Advocacy Through the Medicare Process

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By Risë Marie Cleland

The pace and complexity of changes in cancer service delivery, coding, billing, reimbursement, and regulations, along with the knowledge that further changes are certain can lead to the perception that we have no voice in the future of cancer care in our communities. This is not the case. We have many opportunities to become actively involved in this

process. "Advocacy" is defined as active support. To be an effective advocate for our patients, we need to be educated on the issues affecting cancer care delivery, and we need to actively participate in the process of determining how cancer care will be delivered and reimbursed in our communities. This article will discuss some useful techniques, Web sites, and approaches to advocacy for the Medicare process.

Comment on Proposed Regulations

The Centers for Medicare & Medicaid Services (CMS) maintains a Web site (www.cms.hhs.gov/erulemaking), listing regulations with open comment periods. From this site, click on "submit electronic comments on CMS regulations with an open comment period." You will be directed to a page that lists dockets currently open for comment, the title of the dockets, the published date, and the date the comment period ends. One also can read electronic comments on CMS regulations submitted by others to gather the points of view of those in the oncology community.

At www.regulations.gov, search for all CMS documents open for comment by simple clicking on "documents open for comment" and choosing "CMS" in the drop-down menu. The docket ID, document ID and title, and the PDF and HTML versions of the proposed rule open for comment will be displayed. Comments on the proposed rule may be submitted directly from this page.

In general, the docket is open for comment at least 30 days for Medicaid regulations and 60 days for Medicare regulations. Therefore, it would be reasonable to check this site once every 3 weeks for updates.

CMS publishes proposed rules and regulations in the *Federal Register*, the daily newspaper of the federal government. Each weekday, the National Archives and Records Administration publishes the *Federal Register*, which is available online at www.archives.gov.

Whenever possible, CMS tries to limit publication of regulations and notices in the *Federal Register* to the fourth Friday of each month, allowing for some predictability. Additionally, the proposed physician fee schedule is published in the summer, and the final rule is usually published in November.

Stay informed of proposed regulations by signing up to receive a daily e-mail from the *Federal Register's* table of contents on www.gpoaccess.gov/fr/index.html. Scroll down the list to CMS to access the daily notices and meetings pertaining to CMS.

National Coverage Determinations

A National Coverage Determination (NCD) is a determination of coverage by CMS with national implications. The Medicare Modernization Act of 2003 mandated changes to the NCD process with the goal of making it more transparent.

An NCD is binding to all Medicare contractors, Medicare advantage plans, quality improvement organizations, and administrative law judges. However, you can participate in the process by commenting on the proposed NCDs.

The Medicare Coverage Database link on the CMS Web site (www.cms.hhs.gov/mcd/index_list.asp?list_type=nca) lists open and closed National Coverage Analyses (NCA). Click on the subject of interest to read about the issue, track the actions taken, comment on open items and view public comments received. In formulating your comments on specific issues, it may be helpful to read the comments that have been submitted by other providers and professional organizations.

When a Proposed Decision Memo is issued, it presents another opportunity to share comment within the 30-day public comment period. This time frame may be used to offer informed opinions, to provide additional information and insights on the issue, and to request clarification of posted information.

Any party may request an NCD. According to CMS,¹ a complete formal initial request for an NCD or formal request for reconsideration must:

- Be in writing.
- Include the formal request letter and supporting documentation must be submitted electronically, unless there is good cause for only a hardcopy submission.
- Identify the request as a formal request for an NCD, or a formal request for reconsideration, and identify the NCD development track chosen.
- State the benefit category or categories of the Medicare program to which the requestor believes the item or service applies.
- Include adequate supporting documentation along with the formal request letter.

If you are not familiar with the NCD process, CMS encourages you to contact them informally before formally requesting an NCD. CMS can be contacted by email at cms_caginquiries@cms.hhs.gov.

Local Coverage Determinations

A Local Coverage Determination (LCD), as established by section 522 of the Benefits Improvement and Protection Act, is a coverage decision made by a Medicare contractor concerning what items and services are reasonable and necessary. An LCD may not conflict with an NCD, but it may act as a supplement.

The process under which LCDs are developed is defined in the *Medicare Program Integrity Manual (MPIM)*, Chapter 13. Medicare contractors develop LCDs through the carrier advisory committee (CAC) process described in the following section.

Final LCDs may be considered for revision when new evidence is presented. Medicare beneficiaries, providers, and other interested parties may request an LCD reconsideration.

You can search for LCDs by contractor, state, or alphabetical order on the CMS Web site through the Medicare Coverage Database available at <http://www.cms.hhs.gov/mcd/indexes.asp>.

CAC

The CAC includes physicians from various specialties, including oncology and hematology, a beneficiary representative, and representatives of other medical organizations. The CACs assist Medicare contractors in developing LCDs, and they facilitate physicians and Medicare disseminate information and discuss policies.

