

February 4, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Room 314 G Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Frizzera:

The undersigned organizations are writing to request additional information and an opportunity to formally comment on recent and proposed changes to Medicare's Quality Improvement Organization (QIO) case review program.

QIOs are private contractors retained by Medicare and assigned to each state to conduct medical case review through networks of practicing physicians that are licensed in the state. Case reviews conducted by QIOs include statutory reviews of appeals of early termination from hospitals, nursing homes, home health agencies and comprehensive outpatient rehabilitation facilities; review of EMTALA "dumping" allegations; utilization reviews of the appropriateness of inpatient care; and reviews of beneficiary complaints regarding the quality of health care.

Recently, without a formal notice and public comment process, CMS reassigned a substantial portion of the QIOs' case review responsibilities to other Medicare contractors. The newly assigned contractors are not governed by statutory safeguards providing that QIO case reviews, and that quality, appropriateness, and medical necessity judgments will be made by physicians practicing in the same state in which the questioned care was provided, with the same specialty qualifications as the physician providing or ordering the care. Congress required that QIO contractors consider national standards in making review determinations, but also included the safeguard that the QIOs—

“shall take into account the special problems associated with delivering care in remote rural areas, the availability of service alternatives to inpatient hospitalization, and other appropriate factors (such as the distance from a patient's residence to the site of care, family support, availability of proximate alternative sites of care, and the patient's ability to carry out necessary or prescribed self-care regimens) that could adversely affect the safety or effectiveness of treatment provided on an outpatient basis.” [Source: Social Security Act section 1154(a)(6)]

We are concerned that as a result of this policy change physicians will not be involved in making medical review determinations, and that the contractors making these decisions will no longer operate under these safeguards established in federal law.

On October 31st CMS hosted a special Open Door Forum call signaling further changes are coming to the QIO case review program. During the call, CMS officials stated their intention to substantially revise the manual that guides QIO case review during 2009, and requested comments and suggestions from physicians, providers, and Medicare beneficiary advocates regarding potential changes to the QIO case review program.

It was unclear from these statements whether CMS plans to simply publish a new manual without a formal notice and comment process, promulgate a proposed rule with a public comment period, or issue a final rule without comment period. The undersigned organizations would like to request a proposed rulemaking with comment period for the following reasons:

1. Changes to the QIO manual will trigger the notice and comment requirements of the Administrative Procedures Act, because the QIO manual will be an “agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy” [Source: Definition of “Rule,” 5 USC 551].
2. National physician organizations are interested in ensuring that statutory requirements for QIO case review are fully reflected in the revised Manual’s statement of policy.
3. The QIO case review process is complex and it would be helpful for CMS to outline and explain proposed changes so that medical specialty societies and state medical societies can appropriately assess them.
4. A public comment period will provide CMS with well informed feedback from a variety of medical stakeholders.

We would like your assurance that CMS will follow a formal process of publishing a notice of proposed rulemaking on revisions to the QIO case review manual. We appreciate your time and attention to this request.

Sincerely,

American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Home Care Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Mohs Surgery
American College of Osteopathic Surgeons
American College of Physicians
American College of Preventive Medicine
American College of Radiation Oncology

American College of Surgeons
American Gastroenterological Association
American Medical Association
American Medical Directors Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Psychiatric Association
American Society for Radiation Oncology
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
Association of American Medical Colleges
Congress of Neurological Surgeons
Heart Rhythm Society
Medical Group Management Association
Society for Cardiovascular Angiography and Interventions
The Society of Thoracic Surgeons

Medical Association of the State of Alabama
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Medical Association of Georgia
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey

Medical Society of the State of New York
Mississippi State Medical Association
New Mexico Medical Society
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society