DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

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TO: Laura A. Dummit
Director, Health Care—Medicare Payment Issues

FROM: Mark B. McClellan, M.D., Ph.D.
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Centers for Medicare & Medicaid Services

SUBJECT: General Accounting Office Draft Report (GAO), *MEDICARE: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs,* (GAO-05-72)

Thank you for the opportunity to review and comment on the GAO's draft report entitled, "*MEDICARE: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs*."

We are committed to ensuring that our beneficiaries have appropriate access to inhalation drugs and understand the vital role these medications play in the care of patients with respiratory illnesses. Lung diseases such as chronic obstructive pulmonary disease (COPD) affect large numbers of Medicare beneficiaries. The COPD is the fourth largest cause of death in America behind heart disease, certain cancers, and stroke. We hope to reduce the number of new COPD cases by educating Americans about the disease, its causes, and ways to prevent it. We hope to improve the lives of Medicare beneficiaries and improve beneficiary access to treatment for those who already suffer from these conditions.

Depending on an individual's age and health, a number of steps can be taken to treat or prevent COPD. Because approximately 85 percent of those with COPD are smokers, the first step to avoid the disease is to stop smoking. Smoking has been linked to a large number of health problems and is a leading cause of cancer and pulmonary disease. The Department of Health and Human Services (HHS) has been actively encouraging Americans to quit smoking through its smoking cessation initiatives. Americans who quit smoking will enjoy longer, healthier lives and avoid diseases such as COPD.

We have also recently approved services to address the needs of Americans suffering from COPD, including lung-volume reduction surgery, which, performed in more serious cases, removes the diseased lung tissue, allowing the rest of the lung to function better. Specifically, effective January 1, 2004, Medicare expanded coverage of lung volume reduction surgery to include patients who either have severe, upper-lobe emphysema, or have severe, non-upper-lobe emphysema with low exercise capacity.

A number of drugs are available to treat the persons with asthma or who develop COPD. These include drugs, often inhaled, that expand the bronchial tubes and allow the patient to breathe more freely. Depending on the needs of the individual patient, these medications can be delivered using nebulizers or metered dose inhalers (MDIs). While nebulizers have long been covered under Medicare Part B, the Medicare Modernization Act (MMA) expanded access to MDIs beginning in 2006 through the new Medicare Part D drug benefit.

We recognize many patients require the use of nebulizers and that nebulizers will continue to play an important role in inhalation therapy even after coverage of MDIs begins in 2006. We, therefore, agree with the GAO recommendation that we evaluate the costs of dispensing inhalation therapy drugs used in nebulizers and modify the dispensing fee, if warranted, to ensure that the fee appropriately accounts for the costs necessary to dispense these drugs.

We note the extreme variation that the GAO found in the costs of dispensing these nebulized drugs to Medicare beneficiaries: GAO found that the 2003 per patient monthly costs of dispensing these medications ranged from a low of $7 to a high of $204. We believe that before a final determination can be made as to the dispensing fee for inhalation drugs, we need to more fully understand the reasons behind the current variability in the dispensing of these drugs. We intend to work with those concerned with inhalation therapy and our partners in the Department of Health and Human Services to explore this issue more fully.

In the interim, the GAO's analysis has provided us with information that we will carefully consider with the comments we received from the public on our August 5, 2004 proposed rule policy on inhalation dispensing fees. A number of commenters on our proposed rule cited an industry-sponsored study on the costs of delivering inhalation drug services. Other comments and publicly available cost information were also available to us. After reviewing the comments and the information from the GAO survey and other public sources, we believe that $55.00 to $64.00 per month is a reasonable range for a 2005 fee.

We also appreciate the GAO's work in surveying the acquisition cost of the suppliers of the inhalation drugs. As with dispensing costs, the GAO found that the acquisition cost of these drugs varied widely. The GAO found that acquisition costs of the two most widely utilized drugs, ipratropium bromide and albuterol sulfate, ranged from $0.23 to $0.64 for ipratropium bromide and from $0.04 to $0.08 for albuterol sulfate. The 2005 Medicare payments for ipratropium bromide and albuterol sulfate will be based on manufacturers' quarterly submissions of average sales price data. The Medicare payment each quarter will be based on the average sales price data plus 6 percent. When we compare the acquisition costs of ipratropium bromide and albuterol sulfate to the Medicare payment rates based on the submission of manufacturer's average sales price

data for the second quarter of 2004, we find that the Medicare payment rates would be solidly inside the acquisition cost range found by the GAO.

The GAO also found that acquisition cost was not necessarily related to the size of the supplier. As we seek to encourage prudent purchasing under the ASP+6 percent payment system, we intend to further explore the factors influencing drug acquisition costs.

We look forward to working with the GAO as we address these important issues and ensure appropriate access to inhalation drugs for our beneficiaries who need them.