with 71 million prescriptions dispensed in 2002.[51]

Other classes of anxiolytic-hypnotic medications are available for patients with primary anxiety or sleep disorders. However, only benzodiazepines can be used to arrest acute seizure disorders (status epilepticus) in patients with epilepsy. By 75 years of age, 3% of the general population has developed epilepsy. The prevalence of epilepsy is much higher in older patients.[52] It has been well documented, that prompt administration of benzodiazepines is a first-line intervention to arrest seizures in patients with status epilepticus.[53] In nursing home patients, lorazepam can be given safely with a small definable risk of adverse effects as it has a short half-life, is not affected by the aging consequences of drug metabolism through the liver, and exhibits no significant drug interactions. The risk of untreated status epilepticus is brain damage and death if seizures are allowed to continue for greater than 2.5 hours.[54] Without access to benzodiazepines, such as lorazepam, patients with status epilepticus will require hospitalization. The clinical and economic consequences of unchecked status epilepticus are staggering.[55]

Barbiturates, like benzodiazepines, are useful in treating status epilepticus. Barbiturates are used much less often than benzodiazepines, but for patients with certain seizures disorders, drugs such as phenobarbital, are indicated.[56] Many elderly patients

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[50] See D.E. Tobias, and M. Sey, *General and psychotherapeutic medication use in 328 nursing facilities: a year 2000 national survey,* 16 Consult Pharm. 54 (2001).
[51] A.K. Wagner, *et al,. Benzodiazepine use and hip fractures in the elderly,* 164 Arch. Intern. Med. 1567 (2004).
[52] *See* Epilepsy Foundation. *Epilepsy: A report to the nation.* (1999).
[53] *See* B.K. Alldredge, *et al*., *A comparison of lorazepam, diazepam, and placebo for the treatment of out-of-hospital status epilepticus.* 349 N. Engl. J. Med. 631 (2001).
[54] *See* D.M. Treiman, *Therapy of status epilepticus in adults and children,* 14 Curr. Opin. Neurol. 203 (2001).
[55] *See* C.E. Begley, *et al*., *The cost of epilepsy in the United States: an estimate from population-based clinical and survey data,* 41 Epilepsia 242 (2000).
[56] *See* R. H. Mattson, *et al, Comparison of carbamazepine, Phenobarbital, phenytoin, and primidone in partial and secondarily generalized tonic-clonic seizures*, 313 N. Engl. J. Med .145 (1985).

have been maintained on phenobarbital successfully for years.[57] Drug discontinuation and drug switching in elderly nursing home residents has been shown to cause therapeutic destabilization and seizure exacerbation.[58]

b. *Over- the - Counter (OTC) Agents*

There are over 80 therapeutic categories of OTC agents, covering a variety of clinical needs including smoking cessation assistance, cough/cold preparations, and bowel assistance products. OTC products are considered safe for use by the general population if the entire label information is read and comprehended. But, many frail elderly, especially those who are institutionalized, are simply unable to read the fine print found on over-the-counter product labels. Those with cognitive impairment are even less likely to be able to comprehend the written information. Almost 40% of seniors older than 85 years old will experience severe cognitive loss.[59] This number is even higher for residents already living in a skilled nursing facility. Consequently, the senior who self-medicates with OTC agents may miss important drug interactions. For example, sporadic use of full-dose aspirin can lead to life-threatening bleeding in patients treated with warfarin.

Many OTC drugs are a necessary adjunct to maximize the benefit from prescription agents. Iron supplementation is needed with the erythropoetic therapies Procrit® [60]and Aranesp®.[61] Calcium supplementation is necessary with osteoporosis therapies such as Actonel® [62]and Miacalcin.® [63]Acetaminophen is considered first line therapy for the treatment of mild to moderate musculoskeletal pain in the elderly.[64] Stool softeners are necessary to prevent opioid-induced constipation.[65] When OTC medications are a

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[57] *See* P. Gareri, *et al*., *Treatment of epilepsy in the elderly*, 58 Prog. Neurobiol. 389 (1999).

[58] *See* D. L. Coulter, *Withdrawal of barbiturate anticonvulsant drugs: prospective controlled study*, 93 Amer. J. Mental Retardation. 320 (1998).

[59] *See* D. W. Reynolds, *Cognitive Impairment Research*. available at www.geriatrics.iams.edu/research.asp (last visited Sept. 10, 2004).

[60] Ortho Biotech Raritan, *Prescribing Information Procrit*, June, 2004.

[61] Amgen, *Prescribing Information Aranesp*, January, 2000.

[62] Proctor and Gamble Pharmaceuticals *Prescribing Information Actonel*, May 2003.

[63] Novartis Pharmaceuticals, *Prescribing Information Miacalcin*, April 2003.

[64] *See* B. Ferrel, *et al., Management of Persistent Pain in Elderly Persons*, 50 J. Am. Geriatric Soc. S205 (2002).

[65] *See* American Pain Society, *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain*, 5th ed. 2004.

necessary concomitant therapy, there is risk of therapeutic failure when the covered entity is used alone.

Many other OTC agents are currently covered under state Medicaid programs. For example, the prevalence of Gastroesophogeal Reflux Disease (GERD) is common among the elderly.[66] The most recent trend in coverage for Medicaid patients is the transition to Prilosec-OTC®, (Omeprazole) from legend proton pump inhibitors. Eight states, Florida, Illinois, Indiana, Kansas, Kentucky, Missouri, North Carolina, and Wisconsin, provide Medicaid coverage for this OTC product because of its lower cost.

The potential loss of this coverage with the implementation of Part D will lead to cost shifting to an already burdened elderly population residing in LTC facilities. When over the counter drugs are out-of-pocket costs, Medicare recipients will likely request the physician to prescribe a more expensive covered prescription medication at an additional cost to the program.

c. *Medications used for Unintended Weight Loss*

Unintended weight loss is a life threatening condition, particularly in the frail elderly. Patients suffering from involuntary weight loss may suffer significant decline in health and function, resulting in a higher risk for infection, depression, and death.[67] Approximately 13% of ambulatory older patients and 50- 60% of nursing home residents suffer from involuntary weight loss.[68]

The incidence of unintended weight loss is measured through the Minimum Data Set (MDS) in every skilled nursing facility and reported to CMS. Specifically, the facilities must report weight loss of 5% in the past 30 days, 7.5% weight loss in 3 months, or 10% weight loss in 6 months, or a dietary intake of less than 75% at most meals.[69]

Unintended weight loss is a significant problem with the frail elderly, and if left untreated creates serious side effects for the patient. Some of the consequences of unintended weight loss include; infections, falls, hip fractures, immune dysfunction, anemia, decreased cognition, muscle loss, osteoporosis, and pressure sores. Several medications are utilized to increase weight or enhance appetite that may have other primary indications. Examples include:

Megestrol Acetate

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[66] *See* K. DeVault, ***Extraesophogeal Symptoms of GERD,*** 70 Cleveland Clinic J. of Med. (2003).

[67] See E. P. Bouras, S.M. Lange, J.S. Scolapio, ***Rational approach to patients with unintentional weight loss***, 76 Mayo Clin. Proc. 923 (2001).

[68] *Id.*

[69] *Id.* Significant involuntary weight loss is body weight less than IBW range after physiological causes of weight loss, such as possible malignancies, systemic infections, gastrointestinal orders affecting absorption, endocrine disease and renal or psychiatric diseases have been ruled out. *Id.*

- Megace® is a synthetic, antineoplastic and progestational drug that is FDA-approved for the palliative treatment of advanced carcinoma of the breast or endometrium (i.e., recurrent, inoperable, or metastatic disease). It should not be used in lieu of currently accepted procedures such as surgery, radiation, or chemotherapy.[70] Megestrol oral suspension is indicated for treatment of anorexia and cachexia or unexplained significant weight loss in patients with a diagnosis of AIDS. Doses of 400 mg to 800mg per day in AIDS patients were found to be clinically effective.[71]

Mirtazapine

- Residents in nursing centers may suffer from unintended weight loss for different reasons than ambulatory patients. Studies have shown as much as 36% of nursing home residents with unintentional weight loss suffer from depression. Psychiatric disorders, including depression, account for 58% of cases in these residents.[72] Remeron® (mirtazapine) has been shown to increase appetite and promote weight gain while it also treats underlying depression.[73]

Dronabinol

- This cannabinoid is indicated for the treatment of anorexia accompanied by weight loss. There have been promising weight gain results in studies of patients with Alzheimer's disease as well. Other potential benefits of dronabinol are its antiemetic and analgesic effects.

