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ARTICLES

Medicare’s Coverage with Study Participation Policy: Clinical Trials or Tribulations?

Sandra J. Carnahan*

INTRODUCTION

The Medicare program has, from its inception, sought to balance its duty to safeguard the Medicare trust, with its statutory obligation to pay only for “reasonable and necessary” health care for Medicare beneficiaries, and to honor the government’s promise that its elderly and disabled citizens will receive the best that modern medicine has to offer. Modern medicine is expensive, and costs continue to rise, fueled by an influx of new medical technology and the fast approach toward Medicare eligibility for millions of baby-boomers. The Centers for Medicare and Medicaid Services (CMS) face legal and political restraints

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1. See 42 U.S.C.A. § 1865y(a)(1)(A) (2003) (providing that “no payment may be made . . . for any expenses incurred for items or services . . . not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”).

2. See S. REP. NO. 89-404 (1965), as reprinted in 1965 U.S.C.C.A.N. 1443, 1965 (expressing congressional intent that the Medicare program would “make the best of modern medicine more readily available to the aged”).

3. See DEP’T OF HEALTH & HUMAN SERVS., MEDICARE ENROLLMENT: NATIONAL TRENDS 1966-2005, http://www.cms.hhs.gov/MedicareEnRpts/Downloads/HISMI05.pdf (last visited May 3, 2007). With the exception of 1984, the number of Medicare beneficiaries has grown each year since its inception in 1965. Id. The term “baby boom” refers to the generation born between 1946 and 1964. In 2000, persons between the ages of 65 and 84 made up 10.9% of the U.S. population, but that number is projected to increase to 17% of the total population by 2030. U.S. Census Bureau, PROJECTED POPULATION OF THE UNITED STATES, BY AGE AND SEX: 2000 TO 2050 (2004), http://www.census.gov/ipc/www/usinterimproj/ (follow hyperlink to Table 2a).

with respect to its ability to control costs. Although CMS has discretion in determining how much it will pay for new items and services, it does not have explicit statutory authority to consider cost when deciding whether to cover the intervention in the first instance. Faced with conflicting obligations and statutory restraints, CMS has endeavored to reduce costs, particularly with regard to expensive new technology, through an initiative known as Coverage with Evidence Development (CED). This new coverage policy, published by CMS on July 12, 2006, consists of two arms. The second, more controversial arm of CED is called Coverage with Study Participation (CSP). Under this program, CMS will pay for certain new medical tests, treatments, and biotechnology products, even though it deems the medical evidence insufficient to merit broad national coverage, provided that the services are received in the context of a prospective clinical trial aimed at generating additional evidence. Thus, CSP would restrict payment for certain services to a limited group of Medicare beneficiaries who “agree” to participate in a clinical trial.

The idea of linking coverage to clinical research is not entirely new. In 1995, CMS conditioned payment for an innovative surgical procedure upon patient participation in a clinical trial. In that instance, CMS commenced a seven year clinical trial to compare the outcomes of emphysema patients who underwent lung volume reduction surgery with those patients who were given comprehensive pulmonary rehabilitation. In the face of vigorous opposition

(HHS) and to the Health Care Financing Administration (HCFA). In 2001, HHS changed the name to Centers for Medicare and Medicaid Services (CMS). Id. Since this Article includes background material and legislative history, the designations CMS, HCFA, and Medicare are used interchangeably.

5. See discussion infra Section II.A.


7. See id. at pt. V. The first arm is called “Coverage with Appropriateness Determination” (CAD). CMS explains that items or services designated for CAD are backed by sufficient scientific evidence to satisfy the “reasonable and necessary” statutory standard required for coverage purposes, but additional information is needed to assure the intervention is “appropriately provided.” Id. CAD may be required as a condition of coverage under the following circumstances: (1) if the new service should be restricted to patients with specific conditions and criteria; (2) if the item or service requires providers with specific training or credentials; (3) when “clinical thought leaders” are concerned there may be substantial opportunities for misuse; or (4) if the coverage determination significantly changes the way providers manage patients using the new service. Id. at pt. V.A. Under CAD, CMS will require as a condition of payment (coverage) that the provider must submit to a research database or registry patient information beyond that usually available on the claims forms that are required for payment. Id. To the extent that coverage is contingent upon patients providing additional (beyond billing) information to a registry for research purposes, CAD may raise some of the same issues regarding voluntary informed consent that are raised with the second arm of CED, Coverage with Study Participation.

8. See id. at pt. V.B.

9. See Sean R. Tunis & Steven D. Pearson, Coverage Options for Promising Technologies:
from provider representatives and some members of Congress, CMS restricted payment for lung volume reduction surgery to beneficiaries treated according to a clinical trial protocol. In a 2005 trial involving the use of FDG-PET scans to diagnose certain cancers, CMS conditioned coverage of the scans on participation in a prospective clinical trial or registry. Also in 2005, CMS conditioned coverage of implantable cardioverter defibrillators (ICDs) used for certain indications on participation in a clinical trial or registry. Prior to the publication of its July 2006 "Coverage with Evidence Development" guidelines, however, CMS had not explained its authority for linking coverage with participation in research.

Coverage with Study Participation (CSP) substantially alters the manner in which CMS has traditionally made its national coverage determinations, and raises significant legal and ethical questions. CMS claims that a service designated for CSP does not meet the statutory "reasonable and necessary" standard because, although promising, more evidence is required before the clinical result can be generalized to the Medicare population, or to additional subgroups of Medicare patients. Yet, under CSP, the item or service is somehow boosted to the level of "reasonable and necessary," if provided within the context of a clinical trial.

The statutory authority for CSP is questionable. CMS proposes that a statutory provision permitting payment for research conducted for purposes of quality improvement would also allow it to pay for the CSP clinical trials. This

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10. Id. (noting that the emphysema trial went forward despite strong opposition from some members of Congress and provider representatives).


13. CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. V.B ("CSP allows CMS to determine that an item or service is only reasonable and necessary when it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise."). Among the evidentiary findings that may result in a designation of Coverage with Study Participation (CSP) are: (1) Available evidence may be a product of otherwise methodologically rigorous evaluations but may not have evaluated outcomes that are relevant to Medicare beneficiaries; (2) The available clinical research may have failed to address adequately the risks and benefits to Medicare beneficiaries for off-label or other unanticipated uses of a drug, biologic, service or device; and (3) Available clinical research studies may not have included specific patient subgroups or patients with disease characteristics that are highly prevalent in the Medicare population. Id.

14. See id.
Article posits that the “reasonable and necessary” provision is CMS’s only statutory authority for making coverage decisions, and that CSP represents CMS’s attempt to circumvent the statute’s limitations. Congress has statutorily mandated that CMS withhold payment for Medicare items or services that are not “reasonable and necessary.” If services provided under CSP truly do not meet that standard, then CMS, possibly under intense political pressure, is essentially paying for items or services that are not reasonable and necessary, in violation of its statutory mandate.

