Comments of Long-Term Care Pharmacy Alliance

Center for Medicare and Medicaid Services

Proposed Rule on Payment Reform for Part B Drugs

(Docket No. CMS 1229-P/42 CFR Part 405 (April 20, 2003))

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INTRODUCTION

The Long Term Care Pharmacy Alliance (LTCPA) appreciates this opportunity to respond to the Center for Medicare and Medicaid Services (CMS) proposed rule revising the definition of Average Wholesale Price (AWP). 68 Fed. Reg. 161 (August 20, 2003). Because we dispense Part B drugs, and because much of our Medicaid reimbursement is predicated upon AWP, the proposed rule is of great importance to us. We urge CMS to seriously consider the direct and secondary implications of its proposed rulemaking.

Our comments are divided into multiple sections. In the first section, we describe our membership and the services and products they provide, as well as related cost issues. Section II sets out a proposed set of criteria which we urge CMS to utilize when considering whether, and how, to promulgate a final rule. Section III addresses the potential impact of payment reform on Medicaid policies and urges CMS to carefully and directly identify the impact its proposals will have on the Medicaid program. LTCPA urges CMS to specifically and explicitly indicate in its final rule that any proposed revisions to the AWP definition are not intended to, and should not be, applied to state Medicaid programs and CMS's legal authority to make any changes to the manner in which it understands the term "AWP."

Section IV addresses CMS's legal authority deviate from the statutory definition of AWP. Section V identifies certain issues related to the data that CMS has relied upon for the proposed rule, and data that it may utilize in a final rule, with particular focus on the Agency's (and HHS's) Information Quality Guidelines. In Sections VI-IX, we address the four substantive AWP alternatives that CMS has proposed. In Section X, we also comment upon CMS's proposed increase in oncology service reimbursement, and urge CMS to adopt a similar payment for LTC pharmacy. Finally, we urge CMS to expand upon its regulatory impact analysis in order to comply fully with the statute.

I. BACKGROUND ON LONG-TERM CARE PHARMACIES

A. What is Long-Term Care Pharmacy?

To understand why the options for AWP reform proposed by CMS are not appropriate in, and have failed to consider, the long term care (LTC) and "institutional" context, it is critical to understand the unique role that LTC pharmacy plays in the delivery of drugs to LTC residents. LTC patients have unique drug needs far different from ambulatory Medicare beneficiaries. LTC pharmacy has met those needs through a sophisticated delivery system unlike that used in retail pharmacy. Unfortunately, none of the CMS proposals in its rule reflect LTC resident needs, requirements, the services currently being provided by LTC pharmacy, or the resulting cost saving to the health care delivery. Thus, LTCPA urges CMS to exempt long-term care pharmacies from reform options that will result in decreased reimbursements for Part B covered drugs, and address LTC pharmacy in a separate rulemaking.

B. LTC Residents Typically Need Greater Drug Therapy

Unlike the typical ambulatory Medicare beneficiary, the typical LTC resident is older, in poorer health, and in need of greater care. Studies have documented that the average resident has the following characteristics:[1]

- mean age of 83.1 years;
- usually being admitted to the LTC facility directly from an acute care hospital (62% of residents);
- more than not likely to have impaired or abnormal cognitive function; only 17% of LTC residents were characterized as independent or required limited assistance in performing the activities of daily living;
- typically having three medical conditions, with 45% of residents having four or more conditions and 10% of residents having more than six medical conditions.[2] Typical diseases included cardiovascular clinical conditions (63%), hypertension (31%), coronary artery disease (23%), and congestive heart failure (19%). Significantly, 42% of residents have dementia, and 20% were stroke victims;
- typically on prescriptions for 6 drugs, with 45% taking seven or more drugs, and 20% taking more than 10 drugs. Over 50% of residents are taking cardiac medication, and approximately 40% are taking analgesics.

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

Not only are elderly LTC residents on more medications, but also they require different specialized medications. More specifically, as a person ages their body processes drugs differently (a function of changing metabolism and typical decreases in kidney function).[3] Extensive literature has

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

[2] In the Coalition's experience, LTC residents often have a higher number of illnesses, and a recent HCFA-sponsored analysis has suggested that the actual number many be 7.8 medical conditions. *See* Bodenheimer, J., *Long Term Care for Elderly People, The On-Lok Model,* 341 N. Eng. J. Med. 1324, 1326 (1999) (noting that 1995 data suggest that the average patient was 80 years old, have 7.8 medical conditions, and had impairments impeding performance of 2 to 3 activities of daily living). .

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

documented the need for specific elder drug formularies,[4] and companies have published specialized care guidelines documenting exactly how different drugs typically prescribed react (and interact) in elderly people.[5] While these specialized formularies are often not widely understood or applied outside that segment of the medical community involved in geriatric treatment, the specifics of geriatric care are extremely important in avoiding adverse drug affects and inappropriate treatment.

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

C. LTC Residents Require Enhanced Drug Services Not Contemplated By The Reform Options Proposed by CMS.

In light of the significant patient needs outlined above, both standards of care and federal and state regulations have evolved to provide LTC residents with an enhanced set of services related to their prescription drugs not provided by retail pharmacy.[6] These services include:

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

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

[5] *See, .e.g.,* Geriatric Pharmaceutical Care Guidelines, The Omnicare Formulary (2002), published by Omnicare, Inc. Omnicare is a member of the LTCPA. In contrast to formularies like the Omnicare guidelines, PBMs and retail pharmacy have little no experience in designing or maintaining geriatric formularies.

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

other drug has been provided to the patient, and know, just by looking at the card, how many doses the patient has been given.

