

**VIA Overnight Mail**

September 28, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Comments Submitted Regarding Proposed Rule Entitled:  
Medicare Program Revisions to Payment Policies Under the  
Physician Fee Schedule (FY 2006).**

**Section: Inhalation Drugs and Dispensing Fee**

**File Code CMS-1502-P**

Dear Administrator McClellan:

Lincare Holdings Inc. (“Lincare”) is writing to submit comments to Proposed Rule CMS-1502-P, “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006” (the “Proposed Rule”). Unless otherwise indicated, our comments are directed at those provisions of the Proposed Rule affecting payment for respiratory medications administered through a nebulizer (“inhalation drugs”) and the corresponding dispensing fee.

Lincare is one of the nation’s largest providers of home respiratory equipment and related services to patients in the home setting. Our customers typically suffer from chronic obstructive pulmonary disease, commonly referred to as COPD, such as emphysema, chronic bronchitis or asthma, and require supplemental oxygen, inhalation drugs or other respiratory therapy services in order to alleviate the symptoms of respiratory disease. We currently serve over 600,000 customers throughout the United States through nearly 900 local operating centers and 22 respiratory and infusion pharmacies.

In short, we believe that CMS has an obligation to ensure that the dispensing fee paid to inhalation drug suppliers, including Lincare, adequately covers the necessary costs of supplying inhalation drugs to Medicare beneficiaries. We believe that the dispensing fees established for the 2005 calendar year do not cover the full range of costs incurred by inhalation drug suppliers and, while the changes to a number of longstanding Medicare shipping policies have provided new options to beneficiaries and the inhalation drug suppliers that serve them, these policies have not reduced suppliers’ costs. Indeed, with the pending increase in fuel costs generally, and more recently stemming from the devastation caused by Hurricane Katrina and Rita, Lincare expects transportation and other related costs that depend upon transportation to *increase* in 2006.

While the Proposed Rule predicts that the coverage of metered dose inhalers under the Part D Program will shift a number of beneficiaries away from traditional nebulizer-based medications, there is simply no data available at the present time to support this assertion with an as-of-yet untested Part D program. At a minimum, until additional data is collected by CMS with regard to the conversion of beneficiaries’ longstanding medication needs, Lincare believes it is unwise to gamble with Medicare beneficiaries’ care by adjusting downward the dispensing fee paid to inhalation pharmacy suppliers.

A more detailed summary of our comments follows below.

### ***Background on COPD and Treatments for this Disease***

COPD is the fourth leading cause of death in the United States, following heart disease, cancer and stroke. COPD affects approximately 16 million people, causing significant morbidity from time of onset. Furthermore, it is the only major chronic disease currently increasing in prevalence and mortality. Financially, COPD patients engender a total estimated annual health care cost of more than \$40 billion in the United States alone. Sixty percent of these costs are related to direct medical expenditures (hospital services, emergency department visits, primary care visits, and medication) with the balance being indirect costs associated with morbidity and premature death. Of the total direct medical costs, pharmaceuticals average approximately 10% (\$2.3 billion). Respiratory conditions are attributed with the most frequent reason for hospitalizations, accounting for an estimated 17% of all occurrences.

Inhaled bronchodilators (such as albuterol and ipratropium) are the cornerstone of pharmacological therapy for patients with COPD. The proper use of these respiratory medications can decrease airway resistance and dynamic hyperinflation of the lungs, thereby alleviating the most disabling symptom of COPD, dyspnea, or shortness of breath. Reduction of dyspnea in COPD is the primary goal of respiratory medication therapy, and prudent use of respiratory medications can serve to improve the long-term outcome of the disease in a manner that is both cost effective and minimizes adverse effects.

### ***Costs Incurred by Inhalation Drug Suppliers***

First and foremost, we are writing to provide CMS with information on the various services that inhalation drug suppliers currently furnish Medicare beneficiaries and the associated costs of these services. In addition, we are writing to address whether any of the services being provided by inhalation drug suppliers may be covered through another part of the Medicare program, such as the physician fee schedule or the DME benefit.

