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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-1418-P – Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010

To Whom It May Concern:

The American Association for Respiratory Care (AARC) is the national professional organization representing approximately 50,000 respiratory therapists in the United States. The AARC welcomes the opportunity to comment on the subject rule published in the Federal Register on July 13, 2009, outlining coverage and payment proposals for pulmonary rehabilitation in accordance with Section 144 of PL 110-275. Please note that AARC is also submitting separate but similar comments regarding pulmonary rehabilitation in response to the proposed hospital outpatient rule that has been published in tandem with the physician fee schedule update. Last, we also offer comments on changes in the definition of respiratory therapist in the Comprehensive Outpatient Rehabilitation Facility (CORF) setting as proposed in the subject rule.

Please note that our specific comments on pulmonary rehabilitation are, we believe, virtually identical to comments submitted by our sister societies including 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 (NAMDRC). Because our comments go beyond the singular issue of pulmonary rehabilitation, we determined that it would be more appropriate to submit separate, albeit, identical comments on the specific pulmonary rehabilitation components of the proposed regulation.

Our comments on implementing the new pulmonary rehabilitation benefit focus on three primary areas related to coverage, duration and payment. We are also including as supplementary information a detailed bibliography of peer reviewed literature supporting our recommendations. Importantly, there are numerous areas of the proposed regulation that we support and we highlight those areas as well.

Section II. G. 9. – Section 114(a)
Pulmonary Rehabilitation Services

SUMMARY

Section 144 of PL 110-275 establishes pulmonary rehabilitation as a specific benefit category within Medicare. The proposed rule would, if implemented, have serious detrimental impact on pulmonary rehabilitation programs across the country as well as circumvent the genuine Congressional intent to ensure access to pulmonary rehabilitation services for beneficiaries with specific pulmonary-related diseases.

1. **Payment:** There are several significant flaws inherent in the proposed approach to payment of pulmonary rehabilitation in the physician office setting.
    a. First, there is no validity to the premise that physician work in pulmonary rehabilitation mirrors the physician work in cardiac rehabilitation code 93797.
    b. Pulmonary rehabilitation is not a "new technology." Ironically, the codes that CMS proposes to replace (G0237-39) were classified as "new technology codes in 2002, eight years ago at a payment rate of $25/15 minute increment.
    c. Staffing assumptions are not valid.
    d. Equipment related assumptions are not valid.
    e. The bundling of services that are currently separately billed significantly reduces payment for services if implemented at the proposed rate.

    Collectively, these flaws in determining a payment rate would have the impact of shutting down pulmonary rehabilitation services in the United States when provided in both physician offices AND the hospital outpatient setting.

    We have included specific payment recommendations/options as part of our comments on the proposed hospital outpatient rule, one of which is applicable to the physician office setting --
    - Continue use of the current G codes 0237-39
    - Continue use of the current policy that permits component billing of related services such as 94620, 94664 and 94667,
    - Permit the physician to submit an appropriate E/M code when physician work is appropriate and medically necessary
        - Outcomes assessment is, according to the proposed physician fee schedule rule, a physician evaluation service
        - The intake assessment may be conducted by a physician or pulmonary rehabilitation staff, dependent upon specific patient characteristics. In the case that a physician assessment is appropriate because of patient complexity,

current CMS policy does permit physician billing of an appropriate E/M code.

2. **Coverage:** CMS misreads the clinical literature. Current GOLD guidelines for pulmonary rehabilitation recommend coverage for moderate, severe AND very severe COPD patients. Clinical literature supports inclusion of non-COPD populations as well, such as cystic fibrosis, intertistial lung disease and pulmonary hypertension, among other conditions. Additionally, implementing the proposed restrictions on access to pulmonary rehabilitation would have the effect of denying coverage to beneficiaries who currently have access to this important service as outlined in existing LCDs promulgated by Medicare contractors.

3. **Duration:** 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 which mandates 2 hour minimum sessions, up to 60 hours per beneficiary.

Coverage Criteria

As noted in 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.

Comment

Several CMS contractors have developed their own local coverage determinations (LCDs) for pulmonary rehabilitation services. These LCDs have been developed in consultation with local as well as national pulmonary societies and do reflect the standard of care for coverage of pulmonary rehabilitation services in the United States. Importantly, these policies reflect the discussion of the clinical literature cited below. As a specific reference, we are including as **Attachment A** the relatively short list of ICD-9 codes recognized in these policies.

If the proposed policy with its limited qualifying criteria for beneficiaries is adopted as a formal CMS policy, this restriction will eliminate services for patients currently covered under multiple LCDs, eliminating coverage for Medicare beneficiaries in 15 states. It will also delay any opportunity for these newly excluded beneficiaries to receive pulmonary rehabilitation services for extended periods of time. We do not believe CMS intended this outcome.

The proposed rule defines:

- Moderate COPD (GOLD II) as $FEV_1/FVC < 70\%$ and $FEV_1 \geq 30\%$ to $< 80\%$ predicted with or without chronic symptoms (cough, sputum production, dyspnea).

- Severe COPD (GOLD III) as $FEV_1/FVC < 70\%$ and $FEV_1 < 30\%$ predicted or <50% predicted plus respiratory failure or clinical signs of right heart failure.

In contrast, the 2008 GOLD Guidelines define:

- Moderate COPD (GOLD II) as $FEV_1/FVC < 70\%$ and $FEV_1 > 50\%$ to $< 80\%$.
- Severe COPD (GOLD III) as $FEV_1/FVC < 70\%$ and $FEV_1 > 30\%$ to $< 50\%$.
- Very Severe COPD (GOLD IV) as $FEV_1/FVC < 70\%$ and $FEV_1 < 30\%$ predicted or $FEV_1 < 50\%$ plus chronic respiratory failure.

