



## AMERICAN ASSOCIATION FOR RESPIRATORY CARE

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BY HAND DELIVERY

September 24, 2004

The Honorable Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

RE: **[CMS-1429-P] Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005**

Dear Dr. McClellan:

On behalf of the American Association for Respiratory Care (AARC), I am pleased to submit comments on the proposed rule published in the *Federal Register* on August 5, 2004, to revise payment policies under the physician fee schedule for calendar year 2005. Our comments focus on two specific areas of the proposal:

- **Coding – Respiratory Therapy**
- **Section 305 – Payment for Inhalation Drugs**

The AARC is the national professional association representing 35,000 respiratory therapists who treat high risk patients with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD) including emphysema and chronic bronchitis. The AARC is a member of the U.S. COPD Coalition, represented on its executive committee and on a subcommittee that serves as an advisory body to the Congressional COPD Caucus. One of the primary goals of this activity is to make Americans aware of COPD, encourage early detection, and promote treatment and management based on guidelines supported by the medical community.

An indispensable component in the treatment and management of patients with COPD is the use of inhalation drugs administered through nebulizers, metered dose inhalers (MDIs) or dry powder inhalers (DPIs). The majority of AARC's comments on the proposed rule will focus on

payment for inhalation drugs, however, we wish to first offer a brief comment on the respiratory therapy G codes.

## **Coding – Respiratory Therapy**

**The AARC supports the proposal for a national pricing of respiratory therapy service codes G0238 and G0239.**

### **Section 305 – Payment for Inhalation Drugs**

**The AARC is concerned that the drastic cut in reimbursement for Part B inhalation drugs will significantly limit or eliminate patient access to these important medications.**

We understand the government's concern with a payment formula using the Average Wholesale Price (AWP) versus using the Average Sales Price (ASP). However, the 89 percent reduction in reimbursement from 2004 levels under the ASP payment formula in addition to the 15 percent reduction from 2003 levels under the current AWP payment formula is a steep cut for any industry to bear within such a short timeframe. We believe that this cut will jeopardize patient safety given the inordinately high dependence on albuterol evidenced by the amounts used by many patients. This safety concern can be minimized by management of patients with COPD with anticholinergics, steroids, and other medications as called for in guidelines such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD)<sup>1</sup> and the Global Initiative for Asthma (GINA).<sup>2</sup>

**The AARC supports an increase in the dispensing fee for inhalation drugs.**

Although we are not in a position to offer specific recommendations on a drug reimbursement formula and realize that any change may require legislative action by the U.S. Congress, we do support an increase in the dispensing fee for these drugs to help offset costs including, but not limited to:

- Pharmacy operating costs such as pharmacy personnel, inventory, and home delivery;
- Facility costs such as rent furniture and fixtures, utilities, and information systems;
- Customer service costs including 24-hour on call support, and
- Administrative costs such as monthly follow-up of patients, claims processing, quality improvement programs, regulatory compliance, professional liability insurance, and other general and administrative overhead costs.

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<sup>1</sup> “Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease,” Global Initiative for Chronic Obstructive Lung Disease (GOLD); National Heart, Lung, and Blood Institute 2001 (revised 2004), NGC: 003777.

<sup>2</sup> “Global Strategy for Asthma Management and Prevention,” Global Initiative for Asthma (GINA); National Institutes of Health 1995 (updated 2003), NIH Publication No. 02-3659.

We do not recommend that any increase in the dispensing fee be considered transitional until the implementation of the Medicare Part D drug benefit in 2006. This critical fee must remain an integral component of any future drug reimbursement.

**The AARC supports the cost effective management of Medicare patients requiring inhalation drugs. However, the proposed rule does not recognize that high uses of albuterol may indicate over utilization.<sup>3</sup>**

Studies indicate that patients using short acting beta agonists (i.e., albuterol) alone or as a primary therapy frequently are not on an appropriate treatment regime that includes use of a short acting beta agonist, longer acting beta agonist, steroid, or anticholinergic drugs.<sup>4</sup> Medicare's costs related to the use of albuterol may be due to fact that alternative drug treatment regimes are not adequately considered in the management of the patient's disease.

A study<sup>5</sup> published in the Annals of Pharmacotherapy of almost 11,000 asthma patients demonstrated that using high doses of short acting beta-2 agonists results in the hospitalization of most patients. The study concluded that most patients receiving these drugs are not managed in accordance with recent guidelines by the National Heart, Lung and Blood Institute (NHLBI) and the National Asthma Education and Prevention Program (NAEPP). Studies indicate that drug costs decrease with the implementation of guidelines on drug use as well as periodic spirometry to monitor the effectiveness of management by general practitioners.

