E is for Evidence

Coverage with Evidence Development (CED)

Additional Notes to Accompany Slides
By Ron Milhorn, LLC
March 30, 2006

Slide 3: What CED Appears to be

The reason for this vagueness is that CMS has yet to publish the second draft guidance document on CED. The initial guidance document, and the "clarification" published in July, 2005, left numerous basic questions unanswered.

Slide 4: What CED is not

Given the absence of a clear statement by CMS of what CED is, it is important to distinguish it from previous proposals, generally described as "offering coverage in exchange for data" that were developed in the late 1990's, prior to the decision to allow Medicare of coverage clinical trials. They were designed to collect data that was expected to lead to a coverage determination within a limited period of time. CED is a totally different animal—it does not necessarily lead to normal coverage with a National Coverage Determination (NCD) as the end result.

Slide 7: Services Less than Adequate

Although the offering of coverage may appear to be a positive, it will not take long for sophisticated patients and physicians, as well as malpractice attorneys, to understand that such services simply did not meet CMS coverage standards, whatever they may have been.

Web sites like "injuryboard.com" offer one-stop shopping for both dissatisfied patients and their attorneys for information and advice in filing lawsuits for medical services for which even the slightest concern has been expressed. Once the shortcomings of services offered under CED are known, you can expect them to be featured on such web sites.

Slide 8: Registries Have Limitations

The author admits he is no expert on registries, however, he is drawing on information from organizations such as ECRI, who are experts as to the limitations and pitfalls common to registries.

While registries are excellent tools for giving a longitudinal look at how well services perform over time, they are not given much weight in initial NCD decisions. The lack of any clear and comprehensive statement by CMS of how it

ranks or weighs the various types of medical evidence available raise the question of whether any registry, no matter how rigorously done, will rise to the level of sufficient evidence to justify an NCD.

Slide 9: Claims Process Unforgiving

Admittedly no expert on registries, the author has had a lot of experience in handling registries and other data collection efforts within the context of the Medicare claims process. In a nutshell, the two do not mix well, if at all. Medicare processes over two million claims per day. In order to accomplish this, the claims process requires a high degree of automation, simple "yes/no" answers, and as few questionable situations as possible. Adding any level of complexity to the system is resisted at all levels of the agency, for both budgetary and workload reasons. In addition, any data collection must be factored into a "data collection budget" for the agency, which receives close scrutiny. Finally, any data collection forms to be used must be approved by the Office of Management and Budget (OMB), a process that usually takes a year.

Unlike a registry sponsored by a professional society, most physicians and hospitals will not have an interest in carefully preparing and submitting registry data to CMS. The tendency will be to file whatever is acceptable, rather than take the time necessary to be precise. In addition, studies have shown that even trained nurses will miscode procedures about 10% of the time. Thus, the use of mass-produced registry data for making coverage determinations is extremely suspect and would not meet CMS's usual standards for acceptable research evidence.

Slide 10: Freezes Consideration of Service

Since CMS has not set out any timelines for ending CED, it is possible that a service could remain in CED indefinitely. Unless strong, convincing medical evidence, such as a new clinical trial, is developed outside the CED framework, CMS is unlikely to consider developing an NCD for the service.

As a result, this may discourage entry into the marketplace by others, especially due to the uncertainty as to when, if ever, CED develops enough evidence to allow an NCD for the service.

Slide 11: Potentially Damaging Information Public

Although publicizing a dangerous or useless services is a positive, there is no assurance that CMS intends to review and assure that speculations or conclusions about a CED service meet some standards or are carefully reviewed before publication. CMS has stated it will make the data public for researchers and others to use in evaluating the service.

Moreover, CMS currently does not plan to withdraw CED coverage from a service that appears to be less than adequate. Instead, it plans to publicize the services' shortcomings, allowing patients and physicians to decide for themselves whether to use the service or not.

The uncertainty of the quality of data input to registries, coupled with the pitfalls inherent in assessing and interpreting data, mean that a service covered under CED could be harmed by erroneous interpretations of the data CMS makes available.

Since CMS has not revealed any "end-game" for CED, and has not provided any method for allowing a sponsor to withdraw from CED coverage, there may be no way for a sponsor to avoid a long-term flow of questionable bad news about its service.

Slide 12: Is it Worth it?

The "hassle factor" should not be lightly dismissed. To the extent that CED increases physician and hospital reporting expenses, it will increase the likelihood that the data developed are suspect, since the tendency will be to "get the form off the desk" the quickest way possible. Also, some physicians and hospitals may try and avoid CED services due to the time and expense involved in providing them.

Slide 13: Can you Avoid it?

This is probably the biggest question that CMS has left unanswered. Since they have not outlined precisely what the criteria are for deciding whether or not to offer CED, and since they have "covered" services that they later declare to be CED-like, no one knows the rules for obtaining CED or avoiding it.

Since CMS has been quite vague about what would move a service to CED rather than a non-coverage decision, sponsors have no way of assessing whether they can avoid CED should they wish to do so.

Perhaps the biggest concern that potential sponsors should have is that their competitors may force them into CED. Waiting to approach CMS until you are sure you have sufficient evidence is no defense. A competitor can request an NCD prematurely and force everyone in the industry into a CED situation. CMS's apparent intent to leave a service in CED for some time, especially under a registry approach, could discourage entry into the market. Moreover, given the competition for research funds and resources, CED could discourage development of clinical trials that could provide the evidence necessary to move the service from CED to an NCD.

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