AMERICAN ASSOCIATION FOR RESPIRATORY CARE
9425 North MacArthur Blvd., Suite 100, Irving, TX 75063, (972) 243-2272, Fax (972) 484-2720
http://www.aarc.org, E-mail: info@aarc.org

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Reference: Docket No. SSA-2006—149
Revised Medical Criteria for Evaluating Respiratory System Disorders

As President of the American Association for Respiratory Care (AARC), I am pleased to submit comments on the Social Security Administration's (SSA) proposed rules to revise the medical criteria used to evaluate respiratory system disorders for determining disability eligibility in adults and children. The AARC is a professional association representing over 53,000 respiratory therapists nationwide. Respiratory therapists treat high-risk patients with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD) including emphysema and chronic bronchitis. Our specific comments are outlined below:

Sections 3.00E and 3.00F (pages 7969 and 7977)

SSA proposes to modify its current documentation requirements with respect to spirometry testing standards and spirometic tracings.

According to SSA, testing standards are not generally documented in a patient's medical record and program experience shows that there is no need to verify that the person performing the spirometry test actually followed the standards. To that end, SSA proposes to no longer require proof that spiromety equipment was calibrated on the day the test is given, since daily calibration is the standard of care. Further, spirometric tracings for the satisfactory forced expiratory maneuvers would no longer be required to be documented since the standard of care requires at least three satisfactory tracings before reporting the highest value.

While we understand the logic behind SSA's proposed changes, we are concerned that the advent of physician office-based and home-based spirometry testing may not follow such rigorous standards of care. Therefore, as a precaution in light of possible audits or other oversight, we recommend SSA add a new item "c" under 300.E3 (information that must be included in the spirometry report) to read as follows:

> "c. Upon request, calibration logs and spirometry tracings that confirm standards of care were met if we determine such documentation is necessary for evaluation purposes."

Section 3.00G3a (pages 7969 and 7976)

On page 7969, right-hand column, SSA states that "Spirometry, DLCO tests, resting ABG tests and pulse oximetry offer a sufficiently comprehensive range of PFTs to properly evaluate respiratory disorders." Arterial blood gas tests and pulse oximetry are not pulmonary function tests, but are monitoring devices and produce current status data (they are not diagnostic). Only spirometry and DLCO tests are considered pulmonary function tests.

Therefore, rather than revise the entire section, we recommend revising 3.00D3 on page 7976 as follows:

> 3. "Pulmonary function tests and other monitoring devices used to evaluate respiratory disorders include …."

Section 103.00E (pages 7972 and 7982)

On page 7972, SSA discusses its requirement that prior to purchasing spirometry for children a medical consultant experienced in child care must first determine if the test is needed. According to SSA, the rationale for this is because children, unlike adults, do not routinely undergo spirometry and that for purposes of determining disability in children medical expertise is required.

While we do not have any problem with a medical expert in child care determining whether a spirometry test is required, we disagree with the statement that children are not routinely tested. The National Heart, Lung and Blood Institute's Expert Panel Report 3 on Guidelines for the Diagnosis and Management of Asthma call for use of spirometry to obtain objective measures of lung function and recommend that it be performed at the following times (Page 30 pdf):

> • At the initial assessment.
> • After treatment is initiated and symptoms and PEF have stabilized.
> • During periods of progressive or prolonged loss of asthma control.
> • At least every 1–2 years; more frequently depending on response to therapy.
> — Low FEV_1 indicates current obstruction (impairment) and risk for future exacerbations (risk). For children, FEV_1/forced vital capacity (FVC) appears to be a more sensitive measure of severity and control in the impairment domain. FEV_1 is a useful measure of risk for exacerbations, although it is emphasized that even children who have normal lung function experience exacerbations.

The Guidelines also state that wheezing, especially in children, is a key indicator for the probability of asthma but spirometry is needed to establish a diagnosis (Page 23 pdf). Further, the guidelines recommend use of spirometry "in all patients ≥5 years of age to determine that airway obstruction is at least partially reversible." (Page 16 pdf).

The PDF Summary Report is at http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf
The Full Report is at http://www.nhlbi.nih.gov/guidelines/asthma/

Section 103.02E (pages 7972 and 7983)

In the preamble language on page 7972, SSA states "For a child from birth up to the attainment of age 2, we would evaluate the frequency of the child's CLD exacerbations or related complications that require hospitalization under proposed 103.02E. After the child attains age 2, we would evaluate the CLD under the proposed 103.03 asthma listing." On page 7983, 103.00F (What is CLD, and how do we evaluate it?) item 5 states "After you have attained age 2, we will evaluate your CLD under 103.03. These statements are inconsistent with the regulatory text contained in 103.02E (Chronic respiratory disorders), which states at the end "…After that, evaluate the impairment(s) under 103.03 **or as otherwise appropriate**".

Chronic lung disease (CLD) in children is closely related to chronic obstructive lung disease (COPD) in adults. Further, the etiologies and management of children diagnosed with CLD and asthma are completely different since CLD is more of a fixed obstruction not responsive to asthma-like therapies, which SSA has categorized as episodic.

We believe for these children it may be more appropriate to evaluate them under the chronic respiratory disorder category 103.02E. However, we can accept the language in 103.03E as long as there is an option to evaluate impairments "as otherwise appropriate", which does not lock them into the asthma criteria. Therefore, we recommend SSA revise 103.00F5 to be consistent with 103.02E as follows:

> "After you have attained age 2, we will evaluate your CLD under 103.03 or as otherwise appropriate."

We appreciate the opportunity to comments on these proposed revisions. If you have any questions or desire additional information, please feel free to contact Timothy R. Myers, MBA, RRT-NPS, FAARC, Associate Executive Director, Brands Management at myers@aarc.org, or 972-254-2272.

George Gaebler, MBA, RRT, FAARC
President