AARC urges the Centers for Medicare and Medicaid Services (CMS) to examine the underlying causes of high utilization rates of albuterol. There is a large amount of scientific evidence which concludes that high albuterol use is indicative of poor overall disease management. We believe the best way to manage the cost of these drugs is to undertake steps to insure compliance with guidelines, such as GOLD and GINA, on effective drug management of pulmonary diseases. Unless CMS is willing to address drug management concerns, it will not achieve true long-term cost savings. It is reasonable to expect that reducing the reimbursement for inhalation drugs will trigger an increase in emergency room visits, doctor visits, and hospital admissions. This anticipated result is consistent with other attempts to constrain health care costs simply by reducing reimbursement for services and supplies.

**The AARC supports coverage under the Medicare Part D drug benefit for inhalation drugs used in MDIs. However, this coverage does not alleviate our concerns regarding patient access to inhalation drugs.**

We believe it is important for patients to use the drug delivery system that most appropriately meets their needs whether it's nebulizers or MDIs. Some patients also depend on receiving these drugs using DPIs which deliver medications that are not available via MDIs or nebulizers. We

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<sup>3</sup> "Redefining Treatment in COPD: New Directions in Bronchodilator Therapy," Lipson D.A.; Tret Respir Med 2004; 3(2):89-95, Jan. 1, 2004.

<sup>4</sup> "The Effect of Inhaled Beta-2 Agonists on Clinical Outcomes in Chronic Obstructive Pulmonary Disease," Mahler D.A.; J Allergy Clin Immunol 2002; 110(6 Suppl): S298-303, Dec. 1, 2002.

<sup>5</sup> "Relationship Between Asthma Drug Therapy Patterns and Healthcare Utilization," Shireman T.I., Heaton P.C., et al.; Ann Pharmacother 2002; 36(4):557-64, Apr. 1, 2002.

share CMS' concern "about significant shifts in beneficiary access to inhalation therapy prior to implementation of the Part D drug benefit in light of the reduction in Medicare payment for inhalation drugs beginning in 2005."<sup>6</sup> However, our concern is not temporary and will not be entirely remedied with the coverage of MDIs and inhalation drugs under the Medicare Part D drug benefit.

According to the proposed rule, ". . . since Medicare currently covers inhalation drugs provided through nebulizers, but not alternative forms of inhalation therapy, there are strong financial incentives toward use of the former compared to alternatives."<sup>7</sup> Furthermore, the proposed rule states that "it is likely there will be a substantial shift of Medicare beneficiaries from nebulizers to MDIs beginning in 2006, even absent the Medicare payment changes for nebulizers and inhalation drugs in 2005."<sup>8</sup> Current clinical practice and previous Medicare policy requiring physicians to attest to the medical necessity for a nebulizer versus a MDI do not support those statements. Prescribing a nebulizer versus a MDI is done without the attending physician having a financial incentive for choosing one drug delivery system over another. Despite the availability of MDIs and DPIs, the use of nebulizers is medically necessary in a significant number of Medicare patients for many reasons including:

- Frailty
- Arthritis
- Sight impairment
- Compromised mental capacity
- Exacerbation of a chronic condition such as COPD
- Inability to understand how to effectively use MDIs
- Inadequate hand/breath coordination
- Inadequate inspiratory force and volume

Both nebulizers and MDIs create a mist which must be inhaled in order to be deposited in the lungs. The proposed rule describes an MDI as a "canister of pressurized medication that is propelled directly into the airways of the lungs when a beneficiary presses on the inhaler and breathes in through the mouth . . ."<sup>9</sup> The fact is that when the mist is created by a pressurized canister or an air compressor, it is considered "nebulized." Patients must breathe in a specified manner in order to bring about effective distribution of the medication throughout the lungs. Maneuvers such as breath holding, adequate inspiratory flow, and hand/breath coordination are indispensable to effective use of all drug delivery systems.<sup>10</sup>

It is erroneous to assume that initiating Medicare reimbursement for MDIs beginning in 2006 will suddenly make this the more appropriate drug delivery option resulting in a "substantial shift" of patients from nebulizers to MDIs. This is especially true given the scientific evidence

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<sup>6</sup> "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule"; Fed Reg 2004; 69(150):47549, Aug. 5, 2004.