Cyproheptadine

- This antihistamine causes a mild increase in appetite with a decrease in weight loss. Periactin® is often used to increase appetite in the elderly, however it is on the Beers list, and may be considered potentially inappropriate due to adverse drug reactions. The Medicare benefit also covers the younger disabled population, which may benefit from this drug and not have the risk of heightened side effects in younger patients.

Oxandrolone

- This anabolic hormone is approved by the FDA for the treatment of involuntary weight loss and as adjunctive therapy to promote weight gain after weight loss following major surgery, chronic infections, or severe trauma.[74] It also is indicated to offset the protein catabolism associated with prolonged corticosteroid use, which is common with long-term care residents with COPD or arthritis.

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[70] *See* Bouris, *supra* at note 69.

[71] *Id.*

[72] *FDA Oncology Tools Product Label Details in Conventional Order for megestrol acetate*, available at http://www.accessdata.fda.gov/scripts/cder/onctools/labels.cfm?GN=megestrol%20acetate. (last visited July 8, 2004).

[73] *See* Bouris, s*upra* at note 69.

[74] FDA Oncology Tools Product Label Details in Conventional Order for megestrol acetate, *supra* at note 74.

Additional costs to the health care system are likely to occur with the exclusion of medications to manage weight loss from Part D benefits. Also, because nursing centers must evaluate and manage issues of weight loss by regulation, the exclusion of medications to treat this issue creates a regulatory and financial burden for the system.

We understand that CMS must base the regulation on existing statute, including the definition of a "covered Part D drug," which excludes benzodiazepines, barbiturates, over-the-counter drugs, and medications for unintended weight loss. We will be seeking legislative change in the future to amend Section 423.100 to cover these medications for the frail elderly, and invite CMS to support these efforts.

5. <u>There are a number of drugs that are in danger of not being covered in the two drugs per category schema called for in the regulation</u>.

a. Biotech Injectables and Infusables

Injectable and infusible medications represent one of the fastest growing and most expensive categories of prescription drugs with costs in the United States projected to rise to $26 billion by 2006.[75] Spending on infusible drugs rose 40% in 2002. There are 369 biotech medicines in human clinical testing representing fully a third of all drugs in human clinical testing. Biotech-derived medicines currently account for 5% of the value of the world market and are expected to represent more than 15% by the year 2005. Out of 50 new medicines reaching the market annually, 10 – 15 are biotechnology derived. Chronic disease patients requiring specialty products represent up to 1% of the population and consume 25 – 30% of pharmacy spending in the United States.

In 2003, the Food and Drug Administration approved agalsidase beta (Fabrazyme®) for treatment of Fabry disease, alefacept (Amevive®) and Efalizumab (Raptiva®) for plaque psoriasis and expanded the indications of etanercept (Enbrel®), and infliximab (Remicade®) for treatment of psoriatic plaque disease. These biotech infusible/injectable medications represent significant improvements in the treatment of their associated conditions and are projected to receive expanded indications in 2004 and 2005.

[75] See W. Tercero, *Strategies for managing injectable drugs in a managed care setting*, 10 Managed Care Quarterly 16 (2002).

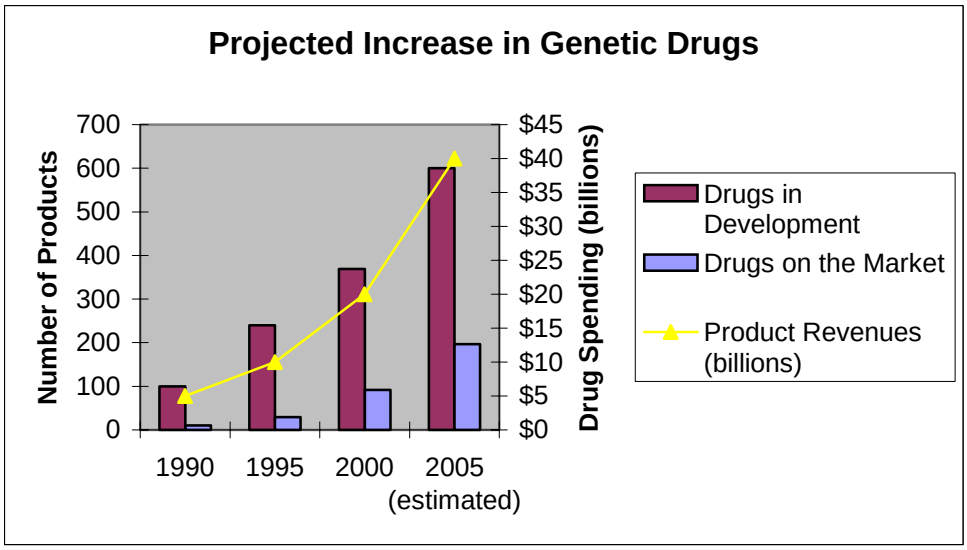
The prevalence of conditions most commonly treated by biotech infusible/injectable drugs is summarized in Table 1.

Table 1: Prevalence of Conditions

Condition	**Prevalence**
Crohn's Disease	500,000 cases in U.S.; 0.178% of total U.S. population (www.veritasmedicine.com)
Gaucher's Disease	2500 cases in U.S.; 0.00089% of total U.S. population (www.ncbi.nlm.nih.gov)
Multiple Sclerosis	350,000 living in U.S.; 0.124% of total U.S. population (www.neurologychannel.com)
Hepatitis C	3.9 million living in U.S.; 1.39% of total U.S. population (www.cdc.gov)
HIV/AIDS	793,000 persons with AIDS in U.S.; 0.282% of total U.S. population (www.cdc.gov)
Growth Hormone Deficiency	70,000 living in U.S.; 0.25% of total U.S. population (www.pituitary.com)
Organ Transplant	22,953 organs transplanted annually; 0.008% of total U.S. population (www.unos.org)
RSV Prophylaxis	315,000 at risk babies in U.S.; 0.11% of total U.S. population (www.MedImmune.com)
Fertility	6 million couples in U.S.; 10% of people of reproductive age (www.parenthood.com)
Oncology	1.3 M new cases of cancer in U.S. in 2002; 8.9 M have had cancer (www.cancer.org)
Arthritis	49 M have arthritis in U.S.; 17% of total U.S. population (www.niams.nih.gov)
Hemophilia	291,000 cases in U.S.; 0.103% of total U.S. population (www.accredohealth.net)

Figure 1 displays projected drug spending increases through 2005 with the number of pharmacogenomic drug products in development.[76] Ninety-nine percent of bioengineered drugs directed specifically toward a genetic defect or deficiency are administered by injection or infusion.

Figure 1



Residents of long-term care facilities are candidates for biotech drugs to improve management of Crohn's disease, rheumatoid arthritis, anemia, cancer, hepatitis C, multiple sclerosis and Parkinson's disease. Over the next few years, it is anticipated that many new genetically-engineered drugs will enter the market with increasing utility in the frail elderly.

b. Anticoagulants

The Sixth (2000) ACCP Guidelines for Antithrombotic Therapy for Prevention and Treatment of Thrombosis outlines the appropriate use of these drugs in patients with atrial fibrillation, venous thromboembolism, valvular heart disease, mechanical heart valves, peripheral arterial occlusive disease ischemic stroke, and other chronic conditions, all of which are prevalent in the frail elderly.[77] For example, the incidence of atrial fibrillation increases with age reaching a prevalence of roughly 10% in patients greater than 80 years old.[78] Long-term care residents with clotting disorders or conditions predisposing them to thrombosis are candidates for oral warfarin therapy, subcutaneous unfractionated or low-molecular weight heparin, hirudin anticoagulants, antithrombotic

[76] *Advance PCS*, 42H Managed Care (2002).

