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## 2015 CSRC-Position Statement pertaining to Concurrent Therapy Approved by the CSRC Board of Directors on August 27th, 2015

On any given day, literally millions of doses of bronchodilator drugs are administered to patients with reactive airways disease (RAD) in the United States. In the vast majority of cases, these doses are administered by laymen, and not licensed caregivers. The population of laymen to which we refer here is patients themselves. And, in the vast majority of those cases, the device used to mobilize the particulate bronchodilator to the airways is the metered-dose inhaler ("MDI"). This method of delivery is consummately appropriate, insofar as the bronchodilator agents delivered are administered to/by patients whose RAD is <u>stable</u>.

Similarly, bronchodilator agents are commonly administered to hospitalized patients whose RAD is stable. The stability of their RAD is traceable to the fact that: 1) the presumptive diagnosis to which the hospitalization is attributable is a co-morbid condition other than RAD itself (congestive heart failure, sepsis, diabetes, cardiac dysrhythmias, trauma, etc); or 2) the acute exacerbation of RAD initially responsible for the patient's admission has been successfully managed to the point that the now-stable patient is being prepared for discharge. In the context of the patients described above, the incidence of serious side effects in the wake of MDI use is virtually zero. Consequently, outpatients receive MDI treatments without being monitored by a caregiver, while their inpatient counterparts will either self-administer the drugs without being monitored, or will receive the MDI dose while being observed by a "med nurse". If and when the MDI is employed by an inpatient in the presence of a nurse, no charge will be incurred by the patient or third-party payor, because nursing care is considered an integral component of inpatient care.

In the balance of this Position Statement, however, we will direct our attention to the delivery of aerosolized adrenergic beta<sub>2</sub>-agonist and/or aerosolized cholinergic agents to patients with RAD whose condition is <u>not stable</u>. Physicians typically wish to deliver higher doses of adrenergic and/or cholinergic agents to patients with exacerbated RAD than is practical by means of an MDI, such that a small-volume nebulizer (SVN) is usually employed, under the watchful eye of a respiratory care practitioner (RCP). It is prudent to employ an SVN in lieu of an MDI here, inasmuch as the former device is capable of delivering a far higher dose of pharmacologic agent(s) than is the latter. Consequently, bronchodilators delivered by SVN are far more likely to elicit: 1) symptom relief; and 2) side effects. This renders the presence of an RCP during the delivery of the drug(s) highly advisable, in order to assess the efficacy of the agent(s) and to be alert to the possible emergence of adverse side effects. In the event that the inpatient in question is a beneficiary of Medicare or Medicaid, the Centers for Medicare and Medicaid Services (CMS) does authorize the institutional care provider to submit a charge for the RCP's services.

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Concurrent Therapy, also termed "stacking", is a practice whereby an RCP initiates an aerosol treatment for a patient and immediately proceeds to initiate one or more subsequent treatments to additional patients in succession before the initial treatment is complete. The practice of stacking, therefore, robs the individual patient of the scrutiny that would be afforded that patient had the RCP remained at the bedside for the entire duration of the treatment. This is problematic for two reasons. First and foremost, the absence of the RCP ensures that any adverse side effect(s) which might emerge will go unnoticed, with potentially dire consequences. Secondly, CMS recognizes that the aerosol treatment "…is not being delivered according to Medicare coverage guidelines: that is, the therapy is not being provided individually."<sup>1</sup> If the recipient of the treatment is a Medicare/Medicaid beneficiary, submission of a charge for the treatment could be considered to constitute Medicare fraud.