Moreover, Coverage with Study Participation is ethically questionable, and may violate the United States Health and Human Services’ (HHS) “Regulations for the Protection of Human Subjects,” which require the voluntary consent of subjects prior to research participation. With CSP, a Medicare beneficiary must either participate in a prospective clinical research trial or be denied a service deemed medically appropriate by their personal physician. Under these circumstances, how can the patient’s research participation ever be truly voluntary, as required by the federal regulations, when the price of non-participation is that Medicare will refuse coverage? Moreover, many elderly and disabled Medicare beneficiaries, for various reasons, may be unable or unwilling to participate in medical research. For those patients, non-participation means denial of the service.

Although CMS insists that the goal of CSP is to enhance access to new medical technology and improve health outcomes for Medicare beneficiaries, in the larger context, CSP appears to be an ethically problematic, thinly-veiled effort to control the high cost of new technology by limiting present coverage and arbitrarily elevating the amount of evidence necessary to meet the “reasonable and necessary” standard. The effect of CSP will be to delay, perhaps for years, full and equal access to potentially life-saving new technology. Moreover, given that Medicare is the nation’s largest insurer of health care, and its coverage policies are adopted by many third-party payers and public health insurance programs throughout the nation, CSP has far-reaching implications not only for Medicare beneficiaries, but for millions of others.

Part I of this Article provides a brief overview of Medicare program essentials, reviews the general CMS process for making local and national coverage determinations, and further explains Coverage with Study Participation.

Part II focuses on the Medicare program’s struggle to define its authority. It examines the statutory language, legislative history, the few court opinions, and CMS’s historical attempts at administrative rule-making to determine the limits of CMS’s authority under the “reasonable and necessary” provision. It also

15. See discussion infra Section III.B.
addresses whether CMS has the statutory authority to require clinical trials for
coverage purposes under the Agency for Healthcare Research and Quality
(AHRQ) provision. This Part emphasizes the historical role that cost
considerations, including cost-effectiveness analysis, have played in determining
whether expensive new technology is “reasonable and necessary.” If CMS has no
authority to consider cost in making its coverage determinations, then engaging
in implicit cost control for the same purpose is equally without statutory support.

Part III examines difficulties with the structure of Coverage with Study
Participation, CMS requirements for the inclusion of elderly subjects in clinical
trials, and the potential for violating federal regulations protecting the rights of
human subjects. This Part concludes that, even if CMS had legitimate statutory
authority to conduct clinical trials, the policy itself is flawed.

Part IV of this Article concludes that Coverage with Study Participation is a
vehicle through which CMS may slow the path of new technology to the nation’s
erly in an implicit effort to reduce program costs. With CSP, CMS has
implicitly woven cost considerations into its coverage criteria, which it has no
authority to do. If items and services are deemed by CMS to be sufficiently
reasonable and necessary for the Medicare population to be approved for
Coverage with Study Participation, then they are sufficiently reasonable and
necessary to be covered for all Medicare patients who medically require the
intervention, whether or not they agree to participate in a trial, and whether or not
their physicians participate in data collection activities. CMS can generate
additional post-coverage data through other means, without denying beneficial
services to Medicare beneficiaries unable to participate in clinical trials. On the
other hand, if interventions designated for CSP truly do not meet the “reasonable
and necessary” standard due to insufficient data, then the intervention should not
be covered, despite political pressure to do so. As it has done in the past,
Congress, after robust public debate, must act to define the role of cost in
coverage determinations, either by expressly allowing CMS to weave cost-
effectiveness into its coverage criteria, or by other means of rationing care.

I. MEDICARE PROGRAM OVERVIEW

A. The Basics

The Medicare program was signed into law on July 30, 1965, amending

by the AHRQ. AHRQ conducts research to enhance the quality of medical care, and to
development medical practice guidelines. Id. § 1320b-12. See also discussion infra Part IV.
the Social Security Act and bringing federally subsidized health insurance to roughly 19 million elderly Americans.\(^\text{19}\) Today, the Medicare program is the nation’s largest insurance company, providing health care for over forty million persons who are over age sixty-five, certain disabled persons, and persons with end stage renal disease.\(^\text{20}\) The Medicare program falls under the auspices of HHS and is administered through the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA). The scope of benefits is prescribed by law, and is divided into four main parts. Part A, or Hospital Insurance (HI), includes hospital, skilled nursing, home health, and hospice care.\(^\text{21}\) Medicare Part B, or the Supplementary Medical Insurance Program (SMI), includes physician and other out-patient services.\(^\text{22}\) Part C, or Medicare Advantage, is a managed care option added by the Balanced Budget Act of 1997,\(^\text{23}\) and includes, at a minimum, Parts A and B, as well as some additional benefits.\(^\text{24}\) Part D, the outpatient prescription drug program effective January 1, 2006, was added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).\(^\text{25}\)

Most eligible persons are automatically enrolled in Medicare, and are eligible for Part A benefits. Part B benefits are voluntary, and most beneficiaries must pay premiums to obtain Part B benefits. Most eligible persons, however, participate in both Parts A and B.\(^\text{26}\)


22. See id. § 1395j. Medicare Parts A and B were included in the original Act.


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CMS contracts with local insurance companies to review and process providers’ day-to-day claims for reimbursement.27 These companies are responsible for assuring that payment is made in accordance with Medicare policy, and that payment is made only for items and services covered under Part A or Part B. Companies that process Part A claims are referred to as fiscal intermediaries, and those processing Part B claims are referred to as carriers.28

B. The Coverage Process

As the nation’s largest health care insurer, Medicare’s policies have tremendous effects, influencing the insurance coverage decisions of other public and private payers, including employers who self-insure their workers.29 Thus, when Medicare determines that it will not cover a particular new technology, that technology will be unavailable not only to Medicare beneficiaries, but to millions of other privately insured persons across the nation. Medicare coverage decisions affect the health care services that physicians order and provide to Medicare beneficiaries. Medicare beneficiaries are free to purchase medical services, including new technology or devices that are available in the marketplace but not covered by Medicare, however they are not likely do so. Given that 19% of Medicare beneficiaries have yearly incomes below $9000, and over half have incomes below $19,000, the practical effect of a non-coverage determination would be to deny the new technology or device to the beneficiary.30

Moreover, Medicare decision-making criteria may considerably impact our nation’s economy, either strengthening or weakening the pharmaceutical, biotechnology, and medical device industries.31 The Medicare program is the world’s largest single payer of health care, and private payers typically adopt

28. See id.; id. § 1395u (regulating CMS contracts pertaining to carriers).
31. See Bradley Merrill Thompson & Brian A. Dahl, The Perspective of Manufacturers, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, supra note 30, at 127, 127-28 (explaining that innovative technology plays a role in setting the standard of care in the health care system, and that the quality of care may be impaired when negative coverage decisions block payment).
Medicare coverage policies. Medicare’s coverage criteria could potentially reduce the availability of investment capital for medical technology, which in turn could reduce industry incentives to create innovative and potentially life-saving technology, which could lead to reductions in employment and reduced exports.\textsuperscript{32}

The starting point for Medicare’s coverage determinations is the statutory provision that will hereinafter be referred to as the “reasonable and necessary” provision. It provides that “no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”\textsuperscript{33} The “reasonable and necessary” criterion essentially mandates that CMS pay the correct amount to legitimate service providers who furnish services that are reasonable and necessary to meet the medical needs of eligible beneficiaries.\textsuperscript{34} The Act lists categories of items and services for which payment may be made, but gives the Secretary the authority to determine which specific items and services within each category will be covered by the program.\textsuperscript{35} For example, Medicare will pay for surgery, but it does not specify the particular types of surgery that may be covered. Thus, CMS would allow payment for a gall bladder operation only if that surgery is medically necessary for a particular beneficiary. Most noteworthy, however, is that the statute neither defines “reasonable and necessary” nor provides criteria for making specific coverage determinations, leaving CMS and local contractors substantial discretion in the decision-making process.