The proposed rule also states that the major national and international respiratory organizations' guidelines (ATS/ERS, ACCP, AACVPR and Global initiative for COPD or GOLD) have recommended PR as the standard of care for COPD stages II and III. In contrast, the GOLD guidelines identify COPD stages II-IV as impacted by exercise deconditioning, social isolation, altered mood states, muscle wasting and weight loss.

According to GOLD 2008 (page 56), in all COPD patients, exercise training results in improved exercise tolerance, dyspnea and fatigue (Evidence A), with greatest improvement seen in stages II-IV. GOLD identifies pulmonary rehabilitation as the standard of care for patients with stages II-IV and that all stages benefit from exercise training programs, improving both exercise tolerance and symptoms of dyspnea and fatigue (Berry MJ et al, 1999).

At stage IV, GOLD recommends patients participate in pulmonary rehabilitation and be considered for surgical treatments. Pulmonary rehabilitation is an integral part of lung transportation and lung volume reduction surgery (LVRS), improving skeletal muscle function (Maury G, et al 2008). In appropriate patients with very severe COPD, lung transplantation has been shown to improve quality of life and functional capacity (Turlock EP, et al 1997, Theodore J, et al 1990, Hosenpud JD, et al 1998, J Heart Lung Transp, Annual report of US scientific registry 1995). Referral criteria for transplant include $FEV_1 < 35\%$ predicted, $PaO2 < 60$ mmHg, $PaCO2 > 50$ mmHg and secondary pulmonary hypertension (Hosenpud JD, et al Lancet 1998, Maurer et al 2008).

The National Emphysema Treatment Trial (NETT) included 1,228 patients with severe and very severe emphysema (FEV1 26.9% predicted - *GOLD stage IV*) who were required to participate in pulmonary rehabilitation. This sample of patients with very severe COPD had significant (< 0.001) improvements in exercise, dyspnea and quality of life (Ries A, et al 2005).

According to ACCP/AACVPR Pulmonary Rehabilitation Evidence Based Guidelines (Ries AL, et al 2007), "a program of exercise training of the muscles of ambulation is recommended as a mandatory component of pulmonary rehabilitation for patients with COPD (Grade of Recommendation 1A)." Patients with very severe COPD are not excluded.

The ATS/ERS Statement on Pulmonary Rehabilitation (Nici L, et al 2006) cites that *"pulmonary rehabilitation should be considered for all patients with chronic respiratory*

disease who have persistent symptoms, limited activity, and /or are unable to adjust to illness despite otherwise optimal medical management." The statement does not exclude the patient with very severe COPD.

According to "State of the Art – Pulmonary Rehabilitation in COPD" (Troosters T, et al, 2005), recent studies in which high intensity training are used have shown that patients with FEV_1 below 40% should not be excluded from exercise training (Casaburi R, et al, 1997, Maltais F, et al, 1997, Foster S, et al 1988). In a large study by Berry and coworkers in 1999, patients with mild, moderate and severe COPD showed the same proportional improvement in exercise tolerance after pulmonary rehabilitation.

Justification for Inclusion of non-COPD Populations in Coverage Criteria for Pulmonary Rehabilitation

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, depression, anxiety, social isolation, nutritional impairments and corticosteroid – associated myopathy.

Those with interstitial lung disease, bronchiectasis, restrictive chest wall disease, fibrothorax and neuromuscular disease achieve benefits in exercise tolerance and quality of life following PR (Foster S, et al 1990, Ferreira G, et al 2006, Smidt N, et al 2005, Congleton J, et al 1997). Ferreira, Feuerman, and Spiegler (2006) evaluated by sub-analysis outcomes of PR among 113 patients with diagnoses other than COPD. Both patients with COPD and those with non-COPD respiratory disease had significant improvements in exercise tolerance and health-related quality of life. Foster and Thomas (1990) also found no significant difference in the magnitude of gains between the COPD and non-COPD patient groups.

Promotion of compliance with complex medication regimens, O_2 therapy, noninvasive assisted ventilation, chest physiotherapy techniques, training in the use of adaptive /assistive equipment, and preparation for and post operative rehabilitation following lung transplantation require more intensive training and education, behavior modification, and partnering between patients and their health care providers than can usually be accomplished in the routine outpatient clinical setting.

In addition to very severe COPD and the criteria covered in the current Medicare contractor LCDs, the non-COPD populations discussed below are currently part of the standard of care provided in pulmonary rehabilitation programs today and should be included in the final rule. (Please refer to the bibliography in Attachment B for further references.)

Cystic Fibrosis

Patients with cystic fibrosis (CF) often experience dyspnea, exercise intolerance, and impairment in QOL. Compared with healthy age- and gender-matched control subjects, patients with CF have reduced maximal exercise capacity (Freeman W, et al 1993. Orenstein DM, et al 1993) impaired muscle strength (Sahlberg ME, et al 2005), and greater resting energy expenditure (Selvadurai HC, et al 2002). Exercise impairment in CF can result from increased airway resistance, dynamic hyperinflation (with resultant respiratory muscle mechanical disadvantage and increased elastic load to breathing), cardiocirculatory limitation, pulmonary hypertension (Orenstein DM et al 1993, McKone EF, et al, 2002, Boas SR, 1997), osteopenia, hypertrophic osteopathy, nutritional impairment and skeletal muscle impairment (Boas SR, 1997).

