AMA
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September 30, 2008

Mr. William E. Kovacic
Chairman
Federal Trade Commission
Office of the Secretary
Room H-135 (Annex F)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Federal Trade Commission; Notice of Public Workshops and Roundtables and Opportunity to Comment; Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901

Dear Chairman Kovacic:

The American Medical Association (AMA) appreciates the opportunity to provide our comments concerning health care quality information in anticipation of the Federal Trade Commission's (FTC) workshops and roundtables to be held in the fall of 2008 on emerging health care competition and consumer issues. The FTC has requested information with regard to specific questions set forth in its *Notice of Public Workshops and Roundtables and Opportunity to Comment; Health Care Competition and Consumer Issues – Comment, Project No. P083901*. Our views are set forth below. Since our responses to the specific questions set forth in the notice overlap considerably, we have consolidated our views to address key aspects of quality information programs.

The AMA has long been and continues to be committed to the development of quality improvement initiatives that increase the quality of care provided to patients. To assist in these efforts, the AMA has been actively involved in discussing and engaging private sector health insurers and the Centers for Medicare and Medicaid Services (CMS) regarding implementation of various quality programs using physician data. **In order for any quality physician program to be effective and meaningful to patients, it is vital that certain elements be integral to the program, including such factors as: physician development of quality measures; appropriate use of quality data; effective educational efforts to help ensure that physicians can easily and properly report data under the program; the ability for physicians to verify the data that is used in developing a physician rating under a quality program; physician appeal rights with regard to various aspects of the program; and a stable physician payment structure.** Further, while Medicare does not have the appropriate infrastructure or statutory authority to publicly report physician level quality data under the Physician Quality Reporting Initiative (PQRI), we discuss below serious issues related to public reporting that need to be addressed. We caution that some private sector public reporting of physician quality data exists, but these programs are in their infancy stages and, as discussed below, there have been significant problems with these programs that can have serious unintended adverse consequences for patients, physicians and the entire validity of the quality program.

As the AMA continues in our ongoing efforts to enhance quality improvement, we strongly urge federal policymakers and the private sector to ensure the development of quality programs that physicians are confident will improve quality of care.

We further emphasize the need for physicians to develop the measures and be integrally involved in the development of a quality program. If a single entity were to be solely responsible for the development of all aspects of a quality program, or if it were too have too much discretion, this would jeopardize the credibility of the program.

Physician Development of Quality Measures

A key tenet in building a quality program is that physicians must develop the quality measures used for reporting data to ensure that they are accurate and clinically relevant to patients. In an effort to develop clinical performance measures that are patient-focused and that can be implemented to improve patient outcomes at the local level, in 2000, the AMA convened the Physician Consortium for Performance Improvement (PCPI). The PCPI actively engages all stakeholders including payers, patient advocates and organizations that are committed to high quality care. The hallmarks of PCPI measures are that the measures are derived from evidence, developed with cross-specialty representation and consensus, and include enhanced relevance to clinical practice.

The PCPI is comprised of over 100 national medical specialty and state medical societies; the Council of Medical Specialty Societies; American Board of Medical Specialties and its member-boards; experts in methodology and data collection; the Agency for Healthcare Research and Quality; and the Centers for Medicare & Medicaid Services (CMS). In addition, on May 30, 2008, the PCPI approved a position statement to expand the involvement of health care professional organizations, including the American Optometric Association, American Physical Therapy Association and American Dental Association, to name a few. This expansion will increase the ability of the PCPI to achieve consensus on its measures and their implementation across the healthcare continuum.

Through a transparent, consensus-based process for developing physician-level measures, the PCPI has worked aggressively in developing to date more than 250 physician performance measures and specifications covering 40 clinical topics and conditions. These measures are available for implementation and many have been adopted by CMS for use in CMS quality improvement demonstration projects and the PQRI. Currently, 77 percent of the 2008 PQRI measures were developed by the PCPI.

PCPI measures, through their translation into CPT II codes, capture clinically relevant information about variations in care, such as whether there are medical or patient reasons for not providing a treatment or service. This practice level information readily lends itself to identifying variation in local healthcare delivery systems and across geographic boundaries. To date, this information has not been readily available or captured at the point of care. Currently, institutions such as academic medical centers, federally qualified health clinics, and local physician practices are using this data on variation to improve the care at the practice level. Discussions are also underway to have PCPI measures embedded in registries and EHRs.

