CMS Proposes Alterations to the “Stark Law” for 2016

In the proposed Medicare Physicians Fee Schedule for 2016, The Centers for Medicare and Medicaid Services (CMS) recognizes the increasing conflict between their goal of transitioning from a system of fragmented medical care to one of shared responsibility and the prohibitions against certain financial relationships established by the Stark legislation. Among the proposed alterations to the 2016 Medicare program are amendments and new exceptions to the law that will allow increased financial integration among physicians and the entities to which they refer patients. As a start, CMS is proposing to allow hospitals, federally qualified health centers, and rural health centers to directly compensate physicians and physician organizations for the hiring of physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives. Additionally, CMS is soliciting comments on the Stark Law’s effect on the healthcare delivery and payment reforms initiated through the Affordable Care Act.

The Stark Law

The concept of physician self-referral, when a physician refers a patient to an ancillary service from which the physician or a family member receives an economic benefit, has been a hot-button since the late 1980s. At that time it was not uncommon for physician practices, particularly in rural or underserved settings, to provide comprehensive services, such as durable medical equipment, out of their offices. The rapidly rising cost of health care in that decade prompted several studies on the cost of care. One of these studies produced evidence showing the volume of clinical laboratory tests greatly increased if referring physicians had some degree of ownership in the lab. Additional examination revealed soaring incidence of radiology procedures and physical therapy when the physician had ownership interest in the radiology or rehabilitation facility.

The Washington Watchline is published monthly and provides timely information to NAMDRC members on pending legislative and regulatory issues that impact directly on the practice of pulmonary medicine.

NAMDRC’s primary mission is to improve access to quality care for patients with respiratory disease by removing regulatory and legislative barriers to appropriate treatment.

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NAMDRC 39th Annual Meeting and Educational Conference will be held:
March 3 –5, 2016
Omni Rancho Las Palmas Resort
Rancho Mirage, CA

NAMDRC
8618 Westwood Center Drive, Suite 210
Vienna, VA 22182-2273
Phone: 703-752-4359
Fax: 703-752-4360
Email: ExecOffice@namdrc.org

“NAMDRC will directly affect your practice more than any other organization to which you belong.”
In 1989, Congress included a section in the Omnibus Budget Reconciliation Act which barred physician referrals of Medicare beneficiaries for clinical laboratory services in which they had a financial interest. This amendment to the Social Security Act is named for United States Congressman Fortney "Pete" Stark, Jr. who was a member of the United States House of Representatives from 1973 to 2013 and who developed and promoted the initial legislation. This prohibition took effect in January 1992. The law included a series of exceptions to the ban in order to accommodate legitimate business arrangements. The Omnibus Budget Reconciliation Act of 1993 expanded the prohibition to additional health services, including durable medical equipment, and applied it to both Medicare and Medicaid. In 1997 Congress gave the Administration the authority to amend the Stark Law by proposing limited exceptions to its restrictions. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, anticipating the requirements of the HITECH Act, established a new safe harbor for arrangements involving the provision of electronic prescribing technology and electronic health records software to physician practices by health care organizations with which they do business.

**Legislative and Policy Conflicts**

While the stated policy of the Department of Health and Human Services is to make medical care patient centered, seamless and cost effective, the President’s fiscal year 2015 budget attempted to remove the Stark exception for in-office ancillary services, including advanced diagnostic imaging, radiation oncology and other therapy services. As a result, an oncology group would be prohibited from referring patients to its own radiation oncology center, and an orthopedic group couldn’t perform MRIs. With the changes in the Medicare program established in the Affordable Care Act, it is now being recognized that the Stark Legislation is too complex and may, in fact, impede physicians’ ability to participate in managed care networks. At the same time, enforcement of Stark Law has become increasingly aggressive. On June 9, 2015, the Health and Human Services Office of Inspector General issued a fraud alert targeting physician compensation arrangements with hospitals and health systems. This effort has highlighted the conflict between the existing laws and the goal of achieving provider integration. The Affordable Care Act included restrictions for physician-owned hospitals, under the assumption that physicians owning hospitals could lead to unnecessary hospitalizations. Yet, the same law established Medicare Accountable Care Organizations and requires 75-percent physician ownership in these models.

