Federal regulations and payment policies have a significant effect on the availability of important therapies for patients with pulmonary disease. As healthcare policy has moved into the arena of “value based care”, the focus of regulatory agencies has shifted from promoting improved quality of care to cost containment. Since its inception, The National Association for Medical Direction of Respiratory Care’s (NAMDRC) core principle has been improving the quality of patient care by reducing barriers to that care. The organization’s priorities have been to identify issues unique to pulmonary medicine that lend themselves to legislative and regulatory action. In recent years the focus has been on improving access to home mechanical ventilation, appropriate use of supplemental oxygen and expanding pulmonary rehabilitation programs. In the last two decades there have been significant advances in medical device technology and evidence based research has refined clinical practice. However, existing federal regulations have created barriers to advanced patient care in the field of pulmonary medicine.

**Home Mechanical Ventilation**

Provision of cost-effective care for patients requiring ventilatory support at home is a true clinical challenge. With the improvement in ventilator technology and non-invasive interfaces, non-invasive ventilation has become the mode of choice for most patients. Since 2010, there has been an increasing body of evidence that non-invasive respiratory support for patients with advanced COPD and other lung diseases can improve quality of life and reduce frequency of hospitalization. Unfortunately, despite the efforts of NAMDRC to educate policy makers at the Centers for Medicare and Medicaid Services (CMS), the Agency continues to cling to a 2001 decision memo regarding ventilator coding and reimbursement. That memo reiterated the agencies position that the key requirement of home mechanical ventilation was the presence of an artificial airway AND that removal of the mechanical ventilator would lead to death. There has been significant advancement in respiratory support technology and techniques since 2001. The increasing use of non-invasive ventilation and bi-level devices in order to reduce...
respiratory complications in patients requiring ventilatory support has caused conflicts among phys-
icians, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and the
individual durable medical equipment suppliers.

The dramatic increase in prescriptions for home respiratory support parallels the improved science
related to care of patients with different modes of respiratory failure as well as implementation of
federal quality improvement programs such as the Readmissions Reduction Program and quality
measures applied to physicians such as reductions in 30 day mortality. NAMDRC has been active-
ly pursuing revisions to the CMS coverage and payment policy to bring it into line with current tech-
nology. Despite the efforts of NAMDRC leadership, the federal agencies such as the Government
Accountability Office, the Office of Inspector General, CMS continues to focus on the device rather
than the patient and their physiology. The NAMDRC leadership has had several face-to-face meet-
ings with the CMS physician bureaucracy as well as follow-up conference calls. Early in 2015, CMS
staff asked NAMDRC to prepare a white paper on the issue. A meeting was held to discuss this at
CMS headquarters in July of 2015. Despite the white paper and several educational sessions,
CMS bureaucracy remained recalcitrant and resistant to change. When CMS made it clear that
they planned to take no action NAMDRC submitted a request for a National Coverage Determina-
tion (reconsideration). This request was filed away and effectually dismissed. It became apparent
that CMS will never reach an agreement with our clinical experts on appropriate categories and re-
imbursement for advanced mechanical ventilators for home use. To make matters worse, the Medi-
care Advisory Payment Commission (MedPAC) in its June 2018 report to Congress recommended
that compensation for home ventilators be transferred to the Competitive Bidding Program. In late
November 2018, when CMS was seeking public comment on the idea of such a move, CHEST,
NAMDRC and numerous other societies submitted strongly worded comments opposed to the rec-
ommendation, citing a wide array of clinical risks associated with such a proposal. In mid-March
2019, CMS announced that as it revamped the competitive bidding program for durable medical
equipment, it would include non-invasive ventilation in the Competitive Bidding Program to take
effect January 1, 2021. Given the recalcitrance of CMS, a number of societies agreed that the only
path to progress would be through legislation.

4945, was introduced in the House of Representatives by Congressman H. Morgan Griffith of
Virginia. This bill was introduced with 21 cosponsors. The purpose of this bill is to exclude
ventilators from competitive acquisition programs under the Medicare program for 5 years, to
require CMS to update national coverage policies to reflect innovation in technology for home
mechanical ventilator devices under the Medicare program, and to establish a technical expert
panel to:

♦ review stakeholder input and clinical literature and make recommendations to the Secretary
with respect to national coverage determinations.