Medicare coverage decisions are made both nationally and locally, but the vast majority (about 90\%) of coverage determinations are made on the local level.\textsuperscript{36} Medicare contracts with private organizations to make Local Coverage Decisions (LCDs), and these contractors develop thousands of local medical review policies to provide guidance to the public and medical community within their geographical area.\textsuperscript{37} LCDs apply only within the area served by the local

\begin{itemize}
  \item See Tunis, supra note 29, at 2197.
  \item Medicare Program; Procedures for Making National Coverage Determinations, 64 Fed. Reg. 22,619, 22,621 (Apr. 27, 1999) (stating that the purpose of local medical review policies is to explain to the public and the medical community “when an item or service will be considered ‘reasonable and necessary’ and thus eligible for coverage under the Medicare statute”). See also Susan Bartlett Foote et al., Variation in Medicare’s Local Coverage Policies: Content Analysis of Local Medical Review Policies, 11 AM. J. MANAGED CARE 181, 181 (2005), available at
\end{itemize}
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In contrast, National Coverage Determinations (NCDs) are made by CMS, and may be generated externally or internally. Approximately eighteen to twenty-four NCDs are issued each year, and are published in CMS program manuals.39 Any interested party, including beneficiaries, may make an external request for a new national coverage determination.40 Most NCD external requests, however, are made by an organization, such as the manufacturer of a drug, device, or medical product, or by a professional medical organization, a provider, or a supplier.41 CMS may make an internal request if it determines an NCD is “in the interest of the general health and safety of Medicare beneficiaries.”42

An NCD may grant, limit, or deny coverage for a “specific medical item or service.”43 A limited NCD, also called coverage with conditions, may limit coverage of an item or service to patients with certain diseases or severity levels,

http://www.ajmc.com/article.cfm?id=2820 (noting that “nearly 50 local contracting organizations develop thousands of local medical review policies”).


41. See Grant Bagley, Current Procedures and Standards for Making Medicare Coverage Decisions, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, supra note 30, at 17, 22.

42. Medicare Program; Revised Process for Making Medicare National Coverage Determination, 68 Fed. Reg. at 55,638. See also CTRS. FOR MEDICARE & MEDICAID SERVS., FACTORS CMS CONSIDERS IN OPENING A NATIONAL COVERAGE DETERMINATION (2006), https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=6. With respect to items and services that are currently covered, an internal NCD may be generated when significant questions exist as to the health benefits of currently covered services; when new evidence indicates that changes may be warranted; when conflicting local policies are causing significant disparities in care; when significant evidence of variation in billing practices exists; or when conflicting carrier or intermediary policies exist. Id. at pts. IV, V. With respect to a new item or service, an internal NCD may be initiated when new technology represents a substantial medical advance and is likely to have significant health benefit if delivered more quickly to beneficiaries; when rapid spread of the technology may have reduce health inequalities or have a significant impact on public policy; or when significant uncertainty exists concerning the health benefits or risks. Id. at pt. V.

43. Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. at 55,634; see also Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 731, 117 Stat. 2066 (to be codified at 42 U.S.C. § 1395y) (amending the Social Security Act to define a national coverage determination as “a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter”).

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or to certain providers or facilities that meet specific criteria.44 A national coverage decision is binding on all Medicare contractors, and takes precedence over any conflicting local policies once the NCD is effective.45 CMS may determine whether an item or service is reasonable and necessary (coverage or non-coverage) based on internal staff evaluation of the submitted evidence and a systematic review of the medical literature.46 Moreover, under certain circumstances, CMS may seek an external health technology assessment to evaluate the performance of a new technology, to appraise the evidence on patient health outcomes as well as its safety and economic impact, or to “identify those areas that need further evidence development.”47 At the present time, CMS contracts with the AHRQ to perform its external technology assessments.48

CMS may also supplement its internal expertise by convening a meeting of the Medicare Coverage Advisory Committee (MCAC) to help determine whether an item or service is “reasonable and necessary.” The MCAC consists of nearly 100 members of varying backgrounds in medicine, the biological and physical sciences, health data and information, patient advocacy, medical ethics, and other related professions, and also includes a smaller representation of industry and

45. See id. at 55,635-36. A national coverage decision may be appealed by an adversely affected Medicare beneficiary. 42 U.S.C.A. § 1395ff(f)(1) (West Supp. 2006) (providing that only eligible Medicare beneficiaries “who are in need of the items or services that are the subject of the coverage determination” have standing to seek review of national or local coverage determinations). A beneficiary may obtain initial review from the HHS Departmental Appeals Board (DAB) and thereafter seek judicial review. Id. The law makes no provision for providers, manufacturers, or other affected industry stakeholders to appeal adverse coverage determinations, although they are allowed to submit written or brief oral statements as amici. See 42 C.F.R. § 426.510(f) (2006). Even though only a beneficiary has standing to appeal a national coverage determination, the appeal would likely be sponsored by providers or other interested stakeholders. See Barry R. Furrow et al., The Law of Health Care Organization and Finance 365 (5th ed. 2004).
46. CTRS. FOR MEDICARE & MEDICAID SERVS., FACTORS CMS CONSIDERS IN COMMISSIONING EXTERNAL TECHNOLOGY ASSESSMENTS, at pt. III (2006), available at http://www.cms.hhs.gov/med/ncpc_view_document.asp?id=7 (defining a systematic review as a comprehensive search of the medical literature, focusing on explicit criteria that can be reproduced, and including an appraisal of the evidence to assess its credibility, usefulness, and importance).
47. Id. In general, factors CMS considers when requesting an external technology assessment include when the evidence is so extensive that timely review may not be possible, the evidence is complex or conflicting, experts have differing opinions, specialized methods are required, when the review requires expertise not currently available within CMS staff, or when the topic being considered will be referred to the Medicare Coverage Advisory Committee (MCAC). Id. at pt. IV.
48. Id. at pt. V. The AHRQ is a federal agency under the auspices of the Department of Health and Human Services. See generally About AHRQ, http://www.ahrq.gov/about/ataglance.htm (last visited May 3, 2007). Its purpose is to improve health care quality, safety, efficiency, and effectiveness. AHRQ contracts with CMS to perform technology assessments, which may be performed in-house, or with one of AHRQ’s thirteen Evidence-based Practice Centers (EPCs), located throughout the United States and Canada. See Evidence-based Practice Centers, http://www.ahrq.gov/clinic/epc/ (last visited May 3, 2007).
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customer interests. MCAC meetings are now conducted in an open public forum, and CMS may seek MCAC advice in addition to commissioning an external technology assessment. Finally, within CMS, the newly-created Council for Technology and Innovation (CTI) assists in coordinating coverage, coding, and payment for new technologies.

