The Elusive “Reasonable and Necessary”: Making a Determination of Coverage with Evidence Development

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On April 7, 2005, the Centers for Medicare and Medicaid Services (CMS) published a draft guidance to describe its proposed approach to deciding when to extend national coverage for a new item or service provided to a Medicare beneficiary. The new approach, Coverage with Evidence Development (CED), would link a national coverage decision for a particular item or service with a requirement to collect prospective data on the Medicare patients receiving that particular item or service.

By law, CMS is obligated to provide coverage to Medicare beneficiaries for healthcare services and items that are “reasonable and necessary.” However, Congress failed to define the term “reasonable and necessary” within the Social Security Amendments that established the Medicare program. Instead, Congress broadly defined categories of available benefits, placed limitations on many of the services for which Medicare beneficiaries might be eligible, and excluded some products and services categories altogether— and left to CMS the responsibility to determine when an advancement, innovation, or improvement of an item or service provided to a Medicare beneficiary that does not fit into one of the defined and covered benefit categories is “reasonable and necessary.”

Initially, determining whether a new item or service was “reasonable and necessary” was relatively simple, and decided by the local contractor in whose area the new item or service was provided. Unfortunately, and as advancements and innovations became more frequent, coverage for identical items and services provided in different locations varied. The likelihood that such differences in coverage would negatively impact Medicare patients’ access to care highlighted the need for coverage decisions that applied equally to all Medicare beneficiaries regardless of location, and culminated ultimately in regulations that described the formal National Coverage Determination (NCD) process by which such decisions would be made. The actual criteria

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2 See id. at 2.
5 Id. at n.3. While CMS had, and currently has, the authority to make national coverage decisions which would be binding on all contractors, only a few national coverage decisions were, and are, made each year. See id.
6 CMS initially used an internal procedure to make national coverage determinations. See 68 Fed. Reg. 55,634, 55,634 (Sept. 26, 2003). In 1999, CMS published its revisions to the National Coverage Determination (NCD) process in the Federal Register to “mak[e it] more open and understandable to the public.” Id. The NCD process was changed again in 2003, this time “to make [it] more efficient and ensure . . . access to all relevant information to make fully informed decisions.” Id. Shortly after the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), CMS notified the industry of the changes to the NCD process mandated by the MMA, and promised further explanation in future guidance. See Medicare Coverage – Process: Changes to the
CMS uses to judge the items or services “reasonable and necessary,” however, have eluded definition for more than 20 years.\(^7\)

Within its April 2005 draft guidance, CMS claims the CED initiative will ensure “that advances in medical technology are available for [ ] Medicare beneficiaries while also ensuring the care they receive is reasonable and necessary – a necessary condition for payment.”\(^8\) CMS further states it intends to extend coverage for certain items and services even when there is insufficient evidence of the benefit to individual patients or the Medicare population, or when the evidence is inconclusive but strongly suggests an individual patient or the Medicare population would benefit.\(^9\) CMS does not anticipate a significant increase in the number of coverage decisions that apply the data collection requirements,\(^10\) and, because the care for these items and services will be provided in accordance with clinical research protocols, CMS expects Medicare patients will likely experience an increase in their overall health outcomes.\(^11\) CMS also believes that physicians and patients will “better understand[ ] the risks, benefits and costs of alternative diagnostic and treatment options” if evidence is collected after the item or service has been provided and covered. In other words, CMS intends to cover some items and services that may or may not be “reasonable and necessary,” and then collect evidence to make its coverage decision, a process that seems to be in direct violation of the law.

More than 60 professional associations and healthcare organizations responded to CMS’s call for public comments on its CED proposal, submitting a total of more than 400 pages in comments.\(^12\) Many commenters supported CMS’s efforts to incorporate evidence-based medicine into its NCD process,\(^13\) but the majority questioned whether CMS had the statutory authority to implement CED.\(^14\) Several also were concerned that, unless used sparingly, CED might actually restrict patient access to needed care, infringe on the physician’s medical judgment, and ultimately be used to limit Medicare coverage.\(^15\)

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\(^{7}\) See Michael M. Gaba, Is CMS’ Coverage with Evidence Development Policy Reasonable and Necessary?, 2 Food and Drug L. 5, 6 (2005); Foote, supra note 4, at 713-18. In 1979, a CMS draft internal proposal listed “safety, economics, and ethical and social factors” as key criteria for evaluating national coverage requests. See id. at 713. In 1989, CMS’s proposed rule added cost-effectiveness, a criterion used by the Food and Drug Administration (FDA) to evaluate new devices. See id. at 715.

\(^{8}\) DRAFT GUIDANCE, supra note 1, at 4.

\(^{9}\) See id.

\(^{10}\) Id. at 2.

\(^{11}\) Id. at 4.