♦ define home invasive ventilators and home noninvasive ventilators;

♦ define the term ‘respiratory failure’ for purposes of establishing criteria for the appropriate use of
home invasive or noninvasive ventilators;

♦ establish medical necessity criteria for the use of home invasive and noninvasive ventilators for
individuals enrolled under part B diagnosed with respiratory failure and for such individuals not
diagnosed with respiratory failure;

♦ and any other aspects of home ventilators and similar devices that the technical expert panel
determines are appropriate to ensure access to medically appropriate devices.
Home Oxygen Therapy

NAMDRC leadership has been working for reform of the Medicare and Medicaid home oxygen regulations and to establish clinically appropriate levels of reimbursement. Similar to home mechanical ventilation, the existing payment methodology for home oxygen therapy has not kept pace with emerging technologies, medical community standards of practice, and the cost structure incurred by home oxygen therapy providers. At any given time there are approximately two million patients on oxygen and 80% are covered by Medicare. Because oxygen is a costly therapy, Medicare reimbursement is tightly regulated. There are four problems with the current regulations; the antiquated prescription framework, the capped rental policy, the effect of the competitive bidding policy and the effect of audits by independent auditors with a financial incentive to deny services.

Current Medicare payment is based on a methodology within a “modality neutral” model where all stationary oxygen delivery systems are paid the same amount regardless of features of the technology or the service intensity associated with caring for the patient. Under this methodology, newer technologies such as portable oxygen concentrators, lightweight liquid oxygen systems, and transfilling oxygen systems, are grouped into the same payment classes as older, less technically capable systems. As outlined in a multi-society letter sent to Administrator Verma, the Competitive Bidding Program has “re-shaped the industry into a non-delivery model of services.” The notable expense of a driver and approved delivery vehicle is no longer a necessity, and the industry has been able to re-invent the way oxygen systems are now provided to beneficiaries. Delivery models, especially those providing liquid oxygen, require far higher capital costs, more frequent deliveries, and more sophisticated operations that understandably increase service costs which are not adequately covered under the current compensation rates. Liquid systems for Medicare beneficiaries who require higher oxygen flow rates as well as continuous flow have become challenging to suppliers because of the need for ongoing visits to the beneficiary’s home.

The impact of the current policy has been most acute in rural areas and in non-competitive bidding areas. The methodology applies pricing derived from highly populated competitive bidding areas to all areas of the country without properly taking into account the increased cost of supplying DME items in these areas. This policy fails to consider the unique attributes of the health care system in rural America, which has distinct cost differences from their urban counterparts. At the urging of Congress and patient advocacy groups CMS issued an Interim Final Rule on May 9, 2018 that provided emergency relief to rural areas until the end of 2018. On November 1, 2018, CMS finalized a rule which extended the rural relief until the end of 2020. At this time, it is unclear what CMS plans to do after 2020. While the relief in strictly rural areas was much needed, non-rural, non-competitive bidding areas did not receive any help. A number of patient and physician groups, including NAMDRC, have submitted a joint letter to CMS calling for the agency to use its authority to “carve out” portable liquid oxygen from the competitive bidding program.

On May 15, 2019, Representatives Cathy McMorris Rogers and Dave Loebsack introduced the Protecting Home Oxygen and Medical Equipment Act of 2019, H.R. 2771, with 37 cosponsors, to address the issue. This bill would eliminate the budget neutrality requirement related to oxygen. Work is being done to introduce a Senate companion bill to H.R.2771. The Bill could be improved by including a liquid oxygen carve out.

Pulmonary Rehabilitation and Site Neutral Payment

Pulmonary rehabilitation has long been an interest of NAMDRC. The organization worked closely with other interested parties to establish pulmonary rehabilitation as a specific benefit category within the Medicare statute. The availability of outpatient pulmonary rehabilitation programs across the country was significantly affected by Medicare’s 2017 Outpatient Prospective Payment
System rule. This rule was in response to the Bipartisan Budget Act of 2015 which required CMS to adopt a “site neutral payment” policy for outpatient services delivered more than 250 yards from a hospital’s main campus. This policy effectively created a financial burden for hospitals with successful programs to expand out into nearby communities. If a hospital moved an off site program to a new location or chose to open a new program beyond the 250 yard threshold, payment would be based on the physician fee schedule rates, less than half of hospital outpatient payment rates.