In 2000, Medicare extended coverage to the “routine costs” of qualifying clinical trials, including “reasonable and necessary” treatment for complications arising from clinical trial participation. Coverage is limited to services that are generally available to Medicare beneficiaries outside of trials. Payment for the test article or service, however, is excluded. For example, in a clinical trial to test an experimental chemotherapy drug, the cost of the drug would not be covered due to its experimental nature, but costs relating to the administration of the treatment, the appropriate monitoring of efficacy or side effects, and the prevention or treatment of complications would be covered as routine costs of the trial.

It is important to note that the term “national coverage determination” refers only to whether a particular item or service is covered nationally by the Medicare program, and does not include any determination as to how much the


50. See CMS, MCAC DRAFT GUIDANCE, supra note 49, at pts. VI, VII. Factors CMS considers when referring topics to MCAC include significant controversy among experts or “some other significant consideration that would affect whether the item or service is ‘reasonable and necessary’ under the Act;” existing studies are flawed or do not address relevant policy questions; studies are conflicting; CMS requires additional review of TA methods or more information on net health outcomes; the perspectives of affected patients and caregivers may be relevant; the technology is controversial among the general public; clarification in an MCAC public forum may be useful in future NCDs; the use of the technology may have a major impact on the Medicare population or program overall; or the viewpoint of patient advocates or other societal viewpoint may be relevant. Id. at pt. V.


53. Id. at 2.

54. Id. See also infra text accompanying note 75.


56. See 42 U.S.C.A. 1395y(J)(6)(A) (West Supp. 2006) (“The term ‘national coverage determination’ means a determination by the Secretary with respect to whether or not a particular
government will pay for a particular covered item or service. The assignment of payment codes and other payment issues are accomplished by a process separate from the coverage determination.\textsuperscript{57}

II. COVERAGE WITH STUDY PARTICIPATION AND THE LIMITS OF STATUTORY AUTHORITY

CMS’s Coverage with Study Participation policy is controversial because it allows coverage of certain items or services outside of the “reasonable and necessary” determination that is essential to the national coverage determination process. Statutory support for CSP is uncertain. This uncertainty was highlighted when CMS issued its July 12, 2006 CED Guidance Document, doing a considerable about-face from the stance it took in an earlier CED Draft Guidance as to the statutory authorization for restricting coverage of certain items or services to clinical trials. A comparison of the relevant parts of the Draft Guidance and the CED Guidance best illustrates CMS’s unstable statutory position.

\textit{A. CMS’s Search for Statutory Support for Coverage with Study Participation}

CMS published its first public notice draft guidance on April 7, 2005, outlining its intention to link a small number of its national coverage determinations to a requirement for prospective data collection, an approach it termed “coverage with evidence development” (CED).\textsuperscript{58} CMS asserted that 42 U.S.C. § 1395y(a)(1)(A), the “reasonable and necessary provision,” was the statutory authority to link coverage decisions to additional data collection.\textsuperscript{59} CMS explained that the available scientific evidence was such that the item or service would only be “reasonable and necessary” if the service was “delivered in the context of specific data being collected” while the service was being provided.\textsuperscript{60} The data collection requirement meant that coverage for certain services would be limited to beneficiaries who enrolled in a clinical trial, or to providers who participated in other prospective data collection activity.\textsuperscript{61} The

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\textsuperscript{57} See Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003) ("[A]n NCD . . . does not include a determination about which code, if any, is assigned to a particular item or service covered . . . or a determination with respect to the amount of payment for a particular covered item or service.").

\textsuperscript{58} CTGS, FOR MEDICARE & MEDICAID SERVS., FACTORS CMS CONSIDERS IN MAKING A DETERMINATION OF COVERAGE WITH EVIDENCE DEVELOPMENT (2005), http://www.cms.hhs.gov/coverage/download/guidanceced.pdf [hereinafter CMS, DRAFT GUIDANCE].

\textsuperscript{59} Id. at 6. CMS asserts that Section 1862(a)(1)(A) of the Social Security Act is the source of its authority for CED. 42 U.S.C. § 1395y(a)(1)(A) (2000).

\textsuperscript{60} CMS, DRAFT GUIDANCE, supra note 58, at 3.

\textsuperscript{61} Id. at 3.
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The purpose of CED was to generate sufficient additional evidence to allow CMS, at some point in the future, to make a national coverage determination which, if positive, would extend the service to all beneficiaries for whom it was medically necessary. CMS suggested the alternative to CED would be non-coverage. The CED Draft Guidance drew over 400 pages of published comments from stakeholders and concerned public members, many of whom questioned CMS’s statutory authority for linking coverage to prospective data collection, and challenged other legal and ethical aspects of the policy.

In July 2006, in response to stakeholder concerns, CMS published a significantly revised guidance document (the “CED Guidance Document”). In this document, CMS announced that its CED policy would have two arms, Coverage with Appropriateness Determination (CAD) and Coverage with Study Participation (CSP). According to CMS, national coverage decisions requiring CAD would encompass those items or services that are supported by sufficient scientific evidence to meet the “reasonable and necessary” standard, but which require the provider to collect additional data at the time the service is provided, and submit the data to a database or registry. The purpose of this additional data collection is to assure CMS that the service it is paying for was provided appropriately to qualifying patients in accordance with the specific national coverage decision.

