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Centers for Medicare and Medicaid Services
Department of Health and Human Services
445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1414-P – Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates and CMS-1413-P Medicare Program Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010

Submitted via the web at <http://www.regulations.gov/>

To Whom It May Concern:

The COPD Foundation is the national not-for-profit organization solely dedicated to representing individuals with COPD in the United States. COPD, or Chronic Obstructive Pulmonary Disease, is an umbrella term used to describe progressive lung diseases, encompassing emphysema, chronic bronchitis, refractory asthma, and severe bronchiectasis. This disease is characterized by increasing breathlessness.

The Foundation is weighing in with comments on the proposed rule published July 20, 2009 in the Federal Register outlining coverage and payment proposals for pulmonary rehabilitation and also the proposed physician fee schedule rule that was published with these proposed regulations.

Chronic Obstructive Pulmonary Disease (COPD) is a preventable and treatable disease. The COPD Foundation was established to speed innovations which will make treatments more effective and affordable, undertake initiatives that result in expanded services for COPD patients, and improve the lives of patients with COPD and related disorders through research and education that will lead to prevention and someday a cure for this disease. We also promote the use of pulmonary rehabilitation as a way to improve function and enhance quality of life.

The COPD Foundation has had an opportunity to review the comments that have been submitted by professional organizations that represent the health care providers who provide pulmonary rehabilitation. The Foundation supports and endorses the comments made by the American Association for Respiratory Care (AARC), the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), and the National Association for Medical Direction of Respiratory Care (NAMDRRC).

The legislation that was passed by Congress with the support of the pulmonary community establishes pulmonary rehabilitation as a specific benefit category within Medicare. The physician fee schedule and hospital outpatient PPS rules as proposed will have a damaging impact on pulmonary rehabilitation programs across the country specifically limiting individual patient access to care. The Foundation also knows that this was not the Congressional intent of the Pulmonary Rehabilitation legislation. Congressional intent was to **ensure** access for beneficiaries with specific pulmonary-related diseases.

Our comments are in respect to the focus on three primary areas that directly affect patient access to pulmonary rehabilitation: payment, coverage, and duration. The Foundation would like to bring to the attention of CMS that pulmonary rehabilitation is very different from cardiac rehabilitation. With respect to equipment, we concede that there are some similarities but a comprehensive pulmonary rehabilitation program includes a treadmill, pulse oximeter, and ECG monitor, exercise bicycles (both upright and recumbent), arm ergometers, exercise bands, and frequently Stairmaster-type equipment. Many hospitals require the pulmonary rehabilitation department to have its own dedicated emergency cart/resuscitation equipment. Oxygen is also a variable as some individuals desaturate during exercise, therefore requiring the availability of portable oxygen systems in which costs do not qualify for oxygen coverage under the Medicare DME benefit. The pulmonary rehabilitation team is multi-disciplinary; the professionals include nurses, respiratory therapists, social workers, psychologists, dietitians, and occupational therapists.

The flaws in the proposed payment methodology would go counter to Congressional intent by promoting the shutting down of pulmonary rehabilitation programs in both the hospital and physician office setting.

Payment:

- a. Pulmonary rehabilitation is not a new technology as classified in the proposed rule. This classification negatively impacts the payment rate.
- b. Staffing outlined in the physician fee schedule rule is inaccurate.
- c. Equipment-related assumptions outlined in the physician fee schedule rule are not valid as noted above.

The flaws in the proposed coverage guidelines also run counter to Congressional intent by inappropriately limiting who can access pulmonary rehabilitation. For instance, the proposed rule does not recognize other pulmonary disorders and too narrowly defines COPD inhibiting access to those Medicare beneficiaries who may already be receiving pulmonary rehabilitation.

Coverage:

- a. The clinical literature and Global Obstructive Lung Disease (GOLD) guidelines for pulmonary rehabilitation recommend coverage for moderate, severe and very severe COPD patients.
- b. The proposed coverage guidelines would restrict and deny access to the patients with severe and very severe disease currently accessing pulmonary rehabilitation.

The CMS definition of pulmonary rehabilitation, the service is “for COPD and other chronic respiratory diseases designed to optimize physical and social performance and autonomy.” However, the actual proposed coverage falls short of the comprehensive CMS definition as it recognizes neither very severe COPD nor any other chronic respiratory diseases.

Pulmonary patients with urgent needs will be left out of this important medical services area. These patients include ones with life threatening illnesses such as:

- Alpha-1 Antitrypsin Deficiency (AATD)
- Acute Respiratory Distress Syndrome (ARDS)
- Asthma
- chILD (children with Interstitial Lung Disease)
- Cystic Fibrosis
- Hermansky-Pudlak Syndrome Network
- Lymphangiomyomatosis (LAM)
- Lung Cancer
- Pulmonary Fibrosis
- Pulmonary Hypertension
- Sarcoidosis

Persons with chronic respiratory diseases other than COPD frequently have disabling symptoms and disease manifestations including dyspnea, fatigue, weakness, deconditioning, exercise intolerance, functional disability, skeletal muscle dysfunction, hypoxemia, systemic inflammation, and other co-morbidities that can include depression, anxiety, social isolation, nutritional impairments and corticosteroid-associated myopathy. Both patients with COPD and those with non-COPD respiratory disease can have significant improvements in exercise tolerance and health-related quality of life with pulmonary rehabilitation. If the proposed policy with its limited qualifying criteria for beneficiaries is implemented, it will eliminate services for patients currently covered.

The proposed rule does not properly interpret the clinical literature and professional guidelines for duration of pulmonary rehabilitation.

Duration:

- a. CMS proposes a limit on the number of billable hours to 36, with one hour of billable service per day. This does not reflect the standard of care in the United States, it does not reflect the standards in the clinical peer reviewed literature, and it is contrary to existing CMS policy as outlined in the Lung Volume Reduction Surgery LCD.
- b. LVRS LCD mandates 2 hour minimum sessions, up to 60 hours per beneficiary.

One typical pulmonary rehabilitation session may last 2-3 hours, very rarely just one hour. The proposed rule establishes a limit of 36 “sessions” with each billable session defined as one hour. This 36-hour payment establishes an inappropriate cap for each beneficiary. The lung volume reduction surgery NCD mandates *a minimum of 44 hours of rehabilitation up to a maximum of 60 hours, in two hour minimum increments*. The proposed policy is in direct contradiction to existing CMS policy and does not reflect the standard for pulmonary rehabilitation the United States. CMS policy for duration of pulmonary rehabilitation should be based on the individual’s medical necessity and reaching a level of optimal care. The Foundation supports a mandate that requires a physician to develop an individualized treatment plan.

We appreciate the opportunity to comment on this important proposed rule establishing a full pulmonary rehabilitation benefit. The Foundation looks forward to the final rule fulfilling the Congressional intent that afforded this desperately needed benefit to so many pulmonary patients.

Sincerely,

John W. Walsh
President

CC: Senator Mike Crapo
Senator Blanche Lincoln