

Testimony of
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before the Committee on Finance of the
United States Senate

Thursday, March 14, 2001

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Testimony

Mr. Chairman and members of this Committee, thank you for inviting me to appear at this hearing on behalf of Apria Healthcare, the homecare pharmacy industry, and the 1200 Apria clinicians who care for thousands of Medicare and Medicaid patients daily.

My name is Lisa M. Getson. I am senior vice president of business development and clinical services for Apria Healthcare, headquartered in Lake Forest, California. Apria Healthcare is one of the nation's largest home healthcare providers of oxygen and other respiratory therapies; home-delivered respiratory medications, home medical equipment and home infusion therapies, including chemotherapy. Every year, Apria provides service to over 1.2 million patients in all 50 states. Our 380 branch locations and 32 regional pharmacies serve urban areas such as Boston, Philadelphia, Atlanta, Houston, Los Angeles and here in the Washington area, as well as the most rural reaches of America such as Moosehead Lake, Maine; rural Wyoming County, West Virginia; Live Oak, Florida; Storm Lake, Iowa; and even Soldotna, Alaska.

My responsibilities at Apria Healthcare include managing the two homecare pharmacies that provide home-delivered inhalation therapies to 46,000 Medicare, Medicaid and managed care patients and the company's 32 regional home infusion pharmacies, which serve over 10,000 patients on any given day. I also provide executive oversight to the clinical respiratory, pharmacy and nursing functions as well as to the marketing department.

I will limit my oral comments to five minutes but have provided additional documentation for the official record. My testimony this morning can be summarized quite simply. There is no

question that drug payments for home infusion and inhalation therapies subsidize other important functions and costs that are not directly reimbursed. We have no quarrel whatsoever with the effort to reform Medicare payments for outpatient drugs, but we are extremely concerned that such reform may occur without a corresponding change in how these other vital services and functions are covered and paid for. We strongly urge the Committee to couple drug payment reform with coverage reform for these home-delivered therapies. If that does not occur, then it may become impossible for responsible homecare providers to serve Medicare beneficiaries.

Definitions of Inhalation and Infusion Therapy

At the outset, permit me to describe briefly what inhalation and infusion therapies are. Inhalation therapy is the process through which a drug or a combination of drugs are delivered into the airways and inhaled directly into the lungs via a device called a nebulizer. These drugs may include bronchodilators (help open narrowed airways), corticosteroids (lessen inflammation of the airway walls); antibiotics (to fight lung infections); expectorants (help loosen and expel mucus secretions); and other drugs. These drugs are used to treat chronic obstructive pulmonary disease (COPD), the fourth leading cause of death in the U.S. which is also on the increase.

Infusion therapy involves the administration of the drug into the body through a needle or a catheter. Typically, infusion drug therapy means that a drug is administered intravenously, but it may also apply to drugs that are provided through other parenteral (non-oral) routes, such as injectables. Examples include intravenous chemotherapy, antibiotics, anti-nausea agents, pain management and other therapies for terminal or chronic illnesses. The drugs must be prepared by licensed pharmacists in hospital-quality clean rooms or with laminar airflow hoods. Many advances in technology and drug therapy have occurred since the late 1970s when home infusion therapy was introduced that have allowed many more therapies to be delivered in the home setting than were possible in the 1970s and 1980s. This is significant for two reasons. Patients and

their caregivers prefer that whenever possible, their medical treatment be provided in the comfort of their homes. In addition, managed care organizations have realized that home healthcare is 30% to 50% less expensive than either inpatient hospitalization or unplanned emergency room visits. Since the 1980s homecare, as a percent of total healthcare expenditures has grown from three to four percent. It is therefore not surprising to me to see that Medicare Part B expenditures continue to increase.

Unlike private payors, Medicare Part B covers very few inhalation and infusion therapies. Current Medicare policy limits payment for these therapies to what is covered and paid for under the durable medical equipment (DME) benefit. The DME benefit only explicitly covers the drugs, supplies and equipment and does not reflect any other services or any other costs integral to the provision of these therapies. This means that the Medicare program does not directly reimburse homecare pharmacies for the complex array of services necessary to furnish these therapies safely and effectively to patients in their homes. There is no question that the payment for the drug subsidizes these services and other related costs. They have to, since under the Part B benefit there is no alternative. Patients receiving infusion and inhalation therapies must receive these services as part of their care. Without question, this is the community standard of care across the country, and it would be reckless for Medicare to deviate from that standard.

