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# Modern Healthcare

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Cherlyn Murer, president and chief executive officer, Murer Consultants

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# Declassifying coverage

*New guidance documents issued by the CMS may clarify the great unknown of Medicare coverage determination*

Some lesser-known provisions of the Medicare Modernization Act of 2003 currently getting a rollout may give healthcare providers and manufacturers a reason to celebrate as the CMS clears up a generally mysterious and unwieldy Medicare approval process.

Section 731 of the Medicare Modernization Act includes requirements that the CMS give the public more information about how it determines at a national level what procedures and technologies are eligible for Medicare reimbursement. In addition, the CMS must create an avenue for public comment as it goes about making coverage decisions.

The changes aim to clear up what historically has been a murky process and give the public and the industry a stronger voice in how Medicare determinations are made.

Many non-Medicare patients are affected by the CMS' decisions about whether a procedure is reimbursable. Insurance companies might be more inclined to cover a new procedure or technology if it is reimbursable under Medicare.

But the current draft guidance doesn't affect decisions made at the local level by fiscal intermediaries and carriers, a process known as local coverage determination. The CMS will take steps to improve that process later, assuming

that the agency follows the mandates of the Medicare Modernization Act.

The latest changes came March 9, when the CMS issued three draft guidance documents on its national decisionmaking process, called national coverage determination, that are the first steps in a series of information exchanges with the public on how it operates.

The changes would potentially quicken the process for getting national approval for medical procedures and devices, allowing healthcare providers to adopt new technologies.

Moreover, the act also mandates that the CMS make reimbursement at the local level more consistent among fiscal intermediaries and carriers, which should make life easier for national healthcare providers.

The changes are expected to give relief to medical-care innovators who depend on getting new procedures and technologies to the market as fast as possible. "Technology moves faster than bureaucracy," said **Cherilyn Murer, president and chief executive officer of Murer Consultants**, a healthcare consultancy that advises hospitals and healthcare companies in reimbursement issues.

The sooner a new treatment gets into production and becomes reimbursable, the faster the product moves along the learning curve, thus decreasing costs, Murer said. And the changes taking place at the CMS as a result of the act will allow the national process to move more quickly and more

easily adapt to changes taking place in the industry, Murer said. "It's very good and it's a very positive thing," she said.

At the local level, where a CMS spokesman estimated 70% to 90% of Medicare determinations are made, improvements mandated by the Medicare Modernization Act are slated to come later, though changes would be welcome. The CMS will be streamlining the number of local decisionmakers contracted out to make local coverage determinations, a new concept taking the place of local medical review policies. There are fewer than 30 of these fiscal intermediaries (who deal with Medicare Part A) and carriers (who deal with Park B).

A CMS spokesman said he couldn't provide a timetable as to when the local coverage determination changes will take place because the current focus is on the national decisions. Both types of improvements are way behind the act's original timetable, which called for the national coverage determination provisions to become effective Jan. 1, 2004, and the local determination provisions to become effective July 1, 2004.

Eventually, though, the CMS will work to reduce variation among determinations made by fiscal intermediaries and carriers. "They're

trying to make them more consistent across the country,” said Wendy Resnick, assistant to the senior vice president and chief financial officer at Shands HealthCare, a nine-hospital not-for-profit system based in Gainesville, Fla.

As a result of the multiple decisionmaker process Medicare uses for local determinations, a fiscal intermediary or carrier in one part of the country might make a decision that conflicts with decisions made in another region.

In theory, as a single-state system such as Shands shouldn't have any problem with variations. Nevertheless, the issue does come up. As a northern Florida provider, variations in what's covered can show up with patients coming from Georgia or when Shands hires doctors from other regions, Resnick said. “In the past, there might not have been consistent medical policies.”

Though local coverage determinations vastly outnumber national ones, if a national coverage determination is issued, fiscal intermediaries and carriers must use that as a guide. Making the national coverage determination more user-friendly could encourage interested parties to apply for one, as opposed to a local determination, Resnick said. Hospitals have a choice to go national or local with a request and historically have opted to go the local route.