To that end, specialty inhalation drug suppliers such as Lincare incur a myriad of costs that should be considered by CMS when establishing or adjusting the dispensing fee to be paid. Inhalation drug suppliers are not typical “retail” or big box pharmacy stores. While some inhalation drugs are relatively common (e.g., albuterol sulfate), other inhalation drugs must be compounded by the supplier based upon specific physician orders. Also, inhalation drug suppliers, such as Lincare, maintain professional staff including pharmacists and respiratory therapists to provide telephonic or in-person patient education and consultative services.

Services furnished by suppliers of inhalation drugs fall within seven broad categories. Those categories, and the percentage of Lincare’s total costs of dispensing inhalation drugs associated with each category, are as follows: 1.) Patient Intake (17.8% of costs); 2.) Compounding, Dispensing and Pharmacy Assessment (19.0%); 3.) Delivery, Set-up and Patient Education (27.3%); 4.) Follow-up and Compliance Monitoring (11.6%); 5.) Quality Assurance, Accreditation, Licensing and Regulatory Compliance (11.0%); 6.) Medicare Billing and Compliance Requirements (9.1%); and 7.) Other Direct and Indirect Costs and Expenses (4.2%). Functionally, the majority of these costs are associated with salaries and related expenses of professional employees, including pharmacists, pharmacy technicians and respiratory therapists, non-professional customer service, support and administrative staff, facility and related expenses (centralized pharmacies and local branch locations), freight and other delivery charges, and business infrastructure costs necessary to operate as a pharmacy and support high quality patient care (MIS and communication systems, licensing and regulatory compliance, accreditation, professional liability insurance).

A more detailed summary of the components of these seven broad categories are set forth below:

## **Patient Intake**

### *Local service center*

- Receipt of patient demographics from ordering physicians
- Receipt of medical information from ordering physicians, including qualifying diagnoses
- Notification of central pharmacy re: medication order
- Verification of patient demographic information
- Verification of beneficiary Medicare coverage and secondary insurer information
- Verification of patient caregiver and/or next of kin information
- Establishment of patient health record in computerized MIS
- Patient assessment by respiratory therapist of clinical condition and assessment of home environment

### *Pharmacy*

- Receipt of verbal or written order for inhalation medications
- Physician contacted to confirm medication order
- Independent database searched to verify physician UPIN number
- Patient pharmacy profile established in computerized MIS

## **Compounding, Dispensing and Pharmacy Assessment**

### *Compounding*

- Specialized facilities (separate from drug storage and dispensing area) and equipment required for de novo pharmacy compounding operations
- Validation and regular review of the compounding process to assure sterility and potency to beyond-use-date of the compounded inhalation medication
- Sterility and dose potency testing of compounded doses
- Specialized training and testing of pharmacists and pharmacy technicians
- Staff competency evaluation and testing
- Environmental monitoring and testing

### *Dispensing*

- Verification of patient demographic information
- Prescription review and verification, including qualifying diagnosis for the ordered medication, dose size and strength, daily dosing frequency (“SIG”) and length of therapy
- Preparation of dispensing label
- Counting and packaging unit doses of medication
- Pharmacist final verification prior to dispensing (correct patient, drug, dose, frequency (SIG), route of administration)
- Pharmacist verification and “wet ink” initialing of prescription label

### *Pharmacy assessment*

- Obtaining information on other medications that the patient may be self-administering
- Assurance that inhalation medications are compatible with other drugs the patient is taking
- Determining other diagnoses and co-morbidities that the patient may be subject to
- Assuring that the inhalation medications are not contraindicated for those secondary diagnoses
- Making patient aware that pharmacy consulting services are available
- Providing a secure, physical space in the pharmacy for “walk in” consulting upon patient request
- Assessing side effects from the prescribed medication

## **Delivery, Set-up and Patient Education**

### *Delivery*

- Packaging and handling of medications for delivery
- Coordinating express and ground delivery services
- Delivery costs: third-party express and ground delivery services, including fuel surcharges
- Obtaining and documenting proof of delivery
- Arrangements for first-dose medication services

#### *Set-up*

- Completion of patient documentation including medical information release forms, HIPAA instruction and compliance forms, certification of patient and/or caregiver training and instruction
- After hours/on-call technical and clinical support

