November 15, 2006

Steven Phurrough, MD
Director
Coverage & Analysis Group
Centers for Medicare and Medicaid Services
Room C1-13-18
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. Phurrough:

This letter should serve as a formal request for a National Coverage Determination (NCD) for pulmonary rehabilitation services. This request is submitted by the American Association of Cardiovascular and Pulmonary Rehabilitation, the American College of Chest Physicians, the American Thoracic Society and the National Association for Medical Direction of Respiratory Care. Currently there is no national policy for coverage of pulmonary rehabilitation services and, therefore, this should be regarded as a new request (Track #1) even though we collectively submitted a similar request in April, 2003.

Benefit categories: We believe pulmonary rehabilitation services are authorized under two distinct provisions of Title XVIII of the Social Security Act.

- Section 1861(s)(2)(B) of the statute authorizes payment for *"hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;"*

  Discussion: According to the Medicare Benefit Policy Manual (20.4.1), services incident to a physician's service provided to a hospital outpatient are specifically

defined. That definition states, *"To be covered as incident to physicians' services, the services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.*

Pulmonary rehabilitation services, as defined in the attached description of the Scope of Services, clearly fits neatly into this definition. Just as cardiac rehabilitation services are covered by Medicare and outlined at 20.10 in the Benefit Policy Manual as "incident to" services, pulmonary rehabilitation services warrant coverage as well.

We fully recognize that various components of pulmonary rehabilitation are covered by Medicare. For example, G codes 0237-239 are used to bill the exercise facet of pulmonary rehabilitation when provided in the hospital outpatient setting and physician office setting. However, in the absence of a national coverage determination, Medicare contractors exercise arbitrary policymaking and either do not pay at all for these codes or frequently establish limits on the usage of these codes that do not reflect the well documented science associated with exercise as a component of pulmonary rehabilitation. Other frequently used codes associated with pulmonary rehabilitation services include

94620: Pulmonary stress testing; simple (six-minute walk test)
94621: Pulmonary stress testing; complex (including measurements of CO2 production, O2 uptake, and electrocardiographic recordings)
94640: Pressurized or nonpressurized inhalation treatment for acute airway obstruction or for sputum induction
94664: Demonstration and/or evaluation of patient utilization of aerosol generator, nebulizer, meter dose inhaler or IPPB device
94667: Manipulation chest wall such as cupping, percussing, and vibration to facilitate lung function
94668: Chest wall manipulation, subsequent
G0375 Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes, up to 10 minutes.
G0376 Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes.

Importantly, we emphasize that Medicare does authorize pulmonary rehabilitation services when provided in conjunction with lung volume reduction surgery (LVRS). Coverage is detailed in the Medicare NCD Manual, Chapter 1, Part 4, Section 240.1. The policy specifically states:

> *The surgery must be preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the NETT and designed to*

maximize the patient's potential to successfully undergo and recover from surgery. The program must include a 6- to 10-week series of at least 16, and no more than 20, preoperative sessions, each lasting a minimum of 2 hours. It must also include at least 6, and no more than 10, postoperative sessions, each lasting a minimum of 2 hours, within 8 to 9 weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial and nutritional needs, be consistent with the preoperative and postoperative services provided in the NETT, and arranged, monitored, and performed under the coordination of the facility where the surgery takes place.

Clearly those components are authorized under some element of the statute because we know Medicare pays only for services authorized under Title XVIII. Despite our repeated requests for CMS to identify the benefit category for pulmonary rehabilitation services as an integral part of LVRS, we must presume that Medicare policymakers rely on the "incident to" provisions of the statute as the specific benefit category for authorization of those services.

It is important to note that CMS required NETT qualified participating facilities to use unique codes for the pulmonary rehabilitation related services provided in conjunction with NETT. We support adoption of similar codes as part of a national coverage policy.

- Section 1861 (cc)(1)(B) of the statute authorizes payment for *physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy* when the service is provided by a comprehensive outpatient rehabilitation facility (CORF). That section of Title XVIII was enacted 25 years ago and CMS has yet to promulgate a definitive national policy to address coverage of pulmonary rehabilitation services provided by CORFs.

We are providing additional information in accordance with the requirements identified in the September 26, 2003 ***Federal Register*** (p. 55634-41).

ATTACHMENT #1: A full and complete description of pulmonary rehabilitation services, including qualifying criteria, the appropriate use of pulmonary rehabilitation in the Medicare population.

ATTACHMENT #2: A definitive bibliography identifying the peer reviewed medical and scientific information currently available that measures the medical benefits of pulmonary rehabilitation services.
Please note that there are two components to this attachment. In 2007 a peer reviewed article entitled, "*Pulmonary Rehabilitation -- Joint ACCP/AACVPR Evidence Based Clinical Practice Guidelines"* will appear in ***CHEST***, the ACCP's journal. As the publication date of that manuscript would likely occur after the 90 day window afforded for CMS review of this NCD request, we cannot submit the manuscript itself but we are including its bibliography as it is an important reference tool for a substantive review of scientific literature supporting pulmonary rehabilitation services.

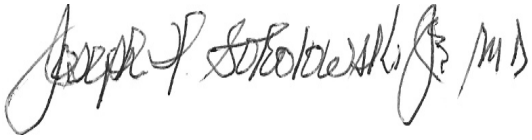
ATTACHMENT #3: Recently published Joint Statement of the American Thoracic Society/European Respiratory Society regarding pulmonary rehabilitation. This submission complements Attachment #2.

ATTACHMENT #4: A copy of excerpts of the National Emphysema Treatment Trial manual citing pulmonary rehabilitation and specifically referenced by CMS in its Lung Volume Reduction Surgery NCD. This attachment verifies that CMS already covers pulmonary rehabilitation services for a portion of the Medicare population, presumably under the "incident to" authority of Section 1861(s)(2)(B)

Therefore, we respectfully request that CMS promulgate an NCD which identifies the components of pulmonary rehabilitation services, as described in detail as an attachment to this document. This NCD should address provision of these services in the hospital outpatient setting, the physician office setting and the CORF setting.

Sincerely,

John Heffner, MD
President
American Thoracic Society



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