Second, the unit dose system provides a uniform and easily managed process for drug delivery through the central distribution point of the LTC nurse, who will actually deliver the drugs to the patient on any given day. Nurses no longer have to place pills into little paper cups to distribute to the patient. Rather, they are able to avoid the multiplicity of drug delivery errors inherent in such an outdated system by relying upon the unit dose system dedicated to each LTC resident. The importance of this uniform distribution system throughout the facility cannot be overemphasized – LTC facility nurses face a significant challenge in distributing multiple drugs to dozens of patients each day, where patients consume an average of 6 medications apiece.[7] The 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 Delivery. LTC pharmacy also provides "around the clock" availability, either through delivery services, med-carts and emergency carts,[8] all of which assist in getting patients necessary medications in a timely manner. This service is particularly important in having intravenous medications available for LTC residents, so that patients do not have to be transported to a hospital for emergency treatment. It is important for CMS to recognize the enormous cost savings to the health care system just from this single service.

3. Consultant Pharmacist Services. In addition to providing the drugs, LTC pharmacy also provides a set of services through consultant pharmacists, who are able to review and assist in patient drug care. These services include, among others, retrospective drug regimen reviews, as required by law, 42 C.F.R. 483.60(c), and prospective drug screenings to monitor for medical appropriateness of the prescribed drugs and for inappropriate drug interactions.[9]

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

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[7] *See also* Tamblyn, R., Medication Use in Seniors: Challenges and Solutions, 51 Therapie 296 (1996). Tamblyn aptly notes that [h]ealth care system policy and practice can have a substantial impact on the drug utilization among seniors." *Id.* at 275. "Although regulatory changes are made in [governmental] drug plan policies to control costs, there is virtually no information on the impact of drug policy interventions on drug utilization patterns and patient outcomes." *Id.* at 276. It is exactly such an analysis that the LTCPA suggests CMS need undertake before applying the discount card proposal to LTC patients.

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

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

> patient's medical conditions, and, more importantly, current drug utilization.[10] Given current technological and other limitations, the only way in which appropriate drug reviews can be conducted, particularly on a prospective (rather than retrospective) basis is for there to be a single dispensing pharmacy for any given patient.[11] Stated differently, the prerequisite to prospective drug regimen review and medication interaction screenings is that there be a single pharmacy from which the patient's medications are dispensed, and which has complete knowledge of the medications that a patient is on at any given time. Without that single source, there is no way for the pharmacy or pharmacist to know the actual drug intake that the patient is consuming, or to monitor for contraindications, inappropriate drug interactions, drug abuse, or inappropriate prescription utilization.

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

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

> First, nursing facility residents consume, on average, a greater number of prescription medications, thus increasing the potential for [drug related problems, or] DRPs. Additionally, in contrast to their ambulatory counterparts, nursing facility residents are placed at higher risk of DRPs because of the 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 that occur within the institutional setting.

Id. at 2095. Thus, to the extent that CMS considers any rule change that will affect reimbursement for drugs in LTC facilities, as the proposed rule will do, it must carefully examine the savings it expects to achieve against the savings that already exist as a result of the standards of care that LTC pharmacy provides to LTC patients.[12]

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[10] Tamblyn, supra, at 275 (noting that risk of inappropriate drug prescriptions could be reduced 20 to 30 percent by ensuring that primary physicians and pharmacists have "better access to information about <u>all</u> 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.*

[12] CMS should also re-evaluate its cost impact and financial analyses to properly reflect true drug consumption costs in the LTC community. While CMS estimates that typical Medicare beneficiary

D. Long-Term Care Pharmacies Have High Dispensing and Related Services Costs

Due to the issues addressed above, pharmacies that serve institutional sites of care, such as nursing homes, have higher costs of doing business than other pharmacies. To quantify this phenomenon, 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 report on the costs of dispensing pharmaceuticals to residents in nursing homes and other long-term care sites.

The BDO Seidman survey found that it costs the major national operators of long-term care pharmacies, on average, approximately $11.37 to dispense a prescription. This figure does not include a return on equity or a profit margin – it simply reflects the costs of operating a long-term care 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.

In reviewing the survey results, BDO Seidman found several reasons why the costs of dispensing prescriptions are higher for long-term care 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 to meet long-term care regulatory requirements;
- 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.[13]

E. Long-Term Care Pharmacies Dispense Part B Covered Drugs and Biologicals, and Other Drugs Affected by AWP

LTC pharmacies today provide virtually all Part B drugs to Medicare-eligible nursing home residents. Medicare, as the primary payor, reimburses the pharmacies through the LTC facilities at 95% AWP for Part B covered drugs and biologicals, consistent with current Federal Law. Unfortunately, the proposed rule does not appear in any way to accommodate for that fact. Thus, at least for LTC pharmacy, LTCPA urges CMS not to adopt any change in this existing methodology – to do

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drug consumption to be $1,351 in 2004, 67 Fed. Reg. at 10280, the Coalition anticipates such spending by LTC residents to be approximately $4,700.

[13] Institutional Pharmacy Dispensing Cost Survey, Prepared by BDO Seidman, LLP, April 5, 2002 (attached).

otherwise is to allow reductions in Medicare Part B drug reimbursement rates to eliminate the ability of LTC pharmacies to operate.

