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Quality Improvement Organization (QIO)
12th Scope of Work
Special Meeting
7500 Security Blvd
Baltimore, Md.

Dear CMS:

This is an addendum to my 4/20/2017 comment already submitted, which is now recommendation 1 of 4:

RECOMMENDATION 1: Medical Disaster Analysis

Herein I propose that the 12th SOW for the QIO include a task to provide analyses of the root cause of medical disasters as defined below, report the findings to the public (with providers de-identified if required), and recommend corrective action.

If this task is successful, the effort could lead to the creation of a National Patient Safety Board whose task would be similar to the National Transportation Safety Board, as well as to other ad hoc investigations enacted in order to understand the root cause of various disasters, such as FEMA with Katrina, NASA with Challenger, and the Intelligence Community with 911.

QIO already has a function to motivate providers to improve quality and perform case review, to reduce adverse evented related to health care, to increase the value of health care, and to assist providers to understand the root cause of a concern in order to improve a process or system. The "Root Cause Analysis" (RCA) SOW is designed to be another task to accomplish the same goals.

The RCA task will make health care safer by identifying processes designed to assure patient safety within hospitals that have failed or were immolated resulting in patient harm.

For this task, a "medical disaster" is defined as

1. An occurrence of multiple cases within an institution the result of which was more than $1 million repaid to Medicare by one or more physicians at a hospital for medically unnecessary services provided to Medicare beneficiaries, whether by settlement or through court judgment; and which
2. Was brought to the government's attention via a Qui Tam (Whistleblower) action.

Two examples of cases that would have been subject to an RCA were those of Drs. Chae Moon and Fidel Relayvasquez at Redding Medical Center, Redding California 1997-2003[i] [ii] [iii] and Dr. Marc Midei, St. Joseph Hospital, Towson, Maryland, circa 2009.[iv]

In both of these examples, hundreds of patients were damaged, Medicare recovered millions of dollars, and the government agencies including the Medicare MAC failed to detect the problem (which is why a Qui Tam suit was filed in both cases). Following the RMC case, the deemed status of The Joint Commission was placed under CMS oversight.

In both hospital cases, no federal administrative entity performed a RCA. The RCA for RMC was performed by me and two co-author physicians from RMC. The RCA for SJH was performed by the Senate Finance Committee, Subcommittee on Health. There is no current routine process to provide RCA for medical disasters as is done for airplane crashes by the NTSB.

A few years ago, St Helena Hospital in California settled a Qui Tam lawsuit involving damage to many patients by a few cardiologists for provision of medically unnecessary services. Despite my request, the California QIO declined to provide a RCA because it is outside its SOW. Other agencies that declined include the OIG, FBI, State Licensing and Certification, California Medical Board, California Medical Association and its Quality Division, and CMS Regional Office 9.

My proposal is designed to rectify this situation. Failure to provide RCA for documented medical disasters is unacceptable. It would be equally unacceptable were there no RCA for the failures of FEMA, NASA, or the Intelligence Community. The NTSB provides RCAs for airplane crashes. The QIO should provide the same function for health care disasters, so we all can learn from proven mistakes.

In the cases of RMC and SJH, the failure discovered was a failure of medical peer review that was required of the medical staff pursuant to 42CFR 482.26 and related Medicare Conditions of Participation. But other causes of medical disasters may be discovered by the QIO, such as a failure of pharmacy services, nursing services, credentialing, etc.

Once the RCA reveals the problem, the QIO would propose remedies for review by CMS and its advisors. For example, if the RCA showed a failure of medical peer review, the hospital could be required to provide external peer review, as RMC offered to do, but never did. Alternatively, a hospital could be measured for effective peer review and the

results posted on Hospital Compare. Currently, there is no quality measure for failure to follow a process designed to assure quality.

The Department of Justice and the OIG/HHS probably can provide CMS with the number of Qui Tam settlements in excess of $1 million that involved provision of medically unnecessary services. CMS would use this data to develop a quantitative work plan for the QIO SOW.

If public reports cannot name specific providers due to court action or negotiations with the DOJ to assure the provider's name is not disclosed, the case file may be forwarded to the QIO with provider names redacted. Public reporting of the RCA of medical disasters should be required.

In the case of RMC, neither the A/B MAC contractor nor the Program Integrity Contractor had sufficient recourses to identify the malfeasance that generated the Qui Tam action and, eventually led to a $500,000,000 payment to CMS and exclusion of RMC from Medicare. The medical review of Dr. Moon was under my general guidance. I ordered the review but we did not have the resources to detect the medical negligence that cost Moon his license to practice. About two years ago, I contacted the PI contractor in Northern California to suggest a remedy to our failed medical review, so that this oversight, now performed by RACs, would be mitigated. Unfortunately, the same lack of resources abides. Consequently, we continue to experience provision of medically unnecessary services, Qui Tam law suits, and multi-million dollar settlements. Worse, we continue to learn nothing about the institutional failures we expect.

Routine RCA will let providers know that their malfeasance cannot go away by repayment of funds that were not originally payable. RCA will also provide case examples to show us where our current efforts are inadequate to assure patient safety, health care quality, and appropriate value. For example, perhaps some ineffective Medicare COPs need revision?