Studies have shown that aerobic exercise training improves the exercise tolerance of patients with CF. (Selvadurai HC, et al. 2002, Gulmans VA, et al 1999, Nixon PA, 1996, Blau H, et al 2002, O'Neill PA, et al 1987, Bradley J & Moran F, 2002), including persons with severe impairment in pulmonary function (De Jong W, et al 1994). Exercise training among patients with CF can also lead to a reduction in symptoms (Schneiderman-Walker J, et al 2000) and improved sense of well-being.

Non-Cystic Fibrosis Bronchiectasis

Randomized controlled investigation of pulmonary rehabilitation in patients with non-CF diffuse bronchiectasis has demonstrated significant gains in exercise endurance, overall exercise capacity and QOL compared to controls (Newall C, et al 2005). Bradley and Moran (2006) has also found beneficial effects of PR on exercise tolerance among patients with bronchiectasis.

Interstitial Lung Disease (ILD)

Patients with ILD have often have severe exertional dyspnea, cough, exercise intolerance, altered lung mechanics with low lung compliance (Marciniuk DD, et al 1994, Markovitz GH & Cooper CB, 1998) , alterations in respiratory drive, and gas exchange disturbances (with diffusion impairment, increased dead space, and ventilation–perfusion mismatch).

Exercise-induced hypoxemia is particularly severe among patients with ILD, especially those persons with moderate to severe disease (Markovitz GH & Cooper CB, 1998, Hsia CC, 1999, Hansen JE & Wasserman K: 1996, Harris-Eze AO, et al: 1994). Although ILD is often refractory to conventional medical treatments, pulmonary rehabilitation targets several areas of morbidity that can contribute to disability and impaired quality of life, including cardiovascular deconditioning, dyspnea and control of mood disorders (Holland AE, et al in Thorax, 2008, Nishiyama O, et al 2008, Ferreira G, et al 2006 & 2009, Jastrzebski D, et al 2006, Naji NA, et al 2006 and Foster S, et al 1990).

A recent multi-center trial of ILD patients found significant improvement in dyspnea and six minute walk distance (6MWD) after pulmonary rehabilitation, consistent with established clinically significant differences (Ferreira A, et al 2009). Nishiyama and colleagues (2008) randomized patients with idiopathic pulmonary fibrosis to outpatient PR or standard therapy. They found significant improvement in 6MWD and the St. Georges Respiratory Questionnaire in the PR group.

Additionally, in a 2008 Cochrane review, Holland and Hill identified improvement in 6MWD, dyspnea and quality of life after pulmonary rehabilitation. In the study by Ferreira, Feuerman, and Spiegler, patients with pulmonary fibrosis, sarcoidosis, asbestosis, cryptogenic organizing pneumonia, eosinophilic granuloma, Churg-Strauss syndrome, hypersensitivity pneumonitis, lymphangioleiomyoma, and ILD due to adult respiratory distress syndrome were shown to achieve significant gains in 6MWT distance and QOL after PR.

Restrictive Chest Wall Disease

Patients with restrictive chest wall disease such as scoliosis, kyphoscoliosis, or changes in the chest wall after thoracoplasty typically have restrictive physiology on pulmonary function testing, progressive dyspnea, and exercise impairment. A program of exercise training improves pulmonary function (forced vital capacity, forced expiratory volume in 1 second [FEV_1], inspiratory capacity, and expiratory reserve volume) and exercise endurance among patients with idiopathic scoliosis (Dos Santos Alves VL, et al 2006).

Significant gains in 6MWD, daily activity score, and dyspnea have been demonstrated after PR among patients with restrictive chest wall disease due to post-tuberculosis thoracoplasty. Improvements have been of comparable magnitude to the gains made by age and FEV_1-matched patients with COPD (Ando M, et al 2003).

Patients with restrictive chest wall disease were also among the groups of patients with non-COPD diagnoses who improved after PR in the studies by Foster and Thomas (1990) and by Ferreira, Feuerman, and Spiegler (2006).

Respiratory Disorders Associated with Obesity

Obesity hypoventilation syndrome is commonly associated with restrictive defects on pulmonary function testing and disturbances in gas exchange (Mohsenin V & Gee JBL, 1993, Rochester DF, 1998). Dyspnea and impaired exercise tolerance are common in obese persons, even in the absence of other comorbid respiratory conditions.

Exercise intolerance in obese persons has a multifactorial basis including derangements in pulmonary function, reduced respiratory compliance, hypoxemia, increased O_2 cost of breathing, exaggerated cardiorespiratory response to exercise, and reductions in respiratory muscle strength (Mohsenin V & Gee JBL, 1993, Rochester DF, 1998). Pulmonary hypertension and other cardiocirculatory disturbances (such as systemic hypertension, diastolic dysfunction, myocardial ischemia, claudication, or microvascular disease) and musculoskeletal disturbances also commonly contribute to exercise impairment.

Impaired exercise capacity in obese persons often leads to decreased participation in social, recreational, or work activities and may ultimately result in decreased ability to perform activities of daily living, with associated deconditioning, anxiety, and depression. Weight loss can lead to improvements in lung function, exercise tolerance, and sleep-disordered breathing (Sugerman HJ, et al 1986, Hakala K, et al 1996, Olsen EJ, et al 2003).