To the extent any change is implemented, LTCPA urges CMS to create a methodology to provide LTC pharmacy with sufficient and appropriate payment to address its unreimbursed dispensing costs. This notion is not new; over two years ago, in 2001, the Government Accounting Office (GAO) recommended in its report that CMS pay "appropriately for drug delivery and administration and not allow potential overpayments for drugs to subsidize payments for related services."[i] [14] . CMS in its proposed rule has also acknowledged this principle as it relates to the oncology community, and proposes at least some measures to address the imbalance in oncology services. There is nothing in the proposed rule, however, that addresses the imbalance that currently exists in LTC pharmacy, or speaks to how CMS proposes to address the inadequacy of the existing dispensing fees paid by State Medicaid programs or the absence of any dispensing fee by Medicare in the LTC context. To respond to the GAO's concern, and to be consistent with its own proposed philosophy and methodology, LTCPA urges CMS to address the costs of individualized packaging, emergency drugs, etc. for long-term care pharmacies.

F. The Proposed Rule Poses A Serious Threat to Long Term Care Pharmacy

Importantly, CMS must also consider the ways in which its rulemaking will impact the Medicaid program. LTC pharmacies depend in large part on the Medicaid program. Indeed, the Medicaid program comprises over 65% of the typical LTC facilities' business. As CMS is aware, many states currently reimburse prescription drugs based upon a percentage of AWP. Thus, CMS must consider, in its rulemaking, the impact that its proposed definition of AWP will have on Medicaid providers if the states adopt the federal definition for Medicaid purposes.

The implications of CMS's proposed rule, and any final rule that may issue, are particularly profound in the current health care environment. State Medicaid programs, looking to save money from shrinking budgets and in a misdirected attempt to reduce prescription drug prices, are slashing their reimbursement rates for drugs without consideration of the LTC pharmacy service costs. As documented by The Kaiser Commission on the Uninsured in its study of state responses to fiscal pressures:

> State cost containment activity continued to focus heavily on reducing provider payments and controlling prescription drug spending. Forty-nine states either froze or reduced provider payments, and 44 states put new mechanisms in place to reduce their spending growth on prescription drugs in FY 2004. At the same time, 18 states planned to restrict eligibility, 20 states planned to reduce the availability of benefits, and 21 states made plans to increase co-payments in FY 2004.[15]

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[14] "Medicare Payments for Covered Outpatient Drugs Exceed Providers' Costs" (GAO-01-1118), September 2001

[15] Vernon Smith, Ph.D., et al. States Respond to Fiscal Pressure: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2003 and 2004 Results from a 50-State Survey. Kaiser Commission on Medicaid and the Uninsured. http://www.kff.org/content/2003/4137/4137.pdf.

In the vast majority of states, LTC pharmacists receive the same reimbursement as retail pharmacists despite LTC pharmacy's far higher costs of dispensing. State Medicaid officers, in targeting the high drug prices charged by manufacturers, are mistakenly cutting LTC care pharmacist reimbursement. Unfortunately, much like the oncology community, LTC pharmacy has survived by cross-subsidizing the loss it endures for each dispensing fee against the margin between actual acquisition cost and the Medicaid reimbursement rate. By reducing (or in some cases eliminating) this margin, without providing a commensurate increase in the dispensing fee reimbursement or accounting for the specialized and increased costs of dispensing drugs to nursing home residents, the States are eliminating the ability of LTC pharmacists to operate. To the extent CMS redefines AWP to a lower reimbursement level, and the states adopt that definition into their own AWP reimbursement methodologies, LTC pharmacy will not be able to provide the levels of service that exist today. Ultimately, nursing home residents will suffer.

II. EVALUATING DRUG PRICING ALTERNATIVES

The proposed rule appears to be driven by an imperative to replace the current payment methodology solely for the purposes of achieving fiscal savings. While this may be a singular objective, recent health policy affirm that being penny wise and pound-foolish can lead to costly mistakes. It is imperative that CMS, in the rulemaking, stand back and examine the strategic criteria that should underlie their decision process. Pharmaceuticals are an integral component of care. Decisions affecting pricing will affect delivery. The debate on drug pricing methodology has focused primarily on ingredient costs, rather than the total delivery costs. In an effort to stimulate this discussion of policy outcomes, the Long Term Care Pharmacy Alliance suggests decision-makers consider the following six criteria as benchmarks for evaluating alternatives.

Clinical Integration: Important aspects of drug therapy management including specialized packaging and dispensing costs, consultation, documentation and transportation are missed with the singular focus on ingredient pricing. The additional costs of meeting the care needs of specialized populations must be recognized to assure clinical responsiveness.

Fairness: Payment must be adequate, appropriate and unbiased. Under current laws, sameness, rather than fairness, leads to anomalies wherein payment is too much for some; too little for others and where regulations and guidance are layered with such complexity that prudent drug management decisions are hard to implement.

Predictability: Volatility undermines clinical and resource allocation decisions. Payers have an obligation to promote stability. Pricing indices should have sufficient observed history to accurately reflect past and forecast behaviors, and allow providers, other stakeholders, and the public the ability to predict future costs and expense, rather than guess at what they will be based upon a set of numbers only disclosed by manufactures in secret to CMS after the fact.

Timeliness: There is a delicate balance between stability and change. Pricing formulas must be timely updated and adaptive to reflect market changes and technology enhancements.

Transparency: Enhanced understanding leads to improved compliance. When all stakeholders understand the essential calculations of the payment formula, and when that formula can be validated and verified, disputes are narrowed.

Administration: Complexity and mystery distracts from patient care. Resources expended on documenting and re-tooling systems adjusting to constant evolving mandates and directives can best be re-directed to care giving.