Nevertheless, national determinations aren't expected to take the place of local ones, which give the industry a less imposing way to request Medicare coverage. Taking away the local determination altogether would be akin to taking away local or county government, Resnick said. People would be fearful of not having as much of a say in the process, she said.

But since expensive procedures and technologies tend to be proposed to Medicare at the national level, an improved national coverage determination process will provide a direct boost to those groups – such as medical devicemakers and suppliers – promoting them. Historically, getting a new device or procedure approved by the CMS for Medicare reimbursement was a lengthy process that ultimately discouraged innovation, Murer said.

Moreover, she said, the system was not set up to accommodate procedures that could save lives and money. A less invasive procedure relying on new technology might get less reimbursement under Medicare guidelines than an existing, more invasive procedure does, she said. The CMS' acknowledgement of the issue and its plan to become more adaptable is a big step, she said.

In a similar vein, technology can sometimes replace humans in patient care, such as in physical therapy treatments, yet the current Medicare structure might financially penalize a provider for making that switch, Murer said.

CMS officials agree that the department's approach to giving approval to procedures and technologies should be updated to accommodate a new wave of medical technologies. “The old reimbursement paradigm doesn't necessarily work so well,” said Sean Tunis, the CMS' chief medical officer.

New approaches to treating patients are being developed. For example, the growing area of pharmacogenomics is one that wouldn't necessarily fit in with the approaches the CMS currently uses to approve payments for Medicare, Tunis said. Pharmacogenomics is the study of how an individual's genetic makeup might respond to different drugs.

In addition, the changes at the CMS create a more definable approach to approving procedures and technology, which will give companies more reassurance in the process, which should prod even more innovation, he said. If the process is fuzzy, it will create uncertainty for people who are investing in and thereby providing capital to new medical technologies and procedures, Tunis said. The CMS is working with the new guidance to reduce the amount of that fuzziness, he said.

“I like the idea of bringing more science to bear,” said Richard Pico, chief medical and technology strategy officer for Perot Systems. And making the national coverage determination process more transparent and expedient also is a good idea, he said.

Tunis noted that the CMS' recent decision procedures already have met or exceeded the timeliness guidelines required of the mandates in the Medicare Modernization Act.

The three guidance documents unveiled March 9 are the first of what will be “a large portfolio” of such documents to be issued by the CMS, Tunis said. They are the first step

in creating a formal process for: how the CMS decides whether to make a coverage determination; how the CMS decides if an outside technology consultation is needed; and how the CMS decides if a request requires medical consultation from its Medicare Coverage Advisory Committee. Public comments on the guidance documents are being accepted until May 9.

The act requires that regular national coverage determinations be completed within six months of the request being made. Those requests that require extra consultation – for either technology or medical expertise – would be given an additional three months for the CMS to make a determination. After the initial six- or nine-month period, the CMS will publish a draft of its coverage decision, allow 30 days for comment and issue a final decision within 60 days.

Industry executives also noted that the national guidelines make it easier for patient representatives to request a national determination. “This is a little more friendly to patients and patient groups,” said Chris Crosswhite, a partner with the law firm Duane Morris.

Murer said the CMS may have been affected by pleas from celebrities such as Michael J. Fox and Katie Couric, who are pushing for more rapid development of treatments and technologies.

The CMS will continue to issue new guidance on general and specific matters as it is able, Tunis said. He also said the CMS hired several researchers with the kind of technical and analytical skills needed to do the kind of decision-making guidance requires.

The amount of guidance offered by the CMS under the new rules theoretically could be infinite. There's no hard upper limit on how many guidance documents are produced, Tunis said. The CMS, which is using the Food and Drug Administration's approach as a model, could tackle eight to 12 general subjects and almost any number of specific procedures. “The FDA has hundreds,” he said, “and we're just getting started.”