[77] See J.E. Dalen, J. Hirsch, G. H. Guyatt, eds. *The Sixth ACCP Consensus Conference on Antithrombotic Therapy*, 119 Chest 1S (2001)

[78] *Id.*

agents, and thrombolytic agents. Each of these subclassifications of medications has very different indications, safety, and efficacy profiles and must be accessible without restriction to the frail elderly.

In particular, while low-molecular weight heparins have a similar mechanism of action, their molecular weight distributions vary, resulting in differences in their activity, receptor affinity and plasma half-lives.[79] These drugs are not interchangeable. Patients cannot be switched among agents without incurring an increased risk of bleeding and potential for thrombosis.[80]

c. Anticonvulsants

Anticonvulsant medications are extensively prescribed for elderly nursing home residents.[81] In 1998, 10.5% of nursing home residents received an anticonvulsant drug. The prevalence of epilepsy increases with age; 3% of those over 75 years have epilepsy.[82] The diverse range of causes of seizure disorders as well as the variation in seizure types in the elderly necessitates access to the full range of anticonvulsant drugs.[83] Since the mid 1990's, over 7 new anticonvulsant medications have been released in the U.S. market to treat one of 8 classifications of epilepsy. The newer medications are not categorized as barbiturates, hydantoins, or suximides and thus would be classified as "Other," in the current USP designation. These drugs represent significant advances in the treatment of epilepsy as they offer different mechanisms of action, fewer adverse effects, better pharmacokinetic profiles or easier administration compared to older drugs.[84] In the elderly, experts advise the use of antiepileptic drugs with minimal cognitive adverse effects, such as carbamazepine, valproic acid, gabapentin and lamotrigine, at the lowest possible dosage.[85] There is no "one best drug" for everyone. All anticonvulsant medications need to be easily available for nursing home patients. Anticonvulsant drug discontinuation due to the need for formulary drug switching would have devastating consequences given that as many as 75% of patients will incur new seizures.[86]

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[79] *See* E. Racine, *Differentiation of the low-molecular weight heparins*, 21 Pharmacother. 62S. (2001).

[80] *See* Dalen, *supra* at note 79.

[81] *See* T.E. Lackner, J.C. Cloyd, L.W. Thomas, I.E. Leppik. *Antiepileptic drug use in nursing home residents: effect of age, gender, and comedication on patterns of use*, 39 Epilepsia 1083 (1998).

[82] *See* Epilepsy Foundation. *Epilepsy: A report to the nation* (1999).

[83] *See* R. E. Ramsay, *et al*., *Special considerations in treating the elderly patients with epilepsy*, 62 Neurol. S24 (2004).

[84] See A. G. Marson , Z.A. Kadir, D. W. Chadwick, *New epileptic drugs: a systematic review of their efficacy and tolerability*, 131 Brit. Med. J. 1169 (1996).

[85] See M. Mendez and G. Lim, *Seizures in elderly patients with dementia: epidemiology and management*, 20 Drugs & Aging 791 (2003).

[86] See D. Chadwick. *et al*., *Outcomes after seizure recurrence in people with well-controlled epilepsy and the factors that influence it*, 37 Epilepsia 1043 (1996).

d. *Non-Sedating vs. Sedating Antihistamines*

Sedating antihistamines, such as diphenhydramine (Benadryl), are available inexpensively without a prescription. Sedating antihistamines have recognized efficacy in providing symptomatic relief of allergic symptoms, but they can cause significant sedation and deterioration in cognitive functioning, mental performance, and psychomotor functioning. Excessive sedation and anticholinergic properties create high risk for bladder obstruction, and central nervous system side effects, leading to falls in the elderly.[87] Non-sedating antihistamines have limited sedation and anticholinergic properties, yet have been shown to be effective in treating allergic rhinitis and urticaria. At least two non-sedating antihistamines, such as fexofenadine (Allegra) and desloratadine (Clarinex) or loratadine (available over-the-counter) should be available on PDP formularies.[88] The advantage of a lower potential for untoward sedation and cognitive impairment compared with first-generation antihistamines make non-sedating second generation antihistamines preferable to older ones despite their greater cost.[89]

e. *Insulins*

Regular, NPH, lente and ultralente insulins are available in many states without a prescription. However, most insurance plans provide prescription coverage for insulin to promote health as part of their strategy for managing patients with chronic medical conditions. There are new rapid-acting insulins that are amino acid analogs, which provide significant advantages over the classic insulins. Rapid-acting insulins, such as aspart (Novolog) and lispro (Humalog), can be taken at the time of the meal to control food-related blood sugar excursions. Basal insulins, such as glargine (Lantus) have been introduced recently, and are usually categorized with long-acting insulins. Each of the insulins has unique action and representatives of the rapid-acting, short-acting, intermediate-acting, long-acting and basal insulin categories must be accessible for elderly patients. PDPs could exclude all new rapid-acting and basal insulins or include Novo and Lilly's ultralente insulins on their formularies and satisfy the two-drug minimum without including glargine.

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[87] *See* M.A. Kaliner, *H1-antihistamines in the elderly*, 17 Clinical Allergy & Immunology 465 (2002); *See* F. E. Simons, T.G. Fraser, J. Maher, N. Pillay, and K.J. Simons, *Central nervous system effects of H1-receptor antagonists in the elderly*, 82 Annals of Allergy, Asthma, & Immunology 157 (1999).

[88] *See* M. Affrime, S. Gupta, C. Banfield and A. Cohen, *A pharmacokinetic profile of desloratadine in healthy adults, including elderly*, 41 Clinical Pharmacokinetic S13 (2002); *See* J.D. McCue, *Safety of antihistamines in the treatment of allergic rhinitis in elderly patients*, 5 Archives of Family Medicine 464 (1996).

[89] *See* R.D. Mann, G.L. Pearce, N. Dunn, S. Shakir, *Sedation with "non-sedating" antihistamines: four prescription-event monitoring studies in general practice*, 320 Brit. Med. J. 1184 (2000).

The biggest concern with insulin therapy in elderly diabetic patients is the occurrence of hypoglycemia causing dizziness and falls. Newer insulins represent a significant advance in the treatment of diabetes.[90]

f. *Selective Serotonin Reuptake Inhibitors (SSRI) and Selective Norepinephrine and Serotonin Reuptake Inhibitors (SNRI)*

Until the late 1980's older patients with depression were subject to significant anticholinergic side effects (i.e. constipation, dry mouth and eyes, urinary retention, mental confusion and dizziness) of tricycles antidepressants or orthostatic hypotension and drug interactions associated with monoamine oxidize inhibitors. While these drug classes are effective antidepressants, the adverse effect profiles are unacceptable in elderly patients.[91] Physicians have been warned that due to the adverse effect profiles, monoamine oxidase inhibitors and tricycles antidepressants are on the Beer's list and not recommended in the elderly.[92]

The SSRIs and SNRIs are safer and equally effective alternatives to tricyclic antidepressants and monoamine oxidase inhibitors in elderly patients. However, variation in anticholinergic potential, adverse effects, likelihood of drug interactions and half-life exists among SSRIs. Fluoxetine (Prozac) and paroxetine (Paxil) are likely to be on most PDP antidepressant formularies as they are SSRIs available in low-cost generic equivalents. Fluoxetine has the greatest number of drug interactions and adverse effects of all of the SSRIs, as well as the longest half-life. Paroxetine causes sedation and has anticholinergic properties associated with falls in the elderly. Falls in elderly patients are associated with hip fractures and significant clinical and economic hardship. Safer SSRIs with fewer drug interactions and less pronounced anticholinergic activity, such as citalopram (Celexa), escitalopram (Lexapro) or sertraline (Zoloft), must be available on PDP formularies for the elderly. SNRIs (e.g. venlafaxine (Effexor XR)) represent another class of antidepressant medications that combine activity at two receptor sites believed to be altered in patients with depression.
Elderly nursing home patients must have unrestricted access to the SSRI and SNRI antidepressant medications so that clinicians can select agents with the least problematic adverse effects, short half-life, liquid or chewable/crushable dosage forms, and few drug interactions.