\(^{12}\) See PUBLIC COMMENTS FOR DRAFT GUIDANCE DOCUMENTS FOR COVERAGE EVIDENCE DEVELOPMENT (undated) available at http://www.cms.hhs.gov/coverage/download/guidcedcomm.pdf (last visited Oct. 29, 2005) (hereinafter, GUIDANCE COMMENTS). The public was invited to submit comments which were due no later than June 6, 2005. See DRAFT GUIDANCE, supra note 1, cover page.


\(^{14}\) See GUIDANCE COMMENTS, supra, note 12. See also Gaba, supra note 7, at 7.

\(^{15}\) See GUIDANCE COMMENTS, supra note 12.
A few commenters cautioned that implementing CED could implicate the Health Insurance Portability and Accountability Act of 1996 (HIPAA), specifically the HIPAA Privacy Regulations. One mentioned complying with the Privacy Regulations would impose limitations on researchers but did not elaborate on its comment. Another suggested that the HIPAA Privacy Regulations might limit access to the data collected, but also failed to specify to whom or how access might be limited. The Washington Legal Foundation, however, raised and then explained how CMS’s proposed approach could potentially violate two specific privacy standards.

First, as a covered entity in its role as the largest payor in the country, the Privacy Regulations require CMS to obtain a written authorization from a patient prior to using or disclosing that patient’s protected health information (PHI) for purposes of research. The CED approach fails to address this standard; no authorization is required prior to enrolling the patient in CED. Second, even if CMS were to modify the CED approach and require an authorization, the authorization would likely be deemed invalid under the Privacy Regulations because payment for the services would be conditioned on signing it. “Subject to specified exceptions, a covered entity ‘may not condition the provision to an individual of treatment, payment, enrollment in the health plan or eligibility for benefits on the provision of an authorization.’”

The other major concern mentioned by virtually every commenter was the cost associated with implementing CED – and the question of who would ultimately be responsible for this cost. The American Medical Association eloquently summarized the problem:

Proper funding of clinical trials and data collection efforts will help produce accurate and valid results. In addition, CMS should keep in mind that if funding and other resources are not available to develop data, poor data or little or no data collection will result in little or no advances in medicine. . . . We urge CMS to carefully consider whether the effort and resources required to collect data are justified by the value of the information that will be generated. The physician community cannot absorb additional unfunded mandates . . . .

17 See also Gaba, supra note 7, at 7-8.
18 See ABBOTT, Letter (June 6, 2005) in GUIDANCE COMMENTS, supra note 12.
19 See INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOMES RESEARCH, Letter (June 6, 2005) in GUIDANCE COMMENTS, supra note 12.
20 See WASHINGTON LEGAL FOUNDATION, Letter (June 6, 2005) in GUIDANCE COMMENTS, supra note 12.
21 See 45 C.F.R. §§ 164.502(a), 164.512(i)(1). An authorization is required unless the covered entity has received approval of a waiver of authorization from an Institutional Review Board or a Privacy Board. Id. §§ 164.512(i)(1)(A), (B).
22 Id. § 164.508(b)(4).
23 See WASHINGTON LEGAL FOUNDATION, Letter (June 6, 2005) in GUIDANCE COMMENTS, supra note 12 (citing 45 C.F.R. § 164.508(b)(4)).
24 See generally, GUIDANCE COMMENTS, supra note 12.
25 AMERICAN MEDICAL ASSOCIATION, Letter (June 6, 2005) in GUIDANCE COMMENTS, supra note 12.
Unless CMS addresses the funding concerns of the commenters or identifies and adopts alternative ways to conduct the same research,\textsuperscript{26} it is likely that Medicare patients will ultimately be the ones to absorb the costs of CED.\textsuperscript{27} Even if CMS’s proposed CED policy was well-intentioned, and the data it planned to collect are critical to ensuring Medicare beneficiaries have access to advances in medical technology, CMS must still address the significant issues raised in the public’s comments. Specifically, CMS must proffer the legal rationale (and basis) behind its proposal to pay for items and services that may ultimately be found to be neither reasonable nor necessary, an action that is in direct violation of its statutory duty. In addition, CMS should re-examine and restructure its CED process so that none of its components jeopardize the agency’s ability to comply with the HIPAA Privacy Regulations; regulations CMS is responsible for enforcing. Given the unanswered legal questions about and the generally overwhelming criticism of its proposed CED policy, hopefully CMS will not implement it without considerable review and revision.

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\textsuperscript{26} The Washington Legal Foundation described several alternatives to increase research into items and services used by Medicare patients. \textit{See} WASHINGTON LEGAL FOUNDATION, Letter (June 6, 2005) \textit{in} GUIDANCE COMMENTS, \textit{supra} note 12.

\textsuperscript{27} \textit{See} Gaba, \textit{supra} note 7, at 8.