



**Testimony of the
American Association for Homecare Submitted for the Record
Before the Subcommittee on Health of the
Committee on Ways and Means on the
Pricing Mechanisms for Drugs Covered under the Medicare Program
October 3, 2002**

The American Association for Homecare (AAHomecare) submits the following testimony on the Pricing Mechanisms for Drugs Covered Under the Medicare Program to the Subcommittee on Health of the Committee of Ways and Means. AAHomecare represents home health agencies and suppliers of durable medical equipment (DME), supplies and services. AAHomecare members represent every segment of the homecare community, including suppliers that furnish infusion and inhalation therapies to Medicare beneficiaries in their homes.

Under the Balanced Budget Act (BBA) of 1997, Congress established payment for Medicare covered drugs at 95% percent of the average wholesale price (AWP) for the drug. A drug's AWP is set by the manufacturer and published in compendia of drug prices produced by a number of companies. Medicare carriers use the prices published in the compendia to calculate drug payments. This payment methodology has been criticized recently because there can be a wide spread between the drug's AWP and the price a physician or supplier pays to acquire the drug. While AWP may not be an ideal methodology for Medicare Part B drug payments, AWP payments for the drugs used in home infusion and home inhalation therapies cover the cost of services necessary to furnish these therapies safely and effectively in the home. Because Medicare does not otherwise reimburse suppliers for the costs of these services, this payment system has permitted beneficiaries to receive quality infusion and inhalation therapies in their homes.

Current Medicare policy limits payment for infusion and inhalation therapies to what is covered and paid for under the DME benefit. This means that the Medicare program does not explicitly reimburse homecare pharmacies for the array of services necessary to furnish these therapies safely and effectively to patients in their homes. This is in contrast to the way private sector health plans typically define and pay for these therapies. Typically, private sector plans make separate payments for the drug and non-

drug components of the therapy. The private sector has embraced home infusion and inhalation therapies, recognizing the patient care benefits and significant savings that accrue from moving care to non-acute settings and preventing otherwise predictable hospitalizations.

A change in the way Medicare pays for covered drugs will require a corresponding change in how these medically necessary services and functions are paid for. Trimming drug payments back without providing for separate payment for those activities that, until now, have been subsidized by the drug payment would be an unwise policy that may have potentially grave consequences for Medicare beneficiaries.

A Revision To AWP Drug Payments Must Include Payment For The Service Costs Of Furnishing Inhalation And Infusion Therapies To Beneficiaries In Their Homes

There is no question that there can be a large spread between the AWP and acquisition costs of drugs used in homecare. However, the acquisition cost of the drug is only a small part of the costs that homecare pharmacies incur in furnishing inhalation and home infusion therapies to Medicare beneficiaries in their homes. Medicare policy limits coverage and payment for these therapies to only the drugs, equipment, and supplies that are used in the therapy. In actuality, however, inhalation and infusion therapies furnished to patients at home involve far more than simply the delivery of drugs, supplies, and equipment to a patient. Provided safely and properly, these therapies require an array of services and ancillary functions provided by trained health professionals. While not separately paid for by the Medicare program, these services and functions are reimbursed in large part through the payments for the drugs, supplies, and equipment. The drug payment in particular subsidizes these services and functions.

In 2001, the American Association for Homecare commissioned a study by the Lewin Group, "Product and Service Cost of Providing Respiratory and Infusion Therapies to Medicare Patients in the Home." The study included statistically valid data from 19 homecare pharmacies of varying sizes and geographic locations. The Lewin study found that the acquisition cost of drugs used in inhalation and infusion therapies represented only 26 percent of the total costs of caring for Medicare beneficiaries. The remaining 74 percent of the total costs were comprised of clinical and administrative labor, billing and collection costs, indirect or overhead costs, inventory/warehouse/delivery expenses and bad debt. These functions and costs clearly are subsidized by the drug payment.

Importantly, these staff and administrative expenses are legitimate clinical and operating costs that are generally recognized by Medicare for providers in other care settings. Direct patient services for home infusion and inhalation therapies include patient evaluation and monitoring and compounding and dispensing drugs and solutions. These therapies require specialized pharmacy services, and pharmacies must have staff available to respond to emergencies and questions regarding therapy. Pharmacies also provide training and education to the patient (and often the patient's family). Inhalation and infusion therapies also require the services of a nurse or respiratory therapist to

perform a variety of functions, including patient screening and assessment, patient training regarding the administration of the pharmaceuticals, and general monitoring of the patient's health status. The pharmaceuticals, equipment, and supplies are delivered to the patient's home. Finally, staff, including licensed pharmacists, pharmacy technicians, respiratory therapists, and registered nurses are on call 24 hours a day. We describe these patient care services and administrative expenses more fully below.