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[90] *See* American Diabetes Association, *Insulin Administration,* 27 Diabetes Care S106 (2004); American Association of Clinical Endocrinologists, *Medical Guidelines for the Management of Diabetes Mellitus: The AACE System of Intensive Diabetes Self-Management,* 8 Endocrine Practice 40 (2002); D.K. Zettervall, *Therapeutic management of type 2 diabetes in the long-term care facility,* 16 Consult. Pharm. 668 (2001).

[91] *See* B.R. Sommer, *et al., Safety of antidepressants in the elderly,* 2 Expert. Opin. Drug Safety 367 (2003).

[92] *See* U. Sambamoorthi, *et al., Diffusion of new generation antidepressant treatment among elderly diagnosed with depression,* 41 Medical Care 180 (2003); *see* D.M. Fick, *et al., Updating the Beers criteria for potentially inappropriate medication use in older adults*, 163 Arch. Intern. Med. 16 (2003).

g Calcium Channel Blockers

More than 25% of those over the age of 65 years of age present with hypertension (HTN) and isolated systolic hypertension (ISH). For those over the age of 80, the lifetime risk for developing HTN is about 90%.[93] More than 8% of those over 80 years of age develop atrial fibrillation. The elderly represent about 13% of the U.S. population but over 40% of prescription drug costs for antihypertensive and related cardiovascular therapy.[94] Untreated HTN in elders results in a 63% chance for stroke, congestive heart failure (CHF), and myocardial infarction (MI).[95] Among individuals over age 75, almost two-thirds (64%) of men and three-quarters (75%) of women have high blood pressure.[96] Data from the Framingham study shows that men aged 65 to 75 have a risk for fatal cardiovascular event 2.4 times normal when HTN is not controlled. The same study shows a risk factor of 8 times for women of the same age.

Calcium channel blockers (CCBs), with sub-classes dihydropyridine (DHP) and non-dihyrpopytidine (NDHP), are indicated for hypertension, angina, vasospastic angina, ventricular rate control, and atrial fibrillation.[97] CCBs reduce the clinical symptoms of angina and are well tolerated.[98] CCBs are recommended for chronic stable angina when beta-blockers are ineffective or not tolerated.[99] CCBs also offer an effective option for beta-blocker intolerance in management of hypertension.

In ISH, CCBs reduce pulse pressure by lowering Systolic Blood Pressure more than Diastolic Blood Pressure.[100] Treatment of patients with ISH, using CCBs as part of an

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[93] *See* www.drugtopics.com (last visited on Sept 5, 2004).

[94] *See* National Health Spending Trends, Health Affairs, referenced in AGS website information, August 2004.
Dihydropyridine (DHP): amlodipine, felodipine, isradipine, nicardipine, nifedipine, nimodipine, nisoldipine. Non-dihydropyridine (NDHP): bepridil, diltiazem, verapamil.

[95] *See* www.drugtopics.com *supra* at note 95.

[96] *See* National Center for Health Statistics. *Hypertension*. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. September 2004.

[97] *See AHFS Drug Information*, 2004 Edition, Electronic Version.

[98] Id.

[99] *See* A.V. Chobanian, *et al.*, and the National High Blood Pressure Education Program Coordination Committee. *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood pressur*., 289 JAMA 2560 (2003); See also *Guidelines Committee, 2003 European Society of Hypertension* – European Society of Cardiology. Presented at Milan Italy, June 2003. www.eshonlne.org.

[100] AHFS, *supra* at note 99.

antihypertensive drug regimen can prevent 29 strokes or 53 major cardiovascular events for every 1000 patients treated over a 5 year period.[101]

The dihydropyridine and non-dihydropyridine classes are similar in terms of antihypertensive effect, but differ in adverse event profiles. Dihydropyridines appear to cause a higher risk for proteinuria Dihydropyridines pose a risk for increased intraglomerular pressure and should not be used with Angiotensin Converting Enzyme Inhibitor (ACE) or Angiotensin Receptor Blocker (ARB) Non-dihydropyridines preserve renal autoregulation. DHPs are free of chronotropic effects and safer for those with left ventricular dysfunction or conduction defects. NDHPs have negative chronotropic and inotropic effects.

The need for Calcium Channel Blockers (CCB) is recognized in step 2 of JNC-VII in the management of hypertension.[102] JNC-VII Guidelines recommend adding a CCB after a thiazide diuretic as Step 2 in treatment of HTN.[103] The United Kingdfom Prospective Diabetes Study (UKPDS) findings also show the clinical impact of tight blood pressure control in diabetic patients and the JNC-VII recommendations list CCBs as compelling for control in this population.[104]

h. *Atypical Antipsychotics*

The atypical antipsychotics are used to manage delusions, hallucinations, severe agitation, aggressive behavior, or delirium. They have FDA approved indications for use in schizophrenia and bipolar disorders.

Psychotic disorders are reported in 10% to 63% of elderly patients in nursing homes.[105] Psychotic symptoms are present in at least 25% of mildly demented patients with Alzheimer's disease and in 50% of patients with advanced Alzheimer's disease.[106] Approximately 26% of nursing facility residents had an order for an antipsychotic drug in March 2004, representing an almost 5% increase in utilization from just a few years earlier.[107]

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[101] *See* J.M. Neutel 17 *Prog Cardiovasc Nurs.* 81 (2002).

[102] Chobanian, s*upra* at note 101.

[103] *Id.* JNC-VII Guidelines are accepted standards of practice in the management of hypertension, Id.

[104] *See* United Kingdom Prospective Diabetes Study (UKPDS) Group. *Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes,* 317 Br. Med. J. 703 (1998).

[105] *See* J. Mintzer, *et. al*., *Psychosis in Elderly Patients: Classification and Pharmacotherapy*, 16 J. Geriatric Psychiatry Neurol. 199 (2003).

[106] *See* C.D. Motsinger, *et al.,.Use of Atypical Antipsychotic Drugs in Patients with Dementia,* 67 Am. Fam. Physician 2335 (2003).

[107] *See* Centers for Medicare and Medicaid Services, *OSCAR Online database*. http:www.cms.hhs.gov (last visited Sept. 9, 2004).

Psychosis in elderly patients is a growing clinical concern because psychotic symptoms most frequently occur as non-cognitive manifestations of Alzheimer's disease, as side effects of drug therapy for Parkinson's disease, or as the primary abnormalities in schizophrenia.[108] Atypical antipsychotic drugs greatly improve quality of life in elderly patients with dementia and behavior disturbances.[109] Atypical antipsychotics also have been shown to be more cost-effective than typical antipsychotics, when total costs of health care utilization are considered (costs of various patient care settings, consultations, laboratory tests and treatment of side effects, as well as drug costs).[110]

Atypical antipsychotics such as risperidone, olanzapine, and quetiapine are at least as effective as conventional antipsychotics, are better tolerated, and have a lower propensity for extra pyramidal side-effects (EPS) (e.g. tremor, slurred speech, and akathisia).[111] Moreover, findings suggest that mortality in elderly patients receiving haloperidol is significantly higher than in those receiving the atypical antipsychotics risperidone or olanzapine (21.4% for haloperidol vs. 4.75 for atypical antipsychotics).[112] In the elderly, late onset movement disorders such as tardive syskinesias are more likely with haloperidol (26% vs. 5% in younger patients).[113] Tardive dyskinesia among elderly taking risperidone was 2.5%.[114] EPS also are more common in haloperidol treated patients than atypical antipsychotic treated patients.[115]

i. *Erythropoietin*

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[108] *See* Mintzer, *supra* at note 107.