With respect to Coverage with Study Participation, however, CMS announced the creation of “a new concept of conducting research,” and declared a new-found source of statutory authority to support the new policy. Unlike its earlier CED Draft Guidance, CMS now asserted that new items and services designated for Coverage with Study Participation, which includes prospective clinical trials, were not supported by sufficient evidence to meet the “reasonable and necessary” standard. CMS purports, however, to have the statutory authority to pay for services under 42 U.S.C. § 1395y(a)(1)(E), which gives CMS the authority to pay for research conducted by the AHRQ. Under this provision,

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62. Id. at 4-5.
63. Id. at 7.
64. See, e.g., Letter from Daniel J. Popeo & David Price to Dr. Steve Phurrough, Director of CMS Coverage and Analysis Group (June 6, 2005) (on file with author).
65. CMS, CED GUIDANCE DOCUMENT, supra note 6.
66. Id. at pt. V.A. CMS indicates that Coverage with Appropriateness Determination (CAD) will require providers to supplement the information routinely submitted through claims for services with additional clinical data collected at the time the service is provided. Providers will submit the additional data to databases or registries associated with the NCD in question. Id.
67. Id.
68. Id. at pt. I.
69. Cf. 42 U.S.C. § 1395y(a)(1)(E) (2000) ("(a) Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or
CMS may pay for research conducted by AHRQ that is reasonable and necessary to meet the needs and priorities of the Medicare program.\textsuperscript{70} The work contemplated by the AHRQ research statute, however, pertains to research conducted for the purpose of improving the quality of medical care, developing clinical guidelines for preventing and treating various health conditions, and evaluating the comparative effects of various services.\textsuperscript{71} Nothing in the AHRQ research statute authorizes CMS to use the resources of this agency to determine whether an item or service ought to be \textit{covered}. Hence, it appears that CMS is attempting to run around the restrictions of the “reasonable and necessary” provision by using Coverage with Study Participation and the AHRQ research statute as the basis for making coverage decisions.\textsuperscript{72}

In its CED Guidance Document, CMS takes the position that it is simply asking AHRQ to act in its normal research capacity to produce additional data that will be publicly available. Then, at some point in the future, CMS may use this data as the basis for a national coverage determination.\textsuperscript{73} CMS has no statutory authority to require clinical trials as a prerequisite to a national coverage determination, and CSP appears to be a thinly-masked attempt to appear as though it is not actively involved in conducting research for this purpose; rather, CMS is merely paying for research conducted by AHRQ. With CSP, however, CMS has designed, from start to finish, a research system for the purpose of generating sufficient information for CMS to use in a future national coverage decision. Indeed, CMS has indicated that in order for providers to get paid for studies conducted pursuant to CSP, the study must be “designed to produce evidence that could be used in a future national coverage decision . . . .”\textsuperscript{74}

At its core, Coverage with Study Participation is a blueprint for research that allows CMS to pay for an item or service that it deems \textit{not} “reasonable and necessary.” CMS’s interpretation of its authority to pay for AHRQ-conducted research essentially renders meaningless the “reasonable and necessary”

\textsuperscript{70} Id. § 1320b-12(a).

\textsuperscript{71} Id.

\textsuperscript{72} See CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. V.B (“New evidence that assists in the Medicare coverage process for the item or service is one of the desired results of CSP.”).

\textsuperscript{73} Id. (“If the research results are published in a peer-reviewed journal, the evidence will be used in an NCD reconsideration to determine if a change in Medicare coverage is appropriate under section [1395y](a)(1)(A).”); id. at pt. VIII.A (“Because NCD analyses are normally based on a review of publicly available evidence, the results of the trial should be published in the peer reviewed literature to be considered in an NCD reconsideration.”).

\textsuperscript{74} Id. at pt. VI.B (“To qualify for reimbursement, such a study must be designed to produce evidence that could be used in a future national coverage decision that would focus on whether the item or service should be covered by Medicare under [1395y](a)(1)(A).”)
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provision, and violates its statutory mandate prohibiting payment for services unless they are "reasonable and necessary." If the intervention is sufficiently "reasonable and necessary" to be covered within the context of a clinical trial, it ought to be available to all for whom it is medically necessary, without such restriction.

B. Can CMS Consider Cost When Determining What Is "Reasonable and Necessary"?

Cost considerations may be a silent, yet principal, driver of Coverage with Study Participation. The manner in which CMS has made its national coverage determinations during the more than forty years of its existence has, for the most part, been less than transparent, due primarily to the uncertain and politically unpopular role that cost considerations have played in coverage decisions. At one point, CMS expressly designated cost-effectiveness as specific criteria to be considered in determining whether expensive new technology would be covered by the Medicare program. At other points, CMS has said specifically that it will not consider cost. In between, CMS has considered cost, but it has done so implicitly, and under other names. Not until recently, with the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003, has the Secretary been statutorily mandated to make public the factors it uses to determine whether an item or service is reasonable and necessary, and thus covered by Medicare.

This Section examines the legislative history and subsequent court and administrative interpretations to ascertain whether CMS has authority under the reasonable and necessary provision to consider cost in making coverage decisions, or, by extension, to control costs by limiting coverage of certain expensive new technology to clinical trial participants. In support of this Article's thesis that Coverage with Study Participation is a means of implicit cost control, this Section also highlights the historical tension between CMS and industry

75. In the CED Guidance Document, CMS indicated its intent to reconsider its Clinical Trial Policy, essentially to encompass payment for CSP trials under (a)(1)(E), which CMS says is the statutory authority for the Clinical Trial Policy. Id. at pt. V.B. In that policy, however, CMS is covering only the reasonable and necessary care related to the trial or complications resulting from the trial, but specifically excludes the "investigational item or service" itself. Granted, with CSP, the item or service is not experimental, but it has been deemed by CMS to be not reasonable and necessary. This remains an apparent attempt to circumvent the limitations of the "reasonable and necessary" coverage provision.
76. See discussion infra Subsection II.B.3.
77. See discussion infra Subsection II.B.4.

stakeholders, who have pressed CMS almost since its inception to make public its views regarding the role of cost in making coverage decisions.

1. Legislative History and the Meaning of "Reasonable and Necessary."

The "reasonable and necessary" provision provides CMS's only clear statutory authority for making national coverage determinations. It provides that "no payment may be made under part A or part B... for items or services which... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member..." Medicare's architects envisioned bringing to the elderly the same level of health care as was then enjoyed by insured, paying, and younger patients. Although little is officially documented as to the origin of the reasonable and necessary phrase, the common understanding among federal officials who worked on the legislation was that the phrase was adapted from an Aetna plan for federal workers under the Federal Employees Health Benefits Program. One official recalls having had only a single weekend in which to convert the Aetna plan into a federal health care plan, and that "[t]here were no quality standards and no cost controls other than a vague stipulation that services had to be 'medically required.'" No additional language from Congress accompanied the 1965 law; thus, there is no indication that the reasonable and necessary language was ever subjected to serious analysis. The statute is silent as to the process that CMS is to follow in making coverage determinations, and it gives no hint as to what factors CMS may legally use to determine if an item or service meets the statutory standard. Moreover, despite a few attempts, CMS has not successfully engaged in the administrative rule-making process to define its coverage criteria.