With these factors in mind, we comment upon the proposed rule, both in terms of the statutory authority for the rulemaking, the data that CMS has used and proposes to use, and the four substantive AWP alternatives that CMS has proposed. We also comment upon CMS's proposed increase in oncology service reimbursement, and urge CMS to adopt a similar payment for LTC pharmacy. Finally, we urge CMS to carefully and directly identify the impact its proposals will have on the Medicaid program, and specifically and explicitly indicate in its final rule that any proposed revisions to the AWP definition are not intended to, and should not be, applied to state Medicaid programs.

III. IMPACT OF MEDICARE POLICY ON MEDICAID

As alluded to above, LTCPA also urges CMS to include specific and direct language in the final rule that its re-definition of AWP is applicable only to Part B drugs, and will not be accepted by CMS in any state plan that proposes to use the new definition for purposes of the Medicaid program.

As CMS knows, the Medicaid statute requires all state reimbursement rates to be sufficient to ensure beneficiary access. 42 U.S.C. § 1936A(a)(30). If any state using an AWP reimbursement benchmark were to adopt any of the four proposed AWP definitions, it would amount to an immediate and significant reimbursement cut, which, given the current insufficient reimbursement rates for dispensing fees, would force LTC pharmacies out of business.[16] This in turn would lead to the elimination of sufficient providers to satisfy the statutory equal access requirement. Until CMS and the states have sufficiently studied this issue, CMS must bar states from implementing any redefinition of AWP as proposed by the department.

Further, and to the extent that CMS and the states are able to study the issue and to guarantee that the section (a)(30) equal access requirement will be met, CMS should, in its rulemaking, make clear that it will not allow any state to modify its definition of AWP, or its payment for covered drugs, to model the Medicare payment for covered Part B drugs or any other proposed reduction unless, like CMS, the state increases the dispensing fees paid to long tem care pharmacies based upon reliable, statistical evidence such as that in the BDO Seidman report.

IV. STATUTORY AUTHORITY

LTCPA also questions the statutory basis of the rulemaking. CMS bases its statutory authority to amend Section 1842(o) of the Social Security Act on Section 429 of BIPA. That statute, however, directs CMS to revise the Medicare payment methodology for drugs under Section 1842(o) based on

[16] We urge CMS to review the events during the winter of 2002 in Massachusetts, when the state proposed reducing reimbursement to "Wholesale Acquisition Cost" or "WAC" minus two percent, and the vast majority of providers announced they would withdraw from the Medicaid program. The same result will occur if state Medicaid programs began adopting any of the four alternatives in the proposed rule.

the GAO report to Congress. It is a clear premise of the separation of powers doctrine that an agency cannot amend a statute with an administrative action – legislation is required. The authority provided in Section 429 is vague, and therefore the clear and concise meaning of the statutory language will preempt any regulation which is in conflict. Where Congress provides specific direction, as it did here in requiring that Part B drugs be paid at 95% AWP, the specific mandate will prevail. See, *e.g. Morton v. Mancari*, 417 U.S. 535, 550-51 (1974) (where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one). Thus, LTCPA urges CMS to reevaluate whether BIPA is a sufficient or valid legislative basis to support this rulemaking.

V. BOTH THE DATA UNDERLYING THE PROPOSED RULE, AND DATA THAT CMS PROPOSES TO USE IN ANY FINAL RULE, VIOLATE THE AGENCY'S INFORMATION QUALITY GUIDELINES.

A. CMS Must Comply With Its Own, and HHS, Information Quality Guidelines.

Beyond the statutory basis, LTCPA also questions whether CMS is complying with its own policies in promulgating a rulemaking predicated upon valid, verifiable, and legitimate data. The U.S. Department of Health and Human Services (HHS) and CMS have each developed guidelines to implement the Office of Management and Budget (OMB) requirement that all federal agencies issue guidelines for ensuring the quality of information that they disseminate to the public. The OMB directive was required to implement section 515 of the Treasury and General Government Appropriations Act for FY 2001. The statute directed OMB to "issue government wide guidelines that provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." LTCPA asserts that the Office of Inspector General (OIG) and GAO studies are not statistically reliable, and do not meet the Information Collection Guidelines promulgated by CMS pursuant to the OMB Guidelines.

Among the types of information cited by CMS to be covered by these guidelines are statistical and actuarial information and studies and summaries prepared for use in formulating broad program policy. CMS gives examples of the type of information designed to help improve the performance of CMS programs, and thus covered by the guidelines.

> Payment updates establish the amount Medicare will pay for particular services or for capitated care of beneficiaries. For example, each year the agency publishes a fee schedule update that determines payments for physician services.[17]

LTCPA asserts that the CMS Proposed Rule on Payment Reform for Part B Drugs would revise the current payment methodology for certain Part B covered drugs and biologicals, comparable to the payment update for physicians. As such, it is subject to the Information Collection Guidelines as defined by CMS.

The data relied upon by CMS in its proposed rule, as well as the payment methodologies proposed by CMS, do not meet the standards outlined by CMS in its guidelines. CMS states refers to utility as an objective of its quality assurance, which is "achieved by staying informed of information needs

[17] http://www.hhs.gov/infoquality/CMS-9-20.htm

and developing new data, models, and information products where appropriate." [18] CMS also refers to objectivity as a quality assurance goal, which "is achieved by using reliable data sources and sound analytic techniques, and carefully reviewing information products prepared by qualified people using proven methods."[19] Even when using external data, CMS states that it is to be produced using "generally accepted methodologies."