**The 2016 Medicare Physicians Fee Schedule**

In the proposed rule, CMS is proposing an exception to the Stark Law for hospitals that wish to provide remuneration to a primary care physician to assist with the employment of a non-physician practitioner (NPP). As proposed, these physician extenders could only be used to provide primary care services, such as general family medicine, internal medicine, pediatrics, geriatrics, and obstetrics and gynecology services. Hospitals would only be permitted to provide assistance for the first two consecutive years of the NPP’s employment by a physician and the amount of assistance would be capped. Furthermore, a hospital may not provide assistance for those NPPs who have practiced or been employed by a physician's office in the hospital’s geographic area for the last three years. While CMS specifically states that the exception would not protect arrangements for assistance to a physician to employ a non-physician practitioner who furnishes specialty care services, such as cardiology or surgical services, they are requesting comments regarding whether there is a compelling need to expand the scope of the proposed exception.
Questions Posed by CMS:

CMS poses several questions for which it seeks feedback:

**Does the physician self-referral law generally and, in particular, the “volume or value” and “other business generated” standards set out in the regulations, pose barriers to or limitations on achieving clinical and financial integration?**

**Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?**

**Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted?**

**Which aspects of alternative payment models are particularly vulnerable to fraudulent activity?**

**Is there need for new exceptions to the physician self-referral law to support shared savings or “gainsharing” arrangements?**

**Should certain entities, such as those considered to provide high-value care to beneficiaries, be permitted to compensate physicians in ways that other entities may not?**

**Could existing exceptions, such as the exception at §411.357(n) for risk-sharing arrangements, be expanded to protect certain physician compensation, for example, compensation paid to a physician who participates in an alternative care delivery and payment model sponsored by a non-federal payor?**

**Have litigation and judicial rulings on issues such as compensation methodologies, fair market value, or commercial reasonableness generated a need for additional guidance from CMS on the interpretation of the physician self-referral law or the application of its exceptions?**

**Is there a need for revision to or clarification of the rules regarding indirect compensation arrangements or the exception at §411.357(p) for indirect compensation arrangements?**

**Given the changing incentives for healthcare providers under delivery system reform, should certain compensation be deemed not to take into account the volume or value of referrals or other business generated by a physician?**
While the current proposal is focused on primary care, physician shortages are not limited to primary care and patients with pulmonary disease are known to have multiple medical problems. In many instances the pulmonologist becomes the primary physician providing care for congestive heart failure, hypertension, diabetes and other common co-morbidities. This step by CMS and the broad questions posed by the agency signals an opportunity for all practices to comment on ancillary service arrangements that would improve the flow of patient care.

The preliminary program for the 2016 NAMDRC Annual Meeting and Educational Conference to be held March 3 -- 5, 2016 at the Omni Rancho Las Palmas is now posted on the NAMDRC Website and may be viewed by clicking on the following link:

https://www.namdrc.org/content/schedule-and-speakers

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.
# NAMDRC MEMBERSHIP APPLICATION

**TWO EASY WAYS TO BECOME A NAMDRC MEMBER**

1. Go to [www.namdrc.org](http://www.namdrc.org) and register for membership online.

2. Mail this application to:

   **NAMDRC**  
   8618 Westwood Center Drive, Suite 210  
   Vienna, VA 22182-2273

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**MEMBERSHIP DUES SCHEDULE**

(Dues for first year include $75.00 Initiation Fee)

*Individual and Small Group Dues ............ $370.00*

Includes groups of up to 6. Please include contact information for all members.

**GROUP MEMBERSHIP DUES**

(For larger groups, please attach a list of names. If a group member wishes to receive mailings at an address other than that indicated above, please attach appropriate information.)

- Groups of 7-10............................ $1,175.00
- Groups of 11-20........................... $1,560.00
- Groups of 21-30........................... $1,930.00

**TOTAL PAYMENT DUE ..................... $___________**

**PAYMENT**

- Enclosed is a check payable to NAMDRC (U.S. Dollars)
- Change my credit card for total payment due
  - American Express
  - VISA
  - MASTER CARD

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**SIGNATURE**

In accordance with IRS Regulations, 95% of your 2015 Annual Dues are tax deductible. NAMDRC’s Federal TAX ID # is 74-2020988.

**FOR MORE INFORMATION, CONTACT NAMDRC**

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E-mail: [ExecOffice@namdrc.org](mailto:ExecOffice@namdrc.org)  
Web Site: [www.namdrc.org](http://www.namdrc.org)