#### *Patient education*

- Instruction of patient and/or caregiver on implementation of drug treatment regimen, anticipated therapeutic outcome and potential side-effects
- Instruction of patient and/or caregiver on proper infection control in the home, safe handling and storage of medications, and emergency preparedness
- After hours/on-call capabilities for home visits for patient set-up, education or troubleshooting

### **Follow-up and Compliance Monitoring**

#### *Follow-up*

- Assessment of patient's retained knowledge of equipment use and purpose of therapy, safety and infection control procedures
- Handling of changes in patient circumstances, including beneficiary change of address, disconnected telephone, change of secondary insurer, illness requiring hospitalization
- Handling and processing changes in physician orders and new prescriptions
- Identifying through patient interaction changes in clinical conditions and reporting same to treating physician
- Providing periodic feedback to the physician on patient compliance and progress

#### *Compliance Monitoring*

- Monthly call to verify patient's ongoing medical status and determine if any changes have occurred in medical condition and/or other medication regimen
- Verification of number of doses consumed since last dispensing and number of doses remaining
- In-home visits to patients as required or as established in plan of care

### **Quality Assurance, Accreditation, Licensing and Regulatory Compliance**

#### *Quality Assurance*

- Employee training and periodic validation of competency
- Periodic validation of all service delivery documentation and record keeping systems
- Compliant investigation and resolution
- Compliance monitoring and auditing of company service and support systems
- Customer satisfaction evaluation and follow-up
- Facility and operating equipment maintenance
- Process improvement programs
- Medical waste management and removal

#### *Accreditation*

- Accreditation agency oversight and compliance
- Demonstration of adherence to pharmacy operations, compounding guidelines promulgated by the United States Pharmacopoeia

#### *Licensing*

- Separate pharmacy licensing and renewal for all states into which inhalation medications are dispensed
- Separate pharmacist licensing and renewal for certain states into which medications are dispensed, as required by state pharmacy regulations
- Special local water and sewage disposal licensing and permitting
- DME distributor licensing

### **Medicare Billing and Compliance**

- Collection and verification of all required documentation

*(Verbal and written order documentation, patient demographic and insurance information, physician demographics and license information, delivery tickets and proof of delivery, proof of initial and ongoing*

*medical necessity, medical information releases, proof of receipt of information privacy notices, proper HCPCS coding of all items dispensed and delivered)*

- Invoice preparation and claim submission to Medicare, secondary insurer and the patient (co-payment and/or deductible)
- Computer systems for electronic batching and transmission of invoices
- Personal financial assessment in the event waiver of co-payment is requested or required
- Collection follow-up procedures
- Posting of payments to individual patient accounts
- After appropriate appeals and collection efforts, write off of unpaid bills as bad debt

#### **Other Direct and Indirect Costs and Expenses**

- Corporate oversight of quality and regulatory systems
- Employee benefits management
- Professional and business liability insurance
- Management information and records management systems
- Communications and networking expenses
- Facility and equipment operating costs, rent, repairs and maintenance
- Mileage/fuel reimbursement for field staff making home visits

At Lincare, we provide these services to facilitate a high level of patient care and, importantly, to manage a patient's COPD or other related illness. At Lincare, and other similarly situated inhalation drug suppliers, we are not merely filling and dispensing drugs to a patient. At Lincare, we offer critical components of the total respiratory services required by patients which go far beyond mere drug dispensing.

We would note that CMS is bound to make payment for Medicare covered items and services in a manner that approximates the costs of the supplier's furnishing of such items and services or be comparable to charges of similarly situated suppliers. Specifically, Section 1842(b)(3) of the Act requires that CMS pay a reasonable cost or charge for any item or service covered under Part B of the Medicare Program. While no "specific" statutory formula has been established regarding the "dispensing fee" calculation, the general statutory payment provisions which mandate that Medicare payments for Part B items and services be "reasonable" should be considered by CMS when calculating a dispensing fee paid to licensed pharmacies furnishing inhalation drugs.

CMS' regulations implementing the statutory mandate of Section 1842(b)(3) also make clear that Medicare must pay a reasonable charge for any covered Medicare Part B item or service and clarify that the Act affords CMS flexibility in determining what is reasonable. See, 42 C.F.R. § 405.500 et. seq. Specifically, the regulations provide that "the law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for." 42 C.F.R. § 405.502(a). The regulations include certain criteria to assist CMS in determining reasonable charges.