Direct Patient Services For Home Infusion And Inhalation Therapies

Patient Evaluation

Initial patient intake is an important component for both inhalation and infusion therapies. The pharmacy must collect information on the clinical status of the patient and assess the potential for drug interactions. For home infusion and inhalation therapies, the patient evaluation is usually based on clinical information obtained from the nurse's assessments, communications with the physician and patient, the physician's orders, analysis of laboratory test results and other pertinent clinical information. Sometimes, the pharmacist will visit an infusion therapy patient, particularly if he or she has the appropriate clinical training and experience.

As therapy proceeds, the pharmacist's findings and recommendations are communicated at intervals to the physician, nurse, and other professionals involved in the care of the patient. Interdisciplinary communication occurs at team conferences and as needed throughout the course of home treatment. Detailed information about the patient's compliance with and response to the prescribed treatment regimen is documented in the database the pharmacist maintains for each patient. Therapy goals are updated periodically and modifications are communicated to other caregivers. The pharmacist also obtains laboratory and other data on the patient from the physician or other sources and adds these data to the clinical monitoring file on the patient.

Compounding and Dispensing Drugs and Solutions

Before filling an order for an infusion or inhalation patient, the pharmacist gathers information about the patient's medical history, reviews and updates the patient's medication profile, examines the attending physician's orders for new or continuing prescriptions, prepares computations needed for processing orders for drugs or equipment, and, if necessary, telephones the patient to answer questions and schedule deliveries.

Home infusion drugs and solutions must be prepared under environmentally controlled conditions, as mandated by various regulatory and accreditation agencies. Sterile admixtures are prepared in a Class 100 clean air environment, using aseptic techniques. Final documents are subject to routine quality control procedures designed to insure the accuracy of the preparations, product integrity, and sterility. Depending on the

pharmacy's volume of business and applicable legal restrictions, trained pharmacy technicians may prepare drugs under a pharmacist's supervision.

Each patient's prescription is filled in quantities and at intervals sufficient for continuous service. Frequency of drug preparation depends on several factors, including expected duration of treatment, frequency of dose administration, home delivery schedules, drug stability or shelf-life, and patient stability. The average time required to compound, dispense, assemble, and package a patient's order depends, in part, on the number of doses in an order, the quantity of each dose, the number of compounded doses per delivery, the volume and number of ingredients and the complexity of compounding.

An order for a medication may be filled in single or multiple doses. Where the patient base is large, a pharmacy technician may perform related tasks under a pharmacist's supervision, if state law permits. If a pharmacy's volume is small, the pharmacist typically performs all tasks needed to compound and dispense drugs.

Patient Monitoring

Appropriate clinical monitoring is essential to ensure the safe administration of home infusion and inhalation drugs. With respect to inhalation therapies in particular, monitoring patient compliance is essential to achieve therapeutic effectiveness. Homecare pharmacies maintain ongoing programs to oversee patients' compliance and to ensure that patients receive appropriate refills of their prescriptions.

As with any other type of medical care, complications may result from infusion therapy. If these complications are not recognized and addressed in a timely manner, serious injury and even death may occur. Ongoing clinical monitoring is therefore essential to minimize or prevent complications associated with infusion therapy and to optimize desirable outcomes. Nurses and pharmacists must be adept in identifying the signs and symptoms of the infectious, metabolic, physiological, and psychosocial complications that can occur, and in managing them.

Throughout the course of therapy, and particularly after a nursing visit, the pharmacist reviews an infusion patient's clinical information collected by the nurse, discusses the findings with the attending physician, assesses the continuing appropriateness of the current medication schedule, participates in multidisciplinary patient care conferences to examine the patient's progress and to establish future goals, and communicates with the patient's other caregivers regarding the patient's compliance and progress. Clinical monitoring activities also include establishing testing and monitoring schedules, reviewing laboratory findings, evaluating any identified problems that may have occurred, and developing corrective action plans.

Administrative And Support Services For Home Infusion and Inhalation Therapies

There are significant direct and indirect administrative and support services that impact the quality of patient care. Home infusion and inhalation therapies cannot be coordinated and delivered effectively without adequate administrative and support personnel. Many of these requirements are established by licensing boards, accrediting bodies, private insurance plans, and federal and state health programs. Other activities are simply part of managing and operating any health care entity. Examples of administrative and support services include quality improvement programs, utilization review, medical records management, coordination of insurance benefits, claims processing, medical waste management, personnel management, inventory control, orientation programs for new employees, and clinical development and education programs for management and staff.