81. See Theodore R. Marmor, The Politics of Medicare 48 (2d ed. 2000). Professor Marmor notes that in 1965, during the late stages of Medicare drafting, a bill proposed by Republican John Byrnes was discussed before the Ways and Means Committee, "which proposed benefits similar to those offered in the Aetna Life Insurance Company's health plan for the federal government's employees." A modified version of the Byrnes proposal was ultimately reflected in Medicare Part B, adding coverage for the costs of doctor's services. Id. at 48-52. One of Medicare's primary drafters, Robert Hoyer, recalls that "the reasonable and necessary provision and other exclusions... were taken from an Aetna policy that was available to federal employees at the time..." See also Jacqueline Fox, Medicare Should, but Cannot, Consider Cost: Legal Impediments to a Sound Policy, 53 BUFF. L. REV. 577, 593 (2005) (interview with Robert Hoyer). Professor Fox reports that the Aetna Life and Casualty policy excludes services and supplies that were "[n]ot reasonably necessary for treatment of pregnancy, illness, or injury, or to improve the functioning of a malformed body member," which differs somewhat from the "reasonable and necessary" language of the Medicare statute. Id. at 594. See also Tunis, supra note 29, at 2196.
82. Ball, supra note 80, at 69.
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In the original Medicare statute, the terms "reasonable" and "necessary" appear separately, almost entirely in the context of whether a particular treatment is medically necessary, or whether the treatment could reasonably be expected to improve the patient's condition. The term 'reasonable' was used repeatedly in the context of payment—that payment will be made for reasonable charges for non-institutional providers, or for reasonable costs incurred by institutional providers. Although the term "reasonable cost" is specifically defined in the statute, the definition focuses on the methods to be used in establishing cost, and provides little limiting language.

The legislative history supports the meaning of "reasonable" as pertaining to the amount to be paid for covered services, as well as services to be included in the future, and the term "necessary" as pertaining to whether the service is medically necessary. For example, the Senate Finance Committee Report which accompanied the original Medicare bill (H.R. 6675) explains that payments to providers would be based on the "reasonable cost" of providing care, and that "reasonable charges" would be the "customary charges for similar services" in the locality. Covered services were to be paid at the "reasonable cost of service ordinarily provided to inpatients by hospitals... including new services and techniques as they are adopted in the future."

In the Senate Report, the phrase "reasonable and necessary" refers to coverage of services that are medically necessary. For example, the report states that "payment could be made for the rental of a special hospital bed to be used by a patient in his home only if it was a reasonable and necessary part of a sick person's treatment," but "personal comfort items and services [such] as massages and heat lamp treatment would only be covered where they contribute meaningfully to the treatment of an illness or injury or the functioning of a

83. See, e.g., 42 U.S.C. § 1395f(a)(2) (2000) (providing that that payment may be made for inpatient hospital services or diagnostic services were "medically required and such services are or were necessary for such purposes" or where "such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary").

84. See, e.g., id. § 1395l(a)(1) (providing that "in the case of services... 80 percent of the reasonable charges for the services; except that an organization which provides medical and other health services... may elect to be paid 80 percent of the reasonable cost of services"). Although the original Act allowed for payment based on reasonable costs or charges, it was later amended to institute the prospective payment system based on diagnostic related groups (DRGs) for hospital payment, and the Resource-Based Relative Value Scale (RBRVS) for physician reimbursement.

85. See id. § 1395x(v)(2)(A) (placing upon the definition of reasonable cost the limitation that payment will be made only for semi-private accommodations, unless private accommodation is medically necessary); id. § 1395x(v)(2)(B) (placing upon the definition of reasonable cost the limitation that if a provider furnishes an item or service more expensive than Medicare allows, payment shall be only the reasonable cost of the equivalent item or service).

87. Id. at 1967.
malformed body member." 88 The Report also cautions fiscal intermediaries to "safeguard[] against unnecessary utilization of covered services." 89 That the patient’s physician was responsible to determine what was medically necessary is also born out by the first section of Title XVIII of the Social Security Act, which prohibits the government from interfering or exercising any control over the practice of medicine. 90

Perhaps most indicative of congressional intent is that the “reasonable and necessary” provision falls under the statutory title “[e]xclusions from coverage,” and the statutory subtitle, “(a) Items or services specifically excluded.” Thus, the “reasonable and necessary” clause is expressed as a negative—that “no payment may be made” for services that are “not reasonable and necessary.” 91 The only sensible inference from this congressional directive is that Medicare is presumed to cover all items and services except those that are not reasonable and necessary, or otherwise excluded by statute.

Thus, the language of the statute and its legislative history bear out that the Medicare program is expected to cover items and services that the patient’s physician deems medically necessary, subject to utilization review. Nothing in the legislative history suggests that CMS has the authority under the “reasonable and necessary” provision to consider the cost of items or services in making coverage determinations. And certainly, Congress could not have contemplated that “reasonable and necessary” could be applied to restrict coverage of a beneficial item or service to a limited group of clinical trial participants, as would be the case with Coverage with Study Participation.

2. CMS Attempts To Weave Economic Considerations into “Reasonable and Necessary” Determinations

In the years immediately following Medicare’s 1965 enactment, little is documented regarding the interpretation of the reasonable and necessary provision by CMS’s forerunner, the Health Care Financing Administration (HCFA). 92 From its inception, HCFA made “reasonable and necessary” national coverage determinations through an informal process. By the 1970s, however, HCFA had become increasingly concerned over the cost of new technology such

88. Id. at 1989 (emphasis added).
89. Id. at 1993.
90. See 42 U.S.C. § 1395 (2000) (“Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or in the manner in which medical services are provided . . . .”).
91. Id. § 1395y(a); id. § 1395y(a)(1)(A) (emphasis added).
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as computed tomography (CAT) scanners and kidney dialysis needed for the End Stage Renal Disease Program, which was already facing annual projected costs thirty-five times higher than original estimates.93 Out of these concerns arose federal agencies to advise Congress and HCFA on coverage issues.94 It was the coverage of heart transplants, however, that ultimately pushed HCFA to attempt to formalize its national coverage policy through the administrative rule-making process.95

The manner in which HCFA handled the matter of heart transplants represents an early agency effort to avoid engaging in direct discussion about the cost of new procedures, but instead to attempt to minimize cost, at least in the short term, by delaying coverage. In 1980, after HCFA discovered that a local administrator had been covering heart transplants performed at Stanford University Medical Center, HCFA announced that heart transplants would be excluded from Medicare coverage, citing concerns over patient selection, as well as social and economic implications.96 HCFA then contracted for a study of the issues, including patient care costs.97 Given the charge to consider cost, the study investigator recommended that the economic impact of heart transplants could be significantly limited by creating demanding criteria for facilities wishing to perform the transplant, and by, for example, limiting selection to patients less than sixty-five years old, which would effectively deny access to the vast majority of the Medicare population.98 Although the directive from senior Medicare officials, as well as the White House, was to limit the potential cost of heart transplantation, the administration took the more politically wise course, and chose to focus not on the cost of transplantation, but on the limited supply of hearts available for transplant.99 Finally, in 1987, nearly seven years after the first successful procedures had been performed (and many needy beneficiaries denied the procedure), HCFA determined that heart transplants were "reasonable and necessary," but adopted the limiting criteria pertaining to facilities and the age of potential recipients.100 Instead of admitting that heart transplants were just