Unfortunately, the GAO and OIG reports, which are cited by CMS as the underlying authority for payment reform, are not reliable data sources as required by CMS's guidelines. For example, a review of the OIG report conducted by the Center for Pharmacoeconomic Studies at the University of Texas at Austin identified serious limitations to the OIG analysis of Medicare-covered drug products, particularly with regard to its calculation of estimated discounts and projected national savings. [20] The review questioned the methodology for sampling, data collection, and the external validity of calculated national savings. It stated that the "sampling technique, based on equal representation of the five types of pharmacies, is not representative of pharmacy participation in state Medicaid programs and introduces a risk of both under-sampling and over-sampling different types of pharmacy providers." In addition, the report did not speak to the issue of non-responders, nor did it describe the characteristics of pharmacies that did respond and the extent of response bias. While pharmacies were sampled evenly across selected categories, the review found a disproportionately large number of "Urban Chain" pharmacy prices utilized in the final calculation of discount off of AWP prices. The review asserted that using only the largest invoice was inappropriate since it may not represent a typical purchasing event for a pharmacy. It also asserted that the study included inappropriate sampling techniques which produce "significant potential for estimation error in the extrapolations."

The review also found that there was a lack in the detailed description of the methodology within the OIG report. As such, the OIG methodology is an explicit violation of the transparency and "reproducibility by qualified third parties" which a standard for the CMS guidelines.[21]

The invalidity of the underlying data used by CMS in formulating its proposed rule, and its failure to comply with its own (and HHS's) procedures for collecting data, invalidate the rulemaking. Both the OIG and GAO data were not peer reviewed, or subject to any of the necessary scrutiny that the information quality guidelines require. LTCPA thus requests that CMS reformulate the proposed rule based upon valid, verifiable, and complete data.

Further complicating the proposed rulemaking is the fact that CMS is basing its reform decisions on data included in the GAO and OIG reports cited in the proposed rule that were published in 2001 based on information gathered in years prior to 2001. Therefore, they do not take into consideration updated market prices or updated market practices. Before relying on data in these

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[18] http://www.hhs.gov/infoquality/CMS-9-20.htm

[19] http://www.hhs.gov/infoquality/CMS-9-20.htm

[20] Michael Johnsrud, PhD., et al. "A Review of the HHS Office of Inspector General Report: Medicaid Pharmacy- Actual Acquisition cost of Brand Name Prescription Drug Products," The Center for Pharmacoeconomic Studies, The University of Texas at Austin, December, 2001 (p. 2-3).

[21] id

reports, CMS should update them to reflect the current market. This would delay implementation of a payment methodology in reliance on such reports, but would result in a more accurate payment.

Another complicating factor is that GAO and OIG failed to adequately distinguish the costs of drugs to LTC pharmacies and thus could not compare general acquisition costs to the costs associated for long-term care pharmacy of both drug acquisition and dispensing. GAO discussed pharmacy dispensing generally, but noted in the report that it did not analyze certain costs to pharmacy suppliers. It is important to note retail pharmacy dispenses a more limited number of Part B covered products than long-term care pharmacies. Therefore, we strongly recommend that, in developing rules to implement payment reform, CMS take into account factors necessary to assure equitable treatment among drug forms and delivery and dispensing modes by incorporating a payment for dispensing and related services which reflects a pharmacy's true costs.

VI. OPTION 1- COMPARABILITY

A. Introduction

Turning to the four differing proposals, LTCPA understands CMS to have proposed four different methodologies to "reinterpret" AWP. The first, is a "comparability" analysis that, in simple terms, would base Medicare payments on the comparable payment made by carriers in their private plans. As explained above, LTCPA believes that CMS does not have the statutory authority to apply this standard to long-term care pharmacies (comparable circumstances do not exist). Application of such payment rates would have a detrimental affect on long-term care pharmacy operations.

B. Comparability Does Not Exist With Private Plans

CMS is proposing to base Medicare payment on the price Medicare carriers pay in their private plans. This price does not incorporate an adequate payment for the special services provided by long-term care pharmacies. CMS states that if "the service is comparable, then the applicable charge under the carrier's private insurance plan may serve as a limitation on the amount that we pay." Providing drugs in a long-term care pharmacy setting is generally not comparable to the charge for providing drugs under a carrier's private insurance plan. As detailed above, long-term care pharmacies provide a host of services that are not typical to other settings, and therefore charges in other settings are not comparable. Without comparability, the private plan charge should not be incorporated into the Medicare payment to long-term care pharmacies.

Nor are long-term care pharmacy services comparable to the provision of services by a mail order facility, which is often used by private plans. Nursing homes do not have the infrastructure to manage 90 day supplies of drugs being shipped directly to the facility. Nor do mail order facilities have the capability of providing the specialized drug packaging, around the clock delivery, and consultant services that are necessary to ensure patient safety. CMS should clarify in its final rule that the comparability statute will not apply private plan charges from a mail order facility to the provision of services in a pharmacy setting, particularly in long-term care pharmacies.

C. Private Health Plan Rates are Unsustainable

At any given time, depending on the nursing home and the state in which it is located, up to half of "private pay" nursing home residents, or about 10% of the resident population, have some type of coverage through a third party for pharmaceutical expenses. LTC pharmacies bill these private plans directly for payment in some cases, and are typically reimbursed at the same rate as retail pharmacy. In addition, private plans are notorious for providing minimal dispensing fees. LTC pharmacies are able to sustain the current system of low reimbursement from private plans because it is a small portion of their business. LTC pharmacies would not able to sustain broader application of private plan rates of reimbursement, which model the reimbursement rates those plans would pay to retail pharmacy or a physician, because they are too low. LTC pharmacies can sustain private plan rates when a minimal portion of its business relies on such payments; it cannot sustain them for coverage of all Medicare Part B covered drugs and biologicals.