[109] *See* Motsinger, *supra* at note 107.

[110] *See* LeCompte, *et al., A 1 year cost effectiveness model for the treatment of chronic schizophrenia with acute exacerbations in Belgium*. ,3 J. Intern. Soc. Pharmacoecon & Outcomes Res. (2000).

[111] *See* http://www.medterms.com/script/main. Individual atypical antipsychotics can be differentially associated with adverse events. For example, quetiapine has not been associated with increased cerebrovascular adverse events as others have been (risperidone and olanzapine. *See* Astra-Zeneca Pharmaceuticals, Wilmington, DE, Data on file; *see* P.P. De Deyn, *et al*., *A randomized trial of risperidone, placebo, and haloperidol for behavioral symptoms of dementia*, 53 Neurology 946 (1999); *see* J.S. Street, *Olanzapine treatment of psychotic and behavioral symptoms in patients with Alzheimer's disease in nursing care facilities: a double blind, randomized trial*., 47 Arch. Gen. Psychiatry 968 (2000).

[112] *See* H.A. Nasrallah, *et al*., *Study of Elderly Links Newer Atypical Antipsychotics with Lower Mortality Rate than Older Antipsychotic Haloperidol* 12 Amer. J. Geriatric Psychiatry, 437.

[113] *See* D.V. Jeste, *et al., Lower incidence of tardive dyskinesia with risperidone compared with haloperidol in older patients,* 47 J. Geriatric Soc. 716 (1999).

[114] *Id.*

[115] *See* G. M. Simpson, *et al*., *Extrapyramidal symptoms in patients treated with risperidone,* 17 J. Clin. Psychopharmacol 194 (1997).

Erythropoietin (EPO) is indicated for the treatment of anemia. Anemia affects about 20-40% percent of older Americans,[116] and even mild anemia in the elderly is associated with increased morbidity and mortality. Anemia is often underdiagnosed and under treated.[117] Approximately 1 to 1.5 % of LTC residents receive EPO treatment.[118] However, a national survey of anemia in nursing homes reported that as many as 50% of patients with anemia had low EPO levels, indicating renal impairment may be a common mechanism of anemia in this setting.[119]

Anemia is not a normal consequence of aging and hemoglobin concentration below the normal range in elderly patients is an important finding. Untreated anemia in geriatric patients is associated with significant clinical outcomes including decreased function, increased disability, increased falls, dementia, congestive heart failure, and increased mortality.[120] Recently, anemia has been associated with loss of physical function, independent of underlying disease status.[121] Anemia decreases myocardial function and increases peripheral arterial vasodilation and activation of the sympathetic and renin-angiotensin-aldosterone system, which affects the initiation or progression of diseases such as heart failure and renal failure A study of 755 elderly patients found that the mortality risk for malignancies and infections was higher in patients with anemia versus those not having anemia.[122]

j. *HMG-COA Reductase Inhibitors (i.e."Statins" or HMGs)*

HMG-COA Reductase Inhibitores (Statins or HMGs) are used for the treatment of hyperlipidemia. The prevalence of hyperlipidemia is 61% among those ages 65-74 (32% diagnosed and 29% undiagnosed) and 62% among those age 75 and older (28% diagnosed and 34% undiagnosed.)[123] Approximately 12 % of LTC residents receive

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[116] *See* A. Artz, D. Fergussoon, P.J. Drinka, M. Gerald, R. Bidenbender, *et al*., *Mechanism of unexplained anemia in the nursing home*, 52 J. Amer. Geriatrics Soc. 423 (2004).

[117] *Id.*

[118] *Id.*

[119] *Id.*

[120] *See* B.W. J.H. Penninx, M. Guralnik, G. Onder, L. Ferrucci, R.B. Wallace, and M. Pahor, *Anemia and decline in physical performance among older persons*, 115 Amer. J. Med. 104 (2003); *see* A.J. Collins S. Li, W. St. Peter, *et al., Death, hospitalization, and economic associations among incident hemodialysis patients with hematocrits values of 36% to 39%*, 12 *J. Amer. Soc. Nephrolog*y 2465 (2001).

[121] *See* T. A. Miettinen, K. Pyorala, A.G. Olsson, *et al*., *Cholesterol-lowering therapy in women and elderly patients with myocardial infarction or angina pectoris: findings from the Scandinavian Simvastatin Survival Study*, 96 Circulation 4211 (1997).

[122] *See* S.J. Lewis, L.A. Moye, F.M. Sack, *et al., Effect of pravastatin on cardiovascular events in older patients with myocardial infarction and cholesterol levels in the average range: Results of the Cholesterol and Recurrent Events (CARE) trial*, 129 Am. Intern. Med. 681 (1998).

[123] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *National Health and Nutrition Examination Survey (NHANES III), 1988–1994*.

HMG-COA Reductase Inhibitors while less than 1% of LTC residents receive the older sequestering agents.[124]

Heart disease accounts for over one-third of deaths among persons 65 years of age and older. Ischemic heart disease (IHD) is the most frequent cause of death among persons 65 years and older. Acute myocardial infarction (AMI) accounts for 43% of the ischemic heart disease deaths, and is the single most frequent cause of death among older adults. The benefit of cholesterol-lowering medication in elderly patients (to at least age 80) with known coronary artery disease and elevated cholesterol has been demonstrated in three large randomized, placebo-controlled, clinical trials.[125]

k. *COX 2 Inhibitors*

COX-2 inhibitors significantly improve the risk-benefit ratio of arthritis therapy. Arthritis and other rheumatic conditions are among the most common chronic conditions and constitute the leading cause of disability, affecting an estimated 42.7 million persons in the United States.[126] Three percent of LTC residents receive conventional non-steroidal anti-inflammatory drugs (NSAIDS) while 10% receive the preferred COX 2s.[127]

Risk factors for serious gastro-intestinal events increase with NSAID use in individuals of advanced age, a history of ulcer or gastro-intestinal complications, or major illness[128] High dose or use of multiple NSAIDS are also associated with a risk of serious gastro-intestinal events.[129]

COX-2s significantly improve the risk-benefit ratio of arthritis therapy.[130] Medical care for arthritis cost nearly $22 billion in 1995.[131] The costs associated with a gastro-intestinal bleed in an dual eligible institutionalized individual far exceed the costs of a COX-2 drug.

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[124] *Id.*

[125] *See Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group,* .339 N. Engl. J. Med. 1349 (1998); *see* Miettinen, s*upra* at note 123 ; and Lewis, *supra* at note 124.

[126] *See* Centers for Disease Prevention and Control, 48 Morbidity & Mortality Weekly Review (May 7, 1999).

[127] *Id.*

[128] *See* Silverstein, *et al*, 123 Ann. Intern. Med. 241 (1995); *see* R. Singh, 25 J. Rheumatol. 8 (1998).

[129] *See* Singh, *supra* at note 130.

[130] A. Praemer, S. Furner, D. Rice, *Musculoskeletal Conditions in the United States*, American Academy of Orthopedic Surgeons (1999).

[131] *Id.*

USP was wise to separate anti-inflammatory medications from analgesics. Similarly, it is imperative that cyclooxygenase –2 selective NSAIDs and non-selective NSAIDs are in separate subdivision classes to assure that more than one safe and effective alternative anti-inflammatory drug exists on PDP formularies for the elderly. If COX-2 and NSAID medications are combined in one drug class, PDPs are likely to limit formulary offerings to generic NSAIDS. Substantial evidence exists to support the contention that only COX-2s should be used in individuals greater than 65 years of age because of their favorable gastrointestinal profile.