In order words, data analytics, and program integrity work is not sufficient. A successful Qui Tam law suit in health care is direct evidence of a regulatory and administrative failure. It is for this reason that I undertook an RCA. The RMC case was the worst disaster I witnessed in my medical career as a practitioner and as a Medicare MAC Medial Director. It is time to institutionalize the RCA activity, so that we can understand errors (including deliberate "errors"), our institutional provider failures, and the failure of CMS itself, so we can take appropriate corrective action which will lead to prevention of future abuse.

The QIO is the appropriate contractor to provide RCA. Eventually, if successful, this effort could lead to a National Patient Safety Board (NPSB) that operates under its own statutory authority.

In summary, a successful Qui Tam law suit in health care is direct evidence of failure of government oversight as well as of provider abuse of patients. The frequency of these cases will predict the amount to budget under the SOW.

RECOMMENDATION 2: Solicit institutional quality concerns from physician.

Reach out to docs to learn about quality concerns in the same manner as the QIO responds to patients and friends who call CMS with an allegation of a premature hospital discharges. To accomplish this task, as part of the task create a "physician ombudsman" QIO poster to be placed in medical staff lounges of every hospital stating

"Concerned about quality within your hospital and threatened by retaliation- call your QIO and let quality professionals investigate. All calls are confidential."

Rationale: Currently, sham peer review is used by hospitals and medical staffs to silence whistleblower physicians, including those who go through a hospital's chain of command. Several docs have contacted me asking how to report poor quality without endangering their practices (i.e. protect themselves from retaliation, such as via sham peer review). Providing poor quality as measured by unnecessary services is lucrative. Attempting to stop it can motivate retaliation. In response to this problem, around 2009 the State of California extended whistleblower protections to physician members of the medical staff of hospitals. But, the punishment is a misdemeanor and the fine no more than $25,000. The California Hospital Association opposed the new legislation. The legislature approved the bill with only one dissenting vote. The California Medical Association sponsored the legislation.

More work is needed to enable physicians who wish to report impaired patient safety to come forward without fear of retaliation. From time to time I receive calls from physicians who tell me about sham peer review or ask me to report a quality problem to the proper authority. One such case resulted in a State audit which found a preventable death following a repair of an abdominal aortic aneurysm. As a result, the hospital was decertified for these procedures because its volume was too low. Now such cases are referred to a regional center 15 miles away.

RECOMMENDATION 3: Follow off-label anti-cancer drug use.

Set up a process to collect more detailed data about off-label anti-cancer drug use in adults in coordination with a similar service spearheaded by the American Society of Clinical Oncology (ASCO). https://cancerlinq.org/

Rationale: CMS permits local part B contractors (MACs) to approve off-label use of anti-cancer drugs. This was part of my job as a part B CMD from 1997-2003. Approval is typically based on 2 studies which are insufficient to gain FDA approval for the use in controversy. Once approved off-label, patients have access to the drug, but additional research of its effectiveness is not required.

In order to better understand the efficacy and toxicity of off-label uses of anti-cancer drugs, more robust case reporting is required. Claims data is insufficiently granular for this purpose.

Off-label uses are those in which there is insufficient evidence for the FDA to conclude the drug is safe and effective for such use. Of course the absence of evidence of effectiveness is not evidence of ineffectiveness. Nonetheless, if Medicare is to continue to pay for expensive off-label treatments in adults, evidence of safety and effectiveness for the off-label drug treatment of adult cancer should be as robust as evidence provided for treatment of pediatric cancer. Treatment of pediatric cancer has improved much faster than treatment of adult cancer because the effects of off-label drug uses are typically collated and reported for children. We should do the same for adults. ASCO has spearheaded this effort and CMS should assist.

A more robust data base of the indications for off-label use and its effect will help research about real world use.

RECOMMENDATION 4: Audit coronary stenting.

The QIO shall audit a sample of coronary arteriograms which allegedly justify the placement of a coronary stent, in order to verify its medical necessity. Alternatively, the QIO shall require a hospital medical staff radiology department to audit a sample of coronary stents placed by cardiologists.

Rationale: Currently, the interpretation of a coronary arteriogram is performed by the same cardiologist who places the stent. In fee-for-service, this situation is an unmitigated conflict of interest. Widespread abuse is reported.

The RAC auditor I contacted about this last year does not have the resources to hire an expert to read the arteriograms to verify that stents placed are medically necessary, even for selected cases where abuse is more likely (e.g. when the high biller is in charge of peer review, and chief of the department).

Through QIO sponsored audits, conflicts of interest will be mitigated. CMS already requires that every 10th Pap smear slide read by a cytotechnologist must be over-read by a pathologist. So there is some precedent for my recommendation.

Thank you for the opportunity to comment.

Respectfully,

Gerald N. Rogan, MD
Medicare Consultant and Beneficiary

[i] http://roganconsulting.com/docs/Congressional_Report-Disaster_Analysis_RMC_6-1-08.pdf
[ii] https://www.youtube.com/watch?v=FmW-CAkI5Cc
[iii] Rogan Chapter in "The Truth about Big Medicine" https://www.amazon.com/Truth-About-Big-Medicine-Righting/dp/1442231602
[iv] https://www.finance.senate.gov/imo/media/doc/12062010%20Finance%20Committee%20Staff%20Report%20on%20Cardiac%20Stent%20Usage%20at%20St%20Joseph%20Medical%20Center.pdf