Pulmonary rehabilitation improves motor skills, locomotion, mobility, and self-care among patients with severe obesity that had experienced a recent episode of respiratory

failure (Whittaker LA & Rochester CL: 2000). PR has also led to significant weight loss as well as improvements in treadmill walking endurance and health status among obese patients with obstructive sleep apnea (Knipper J, et al 2000).

Pulmonary Hypertension

Patients with pulmonary hypertension (PH) due to both primary and secondary causes experience exercise intolerance (Wasserman K, et al 1999, Palange P, et al 2007, Miyamoto S, et al 2000) dyspnea, and impaired health-related QOL. Pulmonary rehabilitation has been found to improve exercise capacity, dyspnea and quality of life in patients with severe chronic PH.

Randomized control investigation has demonstrated that after 15 weeks of exercise and respiratory training, patients with severe PH have been found to have a 111 meter improvement in 6MWD (compared to worsening of 6MWD in controls), as well as improvement in WHO functional class and peak oxygen consumption (Mereles D, et al 2006). Overall compliance with the home-based component of the exercise program was excellent. Patients randomized initially to the control group were subsequently offered PR, and they too achieved gains comparable to those made by the primary training group.

Lung Cancer

Patients with lung cancer, with or without COPD, who are candidates for surgical resection, experience deconditioning and fatigue. Because preoperative exercise tolerance predicts outcomes of thoracic surgery (Schuurmans MM, et al 2002) preoperative PR may improve outcomes for some patients with lung cancer. PR also offers an opportunity to educate patients regarding care strategies such as incentive spirometer use, bronchial clearance techniques, controlled coughing, and other strategies that may reduce risk of postoperative complications.

Sekine and colleagues (2005) conducted an analysis of patients with lung cancer and COPD who underwent PR preoperatively, and compared outcomes with a group of historical control subjects who had not received preoperative PR. Despite lower baseline FEV_1 and forced vital capacity, patients in the group that underwent PR had shorter hospital length of stay, and better actual postoperative FEV_1 as compared with the historical control group.

Of note, exercise tolerance is also often impaired after treatment for lung cancer. Spruit and colleagues (2006) conducted a trial of patients with severely impaired lung function and impaired exercise tolerance after treatment for lung cancer (surgery, chemotherapy, and/or radiation therapy) that underwent pulmonary rehabilitation. Pulmonary rehabilitation led to significant improvements in exercise endurance (145 m, 43.2% increase; $P = .002$) and peak exercise capacity as compared with baseline.

Neuromuscular Disease

Patients with a wide variety of neuromuscular disorders, including stroke, Parkinson's disease, postpolio syndrome, muscular dystrophy, multiple sclerosis, myopathies; survivors of critical illness-related neuropathy and myopathy; Guillain-Barre syndrome, Charcot-Marie-Tooth disease, amyotrophic lateral sclerosis, spinal cord injury, disorders of the neuromuscular junction, and diaphragm paralysis can have several disturbances of

respiratory function, particularly if there is associated weakness of the respiratory and / or bulbar muscles or reduced chest wall compliance (Hill NS & Lynch JP, 2002, Fanburg BL & Sicilian L, 1994, Aboussouan LS, 2005).

In addition to disturbances in pulmonary function (typically a restrictive ventilatory defect), patients with neuromuscular disease commonly experience swallowing dysfunction, aspiration, difficulty clearing respiratory secretions, sleep-disordered breathing (alveolar hypoventilation or obstructive sleep apnea), gas exchange disturbances, and disturbances of respiratory control (Aboussouan LS, 2005, Piper A, 2002). These disturbances, together with abnormalities of the peripheral muscles, can lead to significant exercise impairment and disability during daily life activities, fatigue, deconditioning and impairment in QOL (Sabate M, et al, 1996).

Patients with neuromuscular disorders may benefit from exercise training of the extremities and respiratory muscles to counteract reductions in strength or endurance resulting from deconditioning. Patients with neuromuscular disease were among those who improved in PR in the trials conducted by Foster and Thomas (1990) and by Ferreira, Feuerman, and Spiegler (2006).

There is a sizeable body of literature examining the use of physical activity and various strategies of exercise training to maintain maximal function and QOL of patients with neuromuscular diseases, wherein disturbances of respiratory function were not specifically considered (Shneerson JM, 1998, Fowler WM, 2002, Kilmer DD, 2002, Eldar R, Marineek C, 2000).

Multiple trials have confirmed benefits of

- aerobic or strength training conducted in various rehabilitation settings for patients with multiple sclerosis (Reitberg MB, et al 2005, White LJ & Dressemdorfer RH, 2004, Surakka J, et al 2004, Romberg A, et al 2004), Parkinson's disease (de Goede CJT, et al, 2001, Bergen JL, et al 2002, Baatile J, et al 2000, Koseoglu F, et al 1997);
- stroke (Ouellette MM et al 2004);
- postpolio syndrome (Chan KM, et al 2003);
- myopathies (Alexanderson H & Lundberg IE, 2005, Alexanderson H, et al 2007, Jeppesen TD, et al, 2006, Phillips BA & Mastaglia FL, 2000, Orngreen MC, et al, 2005); and,
- amyotrophic lateral sclerosis (Drory VE, et a, 2001, Bello-Haas VD, et al 2007, Morris ME, et al 2006).

In addition to exercise training, PR may benefit patients with neuromuscular disease by training them in the use of adaptive/assistive equipment to enable them to maintain functional independence and live in their own home. Pulmonary rehabilitation is an ideal setting in which patients can be acclimatized to and trained in the use of non-invasive ventilation and to learn assisted coughing techniques, and use of devices such as the insufflator–exsufflator or intermittent positive-pressure breathing equipment.