Within the COX-2 class, sufficient evidence is mounting to differentiate the safety profile of celecoxib (Celebrex) and rofecoxib (Vioxx). In the elderly, Vioxx has been associated with precipitating myocardial infarction, edema, and hypertension, as well as congestive heart failure. In controlled comparisons, celecoxib has been associated with a lower risk of cardiovascular side effects while affording the same degree of protection to the gastrointestinal mucosa. LTCPA suggests that at least two COX-2 drugs are required on PDP formularies. Scientific evidence should guide plans to include celecoxib as one of the formulary choices.

l. *Proton Pump Inhibitors (PPIs)*

Peptic Ulcer Disease (PUD) is one of the most common gastro-intestinal diseases, affecting approximately 350,000 people and accounting for more than 7,000 deaths annually in the United States.[132] Approximately 90% of these deaths occur in the elderly.[133] The elderly, who are especially susceptible to ulcer-related complications such as bleeding, obstruction, and perforation, have a mortality rate of more than 30% for complicated ulcers.[134]

Over one in five (23 %) of LTC residents receive Proton Pump Inhibitors (PPIs) while 12 % receive H2 Receptor Antagonists (H2RA). Since the introduction of PPIs over ten years ago, numerous studies have confirmed the greater clinical efficacy of the PPIs when compared to the H_2 RAs.[135] H_2 RAs and other medications with anticholinergic effects should be avoided in this population because of the risk of potentiating cognitive impairment.

m. *Antibacterials*

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[132] *See* K. Ozenberg-Ben-Dror, D. H. Barch, R. Rooney, *et al*., *Developing a pharmacist-managed Helicobacter pylori clinic*. Federal Practitioner 7 (1997).

[133] *Id.*

[134] *See* W.R. Garnett, *Acid-related disorders*, U.S. Pharm 119 (1997).

[135] *See* J.W. Freston, *et al.*, *Comparative pharmacokinetics and safety of lansoprazole oral capsules and orally-disintegrating tablets in healthy subjects*, 17 Alimentary Pharmacology & Ther. 361 (2003).

Infections rank as the second leading cause of death in persons over 65 years.[136] Almost half (48%) of bacteremia/sepsis occurs in the older adult and is responsible for 60% of deaths in this population.[137] Third generation cephalosporins are prescribed six times more frequently for LTC residents than first generation cephalosporins. There is an increased potential for morbidity and mortality if a broad choice of agents is not available to effectively manage individual patient response to medication and the evolving resistance patterns of the organisms.

o. *Beta-Adrenergic Receptor Antagonists (Beta-Blockers)*

Cardiovascular disease (CVD) includes coronary heart disease [CHD], hypertension [HTN], heart failure [HF], and stroke. In 1999, 23% of nursing home residents' age ≥ 65 years had a primary diagnosis of CVD at admission, the highest disease category for these residents.[138] The National Committee for Quality Assurance lists beta-blockers use after an MI and control of HTN as two of the five quality-of-care performance measures related to preventing and treating cardiovascular diseases.[139] Multiple HTN therapeutic guidelines (e.g., JNC-VII, WHO/ISH, Hypertension in African Americans) recommend the use of beta-blockers to treat this disease.[140] For example, the JNC-VII lists beta-blockers as first-choice for ischemic heart disease, acute coronary syndromes, post-MI, or asymptomatic or symptomatic HF. The American College of Cardiology/American Heart Association adult

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[136] *See* M.J. Koronkowski, *Infectious Disease and Host Resistance in Older Persons*, Univ. of Illinois Pharmacotherapeutics II (1998). Only deaths from cardiovascular disease rank higher. Among the individual causes of death, pneumonia and influenza rank 6th for persons ages 65-74, 5th for persons ages 75-84 and 4th for persons aged 85 and over. *Id.*

[137] *Id.*

[138] American Heart Association. *Heart Disease and Stroke Statistics — 2004 Update* (2003), available at http://www.americanheart.org/downloadable/heart/1079736729696HDSStats2004UpdateREV3-19-04.pdf (last visited Sept. 5, 2004).

[139] *Id.*

[140] *See* A.V. Chobanian, G.L. Bakris, H.R. Black, W.C. Cushman, L.A. Green, and J.L. Izzo, *et al.*, *The seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure*, 289 JAMA 2560 (2003); European Society of Hypertension Scientific Newsletter, *Update on hypertension management,* 2 WHO/ISH 1-2 (2001) available at http://www.eshonline.org/newsletter/2001/esh_2001_2_No09.pdf (last visited Sept.5, 2004; *see* L.E. Ramsay, B. William, G.D. Johnston, G.A. MacGregor, L. Poston, J.F. Potter, *et al.*, *British Hypertension Society guidelines for hypertension management 1999,* 319 Brit. Med. J. 630 (1999); *see* J.G. Douglas, G.L. Bakris, M. Epstein, K.C. Ferdinand, C. Ferrario, J.M. Flack, *et al.*, *Management of high blood pressure in African Americans: consensus statement of the Hypertension in African Americans Working Group of the International Society on Hypertension in Blacks*, 163 Arch. Intern. Med. 525 (2003); *Drugs for hypertension. Treatment Guidelines from the Medical Letter*, 1 Med. Lett. Drugs Ther. 33 (2003); *ACC/AHA Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult,* http://circ.ahajournals.org/cgi/content/full/104/24/2996#SEC3, (last visited Sept. 5, 2004).

HF guidelines recommend beta-blocker use for all stages of HF, in addition to other medications.[141]

Three specific beta-blockers have been documented to reduce morbidity and/or mortality in patients with HF. The CIBIS-II trial reported a decreased all-cause mortality rate with bisoprolol compared to placebo in NYHA class III or IV HF patients with LVEF $\leq$ 35%.[142] The Metoprolol-CR/XL Randomized Intervention Trial in Congestive Heart Failure (MERIT-HF) documented a lower mortality incidence with sustained-release metoprolol (metoprolol-CR/XL) compared with placebo in chronic HF patients (NYHA functional class II-IV and LVEF $\leq$ 0.40).[143] In addition, results of the MERIT-HF trial were further analyzed and reported a lower rate of the combined end point of total mortality or all-cause hospitalizations (time to first event) with metoprolol-CR/XL.[144] Multiple studies document that carvedilol improves LVEF survival, and HF symptoms and reduces hospitalization to a greater extent than placebo.[145] The results of the COMET trial document a reduction in all-cause mortality with carvedilol compared to metoprolol tartrate (an immediate-release formulation).[146]

The American College of Cardiology/American Heart Association guidelines recommend beta-blocker use as initial therapy in the absence of contraindications in adult patients with chronic stable angina.[147] The American Heart Association/American Stroke Association stroke guidelines recommend beta-blockers in all post-MI and acute ischemic syndrome patients and continued indefinitely. Beta-blockers also are recommended as needed to manage angina, rhythm, or blood pressure in all other patients.[148]

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[141] *Hypertension Management in Adults with Diabetes*, available at http://care.diabetesjournals.org/cgi/content/full/27/suppl_1/s65#T1 (last visited Sept. 8, 2004).

[142] *See The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II): a randomised trial*, 353 Lancet 9 (1999).

[143] *See* A. Hjalmarson, S. Goldstein, B. Fagerberg, H. Wedel, F. Waagstein, J. Kjekshus, J., *et al., Effects of controlled-release metoprolol on total mortality, hospitalizations, and well-being in patients with heart failure: the Metoprolol CR/XL Randomized Intervention Trial in congestive heart failure (MERIT-HF)*, 283 JAMA 1295 (2000).

[144] *See Effect of metoprolol CR/XL in chronic heart failure: Metoprolol CR/XL Randomised Intervention Trial in Congestive Heart Failure (MERIT-HF)*, 353 Lancet 2001 (1999).

[145] *See* B.E. Bleske, E.M. Gilbert, and M.A. Munger, *Carvedilol: therapeutic application and practice guidelines*,. 18 Pharmacotherapy 729 (1998); *see* C.P. Neal and M.G. Kendrach, *Carvedilol use in heart failure*, 32 Ann. Pharmacother. 376 (1998).