Further, in an effort to develop measures that are informative to both physicians and patients, the PCPI is also advancing its work to incorporate the concepts of grouping or bundling of measures and moving beyond individual level measurement. These advances will provide a more comprehensive picture of care and allow the collection and feedback on the quality of care provided at the level where the greatest impact for quality improvement can occur.

Efforts are also underway by the PCPI to better communicate and document why a measure was developed and, if it is a process measure, what is the link to a patient outcome. As a part of the development process, a rationale behind a measure's construction and the reasons it may or may not be used at the individual or group level will be provided. In addition, whether a gap in care or variations in care exist will be explicitly discussed, and any efforts to harmonize with existing measurement sets will be outlined.

Appropriate Use of Quality Data

For physicians, the primary purpose of quality information or performance measurement is to promote improved patient care by ensuring that physicians receive standardized, useful information about how they manage patients with a particular condition compared with established clinical recommendations. Most importantly, this information must be available at the point of care (e.g., in the examination room) while a patient is receiving care. Information on the quality of care received that is not readily available in the office does not assist in meeting the goal of improving patient care. For this reason, performance measurement at the individual physician level is most valuable to patients when feedback is provided on the information that is actionable by the physician.

For other purchasers of health care quality information, such as insurers or consumers, quality information available prior to the point of care would be optimal**. It is critical to understand, however, that the private sector and federal policymakers are in the process of developing a health care infrastructure that yields quality data that is relevant, reliable, accurate, and useful for purchasers. If the quality data does not meet these factors, it can have serious unintended consequences for patients, physicians, insurers and the Medicare program.**

For example, most measurement systems still rely primarily on claims data, and many believe that any quality measurement systems using these data do not provide very accurate physician ratings. This is especially true when coupled with certain private sector practices that rely on cost-of-care, or "efficiency," physician ratings. These ratings attempt to measure the cost for specific episodes of care. The number of incorrect physician ratings can exceed 30 percent, according to J. William Thomas, PhD, a leading scholar on efficiency measurement. Incorrect reporting of physician performance can mislead patients, disrupt patient/physician relationships and unfairly damage physician reputations. The importance of this is magnified when these incorrect ratings are used to assign physicians into tiers and patients have incentives to see physicians in the highest tier(s).

New York Attorney General Andrew Cuomo called attention to this issue in 2007. The Attorney General was concerned that health insurance programs that rely on inaccurate data to rate physicians and place them in tiered networks are a disservice to patients and physicians by steering patients to see the cheapest, but not necessarily the best, physicians. To address those concerns, the Attorney General’s office drafted settlement agreements that were accepted by the major health insurers in New York State. These agreements provide strict guidelines that the insurers must follow for any program using physician profiling. The key to the settlements is the requirement that the insurers must hire an independent ratings examiner that must certify that the insurer is operating within the guidelines of the settlements, and the ratings examiner must report its findings directly to the Attorney General.

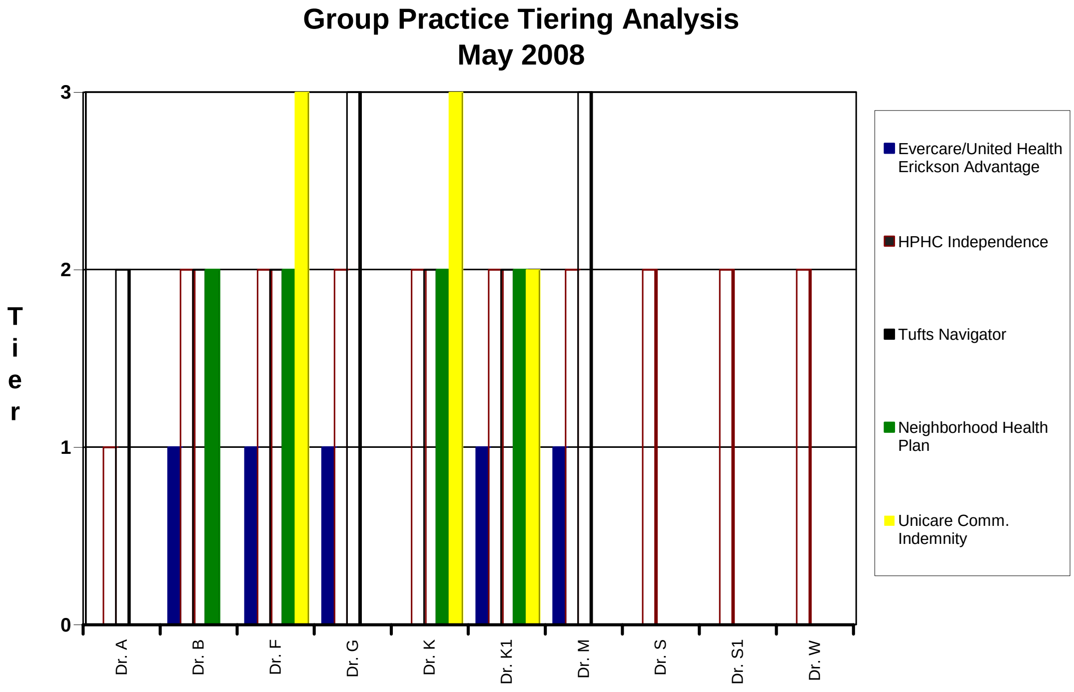
This example strongly highlights the AMA’s concern with physician profiling and reporting on the quality and efficiency of physician services. The accuracy of physician profiling has greatly improved compared to its capabilities a few years ago, but there is still no accepted methodology that produces consistently accurate results, and the myriad of methodologies that are currently used by various insurers and health care coalitions all produce unique findings.