Sessions

The proposed rule makes a critical error in interpretation of the clinical literature and published professional guidelines. The term "sessions" is not synonymous with "hours." One typical pulmonary rehabilitation session may last 2-3 hours, very rarely just one hour. The proposal establishes a limit of 36 "sessions" with each billable session defined as one hour. This 36-hour payment cap, by CMS' own acknowledgement, is below the mean of the reviewed literature, and, more importantly, directly contrary to existing CMS policy found elsewhere related to pulmonary rehabilitation services. 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 broad standard of care in the United States.

Comment

We have consistently recommended that CMS adopt a policy of up to 72 hours of pulmonary rehabilitation, based on the individual's medical necessity and reaching a level of optimal care. Many patients would require less. More importantly, however, the proposed policy's cap on one hour of billable PR per day is not based on any clinical limitation appearing in the literature. Rather, pulmonary rehabilitation "sessions" generally last 2-3 hours per day. While we agree that an individual hour must include physician prescribed exercise, programs must retain the flexibility to design their programs in an efficient manner that provides effective rehabilitation services in accordance with established clinical practice guidelines and accepted standards of care.

Coding – Payment Based on Single Code

The proposed rule recommends establishment of a single G code to replace current G codes 0237-39 AND not permit any additional billable services related to pulmonary rehabilitation. CMS computations establish a payment of $16+, per hour of rehabilitation.

Comment

There are numerous serious flaws in CMS calculations.

- First, the new G code represents one hour of service, while the codes it replaces represent 15 minute service increments. Today, G0237 pays approximately $18-20 for a 15 minute increment; replacing this with a code with less than ¼ the value makes no logical sense whatsoever and will preclude the financial viability of PR.
- The new code is a bundled code, including items such as 94620, 94664 and 94667; services currently billed separately but still an integral part of every pulmonary rehabilitation program. In fact, the statutory mandate for outcomes assessment in effect mandates these services, but there is no payment permitted.
- As noted above, in addition to the identified oximeter/printer, one channel ECG and treadmill, a comprehensive PR program will use both upright and recumbent

bicycles, arm ergometers, Stairmaster devices, exercise bands, weights, oxygen, etc.

- The PR team is multi disciplinary but not as CMS identifies. The professionals include nurses, respiratory therapists, social workers, psychologists, dietitians, and occupational therapists. The nurse blending approach does not resemble the staffing common in PR departments. CNAs and MAs lack the training and scope of practice to safely and adequately care for complex, symptomatic patients with chronic lung disease in a PR setting.
- Perhaps the most problematic assumption by CMS is the premise that physician work in pulmonary rehabilitation mirrors the physician work in unmonitored cardiac rehabilitation 93797. This is a faulty premise for several reasons:
    - The physician work mandated by the statute goes well beyond the physician work in either 93797 or 93798; the statute requires a physician to establish and review a treatment plan as well as be *"involved substantially in directing the progress of the individual in the program,"* and the proposed regulation also requires the physician to conduct the outcomes assessment component of the statutory mandate. Because the proposal creates a bundled code, precluding additional billing, **the work associated with a long standing cardiac code simply is not comparable to physician work in pulmonary rehabilitation. The work included in 93797 is not reflective of these numerous mandated physician services.**
    - The PR team is multi disciplinary but not as CMS identifies. The professionals include nurses, respiratory therapists, social workers, psychologists, dietitians, and occupational therapists. The nurse blending approach does not resemble the staffing common in PR departments. CNAs and MAs lack the training and scope of practice to safely and adequately care for complex, symptomatic patients with chronic lung disease in a PR setting.
    - There appears to be an underlying assumption that once patients are admitted to pulmonary rehabilitation, the actual services received are identical to cardiac rehabilitation related services. The typical pulmonary patient is, in fact, significantly older with more complicated symptoms, lower exercise capacity, and requires significant attention to oxygen/possible desaturation. **The attached Table 1, with citations, provides important support for this premise**.

Physician Fee Schedule Payment Recommendations

We recommend that CMS continue use of the current G codes 0237-39, continue use of the current policy that permits component billing of related services such as 94620, 94664 and 94667, and permit the physician to submit an appropriate E/M code when physician work is appropriate and medically necessary

- Outcomes assessment is, according to the proposed PFS rule, a physician evaluation service
- The intake assessment may be conducted by a physician or pulmonary rehabilitation staff, dependent upon specific patient characteristics. In the case that a physician assessment is appropriate because of patient complexity, current CMS policy does permit physician billing of an appropriate E/M code.

Definitions

We support the specific definitions proposed in the rule focusing on individualized treatment plan, outcomes assessment, physician, physician-prescribed exercise, psychosocial assessment, and pulmonary rehabilitation. We take particular note of the proposed definition for outcomes assessment, defined as

> "***a physician evaluation*** (emphasis added) of the patient's progress as it relates to his or her rehabilitation. The outcomes assessment is in writing and includes the following: pre- and post-assessments based on patient centered outcomes which are ***conducted by the physician*** (emphasis added) at the beginning of the program and at the end of the program; and objective clinical measures of exercise performance and self reported measures of shortness of breath and behavior."

However, at another section of the regulation, CMS defines outcomes assessment as "an objective clinical measure of the effectiveness of the PR program for the individual patient… All such assessments are considered part of the PR program and as such are conducted in the appropriate settings and may not be billed separately." We believe this wording is in direct contradiction to the "outcomes assessment" definition as a physician evaluation included in the formal "Definitions" section of the proposal.