[146] *See* P.A. Poole-Wilson, K. Swedberg, J.G. Cleland A. Di Lenarda, P. Hanrath, M. Komajda, M., *et. al*,. *Comparison of carvedilol and metoprolol on clinical outcomes in patients with chronic heart failure in the Carvedilol Or Metoprolol European Trial (COMET): randomised controlled trial*, 362 Lancet 7(2003).

[147] *ACC/AHA 2002 Guideline Update for the Management of Patients With Chronic Stable Angina*, available at http://circ.ahajournals.org/cgi/content/full/107/1/149 (last visited Sept. 5, 2004).

[148] *See Coronary Risk Evaluation in Patients With Transient Ischemic Attack and Ischemic Stroke: A Scientific Statement for Healthcare Professionals From the Stroke Council and the Council on Clinical*

Beta-blocker is a "generic" term to describe a medication class. (*see* Table 2). Not all beta-blockers have the same pharmacological activity. Certain agents of this class have actions at alpha-receptors while some agents only have an effect at the beta-1 subtype receptor. These differences in pharmacological activity are especially beneficial in some patient types but can be detrimental in other patients. Beta-blockers are recommended as initial drugs-of-choice to treat many different cardiovascular disease states. Limiting the beta-blocker options can lead to suboptimal patient care. Carefully selecting agents from each subclass (i.e., beta-1 selective, non-beta selective, ISA, beta plus alpha activity) is needed to produce a list of beta-blockers that are clinically useful for beneficiaries. (*see* Table 3).

Although each beta-blocker has received FDA-approval to treat hypertension, only certain beta-blockers are approved for other cardiovascular disease states. For example, only three beta-blockers have been documented to reduced morbidity and/or mortality in patients with heart failure. These agents are not all classified within the same beta-blocker subclass. Also, one cannot assume all beta-blockers would be clinically useful in heart failure patients since another beta-blocker, bucindolol, did not reduce mortality in patients with heart failure.[149]

In addition, some beta-blockers should be avoided or prescribed cautiously to patients with concomitant disease states. For example, the American Heart Association / American College of Cardiology state that beta-blockers without ISA are preferred agents in patients with unstable angina or non-ST-segment elevation / non-Q-wave MI.[150] In addition, beta-blockers with only beta-1 activity are preferred in patients with pulmonary disease (e.g., asthma, COPD).[151] According to the Beer's List, propranolol is not recommended for patients with COPD/asthma.[152]

Cardiology of the American Heart Association/American Stroke Association, available at http://circ.ahajournals.org/cgi/content/full/108/10/1278 (last visited Sept. 5, 2004).

[149] *See* Beta-Blocker Evaluation of Survival Trial Investigators. *A trial of the beta-blocker bucindolol in patients with advanced chronic heart failure*, 344 N. Engl. J. Med. 1659 (2001).

[150] *See* CC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina and Non–ST-Segment Elevation Myocardial Infarction, available at http://www.americanheart.org/downloadable/heart/1022188973899unstable_may8.pdf (last visited Sept. 8, 2004).

[151] *See* S. Salpeter, T. Ormiston, and E. Salpeter, *Cardioselective beta-blockers for reversible airway disease,* Cochrane Database Syst. Rev. (2002); *see* M.R. Andrus, K.P. Holloway, and D.B. Clark, *Use of beta-blockers in patients with COPD*, 38 Ann. Pharmacother. 142 (2004).

[152] *See* D.M. Fick, J.W. Cooper, W.E. Wade, J.L. Waller, J.R. Maclean, and M.H. Beers, *Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts.* 163 Arch. Intern. Med. 2716 (2003).

Table 2: Commercially Available Beta-Blockers

Generic Name	Brand Name	Generic Available	Selectivity
Beta-1 Selective			
Atenolol	Tenormin	Yes	Beta-1
Betaxolol	Kerlone	Yes	Beta-1
Bisoprolol	Zebeta	Yes	Beta-1
Metoprolol- immediate release Metoprolol- extended release	Lopressor Toprol XL	Yes No	Beta-1
Non-Beta Selective			
Nadolol	Corgard	Yes	Beta-1 and 2
Propranolol- immediate release Propranolol- extended release	Inderal Inderal-LA	Yes Yes	Beta-1 and 2
Timolol	Blocadren	Yes	Beta-1 and 2
Intrinsic Sympathomimetic Activity			
Acebutolol	Sectral	Yes	Beta-1
Carteolol	Cartrol	No	Beta-1 and 2
Penbutolol	Levatol	No	Beta-1 and 2
Pindolol	Visken	Yes	Beta-1 and 2
Alpha-Blocking Activity			
Carvedilol	Coreg	No	Beta-1 and 2
Labetalol	Normodyne / Trandate	Yes	Beta-1 and 2

Table 3: FDA-Approved Indications for the Beta-Blockers

Generic Name	Hypertension	Other
Atenolol	X	Angina pectoris due to coronary atherosclerosis; post-MI (hemodynamically stable)
Betaxolol	X	-
Bisoprolol	X	-
Metoprolol-immediate release	X	Angina pectoris; post-MI (hemodynamically stable)
Metoprolol-extended release	X	Angina pectoris; HF (NYHA class II or III of ischemic, hypertensive, or cardiomyopathic origin)
Nadolol	X	Angina pectoris
Propranolol-immediate release	X	Angina pectoris due to coronary atherosclerosis; cardiac arrhythmias (SVT's, VT's, etc); post-MI (clinically stable); migraine prophylaxis; essential tremor; hypertrophic subaortic stenosis; pheochromocytoma (adjunctive)
Propranolol-extended release	X	Angina pectoris coronary atherosclerosis; migraine prophylaxis; hypertrophic subaortic stenosis
Timolol	X	Post-MI (clinically stable); migraine prophylaxis
Intrinsic Sympathomimetic Activity		
Acebutolol	X	Ventricular arrhythmias
Carteolol	X	-
Penbutolol	X	-
Pindolol	X	-
Alpha-Blocking Activity		
Carvedilol	X	Mild to severe HF of ischemic or cardio-myopathic origin; left ventricular dysfunction (ejection fraction ≤ 40%) following MI in stable patients
Labetalol	X	-

X= FDA approved indication HF = heart failure MI = myocardial infarction

p. *New Drugs*

Over the past 5 years, the FDA has approved over 100 new molecular entities.[153] This figure does not include the FDA approvals for new dosage formulations (e.g., liquids, extended-release tablets) or new medication indications/uses. During 2004, 14 new molecular entities have been approved, more than 35 medications received a new indication, and 20 new dosage formulations have been approved.[154]

A mechanism of reviewing newly approved medications is vital to all health care entities providing medications to patients.[155] Primary decision issues while evaluating new medications include indications, efficacy, safety, dosing considerations, and cost. Each year, a few of the new molecular entity drugs classified by FDA as "priority review" provide practitioners and patients with a significant therapeutic agent.[156] For example, tiotropium (Spiriva®) was approved during 2004.[157] This agent is indicated for patients with chronic obstructive pulmonary disease (COPD).[158] Only one other medication with the same pharmacology (ipratropium [Atrovent®) is available to treat

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[153] *See* New Molecular Entities (NMEs) Reports, available at http://www.fda.gov/cder/rdmt/ (last visited Sept. 8, 2004). The Food and Drug Administration's (FDA) newly approved medications can be classified as follows: new molecular entity (drug not marketed in U.S. by any manufacturer); new salt (active moiety is marketed in the U.S., but this particular salt, ester, or derivative is not); new formulation (drug marketed in the U.S., but this particular formulation is not); new combination (two or more ingredients in combination not marketed in the U.S.); new manufacturer (already marketed by another firm; duplicated salt, formulation or combination); new indication (already marketed by same firm but used primarily for new indications (uses)). *See* Katz, R., *The introduction of new drugs* in Gennaro, A.R., ed. *Remington: The Science and Practice of Pharmacy,* 20th ed., 930 (2000).