In order to address this access issue, HR 4838 provides a legislative solution. Introduced by Congressman Jim McGovern (D-MA), the bill would exempt services from these restrictions when the total payment nationwide for a particular service by the physician specialty billing the greatest amount under the physician fee schedule was under $2 million. For pulmonary rehab, the physician specialty billing G0424 the greatest aggregate amount is pulmonary – and that amount is actually under $500,000.

Senators Shelley Moore Capito of West Virginia and Amy Klobuchar of Minnesota have introduced legislation, The Increasing Access to Quality Cardiac Rehabilitation Care Act of 2019, S. 2842. There is a pulmonary section in this bill that would allow a physician assistant, nurse practitioner, or clinical nurse specialist to prescribe pulmonary rehabilitation. A companion bill, H. R. 3911, has been introduced in the House.

Since we have not been successful in working with CMS, letters were sent to the Chief Executive Officers of hospitals with pulmonary rehabilitation programs, outside of the main campus, to make them aware that their hospital’s charges are below the national norm and to offer assistance in setting the appropriate charge. An aggressive follow-up is planned by the American Association of Cardiac and Pulmonary Rehabilitation. Ultimately, the goal is to raise the median charge for pulmonary rehabilitation which will improve overall payment rates moving forward.

**Advocacy in the Next Decade**

Scholarly investigations at our academic institutions have improved our insight into disease processes and our appreciation of support systems that can benefit patients with chronic respiratory problems. In the current environment, robust scientific evidence is not enough to guarantee that a novel medical technique or device will disseminate into widespread use. The rate of innovation is sensitive to changes in the financing of health care, including the level of reimbursement that new interventions will be able to obtain. Conflicts within CMS divisions have developed. On the one hand, CMS is profiling physicians on quality measures, such as frequency of readmissions, by the Office of Clinical Standards and Quality, on the other hand, the availability of advanced medical devices for support of patients with chronic respiratory diseases is impeded by bureaucrats responsible for coding, coverage and payment decisions.
With the shift to “Value Based Care”, the Centers for Medicare and Medicaid and their appendages such as the Durable Medical Equipment Carrier Medical Directors have circled the wagons and become much less responsive to input from our societies and patient advocacy groups. This has shifted the balance of determinants of innovation in medical care from factors such as clinical evidence and decisions made principally by doctors and scientists, to administrative decisions based on cost-efficiency and sociopolitical considerations. In meetings with CMS staff, NAMDRC leadership has been left with the impression that current policy makers have difficulty understanding both the evolving sophistication in clinical medicine and the pulmonary physiology involved in newer support techniques. It appears that the major driver of change going forward will be through legislative activity. The legislative proposals noted above, while they could be improved, have the potential to impact the policies of the Centers for Medicare and Medicaid if they receive sufficient support from cosponsors even if they are not passed. To advance any medical legislation will be a challenge as it will require a significant grassroots effort from concerned physicians, as well as patient groups. Individual physician contact with their legislators in Congress will be key to any advocacy effort. In its years of advocacy, NAMDRC has found that the worst case scenario is for a legislator to say, “Why haven’t I heard from any constituents about this problem if it is as bad as you say it is”.

**PRODUCT AND TECHNOLOGY NEWS!**

*NAMDRC is providing this space to our benefactors and patrons who provide us with information about new products and innovations related to pulmonary medicine. NAMDRC reserves the right to edit this copy as appropriate.*
NAMDRC Membership Benefits AT A GLANCE...

- Monthly publication of the Washington Watchline, providing timely information for practicing physicians;
- Publication of Current Controversies focusing on one specific Pulmonary/Critical Care Issue in each publication;
- Regulatory updates;
- Discounted Annual Meeting registration fees;
- The Executive Office Staff as a resource on a wide range of clinical and management issues; and
- The knowledge that NAMDRC is an advocate for you and your profession.

https://www.namdrc.org/content/issue-advocacy

One of NAMDRC’s primary reasons for existence is to provide both clinicians and patients with the most up-to-date information regarding pulmonary medicine. Bookmark this page!