CMS presumes that private plan rates can be comparable to payments made by Medicare. Nevertheless, such charges by private plans can be the result of negotiated terms in contracts with third parties, which may be proprietary in nature. LTCPA is concerned that providers do not have the same negotiating power with Medicare which they may have with private plans. Therefore, providers could be forced to accept a low price in Medicare that does not reflect the beneficial terms for the provider which were negotiated with the private plan. Such a policy would be unfair, and anti-competitive.

D. Statutory Authority

As pointed out by CMS, Section 1842(b)(3) specifically states that payments may be limited to private plan payments "in comparable circumstances." As described above, we do not believe that comparable circumstances exist in applying this provision to long-term care pharmacies (or to oncology practices, for that matter). CMS therefore lacks authority from this statute to apply the comparability option to long-term care pharmacies.

VII. OPTION 2- AVERAGE AWP DISCOUNT

A. Introduction

CMS proposes to reimburse existing drugs and biologicals at 85 percent of AWP, while incorporating a market price determination for new products, as well as those coming off patent. LTCPA asserts that CMS lacks the statutory authority to change the percentage of AWP at which it will reimburse Part B covered drugs and biologicals. LTCPA also opposes the use of a blanket reduction in payment for all drugs, which does not reflect the true acquisition cost plus the cost of dispensing and related services.

B. Statutory Authority

Section 1842(o) of the Social Security Act specifically states that "the amount payable for the drug or biological is equal to 95 percent of the average wholesale price." We believe that CMS lacks the authority to reform Part B payments in a manner inconsistent with this statute. Simply put, 95% is not 85%.

C. 85% AWP Does Not Reflect The Market Price For All Drugs

The OIG and GAO reports relied upon by CMS claim that the AWP overstates the prices paid to wholesalers by pharmacies. Nevertheless, attempts by Medicare to arrive at actual acquisition cost by further discounting AWP will involve guessing at the relationship between selling price and AWP. As shown even in the GAO and OIG reports, the acquisition cost calculated as a discount from AWP can vary significantly by drug. LTCPA believes that a methodology which simply embraces further reductions will only enhance the problems inherent in the current system. Such a policy would not be consistent with the principle of fairness, which should be a fundamental principle of payment reforms, as discussed above.

Retail pharmacies are not required to stock all drugs and biologicals, and therefore they will be able to implement adverse selection in not stocking products on which they cannot profit (i.e. the 85% AWP reimbursement does not cover their costs of acquiring and dispensing those particular products). Long-term care pharmacies do not have this option. Being under contract with a nursing home, the long-term care pharmacy is typically required to provide any medically necessary drug prescribed to the nursing home resident. As a result, a blanket decrease in the AWP reimbursement rate will disproportionately impact long-term care pharmacies.

The CMS proposal also fails to account for time lags in the reporting and documenting of AWP prices, and it inappropriately locks purchasing entities (such as LTC providers) into an old, and usually outdated, AWP from the prior April for the entire following calendar year. Pharmacy pricing is far more flexible and dynamic than the proposal would allow, and the impact of CMS' proposal will be to eliminate constant downward pressures on pricing that pharmacies can exert on manufacturers, and instead replace them with a very static, inflexible system, which will cost all participants additional funds. CMS's proposed time lag and inflexible system will cause greater harm than good, and is simply unworkable in today's marketplace.

The AWP for a drug can change day to day. Commercially available databases currently used by CMS, as well as all other participants in the drug distribution, purchase these databases, which can be adjusted by computers on virtually a daily basis, and certainly at least once a week. Thus, to the extent that CMS chooses this model, LTCPA urges CMS to modify its proposal and require that the agency conduct routine, weekly updates of AWP prices, in order to incorporate up-to-date price increases which are being sustained by pharmacists and physicians.

Further, to the extent that CMS adopts this proposal, we urge CMS to modify its Part B drug reimbursement to an "NDC" based model, rather than by using the lowest of an aggregate of prices for the same drug and blending them into a HCPC J-Code. CMS's current methodology unfortunately artificially dampens the calculated "AWP" by using the "lowest common demoninator" or prices for any particular drugs, even if that drug source is not widely available for a sustained period of time. By moving to a pure AWP model, with no-less-than weekly tape updates, CMS can reimburse based upon actual NDC, rather than a blended, and distorted, price.

D. CPI is Not A Fair Methodology For Updating Prices

An additional flaw in the structure of CMS's proposal is the "delay" built into the proposed system. As CMS already knows, drug prices cannot be predicted to increase by the CPI for medical care each year. There are unforeseeable market forces which can increase the fair market price of a drug beyond the percentage increase in the CPI for that year. As stated above, long-term care pharmacies are under contract with nursing homes and are unable to choose the drugs which they will dispense. They will be forced to suffer losses on drugs whose prices increase beyond the CPI. If CMS is determined to find a different index for updating prices, we believe that the Producer Price Index (PPI) is a more accurate tool and would suggest that CMS replace the CPI index with the PPI index.

E. Exempt Long-Term Care Pharmacies

Even if adopted, long-term care pharmacies should remain exempted from the 85% AWP rate to compensate for the services associated with dispensing to nursing home residents and until CMS has developed a fair and effective manner in which to reimburse these pharmacies for the $11.30 dispensing cost. As already explained, LTC pharmacies have operation costs which far exceed other providers, as discussed above in reference to the BDO Report. We understand that CMS is seeking to eliminate cross subsidization of acquisition costs for services involved in providing drugs. But it is important to note that CMS does not in this rule propose to pay long-term care pharmacies a fee which would fairly compensate for dispensing and related services. Until CMS adopts such a fee, LTC pharmacies should remain reimbursed at 95% AWP.