[154] *See NMEs Approvals in Calendar Year 2004*, available at http://www.fda.gov/cder/rdmt/NMECY2004.HTM (last visited Sept. 8, 2004).

[155] *See* American Society of Hospital Pharmacists, *ASHP statement on the formulary system*, 40 Am. J. Hosp. Pharm. 1384 (1983); *see* C.E. Quinn and A. Barisano, *Understanding, creating, and working with formulary systems*, 5 Am. J. Manag. Care 1311 (1999); *see* J. R. May, *Formulary systems* in J.T. DiPiro, ed., *Encyclopedia of Clinical Pharmacy*, 1st ed. 362 (2003); *see* T.R. Covington and J.L. Thornton, *The formulary system: A cornerstone of drug benefit management* in S.M. Ito and S. Blackburn, eds., *A Pharmacist's Guide to Principles and Practices of Managed Care Pharmacy*, Academy of Managed Care Pharmacy, 35 (1995).

[156] *See* Katz, *supra* at note 155. The FDA categorizes the new molecular entities into two therapeutic classifications: priority review (P) (assigned to drugs that appear to have therapeutic gain over drugs currently available by 1) providing effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug, 2) providing improved treatment or greater effectiveness or safety, and 3) having a modest, but real advantage over convenience, elimination or troublesome side-effects, or treatment of a specific subpopulation of patients); and standard review (S) (assigned to drugs that appear to have therapeutic qualities similar to drugs already approved.). *Id.*

[157] *See* NMEs Approvals in Calendar Year 2004, *supra* at note 156.

[158] *See* Boehringer Ingelheim Pharmaceuticals, Inc. *Spriva* [package insert], Jan. 2004.

patients with COPD, but requires four-time-per-day administration.[159] Not only has tiotropium been reported to improve COPD symptoms compared to ipratropium[160] and increase the therapeutic options to treat this disease, this agent is dosed only once daily. The fewer doses needing to be administered may enhance patient compliance and patient acceptance of medication therapy.

Usually health care institutions review medications still in clinical research (i.e., not approved by the FDA for marketing) with the purpose of determining how the medication could change the usual care of patients. An example of this medication type is ximelagatran (Exanta®). Ximelagatran will be the first medication of this pharmacological class to be taken orally instead of via an injection. This medication has been evaluated in preventing and treating blood clots.[161] The primary oral medication available to prevent and treat blood clots (warfarin [Coumadin®) has a few disadvantages that include determining the patient-specific dose without causing bleeding, frequent blood monitoring, plus drug/drug and food/drug interactions.[24] Ximelagatran may offer some patients a therapeutic advantage compared to warfarin.

Unless CMS establishes a standard mechanism for PDP plans to cover newly approved medications, beneficiaries may be denied new medications documented to produce a greater therapeutic response, reduce adverse effects, reduce morbidity and/or mortality, and/or enhance patient compliance.

The above analysis only begins to touch upon the multiple drug-related problems that will be attendant in shifting Medicare beneficiaries, and particularly those full benefit dual eligibles who today receive virtually all their medically necessary drugs through the Medicaid program, into Part D prescription drug benefits.

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[159] *See* E.R Sutherland and R. M. Cherniack, *Management of chronic obstructive pulmonary disease*, 350 N. Engl. J. Med. 2689 (2004).

[160] *See* W.Vincken, J.A. van Noord, A.P. Greefhorst, T.A. Bantje, S. Kesten, and L. Korducki, *Improved health outcomes in patients with COPD during 1 yr's treatment with tiotropium,* 19 Eur. Respir. J. 209 (2002); *see* J.A. van Noord, T.A.Bantje, M.e. Eland, L. Korducki, and P.J. Cornelissen, *A randomised controlled comparison of tiotropium nd ipratropium in the treatment of chronic obstructive pulmonary disease*, 55 Thorax 289 (2000).

[161] *See* J.A. Heit, C.W. Colwell, C.W. Francis, J.S. Ginsberg, S.D. Berkowitz, J. Whipple, *et al.*, *Comparison of the oral direct thrombin inhibitor ximelagatran with enoxaparin as prophylaxis against venous thromboembolism after total knee replacement: A phase 2 dose-finding study*, 161 Arch. Intern. Med. 2215 (2001); *see* P. Petersen, M. Grind and J. Adler, *Ximelagatran versus warfarin for stroke prevention in patients with nonvalvular atrial fibrillation*: *SPORTIF II: a dose-guiding, tolerability, and safety study*, 41 J. Am. Coll. Cardiol. 1445 (2003).

6. The proposed regulations do not accommodate the range of dose forms that residents of LTC facilities require.

***a**. Dosing and Formulary Selection in the Frail Elderly*

The number of chronic conditions that afflict the frail elderly coupled with these physiological changes require that flexible dosage forms (systems) are available to adequately treat the frail elderly. Many of these options, in all likelihood, will not be adequately included in PDP formularies that otherwise meet USP's proposed Model Formulary Guidelines. Drug delivery systems that are critical to treating the institutionalized frail elderly include:

- **Tablets and Capsules**: Formularies must include solid dosage forms that can be crushed, halved or dissolved or that may already be available in a liquid dosage form.
- **Time Release Medications:** The frail elderly in LTC facilities commonly receive 6 or more separate routine medications each day to treat multiple conditions. If administered four times a day as most of the older medications are, we would be asking the average LTC resident to swallow 24 pills per day. If long-acting medications are used, this number can be reduced by 50 to 75%.
- **Topical Patches:** Due to the swallowing difficulties, topical patches offer the frail elderly another effective dosage form. Care must also be taken with this dosage form as the frail elderly have very thin compromised skin that is susceptible to tears and abrasions.
- **Injectable Medications:** Many of the newer, biotech drugs are available only in an injectable form. Intramuscular (IM) injectable medications are usually reserved as a last resort due to decreased muscle mass in the frail elderly. Many IM injectables also can be administered intravenously.
- **Intravenous (IV) Medications:** This delivery system must be protected for the LTC resident. IV treatment in the LTC facility allows the LTC resident to be treated in place as opposed to being transferred to a hospital. IV therapy is preferred over intramuscular (IM) injections – IM injections are painful, dangerous and difficult to administer due to the decreased muscle mass of the frail elderly.
- **Other Dosage Forms**: Products that utilize unique dosage forms may be overlooked because they are used less frequently. There are many medically necessary drugs administered via various delivery systems in the ophthalmic, optic and inhalants classes. A formulary designed for the "healthy elderly" may exclude many necessary "frail elderly" drugs. An additional concern is the scope of wound care and healing products that will be covered.

b. Liquids, Crushable, Injectable Medications

In the nursing home environment 53-74% of residents have some form of dysphagia, which can have a dramatic impact on nutritional status.[162] LTC residents at risk for developing dysphagia include those who have had a stroke, Parkinson's Disease, Huntington's Corea, Multiple Sclerosis, cancer of the head, neck or esophagus, residents with dementia, and residents who are on medications that cause sedation, impair cognition, or decrease production of saliva.[163]

LTC facilities must take steps to avoid the complications and consequences of dysphagia, which include aspiration pneumonia, choking, chronic malnutrition, decreased quality of life, and unintended weight loss.[164] Issues of dysphagia lead to the placement of feeding tubes to ensure adequate nutrition for these residents. With the number of residents suffering from dysphagia, or receiving all oral nutrition and medications via a feeding tube, it is imperative that alternative dosage forms be made available. Liquid or crushable oral medication or injectable dosage forms are critical in ensuring appropriate drug therapy. If the appropriate dosage forms are not available to our most frail patients, managing their serious illnesses such as congestive heart failure, hypertension, diabetes, or even infection will be impossible. If LTC residents do not have access to these dosage forms under formularies established by PDP plans, in all likelihood they will be transferred to a hospital, a more expensive health care alternative, to receive these medications.

[162] *See* Becky Dorner & Associates, *supra* at note 28.

[163] *Id.*

[164] *See* Shanley, *supra* at note 30.