93. See Julie Kosterlitz, Picking Up the Tab: Medicare Coverage of Heart Transplants, 18 NAT'L J. 1825, 1827 (1986).
95. Id.
96. Exclusion of Heart Transplantation Procedures from Medicare Coverage, 45 Fed. Reg. 52,296, 52,297 (Aug. 6, 1980). See also Fox, supra note 81, at 580-83 (using heart transplant coverage as an example of the role of cost in Medicare coverage determinations).
98. See Fox, supra note 81, at 582.
99. See id. at 583.
too expensive to cover for everyone in need, the issue became one of "a blameless tragedy of access to a scarce resource." 101

The heart transplant controversy prompted HCFA to attempt to clarify its authority under the "reasonable and necessary" provision in 1980. To that end, HCFA drafted a proposed rule outlining criteria it would use in making coverage decisions that included "safety, economics, and ethical and social factors." 102 Although the draft was circulated, it was never published, and no rule was ever promulgated, reportedly due to strong opposition from the medical device industry and organized medicine with respect to the economic criteria. 103 Medical device manufacturers were concerned that a formalized process, particularly one that included external technology assessment to evaluate potential economic impact, would result in unfavorable coverage decisions. 104 And so, HCFA continued to make its coverage decisions through an informal internal process that was closed to the public, and that provided little guidance to its stakeholders.

3. CMS Attempts To Establish Cost-Effectiveness As a Factor in Determining What Is "Reasonable and Necessary"

The need to formally clarify its authority under the reasonable and necessary provision became increasingly evident to HCFA in 1986 as the result of two significant events. First, in Bowen v. Michigan Academy of Family Physicians, the United States Supreme Court held that the statutory bar to federal question jurisdiction did not bar judicial review of Medicare’s administrative standards or policies. 105 Thus, for the first time since its inception in 1965, the door was open to judicial challenge of Medicare’s coverage policies. Second, in Jameson v. Bowen, the United States District Court for the Eastern District of California

101. Fox, supra note 81, at 583.
102. Foote, supra note 94, at 713.
103. Id. at 710-14. Foote’s article provides an insightful account of how stakeholders, particularly the medical device industry, have historically both supported formal rule-making, or opposed rule-making, depending on the industry’s perceived effect such rule-making would have on the development of new technologies.
104. See id. at 713-14. Foote writes that in 1981, the National Center for Health Care Technology, whose job it was to advise Medicare on coverage of new technologies, was dissolved, primarily due to pressure exerted on the Reagan administration by the medical device industry and organized medicine.
105. Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667 (1986) (allowing challenge to validity of regulations where no administrative review is available), limited, Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 17 (2000). In Michigan Academy, an association of family physicians and individual doctors challenged Medicare regulations authorizing payment of benefits in different amounts for similar physicians’ services, depending on whether the physician was board certified, engaged in allopathic medicine, or other criteria. The Court held that the statutory bar applied to judicial review of the amount of benefit determinations, but did not preclude judicial review of the method by which such determinations were made, or of administrative standards. Michigan Academy, 476 U.S. at 681.
allowed judicial review of a specific national coverage policy.\textsuperscript{106} As part of a
settlement agreement in this case, HCFA agreed to prepare and publish a
description of the process used to make coverage decisions, including the
reasoning behind its decisions against a particular technology.\textsuperscript{107} The settlement
agreement also required HCFA to allow for public input into the coverage
process "where appropriate.\textsuperscript{108} In 1987, in partial settlement of the \textit{Bowen}
lawsuit, HCFA published its April 1987 Notice signaling its intent to engage in
formal rule-making to provide standards and procedures for making coverage
determinations.\textsuperscript{109} Although the 1987 Notice indicated that the national coverage
process may involve possible referral of the matter to the Public Health Service
Office of Health Technology Assessment (the predecessor to the Agency for
Health Research and Quality), it contained no provision for general public input
into the technology assessment process.\textsuperscript{110}

Finally, in 1989, amid intense and growing criticism over the lack of
transparency in national coverage policy, and the lack of opportunity for
stakeholder input, HCFA published a notice of proposed rule-making relating to
coverage criteria for health care technology, promising to establish its coverage
criteria and procedures in regulations.\textsuperscript{111} In its notice, HCFA suggested that in
the past, the public, particularly the device manufacturing industry, may have
been confused over its coverage criteria because it used the same "safe and
effective" language used by the FDA.\textsuperscript{112} Essentially, CMS had said it would
consider an item or service to be "reasonable and necessary" if it was safe and
effective, and not experimental.\textsuperscript{113} HCFA now emphasized that its definition
differed from that of the FDA, and that it would consider additional criteria.\textsuperscript{114} In

(settlement agreement and release of claims); see also Foote, supra note 94 at 714 (noting that the
Jameson plaintiff’s challenge was to a Medicare policy that denied coverage for angioplasty
procedure deemed "experimental").

\textsuperscript{107} Jameson, 1987 WL 108970 at *1.

\textsuperscript{108} Id. In settlement of the case, HCFA agreed to publish its coverage process, "including
decisions as to whether new procedures are not covered because they have not yet been found to be
reasonable and necessary and/or safe and effective." Id.


\textsuperscript{110} Id. at 15,562; see also Darrel J. Grinstead, \textit{Evolution of Medicare’s Coverage Policy-Making Process, in Guide to Medicare Coverage Decision-Making and Appeals}, supra note 30, at 1, 9.

\textsuperscript{111} Medicare Program; Criteria and Procedures for Making Medical Services Coverage

\textsuperscript{112} See id. at 4312.

\textsuperscript{113} Id. at 4304, 4308 (HCFA’s historical interpretation of the reasonable and necessary
provision was "a test as to whether the service in question was 'safe' and 'effective' and not
'experimental'").

\textsuperscript{114} Id. at 4312.
a clear departure from its historical interpretation, HCFA, for the first time, claimed that the “reasonable and necessary” provision provided authority for it to use cost-effectiveness as a consideration in whether to expand, continue, or terminate coverage of high-cost technology. HCFA announced that the more expensive a service was, the more likely it was to be referred for national determination, which would include an analysis of its cost-effectiveness.\textsuperscript{115} Simply stated, cost-effectiveness analysis compares the beneficial effects of a service, such as years of life added by treatment or reduction in infection rates, with its medical and non-medical costs, expressed in dollars.\textsuperscript{117} Although careful to note that safety and effectiveness was still the most important criteria, HCFA explained that cost-effectiveness analysis was necessary in light of the “current explosion of high-cost medical technologies,”\textsuperscript{118} and it promised to engage in the rule-making process to establish more specific criteria.\textsuperscript{119}