<sup>7</sup> Ibid; 47546.

<sup>8</sup> Ibid.

<sup>9</sup> Ibid.

<sup>10</sup> "Special Issue: Consensus Conference on Aerosols and Delivery Devices," Respiratory Care Journal 2000; 45(6):588-769 and 45(7):817-874, June & Jul. 2000.

regarding the lack of knowledge and understanding of appropriate techniques in using MDIs by all but respiratory therapists.<sup>11</sup>

We believe it is the drastic reimbursement cuts to Part B inhalation drugs and not the reimbursement for the drug delivery system that may have the most affect on patient access. Reimbursement cuts make it more difficult to access these drugs and force patients to pay more out-of-pocket costs in order to continue their aerosol therapy. A study in the New England Journal of Medicine<sup>12</sup> found that many patients simply stopped taking their medications when faced with higher out-of-pocket expenses. Most patients without significant financial resources will be faced with the difficult choice to forego these necessary medications or access them through an emergency room visit or hospitalization pursuant to an exacerbation of their respiratory condition.

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<sup>11</sup> Studies Regarding MDI Techniques and Training

“Lack of Awareness of Need to Clean CFC-Free Metered-Dose Inhalers,” Slader C.A., Reddel H.K., Bosnic-Anticevich S.Z.; J Asthma 2004; 31(3):367-73.

“Does Introduction of New ‘Easy to Use’ Inhalation Devices Improve Medical Personnel’s Knowledge of their Proper Use?” Chopra N., Ospreescu N., Fask A., Oppenheimer .; Ann Allergy Asthma Immunol 2002; 99(4)395-400, Apr. 2002.

“Rationale for the Choice of Aerosol Delivery System,” Roche N., Huchon G.J.; J Aerosol Medicine 2000; 13(4):393-404, Winter 2000.

“Evaluation of the Long-Term Effectiveness of Three Instruction Modes for Inhaling Machines,” Van der Palen J., Klein J.J., Kerkhoff A.N., et al.; Patient Educ Couns 1997; 31(1Suppl):S87-95, Dec. 1997.

“Inhaler Use in Chronic Obstructive Pulmonary Disease,” Oliver S., Rees P.J.; Int J Clin Pract 1997; 51(7):443-5, Oct. 1997.

“Metered-Dose Inhaler Technique of Patients in an Urban ED: Prevalence of Incorrect Technique and Attempt at Education,” Shrestha M., Parupia H., Andrews B., et al.; Am J Emerg Med 1996; 14(4):380-4, Jul. 1996.

“Characteristics Predicting Incorrect Metered-Dose Inhaler Technique in Older Subjects,” Gray S.L., Williams D.M., Pulliam C.C., et al; Arch Intern Med 1996; 156(9):984-8, May 13, 1996.

“Medical Personnel’s Knowledge of and Ability to Use Inhaling Devices. Metered-Dose Inhalers, Spacing Chambers, and Breath-Actuated Dry Powder Inhalers,” Hanania N.A., Wittman R., et al.; Chest 1995; 107(1):290, Jan. 1995.

“The Influence of Age, Diagnosis and Gender on Proper Use of MDIs,” Goodman D.E., et al., Am J Respir Crit Care Med 1994; 150:1219-21, Nov. 1994.

“Metered-Dose Inhalers. Do Health Care Providers Know What to Teach?” Interiano B., Guntupalli K.K.; Arch Intern Med 1993; 153(20):2385, 2389, Oct. 25, 1993.

“Assessment of Patient Acceptance and Inhalation Technique of a Pressurized Aerosol Inhaler and Two Breath-Actuated Devices,” Nimmo C.J., Chen D.N., et al.; Ann Pharmacother 1993; 27(7-8):922-7, Jul.-Aug. 1993.

“Nurses’ Performance of Inhalation Technique with Metered-Dose Inhaler Plus Spacer Device,” Self T.H., Kelso T.M., et al.; Ann Pharmacother 1993; 27(2):185-7, Feb. 1993.

“Short and Long-Term Retention of a Nursing Home Education Program on Metered-Dose Inhaler Technique,” O’Connell M.B., Hewitt J.M., et al.; Ann Pharmacother 1992; 26(7-8):980-4, Jul.-Aug. 1992.

“Incorrect Use of Metered Dose Inhalers by Medical Personnel,” Guidry G.G., Brown W.D., et al.; Chest 1992; 101(1):31-3, Jan. 1992.

