



LEGISLATIVE AND REGULATORY UPDATES

PHILLIP PORTE

EXECUTIVE DIRECTOR
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Phillip Porte was born and raised in Chicago, Illinois and completed his undergraduate degree at the University of Wisconsin with a Bachelors Degree in English and a minor in Political Science (1970).

After a relatively short stint with City New Bureau, CBS News, and St. Mary of Nazareth Hospital Center, all in Chicago, he arrived in Washington, DC in 1976 to work at the National Health Policy Forum, a foundation funded program that runs educational seminars for Federal health policymakers. While going to graduate school at the George Washington University in the Masters Program for Public Administration, he immersed himself in the nuances of national health policy. In 1978 he opened his own health care consulting and lobbying firm, representing the American Association for Respiratory Care. In the 31 years since, GRQ has established a strong reputation in the field of pulmonary medicine, representing NAMDRC as well as other pulmonary medicine societies, device manufacturers, pharmaceutical companies, and providers of hospital, nursing home and home care.

He has published articles in numerous journals relating to pulmonary medicine coverage and payment issues and has served as Executive Director of NAMDRC, a client of GRQ since 1979, for approximately 17 years.

OBJECTIVES:

Participants should be better able to:

- Understand the impact of Legislative & Regulatory activities on their practice of Pulmonary Medicine

FRIDAY, MARCH 4, 2016 11:15 AM

Regulatory & Legislative Issues

NAMDRC Annual Educational Conference
March 3-5, 2016

Mr. Porte serves as a consultant for Breathe Technologies, Fisher Paykel and Philips, but these do not create a conflict related to the following presentation.

Election 2016 (first poll conducted in 1984)

Question #1

Who would be better for the delivery of health care?

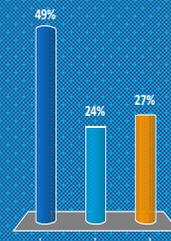
1. Clinton
2. Sanders
3. Other Democrat

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Election 2016

Question #2

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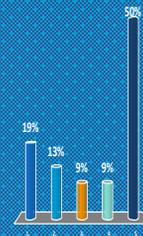
1. Trump
2. Cruz
3. Rubio
4. Bush
5. Kasich

Election 2016

Question #2

Who would be better for the delivery of health care?

1. Trump
2. Cruz
3. Rubio
4. Bush
5. Kasich



Regulatory Issues

- Home Mechanical Ventilation -- The Environment
 - 2001 Decision Memo (*at contractor discretion*)
“(NIV) is the administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the use of more invasive airway access.... It is distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of respiratory support leads to death.”

Home Mechanical Ventilation

- March 2014 DME MACs request “white paper”
 - Late Fall 2014 white paper submitted with three areas of focus
 - COPD
 - Neuromuscular
 - Hypoventilation
- Environment of Growth for E0464
 - \$34.9M in 2012 allowed charges; \$181.1M in 2014 allowed charges
 - Easier to order H MV compared to bi-level/RAD
 - OIG review in 2016

Home Mechanical Ventilation

- Coding changes proposed in summer, 2015, effective 1/1/2016
 - E0465: Home ventilator, any type, used with invasive interface (e.g. tracheostomy tube)
 - E0466: Home ventilator, any type, used with non invasive interface (e.g. mask, chest shell)
- E0460, E0461, E0463, E0464 all deleted

Dialogue with CMS

- Multi society meeting with CMS in July 2015
 - Simple retraction of 2001 Decision Memo still gives contractors discretionary authority
- Denials are occurring, with verbiage such as
 - “The medical record documentation does not support requirements for ventilator therapy. The medical records do not indicate that the beneficiary would be in danger of succumbing to death without a ventilator.”

Dialogue with CMS (cont'd)

- Agreement that we will never agree on existence of RADs, a term created by CMS that does not appear in the clinical literature and clearly circumvents FDA classifications
- Tacit agreement that home mechanical ventilation is integral, standard-of-care treatment for chronic respiratory failure.
- Therefore, can we agree that IF we create clinical definition of chronic respiratory failure, and patient meets those criteria, that HMV is medically warranted/covered?
- Conceptually agreed upon.

Dialogue with CMS (cont'd)

- In terms of bi-level devices/RADs, we argued that a notable part of the reason for the growth in HMVs relate to difficulty in getting access to cheaper, more clinically appropriate bi-level device.
- Clinical examples provided by Drs. Lamberti and Hill.
- National Coverage Determination (NCD) route problematic, according to CMS, because of acknowledged changes in technology associated with HMV. "We don't want to be back here in 3 years having a similar discussion."
- CMS stated it had administrative, regulatory and NCD routes as options, but would not commit until they reviewed the specific "asks."

