Medicare ESRD Network Organizations Manual

Chapter 8 - Publication Policy

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10 - Background

(Rev. 1, 07-11-03)

ENO 800

The mission of the Health Care Quality Improvement Program (HCQIP) is to promote the quality, effectiveness, and efficiency of health care services to Medicare beneficiaries by:

- Monitoring and improving the quality of care;
- Strengthening the community of those committed to improving quality;
- Communicating with beneficiaries and health care providers in order to promote informed health choices;
- Protecting beneficiaries from poor care; and
- Strengthening the health care delivery system.

The Centers for Medicare & Medicaid Services (CMS) supports ESRD Network publications to the extent of describing documented results of HCQIP activities and contributing to the achievement of the program's mission.

20 - Definition

(Rev. 1, 07-11-03)

ENO 810

In the following instruction, the term "publication" refers to any peer-reviewed, referenced, and/or referred document which a Network submits on its own behalf to a professional or trade journal, and which results from a CMS-funded quality improvement activity. "Publication" does not refer to press releases, newsletters, brochures, pamphlets, or letters to the editor (with the exception of letters to the editor that include CMS data that has not previously been published elsewhere). When the Network is unsure if a document falls under the definition of "publication," the Network's regional office (RO) project officer has the discretion to decide whether a document requires CMS review. Project officers may also expand the definition of "publication" if they believe such action is justified. The same criteria outlined in this instruction apply to abstracts submitted for publication or for presentation at professional meetings (excluding CMS, Network, and/or Network Forum sponsored meetings), although RO review time is shortened. (See §30.3.)

30 - Requirements

(Rev. 1, 07-11-03)

ENO 820

The Network's publication must meet the following requirements:

30.1 - Confidentiality

(Rev. 1, 07-11-03)

ENO 820.A

All Network publications must meet the confidentiality requirements specified at <u>42 CFR Part 480, §1160</u> of the Social Security Act, and <u>Chapter 3</u> of this manual.

30.2 - Disclaimer

(Rev. 1, 07-11-03)

ENO 820.B

All Network publications (except abstracts) must include the following disclaimer:

The analyses upon which this publication is based were performed under Contract Number 500-xx-xxxx entitled End Stage Renal Disease Networks Organization for the State (Commonwealth) of sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Centers for Medicare & Medicaid Services, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

Any deviation from the above legend must be approved in writing by the contracting officer.

30.3 - CMS Certification

(Rev. 1, 07-11-03)

ENO 820.C

The Network provides CMS with manuscripts for publication prior to submitting them for publication, and sends the manuscript to its RO project officer, who is responsible for reviewing the manuscript and certifying that the manuscript meets the requirements listed above. Project officers have 30 calendar days from the date of receipt of the manuscript to provide a response to the Network. The Network considers RO review time in relation to any deadlines imposed upon it by the journal or any other publication. In the case of abstracts, the project officer has 10 calendar days to respond to the Network. On an individual basis, the Network can request a more rapid reply from the project officer (for either manuscripts or abstracts). The project officer has the discretion to honor or reject such requests. The Network works with its project officer to establish a process for prompt and efficient review and comment on draft publications (e.g., method of submitting draft publication to the project officer, begin and end dates of project officer review time).

Project officers and/or other RO staff may provide the Network with substantive changes to the manuscript. The Network considers these substantive changes just as it would similar changes suggested by other peer reviewers. The Network must address any confidentiality and/or disclaimer issues raised by the project officer. Once the Network has addressed these issues and the project officer has certified that they have been adequately addressed, the Network may submit the manuscript for publication.

If the Network does not receive certification from the project officer within 30 days of receipt of the manuscript (or within 10 days in the case of the abstract), assume certification and proceed with the publication.

30.4 - Revisions to Original Manuscript

(Rev. 1, 07-11-03)

ENO 820.D

Project officers will review the version of a manuscript which the Network will initially submit for publication. In situations where revisions to a manuscript are made between the time it is first submitted to a journal or other publication and when it is actually published, the Network is responsible for informing the project officer of any changes to the manuscript which relate to Network data and/or CMS policy. The project officer may decide to review revisions of the manuscript. However, project officers are not required to do so. Ultimately, the Network is responsible for the manuscript as published. The Network is liable for any breaches of confidentiality or misrepresentation of CMS policy that results from the publication of a revision of the original manuscript and will be subject to any penalties that may be imposed for doing so.

30.5 - Published Article

(Rev. 1, 07-11-03)

ENO 820.E

The Network must provide a copy of the article, as published, to its project officer.

40 - Disagreements

(Rev. 1, 07-11-03)

ENO 830

Disagreements with the project officer's determinations regarding the manuscript will be resolved by the contracting officer.