CMS has a longstanding history of recognizing services as "related to patient care" and reimbursing providers for these services. Accordingly, CMS should consider all reasonable costs when establishing the costs of the dispensing fee to be paid to inhalation pharmacies that furnish inhalation drugs. Reimbursable patient costs can and should include, among other things, patient set-up, delivery, pharmacy staff, patient refill and related compliance activities, regulatory compliance and risk management, patient/caregiver education and training, facility costs, billing, quality assurance and drug utilization review, and accreditation and licensing activities.

Lincare further believes that the agency has failed to undertake any meaningful study of the costs associated with inhalation drug dispensing services in direct contrast to its prior commitment to the industry. Of note, the final 2005 Physician Fee Schedule expressly states that CMS is "continuing to study these services and associated cost categories as the new payment systems are implemented and we gain experience with them. We intend to revisit this issue and proceed through notice and comment rulemaking in order to establish an appropriate dispensing fee for 2006." 66 Fed. Reg. 66236, 66339 (November 15,

2004). To our knowledge, and notwithstanding the agency's express commitment to study this issue before establishing a dispensing fee in 2006, it has not done so. Instead, the Proposed Rule suggests, without a single published agency study to date that the fee is too high and simply requests that the industry supply CMS with data by September 30, 2005.

We believe that the agency has failed to fulfill its prior commitment to the industry to study this issue in depth and, more importantly, has shirked its APA notice and comment rulemaking obligations to collect meaningful data for a service that could have adverse consequences to Medicare beneficiaries. We strongly encourage CMS to collect and publish the available data in a subsequent rulemaking notice, giving all interested parties an opportunity to comment on the data before establishing a final dispensing number for 2006. This is the standard rulemaking process that CMS follows for other all other Part B RVU adjustments as well as the process employed by CMS throughout the entire Part A program.

As CMS is aware, in October, 2004, CMS released a copy of its letter to the Department of Health and Human Services commenting on a draft report by the Government Accountability Office (GAO) entitled "Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs." CMS noted the extreme variation that the GAO found in the costs of dispensing inhalation drugs to Medicare beneficiaries. GAO found that 2003 per patient monthly costs of dispensing these medications ranged from a low of \$7 to a high of \$204.

Further, CMS has considered an industry-sponsored study prepared by Muse & Associates entitled, "The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries." The Muse study was based on a survey of 109 pharmacies representing 2,448 branch locations and providing services to 337,348 Medicare beneficiaries (estimated by Muse to represent 61% of all Medicare inhalation drug therapy patients in the first quarter of 2004). The Muse study concluded that a dispensing fee of \$68.10 would be necessary to maintain existing levels of service to Medicare beneficiaries and provide an average operating margin of 7% to inhalation drug pharmacies. Muse also estimated that a \$68.10 dispensing fee, in combination with federally-mandated reductions in Medicare payment amounts for inhalation drugs, would result in \$4.0 billion to \$7.0 billion in program savings over a 10-year period. After reviewing the information from the GAO survey, the Muse study and other comments, CMS indicated that it believed that \$55.00 to \$64.00 per month is a reasonable range for a 2005 dispensing fee. CMS ultimately set the dispensing fee at \$57.00 in its 2005 final rule, CMS-1429-FC.

In short, the only studies that have been conducted (both GAO and industry supplied) more than support the current dispensing fee established in 2005 and, further, both suggest that there is ample data to support a *higher*, not *lower*, dispensing fee in 2006.

Of significance, Lincare estimates that the combined drug payment reductions will produce \$10.5 billion of federal budget savings over 10 years, in contrast to the initial CBO estimates of only \$4.2 billion. Accordingly, Lincare believes that the payment reductions will have a far greater adverse impact on DMEPOS suppliers than predicted by CBO or CMS—further warranting extreme caution when considering any modifications to the dispensing fee to be paid to DMEPOS suppliers. Since CMS now is approaching one year's worth of claims data under the new ASP + 6% drug payment methodology, Lincare respectfully requests that CMS re-examine the total impact of the inhalation drug cuts in comparison to original estimates and, further, that this study be performed before adjusting the dispensing fee.