Comment

These specific services are, by CMS' definition which we support, a specific service that contributes to the diagnosis and/or treatment of a specific patient and, therefore, must be regarded as a separately billable service and cannot be melded into the proposed bundled G code.

We also believe there may be value in creating a formal definition of "plan of care" as it relates to pulmonary rehabilitation. We stress this because it is unclear to us the extent of required physician involvement in the development of the formal care plan. At one point the proposal states, *"As part of the written individualized treatment plan the physician should evaluate and include only that education and training which addresses the needs particular to the patient that will further their independence…."* While we agree with that comment, we are concerned that Medicare contractors may interpret it to mean the physician is responsible for development of the plan of care. Importantly, the pulmonary rehabilitation team of health care professionals develops the plan of care and, appropriately so, the program medical director must approve and sign the plan of care.

We do note that the proposal does include a specific section devoted to the "individualized treatment plan" and would ask for clarification to determine if these terms are used interchangeably.

Physician Prescribed Exercise

The proposed rule recommends that every "session" include some physician-prescribed exercise.

Comment

While we strongly support the premise of this requirement, it is important to emphasize that we sense CMS is using the terms "session" and "hour" interchangeably. While a Medicare beneficiary may participate in a two-hour rehabilitation session, we do concur that it is reasonable to expect that in that 120 minute session the beneficiary would exercise at least twice, for example two separate 15-20 minute exercise components. This example constitutes one session that is two hours in duration.

If "hours" is a more appropriate parameter to define the "length" of care for payment purposes, **we recommend that programs be permitted to shape their programs according to individual beneficiary needs, that each hour of billable service be required to have an exercise component, and the number of hours billable per day be capped at 3 or 4**. It is critical to emphasize that this latter recommendation has NO IMPACT on Medicare outlays once the actual cap on number of hours is determined.

Individualized Treatment Plan

As noted above, we strongly support the mandate in the statute that requires a physician to develop, sign and review the individualized treatment plan.

Comment

We strongly urge CMS to clarify that this treatment plan is developed by the physician (referring or PR medical director) but includes components such as the type, amount, frequency and duration of the items and services which, in fact, are recommended by the professional PR team.

Settings

The proposed rule addresses the two primary settings for pulmonary rehabilitation that are addressed in the statute, physician office and hospital outpatient settings. Further, the rule, appropriately so, requires the physician office to have the necessary "cardio pulmonary, emergency diagnostic and therapeutic equipment accepted as medically necessary… for emergency treatment related to a chronic respiratory disease condition. Some examples of this equipment are oxygen, defibrillators, and CPR equipment."

Comment

It is imperative that the costs associated with this required equipment be included as part of the "practice expense" component of any fee calculation. Likewise, the identified equipment related specifically to pulmonary is not accurate. In addition to the identified oximeter/printer, one channel ECG and treadmill, a comprehensive PR program will use upright and recumbent bicycles, arm ergometers, stairmaster devices, exercise bands, etc. Additionally, while some pulmonary rehabilitation patients may indeed have their own oxygen systems under the DME benefit, others will be required to rely on oxygen provided through the physician office because they only desaturate during exertion and do not qualify for long term oxygen therapy under the DME benefit.

Physician Supervision

The proposed rule states, "the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service or procedure… it does not mean the physician must be in the room when the service or procedure is performed." The proposal further states, in addressing the hospital outpatient setting, "the physician must be on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure."

Comment

We support the statement regarding physician supervision in the physician office setting. However, the statement included in this proposal regarding the hospital outpatient setting does not match the more detailed explanation included in the actual Hospital Outpatient proposed rule. That rule states, "For services provided in the hospital and in an on-campus PBD of the hospital, direct supervision would mean that the physician must be present on the same campus, in the hospital or the on-campus PBD of the hospital and immediately available to furnish assistance and direction throughout the performance of the procedure." **We strongly urge CMS to clarify in the final physician fee schedule rule that the definition of direct supervision that applies to hospital outpatient pulmonary rehabilitation is the definition included in the proposed hospital outpatient rule**.

The appropriate use of NPPs in the context of pulmonary rehabilitation should also be considered. While we fully recognize the authorizing statute makes several references to physician supervision, physician prescribed exercise and a requirement for a physician to be "involved substantially in directing the progress of ***individual*** (emphasis added) in the program," we believe it is reasonable to permit either nurse practitioners or physician assistants to fulfill the responsibilities of the physician when performed in accordance with state laws and accepted standards of care. We propose that this is consistent with the intent of Section 1861(s)(2)(K)(i) and Section 1861(s)(2)(K)(ii).

Physician Standards

We support the proposed rule with respect to physician standards.

Conclusion

While there are a number of positive aspects to CMS' proposal to implement the new pulmonary rehabilitation benefit, there are significant problems with the coverage and payment analysis. The proposed policies, if not revised in the final rule, will impede Medicare beneficiaries with chronic respiratory diseases from having access to beneficial services and effectively close pulmonary rehabilitation services across the country due to lack of appropriate payment.

Our respective pulmonary medical societies and organizations met recently with CMS coverage and payment staff to discuss our concerns and we appreciate the opportunity to do so. In these written comments, we elaborate on what we believe are significant flaws in the proposal and offer constructive comments in hopes that CMS will take into consideration our recommendations and make substantive changes in the final rule. Only with major changes will the new pulmonary rehabilitation benefit be consistent with the legislative intent to improve Medicare beneficiaries' access to pulmonary rehabilitation programs that can improve their health and quality of life.