VIII. OPTION 3 – MARKET MONITORING

A. Widely Available Market Prices (WAMP) Are Not Applicable to Long-Term Care Pharmacies

WAMP does not include the cost of services associated with dispensing to nursing home residents. Therefore, if adopted, CMS should exempt long-term care pharmacies and continue to reimburse Part B covered drugs at 95% AWP when dispensed to a nursing home resident.

B. Definition of WAMP

CMS defines WAMP as "the price that a prudent physician or supplier would pay when purchasing the drug from common sources." Yet for drugs not analyzed by GAO or OIG, CMS is proposing to primarily rely on manufacturer data of its sales price to determine WAMP. This does not take into account the fact that pharmacies are at the end of the distribution chain, and are not necessarily acquiring drugs at the same cost that wholesalers acquire them from manufacturers. To reflect true market price, CMS must take into consideration that prices will increase along the distribution chain. It has failed to do so.

Also, CMS does not provide clear standards for the information which it will gather from sources of market-based pricing data. As such, LTCPA is concerned that CMS could incorporate pricing data from a distributor which does not operate nationally, and apply that price to the Medicare payment rate even though that price may not be available in other regions. In addition, there are distributors in the marketplace which are open for business for short periods of time, and which exist for the purpose of making a few quick sales of drugs at extraordinary low prices. These entities tend to

close for business once they have sold their entire stock of drugs. Such prices are not indicative of the true acquisition cost for most providers. Therefore LTCPA proposes that CMS create standards for the data on which it will rely to determine WAMP. First, the data must reflect the price at which entities sell drugs and biologicals nationally, not just regionally, so that they truly are "widely" available. Second, CMS should rely only on data which derives from entities that have longevity in the marketplace, having been in the business of selling any particular drug and biological for at least 18 months.

Lastly, LTCPA is concerned that CMS does not propose to update the WAMP on a regular basis. Market dynamics are such that the acquisition cost for a product can change daily, rendering the CMS determination of the market price meaningless when prices change. LTCPA believes that CMS should update the WAMP at least quarterly to more accurately reflect the market price during a given year. Though WAMP will change even within quarters, we believe that quarterly updates would at least provide better protection to Medicare providers than yearly updates.

C. Paperwork

This option has the potential to be a large administrative burden for providers and CMS alike. As proposed, it can be expected that CMS would be gathering data from many sources to determine the market price. CMS emphasizes in the proposed rule that it will make public any information on which it relies to establish a Medicare payment rate. Therefore, before relying on such data, CMS would have to allow affected providers to comment on the accuracy of such data. CMS proposes to incorporate several sources of data into its determination of WAMP in the proposed rule. In order to be responsive and diligent participants in the Medicare program, providers will be burdened with the responsibility of constantly reviewing data on which Medicare proposes to rely to determine WAMP. This responsibility would be a costly burden, requiring additional staff and resources, and ultimately increasing health care costs generally.

IX. OPTION 4 – COMPETITIVE ACQUISITION

A. Inappropriate Model For Nursing Home Residents

LTCPA strongly believes that the competitive acquisition model is inappropriate for the long-term care pharmacy setting. Many Medicare-eligible beneficiaries live in nursing homes and require specialized services to accompany their drug regimen. Otherwise, these patients are at high risk for medication errors and adverse health events. Long-term care pharmacy services, including specialized packaging, 24/7 delivery, drug utilization reviews and a wide range of emergency services, are currently provided to the majority of nursing home bound Medicare beneficiaries by one long-term care pharmacy. If institutionalized beneficiaries are forced to receive their medications from various contractors, special pharmacy needs will not be provided. The contractor model would undermine the one nursing home-one pharmacy model which protects patients from medication errors and promotes patient safety. This model for reform would not be easily administered in the nursing home setting, which contradicts the principle of ease in administration that LTCPA argues above to be vital for payment reform.

B. Average Sales Price (ASP) Does Not Reflect The Market Price Of All Drugs

LTCPA strongly opposes reliance on ASP as the basis for Medicare payment rates. CMS proposes to use a percent of the ASP as the Medicare payment rate for drugs and biologicals not covered by the competitive acquisition model. CMS defines ASP for a drug for a quarter as the manufacturer's total sales for the quarter, less any sales exempted from the ASP calculation, divided by the total number of units of such drug sold by the manufacturer in such quarter, less any units from sales exempted from the ASP calculation. Those prices change quarterly, based on previous quarter sales data. LTCPA believes that this methodology will tend to understate prices available to smaller purchasers and will be difficult to use as a reimbursement benchmark because of its administrative complexity.

Because prices would change by quarter, reliance on ASP would not be consistent with the principle of predictability, which LTCPA identified above and which should be an underlying principle of any payment reform. As defined by CMS, ASP is not a published number. It is determined quarterly in looking back at manufacturer sales. As such, it is determined after the fact, or in this case, after the sale. LTCPA is concerned that the Medicare reimbursement rate under this model will not reflect the price at which providers are acquiring drugs in that quarter, but instead will reflect the price at which providers acquired drugs in the previous quarter. If the ASP for the current quarter is applied, then providers would not be reimbursed for drugs until after that quarter has ended, causing a long time lag before being reimbursed. In addition, providers would have no way to know the amount which they can expect to be reimbursed at the time the drug is dispensed.

Even an add-on to ASP may or may not cover the cost of a Part B covered drug or biological. As noted by CMS in its proposed rule, the market varies for each product. Again, LTCPA believes a blanket reduction in the reimbursement rate, as would result from a reliance on ASP, would have a disproportionate impact on long-term care pharmacies.