Inhalation pharmacy supplier costs have not gone down in 2005, as CMS appears to suggest in its Proposed Rule. To the contrary, inhalation pharmacy suppliers have seen their dispensing costs rise in the past year, as increases in gasoline prices have adversely affected shipping costs through higher fuel surcharges by common carriers and pharmacy wage inflation has added to direct labor costs. Muse & Associates issued a memorandum to the American Association for Homecare in May, 2005, presenting a method for calculating a justifiable annual update in the dispensing fee for home respiratory services. Muse proposes the creation of a Market Basket Index (MBI) that reflects the year-to-year cost increases associated with providing dispensing services to patients. Muse constructed a customized index based on government published inflation statistics for a compilation of goods and services applied to actual industry data. Using this approach, Muse estimates that costs to provide services covered by the dispensing fee increased by

3.2% from calendar year 2003 to calendar year 2004 and suggests that this percentage be used as the increase from 2005 to 2006 as in other areas of the Medicare program that use the MBI approach for annual updates. This would result in a 2006 dispensing fee of **\$58.82, an increase of \$1.82 over the current fee level**. As a point of reference, CMS notes in the Proposed Rule that the percent change in the CPI for medical care for the 12-month period ending June 2004 was 5.1%.

We also point out that the devastation in the Gulf States as a result of Hurricanes Katrina and Rita have significantly impacted business throughout America that depend upon interstate transport to move goods, services and people back and forth. Among others, UPS has notified customers of an increase in fuel surcharge caps to 12.5% effective October 3, 2005, which when implemented will push up the average delivery cost per package by an additional 4% over increases already established for 2005. In the past year, the IRS has increased the deduction for mileage reimbursement for business travel from \$0.375 to \$0.405, an increase of 8%, and has implemented an additional 20% increase to \$0.485 per mile through the end of this year, reflecting the heavy burden of rising fuel costs on businesses. Likewise, the increase in fuel costs is widely noted as the “straw that broke the camels back” for both Delta Airlines and Northwestern Airlines—both of whom have filed for bankruptcy. While the full economic impact of Hurricanes Katrina and Rita may not be known for some time, we believe it is inappropriate at this point in time for CMS to further reduce payments to inhalation drug suppliers.

Lincare also reminds CMS that it is expected to implement additional quality standards pursuant to Section 302(a) of the Medicare Modernization Act of 2003 (MMA) which requires that the Secretary develop and implement such standards that will be applied by a recognized independent accreditation organization. CMS has just recently published for comment the proposed supplier quality guidelines pursuant to public rulemaking. The 104-page document sets forth proposed supplier business quality standards and supplier product-specific service requirements. We understand that CMS has indicated that these new quality standards will be implemented as early as April of 2006, which will further impact the costs incurred by all DMEPOS suppliers, including inhalation drug suppliers.

Lastly, we note that CMS seeks input regarding whether any of these additional services are reimbursed through any other code (or combination of codes). While the supplier standards (42 C.F.R. 424.57(c)) require that inhalation pharmacies provide these services, CMS does not, to our knowledge, separately reimburse pharmacy monitoring and compliance, delivery or quality assurance of any of the services listed above. Lincare, like other high quality inhalation suppliers, provides these services to facilitate the provision of medical care for patients with complex medical needs. Given that drugs are reimbursed at ASP + 6%, the dispensing fee is effectively the only way in which these important services will be captured and reimbursed.

In short, at a time where costs of inhalation drug suppliers are *increasing* due to a combination of unforeseen natural disasters, general increases in the CPI, and new regulatory requirements imposed by Congress, Lincare strongly opposes any efforts to decrease the current dispensing fee paid to inhalation drug suppliers. In our view, as reflected in the data listed above, we believe the current 2005 dispensing fee is too low and does not adequately cover the costs incurred by a specialty inhalation drug supplier.<sup>1</sup>