While healthcare efficiency has long been an area of intensive research by academics and various healthcare stakeholders (including payers and purchasers), much of the research presented in the peer-reviewed literature is fragmented, and focuses on the production of specific healthcare outputs and services without a general theoretical and/or methodological framework. The current research literature in healthcare efficiency fails to provide a ready approach for evaluating efficiency in previously un-studied areas/aspects of healthcare.

RAND (Southern California Evidence-based Practice Center—RAND Corporation, “Identifying, Categorizing, and Evaluating Health Care Efficiency Measures,” AHRQ Publication No. 08-0030, April 2008.) has recently prepared a comprehensive review of the existing body of scholarly and proprietary (gray) literature on efficiency measures, and constructed a taxonomy/typology to inventory and categorize existing measures, organize information, and to identify gaps in theoretical, methodological, and empirical knowledge in healthcare efficiency.

As a result of this fragmented research with regard to measuring ‘efficiency,” we do not know which, if any, of the methodologies accurately measure physician performance, but we do know that they all produce disparate results. Following is a graph that tracks the ratings of physicians in an actual cardiolology group in Boston, Massachusetts. The Massachusetts General Insurance Commission (GIC), which provides insurance coverage to all of the state’s employees, has mandated that all of the health insurers that participate in the GIC plan must implement some type of tiered physician network that will create incentives for patients to see high-quality and low-cost physicians. The GIC has also pooled all of the participating health insurers' claims data on state employees and is sharing that pooled data with the insurers. This means that, while each of the health insurers is using their own proprietary rating system to rate the physicians and place them in tiers, they are all using exactly the same data set in this process.

As the graph shows, there are five different insurers participating in the GIC program and ten physicians in the group with reported data on patients covered by GIC. Of these ten, seven physicians have data on patients from two or more of the health insurers. Using exactly the same data base, none of these seven physicians received the same rating from the insurers. Moreover, Drs. F, G, and M were ranked in the highest tier by one insurer, the lowest tier by a different insurer, and in the middle tier by others. **Which ratings are correct and which ones are misleading? While the answer to this question is unknown, it is unquestionable that patients in Massachusetts are receiving conflicting and potentially erroneous information about the physicians in this cardiology practice.**



* Excludes Physicians Not Rated

<u>Outreach and Education for Physicians and Other Participants of Quality Programs</u>

In addition to private initiatives, there have been public quality measurement reporting programs and pilots that have provided some key lessons. Specifically, the Medicare PQRI program has provided significant lessons from which we can learn.

The PQRI was established under the Tax Relief and Health Care Act of 2006 (TRHCA), which directed CMS to initially implement a voluntary physician quality reporting program for the period of July 1, 2007 through December 31, 2007, with a bonus payment for participation. According to CMS reports, approximately 16 percent of physicians and eligible professionals participated in the 2007 program, but nearly 50 percent of participants did not receive any bonus payment. It is clear from this alarming statistic that there is significant confusion among physicians about how to successfully meet the requirements of the PQRI.

The Medical Group Management Association (MGMA) recently published results from a member survey on the 2007 PQRI. The survey found that 93 percent of physicians that participated in the PQRI last year had difficulty accessing their PQRI reports, the average time to download a report was five hours, and almost 70 percent found that the reports were of little use in improving quality outcomes. The AMA is also in the process of surveying its members regarding their experiences with the 2007 PQRI program, and we have asked CMS for the raw data so that we can determine whether there are problems with how physicians understand and report on quality measures.