For that reason, if our concerns could be reduced to one sentence, it would be that any policy changes to the drug payments must include a corresponding change in how these medically necessary services and functions are defined and paid for. For these therapies, this debate is not simply a reimbursement issue; rather, it is a coverage issue. Clarification of Medicare coverage in this area is long overdue. The deficiencies in the current system are illuminated by the AWP debate, but did not begin there.

Acquisition Costs and Service Costs Incurred by Providers

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. Provided safely and properly, these therapies require a complex array of services and ancillary functions provided by licensed health professionals such as pharmacists, high-tech infusion nurses with oncology or geriatric certifications; and respiratory care practitioners. While not separately acknowledged or paid for by the Medicare program under the current reimbursement structure, these services and functions are inextricably linked to the delivery of the covered drugs. In fact, through various state and federal legislation and the requirements of accrediting bodies, providers must include most of these services in their daily operations, must have one set of operating procedures and cannot discriminate among patients based on the payor source.

These expenses are legitimate clinical and operating costs that generally are recognized by Medicare for providers in other care settings. For example, these therapies require staff to be available 24 hours a day, seven days a week to respond to emergencies and questions regarding therapy, 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 using company vehicles, overnight delivery services or certified courier services. At Apria Healthcare, one out of every four home infusion patients calls us after 5 p.m. during any given month, often resulting in an after-hours visit or delivery.

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. Examples include quality improvement programs, utilization review, medical records management, coordination of insurance benefits, claims processing, medical waste management, personnel management, inventory control, and patient education materials in multiple languages.

Although Medicare does not currently require accreditation as a condition of participation, the Medicare program and beneficiaries do benefit from working with accredited providers. It is important to note that many, if not most, private payors require their providers and suppliers to be accredited. 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 provider meets or exceeds a verifiable standard of care. If the Medicare program discourages private accreditation as a result of its payment policies, then Medicare beneficiaries ultimately will lose the enhanced quality of care that accreditation achieves for patients. There are no comparable Medicare standards of care, a result of the illogical and incomplete coverage of Part B items and services. The value of accreditation was never more evident than on September 11, when we activated our disaster preparedness plan nationwide. Such a plan is a requirement of the Joint Commission on Accreditation of Healthcare Organizations. Within hours, we provided a range of nebulizers, oxygen, respiratory and home medical equipment to hospitals in New York City, northern New Jersey, Philadelphia and Washington, DC, prepared our clinical staff to assist local hospitals and were referred patients who were discharged quickly from area hospitals to free up hospital beds for the wounded.

In addition to accreditation, there are costs associated with complying with state licensure and professional board requirements. We must comply with the extensive requirements of the following agencies: Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), Department of Justice (DOJ), Office

of Inspector General (OIG); Department of Transportation (DOT), state Medicaid programs; state pharmacy, nursing and respiratory boards.

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;
- Preparing claims;
- Communicating with physicians regarding completion of certificates of medical necessity (CMNs) and other documents required by the program of physicians;
- Communicating with carriers regarding claims, documentation and inexplicable denials;
- Participating in medical review process with carriers on particular claims;
- Delays in payment from the program.

There are other costs of doing business that cannot normally be passed along to any payor. These include: 1) A nationwide pharmacist and nursing shortage causing increased labor expenses and benefit expansions; 2) Uncontrolled and variable fuel increases; 3) Fuel surcharges on business-related travel; 4) Annual rate increases by UPS, FedEx and other carriers; 5) Nominal salary increases to remain competitive; 6) Double-digit increases in business insurance expenses; 7) Increases in real estate and other overhead.

In the summer of 2001, the American Association of Homecare (AAHomecare) contracted with The Lewin Group to conduct what we believe is the most definitive study ever conducted on this subject. Entitled “*Product and Service Costs of Providing Respiratory and Infusion Therapies to Medicare Patients in the Home*” September 10, 2001, 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 the drug represented only 26% of the total costs of caring for Medicare Part B beneficiaries. The remaining 74% 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. I have submitted the study to the Committee.