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<sup>1</sup> CMS reports in the Proposed Rule that at least one major chain drug store suggested that a \$25 dispensing fee would be an adequate amount in its submitted comments to last year’s NPRM. We point out that CMS implemented the dispensing fee on the basis of one fee per customer per 30 or 90-day supply, not on the basis of a separate fee *with each dispense* as suggested by the commenter, which makes a comparison to the \$25 figure tenuous at best. The commenter also pointed out that the ASP methodology was not an appropriate model for reimbursement. In light of the fact that CMS proceeded to implement the ASP model, any references to comments submitted before the ASP system took effect can not be relied upon today. CMS reports in the Proposed Rule that another retail pharmacy indicated that “a dispensing fee of five to six times the prior \$5 dispensing fee was necessary to cover costs.” We believe that statement to be inaccurate. Lincare believes that the referenced retail pharmacy comments suggested a fee of “5-6 times the current supplying fee” in order to cover costs. We believe the commenter was referring to the \$10 supplying fee proposed by CMS in last year’s NPRM, *indicating a required dispensing fee of \$50*

### ***Impact on 90-Day Supply Provisions***

For calendar year 2005, CMS introduced a 90-day supply option for dispensing inhalation drugs—the Proposed Rule seeks comments on the impact of this new option. The 90-day supply schedule has not been widely chosen by Medicare beneficiaries or their prescribing physicians due to a number of clinical, practical and economic considerations. Monthly shipments foster more frequent patient contact and correspond better with patient compliance protocols. Frequent contact with the patient provides opportunities for ongoing education regarding their lung disease and the importance of adhering to the physician prescribed drug regimen to produce a positive health outcome. Even with frequent contact, prescription compliance is challenging among our patients, with compliance rates, as measured by monthly reorders, of approximately 50% for all active patients and 74% for long-term patients on therapy for more than a year.

In addition, there is reluctance on the part of patients to receive a 90-day supply of drugs at one time, not only due to the sheer number of medication vials that need to be stored and refrigerated, but for economic reasons as patients receive larger, quarterly invoices for co-payments due in the month of shipment as opposed to a more manageable monthly payment cycle. As CMS is well aware, many seniors are on a fixed and sometimes limited budget. While 90-day drug supply arrangements are prevalent in the private sector, patients are frequently encouraged to use such programs for maintenance medications by reduced and/or waived copayments offered by the applicable commercial payor. Medicare does not offer such a discount and, indeed, waiver of any coinsurance amounts otherwise due a provider or supplier may subject that provider to fines or penalties.

Provision of 90-day drug supplies also work better for maintenance medications with a stable and managed medical condition such as certain types of heart disease (e.g., cholesterol medications) and/or diabetes. In the COPD population, patient prescriptions (type of drug, dosage, frequency of administration) often change within a 90-day period due to side effects, dosage efficacy or other factors. These changes can occur frequently at the start of therapy as the physician adjusts treatment in accordance with the patient's pulmonary response to the therapy. Additional changes occur over time due to the progressive nature of chronic lung disease, as the patient's lung capacity diminishes.

Our experience with inhalation drug therapy patients indicates an average of 5.1 prescription changes in the initial year of drug therapy, with 32% of active patients with one to three prescription changes and 68% with four or more changes per year. Shipping on a 90-day supply schedule would likely result in an excessive supply of unused medications. Additionally, patients may terminate therapy due to death or other circumstances within a 90-day period with unused supplies of drugs on hand. CMS has not addressed how a supplier should handle drugs not used by beneficiaries who may die before running out of drugs and, at least in other areas of the Part B program, suppliers have been found at fault for items and supplies not used by beneficiaries prior to the date of death.

Lastly, the 90-day dispensing fee established in 2005 is inadequate to cover the costs of dispensing a 90-day supply. In our view, CMS' presumption that a 90-day drug quantity significantly reduces a supplier's costs is flawed. In 2005, CMS established a dispensing fee amount of \$80.00 for a 90-day supply in

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**to \$60.** In any event, Lincare does not believe that the costs incurred by chain drug stores are comparable to those incurred by specialty inhalation pharmacy suppliers. Chain drug stores do not, typically, provide in-home delivery services, respiratory therapy support services, and/or patient education and patient compliance monitoring services (just to name a few). While chain drug stores maintain some inhalation drugs, they do not typically offer the full range of inhalation drugs, including specialty compounded drugs that are requested by many physicians on a per-patient basis. Chain drug stores typically do not employ respiratory therapists who are available to assist patients when drug complications or nebulizer questions arise. Most do not provide billing services to Medicare Part B on behalf of beneficiaries, and require payment of the 20% co-payment in cash at the point of sale.

comparison to a \$57.00 fee for a 30-day supply. Supplying larger dose quantities with less frequency would reduce certain variable costs associated with providing inhalation drug therapy, primarily in the areas of freight costs (modestly offset by larger package size and weight) and opportunities for certain staff reductions due to lower dispensing volumes and less frequent claim submission; however, a majority of the fixed costs remain the same. At a minimum, we estimate that the 90-day dispensing fee should be approximately \$130 in order to encourage pharmacies to shift to a 90-day supply. However, even at that fee, we believe that the clinical and practical considerations of shifting to a 90-day supply would limit the adoption of the practice by inhalation drug suppliers for the reasons outlined above.

