IV. Key to the OPO Codes

The key to the acronyms used in the listings to identify OPOs and their addresses is as follows:

DCTC—Washington Regional Transplant Consortium, 8110 Gateway Road, Suite 101 W, Falls Church, VA 22042
MAOB—New England Organ Bank, One Gateway Center, Newton, MA 02158
MIOP—Organ Procurement Agency of Michigan, 2203 Platt Road, Ann Arbor, MI 48104
MNOP—Lifesource, Upper Midwest Organ Procurement Organization Inc., 2550 University Avenue West, Suite 315 South, St. Paul, MN 55114–1904
MSOP—Mississippi Organ Recovery Agency, Inc., 12 River Bend Place, Suite B, Jackson, MS 39208
NYAP—OPO of Albany Medical College, 47 Scotland Avenue, AP8, Albany, NY 12208
NYFL—Finger Lakes Donor Recovery Network, Corporate Woods of Brighton, Building 120, Suite 180, Rochester, NY 14623
NYWN—Upstate New York Transplant Services, Inc., 165 Genesee Street, Suite 103, Buffalo, NY 14209
OHLC—Life Connection of Ohio, 1545 Holland Road, Suite C, Maumee, OH 43537
OHLP—Lifeline of Ohio, 770 Kinnear Road, Suite 200, Columbus, OH 43212
TNMS—Mid-South Transplant Foundation, 956 Court Avenue, Memphis, TN 38163
VAOP—Virginia Organ Procurement Agency, 1527 Huguenot Road, Midlothian, VA 23113
WISE—Wisconsin Donor Network, Froedtert Memorial Lutheran Hospital 9200 West Wisconsin Avenue, Milwaukee, WI 53226
WIUW—University of Wisconsin OPO, University of Wisconsin Hospital and Clinics, 600 Highland Avenue, Madison, WI 53792

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on the information collection requirements for the issue described below.

Designation of one OPO for each service area:

Section 486.316(e) states the requirements for a Medicare or Medicaid participating hospital to request a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. However, the burden associated with these requirements is currently approved under OMB 0938–0688, HCFA–R–13, Conditions of Coverage for Organ Procurement Organizations, with an expiration date of November 30, 1999.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Groups, Division of HCFA Enterprise Standards, Attention: Louis Blank, HCFA–1062–NC, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Allison Eydt, HCFA Desk Officer, Room 10235, New Executive Office Building, Washington, DC 20503.

Authority: Section 1138 of the Social Security Act (42 U.S.C. 1320b–8).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774 Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: January 5, 1999.

Robert A. Berenson,

Director, Center for Health Plans and Providers, Health Care Financing Administration.

[FR Doc. 99–630 Filed 1–11–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Fraud Alert on Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice

SUMMARY: This **Federal Register** notice sets forth a recently issued OIG Special Fraud Alert concerning physician liability for certifications in the provision of medical equipment and supplies and home health services. For the most part, OIG Special Fraud Alerts address national trends in health care fraud, including potential violations of the Medicare anti-kickback statute. This Special Fraud Alert, issued to the health care provider community and now being reprinted in this issue of the **Federal Register**, specifically highlights physicians' responsibilities in making certifications for home health services and durable medical equipment, and the legal significance of the certifications.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Counsel to the Inspector General, (202) 619–0089.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Inspector General (OIG) issues Special Fraud Alerts based on information it obtains concerning particular fraudulent or abusive practices within the health care industry.

Special Fraud Alerts are intended for widespread dissemination to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs. To date, the OIG has published in the **Federal Register** the texts of 9 previously-issued Special Fraud Alerts.[1] It is the OIG's intention to publish future Special Fraud Alerts in this same manner as a regular part of our dissemination of such information.[2]

In an effort to promote voluntary compliance in the health care industry and assist providers in their compliance efforts, the OIG has developed a Special Fraud Alert, set forth below, that addresses potential problem areas with

[1] See December 19, 1994 (59 FR 65372); August 10, 1995 (60 FR 40847); June 17, 1996 (61 FR 30623); and April 24, 1998 (63 FR 20415).

[2] All OIG Special Fraud Alerts are also available on the internet at the OIG web site at http://www.dhhs.gov/progorg/oig/frdalrt/index.htm.

regard to physician certification in the provision of medical equipment and supplies and home health services. Among other things, this newly-issued Special Fraud Alert addresses: (1) the importance of physician certification for Medicare; (2) how improper physician certifications foster fraud; and (3) potential consequences for knowingly signing a false or misleading certification, or signing with reckless disregard for the truth. A reprint of this Special Fraud Alert follows.

II. Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services (January 1999)

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, waste, and abuse in the Department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, inspections, and investigations.

To reduce fraud and abuse in the Federal health care programs, including Medicare and Medicaid, the OIG actively investigates fraudulent schemes that obtain money from these programs and, when appropriate, issues Special Fraud Alerts that identify segments of the health care industry that are particularly vulnerable to abuse. Copies of all OIG Special Fraud Alerts are available on the internet at http://www.dhhs.gov/progorg/oig/frdalrt/index.htm.

We are issuing this Fraud Alert because physicians may not appreciate the legal and programmatic significance of certifications they make in connection with the ordering of certain items and services for their Medicare patients. While the OIG believes that the actual incidence of physicians' intentionally submitting false or misleading certifications of medical necessity for durable medical equipment or home health care is relatively infrequent, physician laxity in reviewing and completing these certifications contributes to fraudulent and abusive practices by unscrupulous suppliers and home health providers. We urge physicians and their staff to report any suspicious activity in connection with the solicitation or completion of certifications to the OIG.

Physicians should also be aware that they are subject to substantial criminal, civil, and administrative penalties if they sign a certification knowing that the information relating to medical necessity is false, or with reckless disregard as to the truth of the information being submitted. While a physician's signature on a false or misleading certification made through mistake, simple negligence, or inadvertence will not result in personal liability, the physician may unwittingly be facilitating the perpetration of fraud on Medicare by suppliers or providers. Accordingly, we urge all physicians to review and familiarize themselves with the information in this Fraud Alert. If a physician has any questions as to the application of these requirements to specific facts, the physician should contact the appropriate Medicare Fiscal Intermediary or Carrier.

The Importance of Physician Certification for Medicare

The Medicare program only pays for health care services that are medically necessary. In determining what services are medically necessary, Medicare primarily relies on the professional judgment of the beneficiary's treating physician, since he or she knows the patient's history and makes critical decisions, such as admitting the patient to the hospital; ordering tests, drugs, and treatments; and determining the length of treatment. In other words, the physician has a key role in determining both the medical need for, and utilization of, many health care services, including those furnished and billed by other providers and suppliers.

Congress has conditioned payment for many Medicare items and services on a certification signed by a physician attesting that the item or service is medically necessary. For example, physicians are routinely required to certify to the medical necessity for any service for which they submit bills to the Medicare program.

Physicians also are involved in attesting to medical necessity when ordering services or supplies that must be billed and provided by an independent supplier or provider. Medicare requires physicians to certify to the medical necessity for many of these items and services through prescriptions, orders, or, in certain specific circumstances, Certificates of Medical Necessity (CMNs). These documentation requirements substantiate that the physician has reviewed the patient's condition and has determined that services or supplies are medically necessary.

Two areas where the documentation of medical necessity by physician certification plays a key role are (i) home health services and (ii) durable medical equipment (DME). Through various OIG audits, we have discovered that physicians sometimes fail to discharge their responsibility to assess their patients' conditions and need for home health care. Similarly, the OIG has found numerous examples of physicians who have ordered DME or signed CMNs for DME without reviewing the medical necessity for the item or even knowing the patient.

Physician Certification for Home Health Services

Medicare will pay a Medicare-certified home health agency for home health care provided under a physician's plan of care to a patient confined to the home. Covered services may include skilled nursing services, home health aide services, physical and occupational therapy and speech language pathology, medical social services, medical supplies (other than drugs and biologicals), and DME.

As a condition for payment, Medicare requires a patient's treating physician to certify initially and recertify at least every 62 days (2 months) that:

- The patient is confined to the home;
- The individual needs or needed (i) intermittent skilled nursing care; (ii) speech or physical therapy or speech-language pathology services; or (iii) occupational therapy or a continued need for occupational therapy (payment for occupational therapy will be made only upon an initial certification that includes care under (i) or (ii) or a recertification where the initial certification included care under (i) or (ii));
- A plan of care has been established and periodically reviewed by the physician; and
- The services are (were) furnished while the patient is (was) under the care of a physician.

The physician must order the home health services, either orally or in writing, prior to the services being furnished. The physician certification must be obtained at the time the plan of treatment is established or as soon thereafter as possible. The physician certification must be signed and dated prior to the submission of the claim to Medicare. If a physician has any questions as to the application of these requirements to specific facts, the physician should contact the appropriate Medicare Fiscal Intermediary or Carrier.