“Use and Misuse of Metered-Dose Inhalers by Patients with Chronic Lung Disease. A Controlled, Randomized Trial of Two Instruction Methods,” De Blaquiere P., Christensen D.B., et al.; Am Rev Respir Dis 1990; 141(6):1603, June 1990.

<sup>12</sup> “The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending,” Huskamp H.A., Deverka P.A., et al.; N Engl J Med 2003; 349:2224-2232, Dec. 4, 2003.

**The AARC recommends a separate payment for patient/beneficiary training by providers with documented evidence of education, clinical training, and competency testing, such as respiratory therapists.**

Patient training in the use of a nebulizer, MDI, or DPI is a key factor in producing effective treatment outcomes.<sup>13</sup> Respiratory therapists are the only health care providers with specialized education, clinical training, and competency testing in all aspects of respiratory therapy including aerosol and intermittent positive pressure breathing (IPPB) therapies. Respiratory therapists are trained to assess the patient's condition, recommend a course of action to the attending physician, provide breathing exercises, aerosol therapy (using nebulizers, MDIs and DPIs), mechanical ventilation and suctioning, and evaluate the patient's response to these treatments. (Monitoring the use of aerosol drugs is a requirement of the GOLD guidelines.)

The minimum educational requirement for entry to practice respiratory therapy is an associate degree from an accredited respiratory therapy program. Upon completing their education, respiratory therapy graduates are competency tested by the National Board for Respiratory Care using tests accredited by the National Commission on Certifying Agencies. This examination is based upon a national job analysis conducted every five years. Laws regulating the practice of respiratory therapy in 48 states, the District of Columbia, and Puerto Rico require completion of this competency examination. Under state law, respiratory therapists provide services according to a defined scope of practice.

In addition to a defined scope of practice, respiratory therapists utilize clinical protocols or practice guidelines that improve the quality of care and significantly reduce the misallocation of respiratory therapy services. Respiratory therapists utilize a number of clinical practice guidelines (CPGs) related to the administration of aerosol therapy including the following:

- Assessing Response to Bronchodilator Therapy Point of Care
- Bland Aerosol Administration
- Intermittent Positive Pressure Breathing
- Management of Airway Emergencies
- Selection of a Device for Delivery of Aerosol to the Lung Parenchyma
- Selection of Aerosol Delivery Device
- Selection of Device, Administration of Bronchodilator, and Evaluation of Response to Therapy in Mechanically Ventilated Patients
- Training the Health-Care Professional for the Role of Patient and Caregiver Education

These CPGs have been published in the clinical, peer-reviewed *Respiratory Care Journal*, and may be found on the AARC's web site ([www.aarc.org](http://www.aarc.org)). Some are located on the Agency for Healthcare Research and Quality's National Guideline Clearinghouse web site ([www.guideline.gov](http://www.guideline.gov)) as well.

It is important to note that all the CPGs include a section regarding the appropriate personnel to deliver clinical services. For example, the CPG for Selection of Aerosol Delivery Device outlines the following requirements for appropriate personnel.

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<sup>13</sup> Studies Regarding MDI Techniques and Training

- 10.2 Personnel:
- 10.2.1 Knowledge and skills at several levels are required to fully utilize and apply these devices;
  - 10.2.1.1 Level II personnel provide initial assessments and care of the unstable patient;
  - 10.2.1.1.1 Utilizing proper technique for administration of MDI, accessory device, dry powder inhaler, SVN, LVN, USN; and SVN via IPPB;
  - 10.2.1.1.2 Practicing proper use, maintenance, and cleaning of equipment;
  - 10.2.1.1.3 Encouraging effective breathing patterns and coughing techniques;
  - 10.2.1.1.4 Modifying technique in response to adverse reactions;
  - 10.2.1.1.5 Modifying dosages and/or frequency as prescribed in response to severity of symptoms;
  - 10.2.1.1.6 Assessing patient condition and response to therapy;
  - 10.2.1.1.7 Performing auscultation and inspection and taking vital signs;
  - 10.2.1.1.8 Performing peak expiratory flow rate, spirometry, or ventilatory mechanics;
  - 10.2.1.1.9 Recognizing and responding to therapeutic and adverse responses and complications of medication and/or procedure;
  - 10.2.1.1.10 Understanding and complying with Universal Precautions.

The AARC is concerned that focusing solely on the cost of inhalation drugs ignores critical patient training and assessment components which are essential to effective aerosol therapy. Furthermore, we are concerned that the proposed rule is vague and unclear as to the criteria for appropriate personnel who may train the patient on inhalation drug utilization.

