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Overhauling the Medicare Coverage with Evidence Development Guidance Policy? Comments Requested by CMS

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On November 7, 2011, the Centers for Medicare & Medicaid Services ("**CMS**") issued a public solicitation for comments on the Medicare program's coverage with evidence development ("**CED**") guidance policy. **Comments are due by January 6, 2012**. In CMS's most recent solicitation for comments, CMS describes CED as a mechanism "through which we provide conditional payment for items and services while generating clinical data to demonstrate their impact on health outcomes."[1] We urge all clients interested in Medicare coverage for new items and services to submit comments.

By way of background, CMS may cover and reimburse an item or service only if it is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. . . ."[2] Beginning in 2005, CMS sought to develop a formal policy linking Medicare coverage to clinical trial results. The agency issued a draft CED guidance document in April 2005, and, after receiving numerous comments, it issued a final CED guidance document in July 2006 ("**2006 Guidance**"). In the 2006 Guidance, CMS distinguished between two types of CED: coverage with appropriateness determination ("**CAD**") and coverage with study participation ("**CSP**"). Under CAD, additional clinical data is required that is not routinely available on claims forms to ensure that the item or service is being provided to appropriate beneficiaries according to the clinical criteria described in the national coverage determination ("**NCD**"). CMS's objective under this type of CED was to ensure that payment is made only when the beneficiaries have the underlying diagnoses that match the scope of the NCD.

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[1] https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=8&McdName=National+Coverage+Determinations+with+Data+Collection+as+a+Condition+of+Coverage%3a+Coverage+with+Evidence+Development&mcdtypename=Guidance+Documents&MCDIndexType=1&bc=BAAIAAAAAAAA&

[2] 42 U.S.C. § 1395y(a)(1)(A).

Under CSP, Medicare coverage for certain items and services may be approved when the existing evidence is inadequate to determine whether the "reasonable and necessary" standard is met, but where beneficiaries may be enrolled in a clinical trial that is expected to generate sufficient data in a clinical trial registry to allow CMS to make a final coverage determination. CMS currently lists six NCDs that are subject to CED: (1) Cochlear Implantation; (2) Chemotherapy for Colorectal Cancer; (3) PET (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers; (4) Implantable Cardioverter Defibrillators; (5) PET (FDG) for Dementia and Neurodegenerative Diseases; and (6) Long-Term Oxygen Treatment.

Under CMS's current procedures, CED is incorporated into the formal NCD process. However, unlike the NCD process, the decision to consider a CED option is entirely within CMS's discretion. As a result, interested parties must submit requests for a new or revised NCD and may not know for some time whether CMS will condition coverage on CAD or CSP. Although this may help introduce some technologies into the market sooner, it may also significantly increase the cost to the manufacturer or supplier if a clinical trial registry is required.

In addition to the NCDs, a number of Medicare Administrative Contractors have issued local coverage determinations with data collection or trial enrollment as a condition of coverage. In conjunction with the release of the solicitation for comments, CMS stated that it is "removing" the current CED guidance document. As such, there are questions as to whether: (1) CMS and the Medicare contractors will continue to show deference to the 2006 Guidance until the new guidance document is released in final form; and (2) CMS will be starting from a clean slate and thereby potentially overhauling its CED guidance policy.

In CMS's recent comment solicitation, CMS indicated that "[o]ur intended outcome is to mature CED so that it fulfills its potential as a mechanism that simultaneously reduces barriers for innovation and enables CMS to make better informed decisions that improve health outcomes for Medicare beneficiaries."[3] CMS also stated that it is . . .

> committed to improving health outcomes for its beneficiaries. However, many new technologies are developed with insufficient attention to addressing the needs of the Medicare beneficiary population. Though the scientific evidence may be promising, it may not be sufficient to support broad coverage. Conversely, a non-coverage decision could limit further evidence development, thereby making it more challenging to conduct studies that could better define the patient population that might benefit from an item or service.

[3] See fn. 1, *supra*.

CMS is soliciting specific comments on the following:

- The implementation of CED through the NCD or other avenues under Part A and Part B;
- The potential impact of CED on the Medicare program and its beneficiaries; and
- A suggested approach to CED to maximize benefit to Medicare beneficiaries.

While this particular initiative directly applies only to the Medicare program, what CMS ultimately adopts in this context may have broader ramifications across other payors. Given the importance of coverage determinations to our health care system, we suggest that interested parties, including patients, providers, manufacturers, payors, and other stakeholders, consider providing comments by **January 6, 2012,** on the above topics and on any other relevant CED topics. Ultimately, there needs to be an appropriate balancing of these types of policies and processes.

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*This Client Alert was authored by **Jason B. Caron**, **Lynn Shapiro Snyder,*** and ***Robert E. Wanerman**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.*