DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

ADVISORY OPINION 21-03 ON MEDICARE COVERAGE WITH EVIDENCE DEVELOPMENT
JANUARY 14, 2021

The Office of the General Counsel ("OGC") has received a question from a trade association about the appropriate application of coverage with evidence development ("CED") in Medicare. This advisory opinion addresses that question.

The Centers for Medicare & Medicaid Services ("CMS") has been using CED as the basis for coverage of items and services since at least July 12, 2006, when it first issued a guidance document outlining this theory of coverage.[1] As CMS summarized at the time, the purpose of CED "is to generate data on the utilization and impact of the item or service evaluated in the [National Coverage Determination ("NCD")], so that Medicare can a) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; b) consider future changes in coverage for the item or service; c) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service." In 2014, CMS issued a revised CED guidance document, stating, in pertinent part, as follows: "CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary."[2]

Social Security Act ("SSA") Section 1862(a)(1)(A) provides that "no payment may be made . . . for items and services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member," unless an exception in one of the succeeding subparagraphs in SSA Section 1862 applies. Thus, if an item or service is reasonable and necessary for diagnosis, treatment, or improving bodily function, or satisfies an exception, Medicare may cover it. But if an item or service is not reasonable and necessary and does not fall within an exception, then Medicare is prohibited from paying for that item or service.

---

[1] CMS, Guidance for the Public, Industry, and CMS Staff, *National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development* (July 12, 2006), *available at* https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/ced.pdf.

[2] CMS, Guidance for the Public, Industry, and CMS Staff, *Coverage with Evidence Development* (Nov. 20, 2014), *available at* https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.

CMS generally issues NCDs based on the conclusion that available evidence establishes that an item or service is "reasonable and necessary" under SSA Section 1862(a)(1)(A). In previously issued guidance, CMS has explained that NCDs using CED can instead offer coverage under the exception set forth at SSA section 1862(a)(1)(E). Section 1862(a)(1)(E) permits payment by Medicare for items and services "in the case of research conducted pursuant to section 1142," where payment is "reasonable and necessary to carry out the purposes of that section." SSA Section 1142(a)(1) describes the authority of the Agency for Healthcare Research and Quality ("AHRQ") to "conduct and support research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically . . . ." Thus, CMS has interpreted (a)(1)(E) as authorizing Medicare payment for an item or service that is *not* reasonable and necessary for the diagnosis or treatment of illness or injury, but that is reasonable and necessary for purposes of research that AHRQ "support[s]."

Section 1142(b)(3) also states that "[i]n establishing priorities under paragraph (1) for research and evaluation . . . the Secretary shall assure that such priorities appropriately reflect the needs and priorities of [Medicare], as set forth by the Administrator of [CMS]." AHRQ and CMS collaborate under SSA Section 1142 to coordinate AHRQ priorities with the needs and priorities of the Medicare program. AHRQ has reviewed all NCDs using CED that were established under SSA Section 1862(a)(1)(E) and has also set forth general standards for CED studies. The record for each NCD using CED also contains a letter from AHRQ officials verifying AHRQ's support under SSA Section 1142 for the associated clinical trials and research required as a condition of coverage. AHRQ neither conducts nor financially contributes to the research.

CMS has previously interpreted SSA Section 1862(a)(1)(E) as authority to make Medicare payment for items and services provided to study participants in CED clinical trials, under the theory that AHRQ "supports" this research by endorsing it. Accordingly, although AHRQ is neither conducting the research, nor actively supporting the research through funding or other means, CMS has taken the position that AHRQ's endorsement of the research is sufficient to qualify as "support" under SSA Section 1142.

OGC has re-examined this issue and concluded that this prior interpretation of "support" leads to Medicare payment that is unlawful under Section 1862, because AHRQ has not been "supporting" the clinical trials and research required as part of an NCD using CED. The term "support" as used in SSA Section 1142 is not defined, but this broad reading of the term is fundamentally inconsistent with the regulatory definition of "support" at 42 C.F.R. § 93.221. While this definition applies to research oversight under Title IX of the Public Health Service Act ("PHS Act"), and therefore is not controlling for purposes of interpreting the term "support" under SSA Section 1142, OGC now believes that the correct interpretation of the term "support" is to read it as having a meaning consistent with the definition of this term at 42 C.F.R. § 93.221. This regulation defines Public Health Service (including AHRQ) "support" to mean "funding, or applications or proposals therefor, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be

provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or sub contracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts." The term "support" is used throughout the PHS Act and is commonly understood to mean funding, whether by grant or otherwise. *See, e.g.*, PHS Act §§ 301(a)(3), 306(e), 405(b)(2) ("Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements."). Therefore, in order for an NCD using CED to lawfully invoke the exception at SSA Section 1862(a)(1)(E), AHRQ must "support" the study within the meaning of the definition at 42 C.F.R. § 93.221, which will involve more than merely endorsing the clinical study.

This advisory opinion sets forth the current views of the Office of the General Counsel.[3] It is not a final agency action or a final order, and it does not have the force or effect of law.

//s//

Robert P. Charrow
General Counsel

[3] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]").