**The AARC supports the adoption of specific criteria documenting the education, training, and competency testing of individuals qualified to assess the patient’s need for aerosol or IBBP therapies as well as the selection of an appropriate drug delivery system.**

DMEPOS regulations state “The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare covered items safely and effectively.”<sup>14</sup> The proposed rule states “Beneficiary training by a physician or physician’s staff regarding use of a nebulizer would meet the definition of ‘another qualified party’ for purpose of this supplier requirement.”<sup>15</sup> The AARC questions what competency measures are used to determine if, or how, a person becomes “qualified” to provide patient training as well as assess the need for a particular respiratory therapy modality. Are these individuals deemed to be qualified simply by their employment by a durable medical equipment (DME) company or a physician’s office? The AARC does not support the fact that employment automatically confers knowledge and competency related to the selection of a respiratory therapy modality or a drug delivery system for aerosol therapy. How can there be a designation of “qualified” without criteria?

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<sup>14</sup> Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges. Code of Federal Regulations, Section 424.57(c)(12).

<sup>15</sup> “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule”; Fed Reg 2004; 69(150):47550, Aug. 5, 2004.

According to several studies,<sup>16</sup> there is a lack of competency regarding training and assessing a patient's technique in the use of inhalation drug delivery systems. These studies conclude that respiratory therapists were the only group who were able to demonstrate the correct techniques for using MDIs and DPIs. This conclusion was the same in every published study. It is certainly possible and desirable for others to invest in the time and expense to acquire the knowledge and skills necessary to evaluate the patient, determine the therapy modality, and select the most effective drug delivery system. According to the published, peer-reviewed, scientific evidence, this has not happened to the extent that all patients requiring aerosol therapy have access to appropriate training in order to gain optimum benefit from these drugs.

The AARC believes that individuals permitted to provide patient training must be qualified by documenting their education in all aspects in the use of nebulizers, MDIs and DPIs. AARC is extremely concerned with the reference in the proposed rule to IPPB machines.<sup>17</sup> As written in the proposed rule, it appears that IPPB falls within the same mode of bronchial hygiene as aerosol therapy. This is not the case. Aerosol therapy and IPPB therapy are two different clinical interventions. The issue of IPPB therapy brings on a host of safety concerns since the appropriate inspiratory pressure must be selected based on a comprehensive patient assessment and titration. There are several instances in which IPPB is contraindicated or deemed harmful to patients.

Without properly trained personnel to correctly train patients, Medicare will continue to experience larger expenditures for pulmonary patients because of high consumption of health resources. If CMS wishes to manage drug costs, it should be prepared to adopt an education fee for health care professionals who are qualified by virtue of their education, training, and competency testing. For respiratory therapists, salary equivalency guidelines<sup>18</sup> should be factor into the calculation of this fee. CMS will then obtain more value with more effective use of drugs and delivery systems.

A reasonable education fee will reduce costs in the long run if family practice physicians are able to utilize the expertise of respiratory therapists to evaluate and train their patients. Better trained patients on the correct treatment regimen using the appropriate drug delivery system with the correct technique will decrease the need for albuterol. Medical management must include other drugs that are consistent with universally accepted evidenced based guidelines. There are well-designed published studies linking a decrease in the use of short acting beta agonists to a lower consumption of health care resources such as hospital admissions. It is notable that two of these published investigations focused on large samples of Medicaid patients in two different states.<sup>19</sup>

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<sup>16</sup> Studies Regarding MDI Techniques and Training.

<sup>17</sup> "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule"; Fed Reg 2004; 69(150):47548, Aug. 5, 2004.

<sup>18</sup> Code of Federal Regulations, 42 CFR 413.106.

<sup>19</sup> "Relationship Between Asthma Drug Therapy Patterns and Healthcare Utilization," Shireman T.I., Heaton P.C., et al.; Ann Pharmacother 2002; 36(4):557-64, Apr. 1, 2002.

"Medicaid's Beta-2 Agonist Recipients and Their Treatment by National Standards," Reddy P., Kelly E.T. III, et al.; Ann Pharmacother 2001; 35(6):682-6, June 1, 2001.

The AARC appreciates the opportunity to offer these comments. If we can provide additional information or assistance, please contact AARC Director of Government Affairs Jill Eicher at 703-548-8538 or at [eicher@aacrc.org](mailto:eicher@aacrc.org).

Sincerely,

Janet M. Boehm, MS, RRT  
President