C. Wholesale Acquisition Cost (WAC)

For physicians not choosing the competitive bidding model, CMS is proposing that multi-source drugs be reimbursed at the lesser of the chosen percent of ASP or WAC. WAC is to be based on the manufacturer list price for the drug to wholesalers and direct purchasers. LTCPA members do not typically acquire drugs at WAC, but instead are often required to pay a price above WAC, being last in the distribution chain. Therefore, we are concerned that reimbursement at WAC is an inappropriate benchmark, particularly for long-term care pharmacies.

In the marketplace, once WAC is determined, payers add a percentage to WAC to arrive at a "reasonable" estimate of actual acquisition cost. The extent to which this index is accurate depends on the accuracy of the survey data which is the basis of the add-on. Low-volume pharmacies particularly will be disadvantaged if they aren't able to access drugs at the same cost they are acquired by wholesalers, i.e. WAC. Even in the current market, the methodology used to arrive at the add-on has the potential to under-reimburse pharmacies for ingredient costs (as is the case with AWP). To eliminate that add-on is unsustainable in the pharmacy setting, particularly for long-term care pharmacies which have the additional costs of dispensing and related services.

X. THE PROPOSED RULE COMPLETELY FAILS TO ADDRESS POTENTIAL IMPACTS ON LONG-TERM CARE PHARMACIES.

A. Introduction

As is reflected in our comments above, each of the four options presented by CMS in the proposed rule will result in a reduction in payments for Part B covered drugs. LTCPA appreciates that CMS has understood that oncology doctors have long subsidized their insufficient practice service reimbursement by collecting generous reimbursements on the oncology drugs themselves, and that oncology practices must be given a simultaneous increase in practice expense reimbursement if drug reimbursement is reduced as CMS proposes.

Unfortunately, the very same subsidization problems exist in the long term care pharmacy context. Pharmacy costs include not only the ingredient cost of the drug itself, but also the administrative cost of dispensing. However, the proposed rule makes no provision for increased payment for dispensing services to long term care pharmacies under Part B.

Long-term care pharmacies are not treated as physicians are treated; there is no fee schedule for pharmacies. Therefore, to treat long-term care pharmacies fairly, it will be necessary for CMS to provide a payment for unit-dose packaging, 24-hour emergency services, and medication management which are currently not paid for at all by the federal government. Section 1842(o)(2) of the Social Security Act authorizes such a payment. A blanket reduction in Part B drug payments to address "cross subsidization" in the long-term care pharmacy setting would simply leave pharmacy providers unpaid for vital services, and potentially threaten patient care and safety.

B. CMS Should Exclude LTC Pharmacy From The Scope of Its Rule and Leave LTC Pharmacy At Current Reimbursement Rates Until The Agency Accounts for the $11.37 Cost That LTC Incurs In Dispensing Each Drug and Develops a Mechanism to Provide Those Fees To LTC Pharmacy.

In order to be consistent with the goal of clinical integration, as proposed by LTCPA, CMS should exclude LTC pharmacy form the scope of its rule until the agency can study the administrative costs of dispensing pharmaceuticals to nursing homes. If CMS intends to eliminate the practice of potential overpayments for drugs subsidizing payments for related services in dispensing the drugs, then it will be imperative that CMS understand the real costs involved, and begin to fairly compensate for those services. Until such a study is complete, CMS should exclude from the scope of its rule any reduced reimbursement to LTC pharmacy, which should remain at today's existing levels (95% AWP).

To aid CMS in its analysis, LTCPA submits for the record its own study of dispensing costs, that demonstrates the average cost for an institutional LTC pharmacy provider across the United States of distributing drugs is $11.37 per scrip. A copy of the study, also attached, represents a baseline for CMS in analyzing the service costs of dispensing part B prescription drugs. As explained in great detail above, long-term care pharmacy providers provide extensive services to nursing home residents, which far exceed the costs of regular dispensing conducted by retail pharmacy. As such, LTCPA recommends that CMS recognize such costs, just as they propose to do for oncology administration services, by providing a dispensing fee to cover these costs.

XI. REGULATORY IMPACT ANALYSIS

As provided in these comments, the actions of CMS to reform reimbursement of Part B covered drugs and biologicals could have a drastic impact on pharmacy providers. As CMS notes in its proposed rule, it is required under the Regulatory Flexibility Act to analyze regulatory options for small businesses and other entities. CMS also notes that physicians and non-physician practitioners are small businesses under the FRA if they generate revenues of $8.5 million or less. CMS also includes an analysis of DME suppliers and small rural hospitals. LTCPA is concerned that, though its own members do not meet the standard defining a small business, CMS has excluded from its analysis those small long-term care pharmacy entities which provide vital services to nursing home residents, and which could be disproportionately affected by the proposed rule. In fact, CMS does not address community pharmacy at all in its regulatory impact analysis.

LTCPA believes that CMS is not in compliance with the Regulatory Flexibility Act until it conducts a regulatory impact analysis reviewing each proposed option and its impact on community pharmacy providers, particularly long-term care pharmacies. CMS notes in its proposed rule that it must conduct such an analysis unless it can certify that a rule would not have a significant economic impact on a substantial number of small entities. LTCPA has provided extensive comments above which outline the necessary services provided to nursing home residents in the interest of patient safety and quality of care, and the significant impact of payment reductions when such costs are not addressed by Medicare through an added payment.. As such, we believe that the rule must be reproposed once a valid analysis is complete.