Physician Orders and Certificates of Medical Necessity for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for Home Use

DME is equipment that can withstand repeated use, is primarily used for a medical purpose, and is not generally used in the absence of illness or injury.

Examples include hospital beds, wheelchairs, and oxygen delivery systems. Medicare will cover medical supplies that are necessary for the effective use of DME, as well as surgical dressings, catheters, and ostomy bags. However, Medicare will only cover DME and supplies that have been ordered or prescribed by a physician. The order or prescription must be personally signed and dated by the patient's treating physician.

DME suppliers that submit bills to Medicare are required to maintain the physician's original written order or prescription in their files. The order or prescription must include:

- The beneficiary's name and full address;
- The physician's signature;
- The date the physician signed the prescription or order;
- A description of the items needed;
- The start date of the order (if appropriate); and

the diagnosis (if required by Medicare program policies) and a realistic estimate of the total length of time the equipment will be needed (in months or years).

For certain items or supplies, including supplies provided on a periodic basis and drugs, additional information may be required. For supplies provided on a periodic basis, appropriate information on the quantity used, the frequency of change, and the duration of need should be included. If drugs are included in the order, the dosage, frequency of administration, and, if applicable, the duration of infusion and concentration should be included.

Medicare further requires claims for payment for certain kinds of DME to be accompanied by a CMN signed by a treating physician (unless the DME is prescribed as part of a plan of care for home health services). When a CMN is required, the provider or supplier must keep the CMN containing the treating physician's original signature and date on file.

Generally, a CMN has four sections:

- Section A contains general information on the patient, supplier, and physician. Section A may be completed by the supplier.
- Section B contains the medical necessity justification for DME. This cannot be filled out by the supplier. Section B must be completed by the physician, a non-physician clinician involved in the care of the patient, or a physician employee. If the physician did not personally complete section B, the name of the person who did complete section B and his or her title and employer must be specified.
- Section C contains a description of the equipment and its cost. Section C is completed by the supplier.
- Section D is the treating physician's attestation and signature, which certifies that the physician has reviewed sections A, B, and C of the CMN and that the information in section B is true, accurate, and complete. Section D must be signed by the treating physician. Signature stamps and date stamps are not acceptable.

By signing the CMN, the physician represents that:

- He or she is the patient's treating physician and the information regarding the physician's address and unique physician identification number (UPIN) is correct;

The entire CMN, including the sections filled out by the supplier, was completed prior to the physician's signature; and

The information in section B relating to medical necessity is true, accurate, and complete to the best of the physician's knowledge.

Improper Physician Certifications Foster Fraud

Unscrupulous suppliers and providers may steer physicians into signing or authorizing improper certifications of medical necessity. In some instances, the certification forms or statements are completed by DME suppliers or home health agencies and presented to the physician, who then signs the forms without verifying the actual need for the items or services. In many cases, the physician may obtain no personal benefit when signing these unverified orders and is only accommodating the supplier or provider. While a physician's signature on a false or misleading certification made through mistake, simple negligence, or inadvertence will not result in personal liability, the physician may unwittingly be facilitating the perpetration of fraud on Medicare by suppliers or providers. When the physician knows the information is false or acts with reckless disregard as to the truth of the statement, such physician risks criminal, civil, and administrative penalties.

Sometimes, a physician may receive compensation in exchange for his or her signature. Compensation can take the form of cash payments, free goods, or any other thing of value. Such cases may trigger additional criminal and civil penalties under the anti-kickback statute.

The following are examples of inappropriate certifications uncovered by the OIG in the course of its investigations of fraud in the provision of home health services and medical equipment and supplies:

A physician knowingly signs a number of forms provided by a home health agency that falsely represent that skilled nursing services are medically necessary in order to qualify the patient for home health services.

A physician certifies that a patient is confined to the home and qualifies for home health services, even though the patient tells the physician that her only restrictions are due to arthritis in her hands, and she has no restrictions on her routine activities, such as grocery shopping.

At the prompting of a DME supplier, a physician signs a stack of blank CMNs for transcutaneous electrical nerve stimulators (TENS) units. The CMNs are later completed with false information in support of fraudulent claims for the equipment. The false information purports to show that the physician ordered and certified to the medical necessity for the TENS units for which the supplier has submitted claims.

A physician signs CMNs for respiratory medical equipment falsely representing that the equipment was medically necessary.

A physician signs CMNs for wheelchairs and hospital beds without seeing the patients, then falsifies his medical charts to indicate that he treated them.

A physician accepts anywhere from $50 to $400 from a DME supplier for each prescription he signs for oxygen concentrators and nebulizers.