Increased Utilization of Inhalation Therapies

What is driving the increased utilization in respiratory medications? 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. Please keep in mind that homecare pharmacies fulfill legal prescriptions written by licensed physicians who diagnose and treat patients in their offices. We believe the increased utilization is due to three primary factors:

1) The increased incidence of Chronic Obstructive Pulmonary Disease (COPD) in America.

According to a report recently released by the National Institutes of Health, 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. These death rates exceed those of diabetes and Alzheimer's. The number of lung cancer (highly linked to COPD) cases among women has jumped more than 600 percent since 1950, and in fact about 53% of Apria's patients are women. Patients with Black Lung Disease are aging and require many respiratory services. Overall 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.

2) The approval of generic ipatropium bromide by the Food and Drug Administration in

1995. Not unlike other newly-approved drugs, the growth in utilization of inhalation therapies is related to increased physician demand for the drug. Over 1400 clinical studies have been published during the 1990s and overwhelmingly affirmed the efficacy of early treatment with ipatropium, particularly in conjunction with albuterol sulfate. Utilization for ipatropium has been driven by the clinical needs of the patient group and physician prescribing patterns. Historical factors have influenced the relationship between this drug's AWP and the acquisition cost of the drug. Specifically, when it was first released, the manufacturer encountered severe production shortages. As the manufacturers' increased production, a generic became available causing supplies to increase dramatically, resulting in lower prices for the drug.

3) COPD is incurable but can be managed as the disease progresses. As patients worsen or experience exacerbations, the number of treatments per patient increases, accounting for the higher volume for these drugs. COPD patients are being 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 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. Again, the government agencies have not studied the additional cost savings that could be afforded under Part B when compared with ER visits or inpatient hospitalization under Part A.

Patients Benefit from Homecare

I would like to briefly outline how two Medicare beneficiaries benefited from home infusion and home inhalation therapies in rural parts of West Virginia and Maine. In rural Wyoming County, West Virginia, Apria respiratory therapists often have to meet a family member in the mouth of the local hollow to transfer the respiratory equipment to their tractor or four-wheel drive to get up the mountain where patient education and assessment can ensue. In bad weather, we have to use the National Guard to deliver back-up oxygen to these patients and we even deliver to two

Medicare patients currently by carrying equipment over two swinging bridges to reach their homes. They have been able to be treated at home for over two years rather than being hospitalized intermittently in the city hospital.

In Boothbay, Maine, we took care of a Medicare patient who was at the end of his 20-year battle with cancer. After being admitted to homecare about 1.5 years ago with severe malnutrition and anemia, the Apria clinical team conducted weekly teleconferences with his primary care physician to stabilize his condition and increase his weight gain. By the end of his life, he was able to enjoy a reasonable quality of life with his family by being treated largely at home until his death last month.

Conclusion

In conclusion, we understand the Committee's interest in reforming Medicare reimbursement for drugs. Any system where reimbursement for important services or functions is subsidized by the reimbursement for some other item cries out for reform. However, in the process of achieving that reform, there must be a corresponding creation of a payment structure for the services required to furnish inhalation and infusion therapies in the home. Thus, we need another step. Congress has to clarify coverage for these therapies in the homecare setting before reimbursement changes are implemented. We believe that the Lewin Group study I described earlier contains the most accurate and up-to-date information about the total costs borne by providers. If, however, the Medicare program believes that further study of these service costs is necessary, some of the analysis to date regarding physicians' office costs could establish useful benchmarks for similar costs. In a number of areas, the costs probably are not materially different between physicians and providers. In fact, in some areas we incur additional costs that the physicians do not, such as delivery, accreditation and certain clinical support services. If there is to be further study, we

recommend that a credible organization such as MedPAC or the Institute of Medicine work with the homecare pharmacy industry to conduct a formal study of the service components and related costs that homecare pharmacies incur when providing care to Medicare beneficiaries.

Finally, we recommend that Congress adopt the approach proposed in the Engels bill, H.R. 2750, that would define the items and services covered under a Medicare benefit for home infusion therapy. A similar approach would work equally well for inhalation therapy.

Mr. Chairman, thank you for the opportunity to present this information to the Committee. I will be happy to answer any questions you have today or respond to written questions after the conclusion of this hearing.

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