### ***Revised Time Frame for Delivery Refills***

CMS seeks information on how revised guidelines regarding the time frame for delivery of refills has affected the need for overnight delivery services and the extent to which suppliers have shifted their shipping to ground services. Our mix of ground and express shipments has changed only slightly in 2005 versus a year ago. In calendar year 2004, we shipped 58.2% of our volume overnight or express and 41.8% ground. This year, our overnight and express shipments account for 57.7% of volume, with ground comprising 42.3%. One of the challenges with moving more volume to ground is the irregular ordering patterns of many patients. Many patients simply wait until they are out (or virtually out) of medication before authorizing a refill, precipitating the need for overnight delivery. Medicare rules require that the DMEPOS pharmacy not allow more than a 30-day supply of drugs on hand (assuming a 30-day supply schedule). While CMS has attempted to mitigate the impact of this by allowing shipments to occur on the 25<sup>th</sup> day of a 30-day shipment cycle thereby allowing overlapping claims for drug payments, we have experienced numerous problems with claims processing by the DMERCs for the associated dispensing fee (HCPCS code G0371). The DMERC claim processing systems were set up to process G0371 as “one unit per 30-day period.” We have received tens of thousands of dispensing fee claim denials as a result, with DMERC systems unable to reconcile dispensing fees that may occur within 25 to 29 days of each other. While Lincare is pursuing an adjustment of these claims through the appeal processes, this has resulted in additional costs being incurred by Lincare personnel, considerable frustration when dealing with the DMERCs and, most importantly, a significant delay in receiving proper payment. While we are aware that CMS has instructed the DMERCs to rectify this claims processing problem, we have not seen a complete resolution of the issue.

### ***Impact of Metered Dose Inhalers Under Part D***

The Proposed Rule appears to suggest that the availability of metered dose inhalers (MDIs) under Medicare Part D will impact the need for traditional inhalation drugs furnished in connection with nebulizer devices which are currently covered under Part B. We disagree with this presumption. Over the past decade, MDIs have become the first line of therapy for the vast majority of patients with airway disease. Most clinicians with whom we work agree that nebulizers are prescribed for administering bronchodilator medications to patients with severe disease at risk for hospitalization and those incapable of using MDIs for a variety of reasons, including inadequate manual dexterity, poor inspiratory effort and mental impairment. In considering this particular aspect of respiratory medication delivery, there can be no doubt that a certain percentage of the patient population does and always will have difficulty performing effective MDI technique. For this portion of the population, of which the elderly Medicare beneficiary is likely to be a significant component, available medical literature may even suggest a contraindication for MDI delivery. It is our belief that the vast majority of physicians are aware of the potential difficulties of MDI delivery and do exercise appropriate judgment on a patient-by-patient basis. Once the need for inhalation therapy is established, the choice of delivery system should, and for all practical purposes does, reside exclusively with the prescribing physician.

Importantly, the push to “switch” beneficiaries from nebulizer-based medications to MDIs may have a significant adverse financial impact on such beneficiaries. By our estimates, beneficiary out of pocket costs in 2006 for MDIs covered under Medicare Part D *will substantially exceed the costs* for inhalation drugs already covered under Part B. Consider the following analysis of projected annual costs for a standard MDI regimen under Medicare Part D for the most commonly prescribed respiratory medications:

<u>MDI</u>	<u>Annual Drug Costs (*)</u>	<u>Patient Deductible</u>	<u>Patient Co-Payment</u>	<u>Part D Premium</u>	<u>Total Patient Cost/Yr</u>
Combivent	\$1,828.71	\$250.00	\$394.68	\$386.40	\$1,031.08
Generic Albuterol	\$83.65	\$83.65	\$0.00	\$386.40	\$470.05
Proventil	\$496.73	\$250.00	\$61.68	\$386.40	\$698.08
Atrovent	\$1,656.83	\$250.00	\$351.71	\$386.40	\$988.11
Advair 250/50	\$1,521.29	\$250.00	\$317.82	\$386.40	\$954.22

(\*) *derived from sample of mail order pricing for retail pharmacies in Florida, New York and California markets as published on [www.medicare.gov](http://www.medicare.gov) website under Medicare-Approved Drug Discount Cards*

**(\*\*) Part D Assumptions:**

*Monthly premium of \$32.20*

*Yearly deductible of \$250.00*

*25% coinsurance up to \$2,250*

*100% coinsurance up to \$3,600*

*5% coinsurance beyond \$3,600*

Beneficiaries under Part B Medicare enjoy the benefit of coverage for inhalation drugs delivered via a nebulizer. The annual patient out-of-pocket costs for a standard regimen of inhalation drug therapy ranges between \$273.30 and \$586.06, including co-payments and annual patient deductibles. In the absence of other considerations, Medicare beneficiaries will experience a *financial loss* in most instances if they were to abandon inhalation drug therapy under Part B in favor of MDI therapy under Part D. In addition, with the announcement by the FDA that MDIs using chlorofluorocarbon (CFC) propellants must no longer be produced, marketed or sold in the United States after December 31, 2008, it is expected that new CFC-free MDIs may be more expensive than the CFC-containing products they replace. In short, MDIs are not a fungible substitute for traditional inhalation medications and, indeed, beneficiaries' costs and consequently, the Medicare Program's costs, may actually increase with the availability of MDIs under Part D.

***Conclusion***

As CMS is well aware, the availability of inhalation medications to patients in the home setting is met by a relatively small number of niche pharmacies that are able to meet the unique distribution and patient care needs of these Medicare beneficiaries. Changes in reimbursement for inhalation drugs, first taking effect in 2004 with a reduction in the AWP-based payment rates for inhalation drugs, and in 2005 with the implementation of the ASP-based reimbursement system with dispensing fee, have had a *significant economic impact on Lincare* and other home respiratory therapy providers. We have witnessed both local and national inhalation pharmacies withdraw from the provision of inhalation drug therapy and expect continued consolidation in the market.

At Lincare alone, we estimate that there was a *\$54 million reduction* to our revenues in 2004 and project an additional reduction of approximately *\$140 million in 2005* as a result of these reimbursement changes. Lincare has worked hard to preserve a consistent level of high quality care for the home respiratory patient. Over the past year, we have found ways to become more efficient in the delivery of care to our patients through process improvements, improved productivity and, where possible, modest staff reductions. We remain concerned that CMS continues to discount the nature and type of services that an inhalation pharmacy supplier offers to Medicare beneficiaries. We are concerned that CMS' apparent efforts to reduce the dispensing fee to some arbitrary amount, perhaps as suggested by a national chain drug store (in comments submitted over a year ago, prior to the implementation of the ASP reimbursement system, and which may have been misconstrued), would significantly disrupt access to these inhalation drugs by Medicare patients suffering from COPD and other pulmonary diseases. Certainly, this was not the intent of Congress in passing legislation in 2003 to expand coverage for prescription drugs for Medicare beneficiaries.

Lincare wishes to thank CMS for the opportunity to comment on the Proposed Rule. We support CMS in its efforts to validate the payment mechanism for inhalation drugs and recognize that balancing the fiscal realities of the Medicare program against maintaining quality health care and access to needed drugs are the primary objectives of sound administration of the program. We believe that access to these critical medications and related therapies can only be preserved by maintaining the current \$57.00 dispensing fee and, indeed, we believe that the data actually supports an *increase* rather than a *decrease* to the current dispensing fee. We encourage CMS to carefully consider the data submitted by all suppliers and, if necessary, to propose a supplemental rulemaking that will outline the process to collect this data and/or we encourage CMS to engage appropriate experts to fully and finally evaluate the necessary services and costs associated with the dispensing of inhalation drugs to Medicare beneficiaries.

Respectfully submitted,

/Paul G. Gabos/