Key lessons from the PQRI are that quality reporting programs must allow both physicians and CMS adequate lead time to implement changes and must undertake aggressive education and outreach activities for physicians and eligible professionals on how to successfully participate. Educational programs must include detailed confidential interim and final feedback and compliance reports that clearly inform physicians of any reporting errors and how to correct these errors. These reports must also be issued on a timely basis. PQRI reports were issued far too late for physicians to address reporting problems. Timely, detailed reports will assist in increasing the number of eligible professionals that successfully report in programs like the PQRI. Accordingly, public and private quality reporting programs must clearly inform physicians of the requirements that must be met to successfully participate in such programs.

Physician Verification of Quality Data

Additional lessons regarding quality reporting can be gleaned from another public sector example. The Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Project is a CMS-funded quality improvement organization (QIO) special project in which the Delmarva Foundation for Medical Care has subcontracted with 6 communities, or pilot sites. These pilot sites are testing methods to aggregate Medicare claims data with data from commercial health plans and, in some cases, Medicaid, in order to calculate and report quality measures for physician groups and, in some cases, individual physicians.

The six communities working with Delmarva are:

- Arizona State University Center for Health Information & Research (CHIR);
- California Cooperative Health Care Reporting Initiative (CCHRI);
- Indiana Health Information Exchange (IHIE);
- Massachusetts Health Quality Partners (MHQP);
- MN Community Measurement (MNCM); and
- Wisconsin Collaborative for Healthcare Quality (WCHQ).

On September 17, CMS hosted a BQI Annual Meeting to discuss the experiences and lessons learned by the six communities that participated in the BQI pilot. As expressed by all six communities, significant problems exist with aggregating Medicare data with other payer data. Specifically, shortcomings remain with the ability to analyze data to understand how to define the physician group being measured, and how to verify and accurately assign the quality reporting scores generated from the data. Public and private quality reporting initiatives, like the BQI Pilot, need active physician input to be credible. Physicians must be able to review the data behind their scores, and request a reconsideration process if necessary.

The experiences of the BQI Pilot prove that many challenges remain regarding how all payer data is used. Much of the data generated from the six communities participating in the Pilot could not be reviewed for accuracy by participating physicians, as CMS would not provide patient identification information to physicians to assist with verification of the data behind their scores. Overall, quality reporting entities must be able to trust the data generated from quality reporting initiatives. **However, if quality data cannot be verified, programs like the BQI Pilot are misleading exercises that do not permit physicians to realize internal quality improvement for their patients and practices. If quality reporting program data cannot be validated, then it calls into question how actionable and meaningful such programs are for patients and physicians.**

Public Reporting of Quality Data

Public reporting of quality data, if not approached thoughtfully, can have unintentional adverse consequences for patients. Significant barriers in the public reporting process must be addressed for effective reporting. If not, patient de-selection can occur for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or economic and cultural characteristics that make them less adherent with established protocols. Further, health literacy may not be adequate to comprehend basic medical information. Programs must be designed so that appropriate information is available to patients to enable them to make educated decisions about their health care needs.

If done correctly, public reporting has the potential to help provide such appropriate information to patients. There remain, however, several critical issues that must be resolved before public reporting provisions can be implemented. There must be a method for ensuring that any publicly reported information is: (i) correctly attributed to those involved in the care; (ii) appropriately risk-adjusted; and (iii) accurate, user-friendly, relevant and helpful to the consumer/patient. Moreover, physicians and other providers involved in the treatment of a patient must have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Any such comments should also be included with any publicly reported data. This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by physicians and other professionals or providers involved in the patient’s care.

Need for Physician Appeals Process

As discussed above with regard to public reporting, it is critical that physicians and other providers involved in the treatment of a patient have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. In addition, physicians should have appeal rights with regard to other aspects of the quality program. For example, under the PQRI, CMS is required to list on the Internet those physicians and other "eligible professionals" who satisfactorily submit data under the PQRI. Under these circumstances, it is critical that there be a requirement that those who participate, but who will not be listed as a successful participant, be informed of the reasons why they will not be listed and allow such physicians an opportunity to correct any errors and/or provide a written explanation for such lack of success. Physicians should also be able to elect whether this explanation may be available to the public. Without this requirement, physicians will not have an opportunity to understand why they did not successfully meet the program requirements or to correct any program glitches that have resulted in an erroneous determination that they did not successfully submit data.

Quality programs should also provide physicians an opportunity to explain why they did not participate in a particular program and detail any quality improvement initiatives in which the physician is participating. This information should also be provided to the public.

