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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-24-09-EMTALA

DATE: March 27, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight

Group (QSOG) and Survey Operations

Group (SOG)

SUBJECT: Clarification on Release of 60-Day Quality Improvement Organization

Reports by CMS

Memorandum Summary

- CMS is clarifying procedures related to the release of the Quality Improvement Organization's (QIO) 60-day report, requested for CMS's referral of an EMTALA case to the HHS Office of the Inspector General (OIG) and for OIG's investigation of the case.
- Specifically, the 60-day report may <u>not</u> be released to the affected physician and/or hospital until after the OIG investigation is completed and the OIG closes the case.

Discussion:

CMS is clarifying procedures related to the release of the QIO 60-day report. The 60-day QIO report is requested in anticipation of CMS's referral of the case to the HHS OIG and for the OIG's investigation of the case. This request for a 60-day QIO report occurs after CMS has notified the hospital of its Emergency Medical Treatment and Labor Act (EMTALA) violation and before the case is referred to OIG.

Background:

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90), PL 101-508, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), PL 108-173, added § 1867(d)(3) to the Social Security Act. This section, titled "Consultation with Quality Improvement Organizations," requires a 5-day QIO review before CMS makes a compliance determination as part of the process of potentially terminating a hospital's participation in Medicare. A subsequent 60-day QIO review is both requested by CMS and required before the OIG imposes civil monetary penalties (CMPs) against the hospital or physician.

The OIG has the exclusive authority to assess CMPs against the hospital or physicians and to exclude physicians from the Medicare program for repeated or gross and flagrant violations of EMTALA (42 CFR 489.24).

The QIO reviews and issues a medical opinion as to whether or not an individual presenting to the emergency department had an emergency medical condition; the appropriateness of the medical screening examination, stabilizing treatment, and transfer; and/or whether the individual's emergency medical condition was stabilized.

CMS shall release, upon request, the 5-day QIO review to the affected physician and/or hospital after CMS has determined whether the hospital violated or was in compliance with EMTALA. In addition, CMS may release the 5-day QIO review to the EMTALA complainant or their representative upon request. When releasing any QIO report, the QIO reviewing physician's identity is <u>not to be disclosed</u> unless they consent to the release of their identity in accordance with the disclosure regulations at 42 CFR 480.133.

If a 60-day review is necessary because CMS has found a violation of EMTALA and intends to refer the case to the OIG, the QIO must offer the involved physician(s) and hospital(s) an opportunity to discuss the case and submit additional information before the QIO completes its 60-day QIO review (489.24(h).

Within 60 calendar days of receiving the case, the QIO must submit to CMS a report on its findings. The report provides an expert medical opinion regarding whether the individual had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there are any medical utilization or quality of care issues involved in the case. When no screening examination was provided to the individual, or when a delay would jeopardize the health or safety of individuals, a 60-day QIO review is not required before the OIG may impose CMPs or exclude a physician from the Medicare program.

If the 60-day QIO report supports the EMTALA violation, CMS will refer the matter, including the report and all appropriate documentation, to the OIG for investigation. The 60-day report may not be released, upon request, to the affected physician and/or hospital until after the OIG investigation is completed and the OIG closes the case. To determine whether the case is open or closed, CMS should consult with the Office of Counsel to the Inspector General.

Contact:

Where the case has been referred to the OIG, the hospital and/or physician should direct questions about the 60-day QIO report to the Office of Counsel to the Inspector General (OCIG). In most cases, the hospital or physician would have a point of contact at OCIG. If not, the hospital may contact OCIG at (202) 619-2078 or their CMS Location.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/
Karen Tritz
Director, Survey Operations Group

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to specific provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- Understand surveyor evaluation criteria
- Recognize deficiencies
- Incorporate solutions into your facility's standards of care

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.