The complexity of our nation’s health care system in general, and Medicare in particular, create a true challenge for physicians and their office staffs. One of NAMDRC’s key strengths is to offer assistance on a myriad of coding, coverage and payment issues.

In fact, NAMDRC members indicate that their #1 reason for belonging to and continuing membership in the Association is its voice before regulatory agencies and legislators. That effective voice is translated into providing members with timely information, identifying important Federal Register announcements, pertinent statements and notices by the Centers for Medicare and Medicaid Services, the Durable Medical Equipment Regional Carriers, and local medical review policies.

ABOUT NAMDRC:

Established over three decades ago, the National Association for Medical Direction of Respiratory Care (NAMDRC) is a national organization of physicians whose mission is to educate its members and address regulatory, legislative and payment issues that relate to the delivery of healthcare to patients with respiratory disorders.

NAMDRC members, all physicians, work in close to 2,000 hospitals nationwide, primarily in respiratory care departments and critical/intensive care units. They also have responsibilities for sleep labs, management of blood gas laboratories, pulmonary rehabilitation services, and other respiratory related services.
MEMBERSHIP OPPORTUNITIES WITH NAMDRC

INSTITUTIONAL MEMBERSHIPS

NAMDRC has restructured its membership opportunities to more accurately reflect how physicians practice medicine, acknowledging that genuine “private practice” is nowhere near as prevalent today as it was even five years ago. Physicians are now employees of hospitals and medical systems.

To improve our communication with you and hospital based colleagues, we have revamped our dues structure, with individual/small practice remaining basically the same as it is today. We are renaming our group practice options into two specific categories:

Institutional Membership/Gold for institutions that identify at least seven physicians, but no more than 20 physicians as members of NAMDRC. Every identified physician will receive our monthly newsletter, the Washington Watchline, and the institution will receive two half price registrations for our Annual Conference at the standard member rate.

Institutional Membership/Platinum for institutions that identify at least 21, but no more than 50 physicians as members of NAMDRC. Every identified physician will receive our monthly newsletter, the Washington Watchline, and the institution will receive four half price registrations for our Annual Conference at the standard member rate.

Small Group Practice (1-6 physicians) $295 for renewal
$395 for new member (includes one-time $100 initiation fee.)

Gold Institutional Membership (7-20 physicians) $1750

Platinum Institutional Membership (21 – 50 physicians) $2500

If you are based at a particular institution, we believe this is an excellent way to bring NAMDRC and its benefits to the attention of many of your colleagues. And the aggregate cost, per membership, drops dramatically under these new membership categories.

RENEW NOW!

JOIN NOW!

Go to www.namdrc.org and join and/or renew your membership online.
NAMDRC INSTITUTIONAL MEMBERSHIP APPLICATION

Please select the category you are applying for:

☐ Small Group Practice (1-6 physicians)  $295/year for renewal

☐ NEW Small Group Practice (1-6 Physicians)  $395 for new member/year
   (includes one-time $100 initiation fee)

☐ Gold Institutional Membership (7-20 physicians)  $1750/year
   Includes two half price registrations for NAMDRC Annual Conference at the standard member rate.

☐ Platinum Institutional Membership (21-50 physicians)  $2500/year
   Includes two half price registrations for NAMDRC Annual Conference at the standard member rate.

INSTITUTIONAL MEMBERSHIP INFORMATION

Institutional Name: ______________________________________________________________________________________________
Contact Person: ________________________________________________________________________________________________
Email address: _________________________________________________________________________________________________
Address: _____________________________________________________________________________________________________
City: __________________ State: __________________ Zip: ___________________________
Phone: __________________ Fax: __________________

PAYMENT INFORMATION (Make check payable to “NAMDRC”)

☐ American Express  ☐ MasterCard  ☐ Visa

Credit Card Number __________________ Expiration Date __________________ CCV __________________
Name as it Appears on Credit Card ________________________________________________________________________________
Billing Address (If Different From Above) _____________________________________________________________________________
Printed Name __________________________ Signature __________________________
Email __________________________ Phone __________________________

USE THE ATTACHED MEMBERSHIP FORM TO LIST ALL MEMBERS OF YOUR GROUP
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