Section II. G. 9. – Section 114(a)
Section II. K. Comprehensive Outpatient Rehabilitation Facilities (CORF) and Rehabilitation Agency Issues

Definition of Respiratory Therapist

CMS proposes to modify the definition of a respiratory therapist who furnishes services in the CORF setting to include Certified Respiratory Therapists (CRT) who have completed advanced level training from a national accrediting body and who are eligible to take the registry exam to become a Registered Respiratory Therapist (RRT). This revision reverts back to the definition that was previously contained in regulations for many years.

Comment

We concur with the proposed changes and we applaud CMS for being sensitive to ensuring that qualified respiratory therapists continue to furnish services for which they have been educated and competency tested.

In polling some of our membership regarding the differences between the types of services furnished by a CRT as compared to a RRT, we have been informed that there is virtually no difference. For example, one member who has been a CRT for 35 years was the coordinator of a hospital-based PR program that she initiated, in addition to initiating several start-up PR programs in the CORFs. She indicated that nothing she did has ever

been differentiated from that of an RRT. Another member who has been a CRT for 25 years indicated that he is responsible for all aspects of the PR program and performs duties identical to that of any RRT in the facility.

Both CRTs and RRTs are educated and competency tested in a variety of areas. These include the affective, psychomotor and cognitive domains, supervised pre-clinical ((didactic and laboratory) and clinical activities, as well as documentation of competence through tests determined to be valid and reliable. Both the CRT and RRT exams include testing cognitive levels with respect to recall, application and analysis of the following categories: patient data evaluation and recommendations, equipment application and cleanliness, and therapeutic procedure initiation and modification.

With respect to the latter category, CRTs and RRTs are expected to maintain a patent airway including the care of artificial airways, remove bronchopulmonary secretions, achieve adequate respiratory support, independently monitor treatment techniques based on the patient's response, recommend modifications in the respiratory care plan based on the patient's response, and determine the appropriateness of the prescribed respiratory care plan and recommend modifications when indicated. In the CORF setting, their work focuses heavily on breathing techniques, other types of education and group exercise. Other functions involve the 6-minute walk test, inhaler instruction, respiratory therapy instruction, and the initial assessment by the rehabilitation staff.

Since 2005, the testing requirements by the National Board for Respiratory Care (NBRC) have changed. The NBRC now requires graduates of the advanced-level respiratory care education programs to take both the CRT and RRT competency examinations within three years of graduation. Thus, by definition every respiratory therapist will be RRT eligible and must pass the RRT exam within three years. This change moves the professional of respiratory therapy in a definitive direction where every educational program will be at the advanced level.

We appreciate the opportunity to comments on these important issues.

Sincerely,

Timothy R. Myers, BS, RRT-NPS
President

Attachments

Attachment A

SUPPLEMENTARY MATERIAL SUPPORTING RECOMMENDATIONS

Peer Reviewed Literature Expanded Diagnoses/

Duration of Pulmonary Rehabilitation

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Attachment B

SUPPLEMENTARY MATERIAL SUPPORTING RECOMMENDATIONS
Excerpts from Current LCDs on Pulmonary Rehabilitation
Authorizing Coverage Beyond Proposed Diagnoses

- **Trailblazer LCD approved ICD-9 diagnostic codes:**

Medicare is establishing the following limited coverage for **CPT / HCPCS codes 94667, 94668, G0237, G0238 and G0239:**

Covered for:
340 Multiple Sclerosis
357.0 Acute infective polyneuritis
358.00-358.01 Myasthenia gravis
491.0–491.1 Chronic bronchitis
491.20 Obstructive chronic bronchitis, without exacerbation
491.8 Other chronic bronchitis
492.8 Other emphysema
493.20 Chronic obstructive asthma, unspecified
493.81–493.82 Other forms of asthma
494.0–494.1 Bronchiectasis
496 Chronic airway obstruction, not elsewhere classified
500-504 Pneumoconioses and other lung diseases due to external agents
506.0 Bronchitis and pneumonitis due to fumes and vapors
506.4 Chronic respiratory conditions due to fumes and vapors
506.9 Unspecified respiratory conditions due to fumes and vapors
508.1 Chronic and other pulmonary manifestations due to radiation
515 Postinflammatory pulmonary fibrosis
516.0 Pulmonary alveolar proteinosis
516.2–516.3 Other alveolar and parietoalveolar pneumonopathy
516.8 Other specified alveolar and parietoalveolar pneumonopathy
518.1 Interstitial emphysema
518.7 Transfusion related acute lung injury (TRALI)
518.89* Other diseases of lung, not elsewhere classified
Note: Use 518.89* for patients who have become oxygen dependent following an illness.
737.30 Scoliosis (and kyphoscoliosis) idiopathic

- **National Government Services (NGS) LCD approved ICD-9 diagnostic codes:**

ICD-9-CM Codes That Support Medical Necessity:

It is the responsibility of the provider to code to the highest level specified in the *ICD-9-CM (e.g.,* to the fourth or fifth digit). The correct use of an ICD-9-CM code does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