In a previous Position Statement, the California Society for Respiratory Care (CSRC), in the wake of comprehensive research into the issue of Concurrent Therapy, concluded that ".....aside from declared disaster, there is no compelling medical, ethical, or safety rationale for the continuation of this practice" and "....takes the position that [it] should be abandoned....in the interests of patient safety, interventional efficacy, and the ethical practice of Respiratory Therapy." <sup>1</sup>

California's Respiratory Care Board (RCB) also inveighed against the practice of stacking in a strongly-worded statement in 2003 that reads, in part, "…we would strongly discourage any organization from adopting a policy which leaves patients unattended for administration of medication" because it "…would be contradictory to safe practice".<sup>2</sup>

It is understood and acknowledged that the dose response curves of bronchodilator aerosols typically require that two to five minutes elapse between the initial inhalation of that aerosol and the actual onset of salutary (as well as adverse) effects. Certain technological advances have emerged since the CSRC's Position Statement was issued in 2007, most notably the development of the breath-actuated nebulizer (BAN), the waste-reducing nebulizer (WRN), and the vibrating mesh nebulizer (VMN). The BAN and the WRN incur far less wastage of aerosol than is observed with a conventional ("Tee-type") nebulizer, and also deliver a higher dose of drug than their Tee-type counterparts within a shorter timeframe.<sup>3</sup> The VMN is another new category of aerosol device that elaborates an entire (three-milliliter) dose of aqueous solution within a six-minute time window.<sup>4</sup> Hence, the duration of therapy with a BAN, a WRN, or a VMN, although far shorter than the fifteen-to-twenty-minute duration of therapy

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required when using conventional SVNs, is still sufficiently long to enable the RCP to detect adverse side effects while s/he is still at the patient's bedside.

Finally, it is recognized that the RCP's ability to deliver a quantitatively enhanced dose of aerosolized bronchodilator within an abbreviated time window through the use of any technologically advanced nebulizer has largely removed the fundamental motive that led some respiratory care departments to resort to stacking in the past. Stated another way, departments that have invested in these newer technologies enable their therapists to deliver more treatments, and more effective (higher-dose) treatments, during a given shift than was possible in the past. The convergence of these events will, it is hoped, result in the abandonment of stacking once and for all. This view is echoed in a clear and unambiguous Position Statement recently published by the Oklahoma Board of Medical Licensure and Supervision.<sup>5</sup>

It should also be noted that the development of the Uniform Reporting Manual by the American Association for Respiratory Care (AARC) has provided managers with a tool for implementation of a time-based standard for workload determination. Use of unweighted metrics of workloads may lead to inaccurate staffing assessments and result in underestimating the number of staff needed. In addition, the use of appropriate evidence-based assessment-driven protocols helps to reduce the incidence of misallocation of therapies, which can adversely impact workloads and render the use of concurrent therapy more probable.

It must also be recognized that the AARC enunciated their strong opposition to Concurrent Therapy in a White Paper<sup>6</sup>, the full text of which can be accessed from the CSRC website: <u>www.csrc.org/page-1211546</u>

Finally, the Centers for Medicare and Medicaid Services (CMS) have suggested that, because stacking robs the RCP of the ability to focus her/his full attention on the patient, "....it is unlikely that the services being delivered are at the complex skill level required for coverage by Medicare."<sup>7</sup> This unambiguous and unequivocal language renders it highly likely that a care provider that submitted a claim for a Medicare/Medicaid client who received a "stacked" treatment would be subject to the full range of penalties provided in connection with Medicare fraud.



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In summary, then, it is the position of the California Society for Respiratory Care to advocate for safe practice and quality care, and to denounce the practice of concurrent therapy as unethical, unsafe, and unconscionable.

## References

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5. Position Statement (State of Oklahoma Board of Medical Licensure and Supervision); Concurrent Therapy, retrieved from http://www.okmedicalboard.org/ respiratory\_care\_practitioners/download/574/Position\_Statement.pdf on September 3rd, 2015.

6. AARC White Paper on Concurrent Therapy, Irving, TX, the American Association for Respiratory Care, 2005.

7. Federal Register, HCFA Proposed Rules. 23983-24036 [01-11560], May 10, 2001, Vol.. 66, No. 91, <u>http://www.access.gpo.gov/su\_docs/fedreg/a010510c.html</u>