Potential Consequences for Unlawful Acts

A physician is not personally liable for erroneous claims due to mistakes, inadvertence, or simple negligence. However, knowingly signing a false or misleading certification or signing with reckless disregard for the truth can lead to serious criminal, civil, and administrative penalties including:

Criminal prosecution;

Fines as high as $10,000 per false claim plus treble damages; or

administrative sanctions including: exclusion from participation in Federal health care programs, withholding or recovery of payments, and loss of license or disciplinary actions by state regulatory agencies.

Physicians may violate these laws when, for example:

They sign a certification as a ''courtesy'' to a patient, service provider, or DME supplier when they have not first made a determination of medical necessity;

They knowingly or recklessly sign a false or misleading certification that causes a false claim to be submitted to a Federal health care program; or

They receive any financial benefit for signing the certification (including free or reduced rent, patient referrals, supplies, equipment, or free labor).

Even if they do not receive any financial or other benefit from providers or suppliers, physicians may be liable for making false or misleading certifications.

What To Do If You Have Information About Fraud and Abuse Against Medicare or Medicaid Programs

If you have information about physicians, home health agencies, or medical equipment and supply companies engaging in any of the activities described above, contact any of the regional offices of the Office of Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations:

Field offices	States served	Telephone
Boston	MA, VT, NH, ME, RI, CT	617–565–2664
New York	NY, NJ, PR, VI	212–264–1691
Philadelphia	PA, MD, DE, WV, VA, DC	215–861–4586
Atlanta	GA, KY, NC, SC, FL, TN, AL, MS	404–562–7603
Chicago	IL, MN, WI, MI, IN, OH, IA, MO	312–353–2740
Dallas	TX, NM, OK, AR, LA, CO, UT, WY, MT, ND, SD, NE, KS	214–767–8406
Los Angeles	AZ, NV, So. CA	714–246–8302
San Francisco	No. CA, AK, HI OR, ID, WA	415–437–7961

To Report Suspected Fraud, Call or Write: 1–800-HHS-TIPS (1–800–447–8477), Department of Health and Human Services, Office of Inspector General, P.O. Box 23489, L'Enfant Plaza Station, Washington, D.C. 20026–3489.

Dated: January 6, 1999.

June Gibbs Brown,

Inspector General.

[FR Doc. 99–631 Filed 1–11–99; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Meeting of the National Reading Panel

Notice is hereby given of the fifth Washington area meeting of the National Reading Panel. The meeting will be held on Thursday, January 21, 1999, from 12:30 to 6:00 PM at the Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW, Washington, DC 20007. The entire meeting will be open to the public.

The National Reading Panel was requested by Congress and created by the Director of the National Institute of Child Health and Human Development in consultation with the Secretary of Education. The Panel will study the effectiveness of various approaches to teaching children how to read and report on the best ways to apply these findings in classrooms and at home. Its members include prominent reading researchers, teachers, child development experts, leaders in elementary and higher education, and parents. The Chair of the Panel is Dr. Donald N. Langenberg, Chancellor of the University System of Maryland.

The Panel will build on the recently announced findings presented by the National Research Council's Committee on the Prevention of Reading Difficulties in Young Children. Based on a review of the literature, the Panel will: determine the readiness for application in the classroom of the results of these research studies; identify appropriate means to rapidly disseminate this information to facilitate effective reading instruction in the schools; and identify gaps in the knowledge base for reading instruction and the best ways to close these gaps.

The agenda for this meeting will include discussing the recommendations made by the science members of the National Reading Panel, who have been developing a proposed methodology to select and evaluate research studies. A period of time will be set aside at approximately 4:00 PM for members of the public to address the Panel and express their view regarding the Panel's mission. Individuals desiring an opportunity to speak before the Panel should address their requests to F. William Dommel, Jr., J.D., Executive Director, National Reading Panel, c/o Ms. Amy Andryszak and either mail them to the Widmeyer-Baker Group, 1875 Connecticut Avenue, NW, Suite 800, Washington, DC 20009, or e-mail them to *amya@twbg.com,* or fax them to 202–667–0902. Requests for addressing the Panel should be received by January 15, 1999. Panel business permitting, each public speaker will be allowed five minutes to present his or her views. In the event of a large number of public speakers, the Panel Chair retains the option to further limit the presentation time allowed to each. Although the time permitted for oral presentations will be brief, the full text of all written comments submitted to the Panel will be made available to the Panel members for consideration.

For further information contact Ms. Amy Andryszak at 202–667–0901. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Amy Andryszak by January 15, 1999.