135 SARCOIDOSIS
277.00 CYSTIC FIBROSIS WITHOUT MECONIUM ILEUS
277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
491.0 SIMPLE CHRONIC BRONCHITIS
491.1 MUCOPURULENT CHRONIC BRONCHITIS
491.20 OBSTRUCTIVE CHRONIC BRONCHITIS WITHOUT EXACERBATION
491.21 OBSTRUCTIVE CHRONIC BRONCHITIS WITH (ACUTE) EXACERBATION
491.22 OBSTRUCTIVE CHRONIC BRONCHITIS WITH ACUTE BRONCHITIS
491.8 OTHER CHRONIC BRONCHITIS
491.9 UNSPECIFIED CHRONIC BRONCHITIS
492.0 EMPHYSEMATOUS BLEB
492.8 OTHER EMPHYSEMA
493.20 CHRONIC OBSTRUCTIVE ASTHMA UNSPECIFIED
493.82 COUGH VARIANT ASTHMA
494.0 BRONCHIECTASIS WITHOUT ACUTE EXACERBATION
494.1 BRONCHIECTASIS WITH ACUTE EXACERBATION
496 CHRONIC AIRWAY OBSTRUCTION NOT ELSEWHERE CLASSIFIED
500 COAL WORKERS' PNEUMOCONIOSIS
501 ASBESTOSIS
502 PNEUMOCONIOSIS DUE TO OTHER SILICA OR SILICATES
503 PNEUMOCONIOSIS DUE TO OTHER INORGANIC DUST
504 PNEUMONOPATHY DUE TO INHALATION OF OTHER DUST
505 PNEUMOCONIOSIS UNSPECIFIED
506.4 CHRONIC RESPIRATORY CONDITIONS DUE TO FUMES AND VAPORS
506.9 UNSPECIFIED RESPIRATORY CONDITIONS DUE TO FUMES AND VAPORS
508.1 CHRONIC AND OTHER PULMONARY MANIFESTATIONS DUE TO RADIATION
515 POSTINFLAMMATORY PULMONARY FIBROSIS
516.0 PULMONARY ALVEOLAR PROTEINOSIS
516.2 PULMONARY ALVEOLAR MICROLITHIASIS
516.3 IDIOPATHIC FIBROSING ALVEOLITIS
516.8 OTHER SPECIFIED ALVEOLAR AND PARIETOALVEOLAR PNEUMONOPATHIES
516.9 UNSPECIFIED ALVEOLAR AND PARIETOALVEOLAR PNEUMONOPATHY
518.89 OTHER DISEASES OF LUNG NOT ELSEWHERE CLASSIFIED

- **First Coast Service Options LCD Approved ICD-9 diagnostic codes:**

ICD-9 Codes that Support Medical Necessity
135 SARCOIDOSIS
277.00 CYSTIC FIBROSIS WITHOUT MECONIUM ILEUS
277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
491.0 - 491.9 SIMPLE CHRONIC BRONCHITIS - UNSPECIFIED

CHRONIC BRONCHITIS
492.8 OTHER EMPHYSEMA
493.00 - 493.92 EXTRINSIC ASTHMA UNSPECIFIED - ASTHMA UNSPECIFIED WITH (ACUTE) EXACERBATION
494.0 - 494.1 BRONCHIECTASIS WITHOUT ACUTE EXACERBATION - BRONCHIECTASIS WITH ACUTE EXACERBATION
496 CHRONIC AIRWAY OBSTRUCTION NOT ELSEWHERE CLASSIFIED
500 COAL WORKERS' PNEUMOCONIOSIS
501 ASBESTOSIS
502 PNEUMOCONIOSIS DUE TO OTHER SILICA OR SILICATES
503 PNEUMOCONIOSIS DUE TO OTHER INORGANIC DUST
504 PNEUMONOPATHY DUE TO INHALATION OF OTHER DUST
505 PNEUMOCONIOSIS UNSPECIFIED
506.4 CHRONIC RESPIRATORY CONDITIONS DUE TO FUMES AND VAPORS
508.1 CHRONIC AND OTHER PULMONARY MANIFESTATIONS DUE TO RADIATION
515 POSTINFLAMMATORY PULMONARY FIBROSIS
516.0 PULMONARY ALVEOLAR PROTEINOSIS
516.2 PULMONARY ALVEOLAR MICROLITHIASIS
516.3 IDIOPATHIC FIBROSING ALVEOLITIS
516.8
OTHER SPECIFIED ALVEOLAR AND PARIETOALVEOLAR PNEUMONOPATHIES
518.89 OTHER DISEASES OF LUNG NOT ELSEWHERE CLASSIFIED
519.00 - 519.9 TRACHEOSTOMY COMPLICATION UNSPECIFIED - UNSPECIFIED DISEASE OF RESPIRATORY SYSTEM
V42.6 LUNG REPLACED BY TRANSPLANT

SUPPLEMENTARY MATERIAL SUPPORTING RECOMMENDATIONS

Table #1 – Key Differences – Cardiac vs. Pulmonary Rehabilitation Patient Mix/Acuity

	Pts	Age	Pre - Exercise test		O2 needs	Symptoms	
			METS	Watts		at rest	only at max exer
Cannistra LB et al. Am J Cardiol 1992;69:1274	225 MIs	55	5.1		0%	2%	34%
Engblom E et al. JCPR 1997;17:29	119 CABG	54		100	0%		
Wosurnu D et al. Eur Heart J 1996;17:854	81 CABG	58	7.8		0%		
Plankeel et al Chest 2005;127:110	290 COPD	66	3.4	62	29%	30%	2%

Cardiac Rehab (recent Cochrane review): 50 trials, mean age < 60 in 46 (< 55 in 35), 61-65 in 4, none over 65

Pulmonary Rehab (recent Cochrane review, ACCP/AACVPR 1997 evidence-based review Table 2, Lacasse meta-analysis 1996): 34 trials, < 60 in 6 (< 55 in 1), 61-65 in 15, 66-70 in 12, >70 in 1

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