Accreditation, for example, is an indirect cost that affects the quality of care delivered by homecare suppliers and providers. Accredited companies must meet quality standards for patient care and business functions in order to maintain accreditation. Accreditation offers the public the assurance that an accredited company meets or exceeds an objectively verifiable standard of care. It will be a setback for Medicare beneficiaries if Medicare reimbursement does not adequately reimburse providers and suppliers for the cost of meeting quality standards. If accreditation costs are ignored by Medicare, Medicare beneficiaries will receive a lower standard of care than individuals enrolled in private sector health plans. In addition to accreditation, there are costs associated with complying with state licensure and professional board requirements.

Homecare pharmacies also incur significant costs in complying with Medicare program rules, especially those pertaining to billing and documentation. These include, among others, the following:

- Accumulating documentation to support claims for services
- Preparation of claims
- Communication with physicians regarding completion of certificates of medical necessity and other documents required by the program of physicians.
- Communication with carriers regarding claims and documentation
- Participating in medical review process with carriers on particular claims
- Delays in payment from the program

It is worthwhile to note that both the General Accounting Office (GAO) and the Office of Inspector General (OIG) for the Department of Health and Human Services have acknowledged that the costs of complying with Medicare program rules are higher than the costs of compliance for other government and private payers¹. In a comparison of payments for home oxygen therapy by Medicare and the Veterans Administration (VA),

¹ Letter dated May 15, 1997, Re: Comparison of Medicare and VA Payment Rates for Home Oxygen, from William Scanlon, Director, Health Financing and Systems Issues, GAO to William Roth, Chairman Committee on Finance, United State Senate; Medicare Payments Use of Revised "Inherent Reasonableness" Process Generally Appropriate, GAO/HEHS- 00-79, July 2000; OIG Advisory Opinion 98-8.

the GAO concluded that Medicare's documentation and other administrative requirements warranted a 30% higher payment for oxygen. The GAO also acknowledged that CMS must account for the costs of the services necessary to furnish Medicare covered items when performing inherent reasonableness reductions. Similarly, the OIG concluded that the higher costs of complying with Medicare program rules could justify charging Medicare more than other private or government payers.

Utilization For Drugs Used In Inhalation Therapies Is Directly Related To The Increase In The Number Of Patients With Chronic Obstructive Pulmonary Disease (COPD)

It has been suggested that the increase in the utilization of drugs used in inhalation therapies is related to the difference between the drugs' acquisition costs and the AWP for the drugs. It is important to remember that physicians – not homecare pharmacies -- prescribe these medications. It is likewise crucial to consider the broad demographics of the patient population that receives these drugs.

Patients who require inhalation therapy suffer from chronic obstructive pulmonary disease (COPD). According to a report recently released by the National Institutes of Health², COPD is the fourth leading cause of death in the United States, and, of all leading causes of death in the United States, the incidence of COPD continues to rise. Death rates from COPD increased 22% in the last ten years. The number of patients with COPD doubled in the last 25 years, along with expenses related to the disease. Between 1985 and 1995, for example, the number of physician visits for COPD increased from 9.3 million to 16 million. The number of hospitalizations for COPD in 1995 was estimated to be 500,000. Medical expenditures for COPD in 1995 amounted to \$14.7 billion.

Inhalation drug therapy plays a critical role in the management and stabilization of COPD. COPD patients are diagnosed earlier and placed on these medications sooner to stabilize their symptoms and, as a result, reduce other medical expenses, such as repeat hospitalizations and physician visits, that are associated with the disease. The use of two respiratory medications, Ipratropium Bromide and Albuterol Sulfate, individually and in combination are widely supported in the clinical literature. The costs of treating these patients with inhalation therapy are modest, especially in light of the potential for a reduction of other health care expenses for this population.

Finally, respiratory drugs are for a chronic, ultimately fatal illness that requires daily drug therapy to help people with COPD avoid exacerbations. Many of these individuals remain on these medications for the remainder of their lives. As COPD progresses, the number of treatments per patient increases, accounting for the higher volume for these drugs.

² GOLD Initiative For Chronic Obstructive Pulmonary Disease, April 2001.

Conclusion

A comprehensive analysis of the services necessary to safely furnish inhalation and infusion therapies to beneficiaries in their homes must be part of any proposal to revise drug payments. Medicare payment for covered drugs should not be changed without providing a mechanism for Medicare to cover and pay for those services. For any reduction in payment for covered drugs, there must be a corresponding payment for the services required to furnish inhalation and infusion therapies in the home. We remain willing to work with Congress and the Centers for Medicare and Medicaid Services to develop an appropriate mechanism to accomplish this important objective. For additional information, contact Asela M. Cuervo, 703-836-6263.