The *Medicare Program Integrity Manual (MPIM)* Chapter 13: *Local Coverage Determinations* CMS dictates that Medicare Carriers and Intermediaries present draft LCDs for public comment before presenting the draft policy to the CAC.

Comments on draft policies can be submitted in writing by email, through teleconference, or in person at open meetings. These meetings are held before each CAC meeting and allow interested parties to present relevant information and comments regarding the draft LCD.

Parties interested in making a presentation at one of the open meetings must register with their Medicare carrier/intermediary. Information on registering to present at an open meeting is available on the Medicare contractor's Web site.

Draft LCDs requiring a comment period are open for comment for a minimum of 45 calendar days. After the comment period ends and a final LCD is developed, there will be another 45 calendar-day comment period on the final LCD. All draft LCDs, the start and stop date of the comment period, as well as information on how to comment on the policy must be posted on the contractor's Web site.

Open-Door Forums

CMS hosts open-door forums for a live dialogue between CMS and the provider community on current program issues. These forums are held by conference call and are open to the public for anyone who wishes to attend or participate in these forums. Participants have an opportunity to comment or ask questions related to the forum topic.

The forums are commonly attended by carrier medical directors, CMS personnel, providers, office administrators, billing managers, industry representatives, and others interested in the particular forums topic. Audio files of special open-door forums may also be available on the open-door forums' Web page, www.cms.hhs.gov/opendoorforums.

To be notified of upcoming forums by email, register for the CMS mailing lists at www.cms.hhs.gov/apps/maillinglists by choosing "areas of interest." Available mailing lists include CAP physicians, hospitals, nurses, physicians, pharmacy, and rural health. Once registered, you will be notified by email of upcoming forums.

Physicians Regulatory Issues Team

The Physicians Regulatory Issues Team (PRIT) was created by CMS in 1998 in an effort to simplify Medicare requirements or eliminate unnecessary regulations and to improve the responsiveness of the agency to providers. Physicians can contact the PRIT directly to report problems they are encountering or to ask the PRIT to clarify an issue.

The PRIT is composed of CMS subject matter experts. William Rogers, MD, leads the team of CMS leadership staff, regional office staff, physicians, and technical experts that make up the PRIT.

Providers can view past and active PRIT Issues and track their status by clicking on the issue on the PRIT Web page. An example of an issue that the PRIT addressed is the clarification of language in CMS Transmittal 788, which appeared to require the consulting physician to verify that the requesting physician had entered the request for a consultation in the patient's chart. The PRIT clarified that Medicare does not expect the consulting physician to verify that the requesting physician has documented the consultation request in his/her patient's medical record. PRIT can be contacted by email at prit@cms.hhs.gov.

Freedom of Information Act

Through the Freedom of Information Act (FOIA), enacted in 1966, you can request and receive most records in the custody of CMS. The FOIA only applies to documents, and it does not require an agency to compile data into a document.

CMS' Web site and your Medicare carrier's Web site contain detailed instructions on the FOIA and how to request information under the act. Physicians most commonly request Medicare Part B charge and reimbursement information.

Consider the following practical example of a recent request under the FOIA to a Medicare Carrier. A written request to a Medicare carrier under the FOIA described the US Pharmacopoeia Drug Information listed unlabeled use of a particular drug, and it cited the reference to the Medicare Carrier Manual section 2049.4C, which gives Medicare carriers the authority to extend coverage to unlabeled uses in specified compendia. The requestor asked the carrier whether the newly listed unlabeled use would be included in an update as a covered diagnosis by the carrier. The requestor also asked for the effective date of coverage and recommended coding and billing guidelines. The Freedom of Information Coordinator for the Medicare carrier responded in writing

with the affirmation of coverage for the unlabeled use of the drug and the primary and secondary diagnoses necessary for proper claim submission. The written confirmation of coverage and the primary and secondary diagnoses necessary for proper coding and billing received from the carrier on their letterhead provides support for the practice should there be an improper denial.

Resources: State Societies

In response to the Medicare Modernization Act of 2003 and the complex and challenging changes in oncology reimbursement, most states now have active oncology societies, and they are joining forces to form regional societies that will reflect the new Medicare administrator contractor regions.

State societies are particularly powerful voices for the oncology community, developing strong cooperative partnerships with their Medicare carrier medical director. Become an engaged and active member in your state oncology/hematology society.

ASCO maintains a list of hematology and oncology CAC members, state hematology/oncology societies, Medicare contractors, Medicare carrier medical directors, and their contact information on their Web site at www.asco.org/cac.

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Reference

1. Centers for Medicare & Medicaid Services: Guidance for the public, industry, and CMS staff: Factors CMS considers in opening a National Coverage Determination. http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=6