A Stable Physician Payment Structure is Critical for Quality Improvement Programs

To fulfill policymakers' vision of an HIT-based health care system, which is needed for participation in quality improvement programs, there must be a stable physician payment system (under Medicare and in the private sector) that provides positive physician payment updates that accurately reflect increases in medical practice costs. Physicians face cuts of over 40 percent in their Medicare payment rate over the coming decade. Often private sector payment rates follow suit.

HIT and quality initiatives require significant financial investment by physicians, and it is neither practical nor feasible to transition to an HIT-based system, with quality programs, when physicians, especially those in small practices, must first ensure that they can keep their doors open. Indeed, a study by Robert H. Miller and others found that initial electronic health record costs were approximately $44,000 per full-time equivalent (FTE) provider, and ongoing costs were about $8,500 per FTE provider per year. (Health Affairs, September/October, 2005). Initial costs for 12 of the 14 solo or small practices surveyed ranged from $37,056 to $63,600 per FTE provider. An AMA survey found that if Medicare physician payment rates are cut 40 percent by 2016, about 8 in 10 physicians will forgo investments in their practice, including the purchase of new medical equipment and information technology. These alarming statistics clearly show the need for adequate physician payment if the vision of an HIT-based system, with quality programs, is to be achieved.

Other Marketplace Barriers to Physician Participation in Quality Initiatives

The AMA strongly believes that current FTC enforcement policy—embodied today in the Statements of Enforcement Policy in Health Care—is a barrier to physicians' ability to participate in the full range of health care quality initiatives. We believe that the Statements of Enforcement Policy in Health Care go too far in deterring the formation and operation of legitimate physician networks that are necessary for small and solo physician practices to achieve the scale required to participate in many quality improvement initiatives. By teaming up with other practices in a network, small practices may gain the scale necessary both for care coordination and for the aggregation of data necessary to the implementation of performance-based incentives. Accordingly, we believe that the Statements should provide the flexibility to allow negotiation by a network of performance-based incentives tied to the achievement of specified quality goals by network members.

In addition, we believe the current self-referral laws pose significant obstacles to physicians, group practices, and integrated health systems that want to participate in quality improvement initiatives. Many of the provisions represent attempts to micromanage physician practices. The endless modifications and alterations endeavor to regulate every aspect of a physician's practice. Moreover, they continually force physicians and health care entities to re-structure longstanding relationships previously thought to be acceptable, driving up the cost of health care and making it more difficult to embrace new programs at the very time physicians are facing pressure to participate in these programs and we should be looking for ways to make health care more affordable. The Stark rule remains complex, exceptionally lengthy, at times unclear, and often beyond the scope of the average physician to fully comprehend and comply. As it is, the law threatens to punish even unintended violations and any deviation of a physician's relationship with an entity, however minor or unintended, yields dramatic consequences. Fear of accidentally violating one of the complex provisions of the Stark law inhibits participation in many quality improvement initiatives.

Thus, we believe that refining the regulations to simplify compliance will reduce the risk of making illegal many non-abusive physician relationships that have nothing to do with self-referral and protect certain physician arrangements that create efficiencies and better quality patient care. Focusing efforts on these laudable goals, rather than further complicating already complex regulations in an attempt to anticipate and restrict every potential physician action for which there might be unsubstantiated anecdotal evidence of abuse, or the potential for abuse, would be of much greater benefit to the health care system as a whole.

Harmonization of Health Care Quality Measurement and Reporting

Measure developers have an obligation to ensure that measures are harmonized to the greatest extent possible. While complete harmonization cannot always be achieved, an explanation on why measures across settings or levels of measurement may differ should be explicitly provided. Further, as discussed above, there must be harmonization of methodologies to accurately measure physician performance. If not, different insurers end up with different ratings for the same physicians using the same data base. This completely undermines the credibility of program and makes it meaningless for consumers.

To this end, we note that the *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) directs the Secretary of the Department of Health and Human Services to contract with a consensus-based entity, such as the National Quality Forum, to perform various activities that will assist in: priority setting for health care performance measurement in all applicable settings; endorsement of standardized health care performance measures; updating measures (or retiring if obsolete) as new evidence is developed; and promoting the development and use of electronic health records that contain the functionality for automated collection, aggregation, and transmission of performance measurement information.

The AMA appreciates this opportunity to provide our views regarding quality initiatives and their impact on competition, and we look forward to working with federal policymakers and the private sector to address the foregoing issues raised to ensure that quality initiatives achieve their intended and most important goal—to help patients and provide them with access to high quality, cost-effective care.

Sincerely,

Michael D. Maves, MD, MBA