Dialogue with CMS (cont'd)

- Agreement reached to submit specifics as soon as practicable.
- Working group submits document before Thanksgiving, and CMS discussion occurs 1st week in December.
- Only VIABLE route to solution is
 - NEW NCD for bi-level devices
 - Reconsideration of existing, one sentence NCD for home mechanical ventilation

Key conceptual recommendations - HMV

- If patient has confirmed “chronic respiratory failure,” home mechanical ventilation is integral to the standard of care treatment regimen.
- There is no need to distinguish between invasive and non invasive HMV for coverage purposes.
- There are three primary qualifying diagnoses that would lead to chronic respiratory failure. Based on the individual’s medical need, the order for HMV may be intermittent, nocturnal, or continuous.
- There is no scientific evidence for these patients that removal of HMV leads to imminent death. Rather, removal of HMV would lead to likely harm and eventual death.

Review of HMO policies

- We're in the current morass because
 1. Archaic policies
 2. Ease of access to HMOs
 3. CMS efforts to save \$\$
 4. All of the above

Election 2016 -- Know Your Audience

Question # 3

Knowing what you know now, if the general election was held at the end of this conference, who would you vote for?

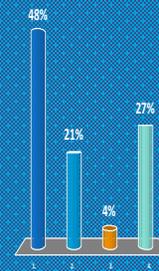
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3. An Independent candidate
4. The choices are so poor, I will likely not vote

Election 2016 -- Know Your Audience

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NCD vs LCD for Bi-Level Devices

- There is no National Coverage Determination for bi-level/RAD devices.
- In order to make changes in current LCD that DME MACs are not willing to make, only alternative is NCD, in effect tying hands of DME MACs.
- Formalize most of current LCD into NCD with modest changes.
- Certainly upsides and downsides.

Key conceptual recommendations – Bi-Level Devices

- **Restrictive Thoracic Disorders:** An E0470 or E0471 device is covered when criteria below are met --
- A. One of the following:
 - a. An arterial blood gas PaCO₂ done while awake is greater than or equal to 45mm Hg, or
 - b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 30 minutes), or
- B. In the opinion of the treating physician, chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary limitation.

Key conceptual recommendations – Bi-Level Devices – COPD

- Current LCD policy covers an E0470 device if certain criteria are met. Additionally, an E0471 device is covered in either of two situations depending on the testing performed to demonstrate medical need. An E0470 or E0471 device is covered when criteria (A-D) below are met:
 - A. Patients with COPD must have GOLD Stage 3 or 4 airway obstruction and
 - B. An arterial blood gas PaCO₂ done while awake is greater than or equal to 52 mm Hg.

Bi-Level Devices – COPD (cont'd)

C. Prior to initiating therapy, obstructive sleep apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out as the predominant reason for the hypercapnia in the opinion of the treating physician.

(Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

Bi-Level Devices – COPD (cont'd)

D. If the above criteria for beneficiaries with severe COPD are met, either an E0470 or E0471 device (based upon the judgment of the treating physician) will be covered for the first three months of therapy.

Bi-Level Devices – cont'd

- **Central Sleep Apnea or Complex Sleep Apnea:** An E0601, E0470 or E0471 device is covered when prior to initiating therapy, a complete facility-based attended PSG is performed documenting the following: (A and B):

- A. The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA); and
- B. Significant improvement of the sleep-associated hypoventilation with the use of an E0601, E0470 or E0471 device on the settings that will be prescribed for initial use at home.

If all of the above criteria are met, either an E0601, E0470 or an E0471 device (based upon the judgment of the treating physician) will be covered for beneficiaries with documented CSA or CompSA for the first three months of therapy.

Bi-Level Devices – Hypoventilation Syndrome

Hypoventilation Syndrome: Currently an E0470 device is covered if certain criteria are met. We believe the policy should also apply to E0471 based on our suggested revisions below. With these changes it is no longer necessary to set separate criteria for E0471.

- A. An initial arterial blood gas PACO₂ done while awake is greater than or equal to 45 mm Hg.
- B. Spirometry shows an FEV₁/FVC greater than or equal to 70%. This also includes patients with parenchymal lung disease leading to restriction AND hypercapnia that do not meet the criteria for the first category, Restrictive Thoracic Disease.

Hypoventilation Syndrome (cont'd)

C. An arterial blood gas PaCO₂, done during sleep or immediately upon awakening, shows the beneficiary's PaCO₂ worsened greater than or equal to 7 mm HG compared to the original result in criterion A (above).

Hypoventilation Syndrome (cont'd)

D. A facility-based PSG or HST demonstrates oxygen saturation $\leq 88\%$ for ≥ 5 minutes of nocturnal recording time (minimum recording time of 30 minutes) that is not caused by persistent untreated sleep disordered breathing events – i.e., AHI is shown to be less than 10. If there are persistent sleep disordered breathing events or oxygen saturation $\leq 88\%$ for ≥ 5 minutes of nocturnal recording time (minimum recording time of 30 minutes), they are occurring with CPAP already at 16 cmH₂O or the highest patient tolerated level. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 or E0471 coverage for obstructive sleep apnea.)

Review of Bi-Level Policies

- A relatively easy way to characterize the bi-level morass is:
 1. Unwillingness of DME MAC contractors to create reasonable policies
 2. It is Donald Trump's fault
 3. It is tied to Hillary's e-mails