Using cost-effectiveness criteria to determine whether an item or service was reasonable and necessary proved extremely controversial, drawing criticism from the public, technology manufacturers, and other stakeholders. Public representatives were concerned that cost considerations would bar approval for technology that would have been approved in the past, which would leave Medicare’s elderly and often poor beneficiaries unable themselves to pay for needed services.\textsuperscript{120} Health care providers complained that cost-effectiveness was simply a means of rationing needed care.\textsuperscript{121} Medical device companies were concerned that their technology would be denied coverage absent proof of cost-effectiveness, and that conducting the necessary pre-market clinical trials would impose an additional financial burden, and delay diffusion of the

\begin{footnotesize}
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\item \textsuperscript{115} \textit{Id.} at 4308-09 (stating that the requirement that a covered service be reasonable “encompasses the authority to consider cost as a factor in making Medicare coverage determinations”).
\item \textsuperscript{116} \textit{See id.} at 4305.
\item \textsuperscript{117} \textit{Id.} at 4309. HCFA defined cost-effectiveness analysis as “an analytic tool that seeks to compare the incremental cost with the additional effectiveness of the procedure or technology.” \textit{Id.}
\item \textsuperscript{118} Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4308-09.
\item \textsuperscript{119} \textit{Id.} at 4308. Other criteria regarding device coverage include whether the service is accepted in the medical community as safe and effective (described by HCFA as the most important criteria), the status of the device as experimental or investigational, and whether the service is appropriately furnished in an acceptable setting and by qualified personnel. \textit{Id.} at 4306-08.
\item \textsuperscript{120} \textit{See Robert Pear, Medicare To Weigh Cost As a Factor In Reimbursement, N.Y. TIMES, Apr. 21, 1991, at A1 (reviewing public comments and draft of final rule).}
\item \textsuperscript{121} \textit{Id.} (noting that providers believe the policy “lays a foundation for the rationing of medical technology”).
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technology.122

The cost-effectiveness backlash effectively halted publication of a final rule, and ten years later, in 1999, HCFA flatly announced that it had decided not to adopt its controversial 1989 proposed rule.123 HCFA continued to implement coverage criteria informally, internally, and without input from concerned stakeholders. Instead of using cost-effectiveness criteria, however, HCFA adopted new terminology, focusing on whether the new technology was "comparable" to already-existing technology, or whether it had "demonstrated medical effectiveness."124

Industry confusion over the role of cost in the decision-making process may have been fueled by inconsistent policy statements publicly made by HCFA top officials. For example, in an ABC News Nightline broadcast in December 1996, an HCFA administrator denied that cost was an important consideration in making coverage decisions, stating that money is "truly not an issue for us. We are obligated by law to pay for all services that are necessary and appropriate for Medicare beneficiaries."125 Yet, to the contrary, HCFA's chief medical officer confirmed at a 1998 public town hall meeting that Medicare could not continue to pay for all beneficial new technology or surgical procedures, particularly when benefits may be marginal as compared to currently covered technology.126

In 1999, HCFA published its process for national coverage decision-making, promising to publish final coverage criteria, followed by sector-specific guidance.127 In 2000, HCFA again published a Notice of Proposed Rulemaking indicating two criteria it would apply in making its national coverage decisions.128 First, an item or service would be reasonable and necessary if

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122. Id.
124. See Foote, supra note 94, at 716-17 (noting that some questioned whether the new terminology was merely a substitute for cost-effectiveness).
126. Id. (describing statements of Jeffrey Kang, HCFA's chief medical officer).
objective scientific evidence showed that it had “medical benefit” for a defined population.\textsuperscript{129} Second, the item or service must provide “added value,” which essentially meant that the service would be covered if no substantially more beneficial alternative that was currently covered was available.\textsuperscript{130} The cost of an item, however, would be considered if the new item and the currently covered item were of equivalent benefit. In that case, the new item would be covered only if it cost less.\textsuperscript{131} Again, stakeholders were largely opposed to using cost as coverage criteria, even though it would be applied in only a limited number of cases. Some believed that added value was simply new terminology for cost-effectiveness.\textsuperscript{132} Opponents were concerned that in an effort to save money, new technologies would be compared to currently covered items or services that were not truly comparable, and that the proposal would ultimately limit treatment options.\textsuperscript{133}

Finally, in 2003, CMS officially threw up its hands and declared that, due to “competing interests about the coverage criteria” it would not develop a proposed rule based on the May 2000 Notice of Intent, and would not pursue rule-making with respect to its coverage criteria; rather, it would continue to make coverage decisions as it had for over thirty-five years, interpreting internally what was reasonable and necessary.\textsuperscript{134}


Although local decisions continue to vastly outnumber decisions made on the national level, national decision-making has taken on greater significance, partly due to concern over local inconsistency among carriers as well as the increasing complexity of the Medicare program. As early as 2001, the Medicare Payment Advisory Commission, in a report to Congress, recommended elimination of the local coverage process.\textsuperscript{135} Two years later, a General

\textsuperscript{129} Id. at 31,127.
\textsuperscript{130} Id.
\textsuperscript{131} Id.
\textsuperscript{132} See Foote, supra note 94, at 719 (“The added value criterion was particularly problematic because it implied economic evaluation, like cost-effectiveness or comparability, in a new form.”).
\textsuperscript{133} See Judith Lorette et al., The Perspective of the Centers for Medicare and Medicaid Services, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, supra note 30, at 149, 158.
\textsuperscript{134} Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003) (“Given that there are substantial competing interests about the coverage criteria, we believe it best not to pursue rulemaking. In the meantime, as we have done in the past 35 years, we would continue to need to make coverage decisions and interpret what is ‘reasonable and necessary.’”)
ACCOUNTING Office (GAO) report recommended that CMS eliminate the development of new local coverage policies. At the same time, the GAO report expressed concern that the national coverage process was slow, that CMS did not publish its draft national coverage policies for public comment, and that CMS did not consistently consult with outside experts in developing coverage policies.

Stakeholders, particularly medical device manufacturers, were concerned that increased emphasis on what they perceived as cumbersome national decision-making would be used by CMS as a means to cut costs by slowing down the influx of expensive, but vital, new technology to the nation’s elderly and disabled, no doubt slowing industry profits as well. National decision-making is troublesome to manufacturers of expensive new health care technology because it threatens to eliminate the flexibility they have had in the local process. Often, manufacturers will pursue coverage at the local level in several regions before seeking a national coverage decision. Local coverage is more desirable to manufacturers because local carriers may allow coverage even when experience and data on a particular device would be insufficient for an NCD.

reduce complexity, inconsistency, and uncertainty in the Medicare program, MPAC recommended that “CMS should move to a standard nationwide system of claims processing and eliminate local descriptions of policy and regulation”).

136. GENERAL ACCOUNTING Office, MEDICARE: DIVIDED AUTHORITY FOR POLICIES ON COVERAGE OF PROCEDURES AND DEVICES RESULTS IN INEQUITIES 5 (2003). The GAO report concluded that coverage authority at both the national and local level has resulted in coverage inequities for Medicare beneficiaries with similar medical conditions based on the location of their treatment, and has created administrative inefficiencies. Id. at 4. The GAO recommends that “CMS eliminate claims administration contractors’ development of new local coverage policies for procedures and devices that have established codes” and that “CMS establish a new process for making national coverage policy.” Id. at 5.

137. Id.

138. See Grinstead, supra note 110, at 5. In regard to allowing CMS more control over coverage of new technology, Grinstead notes, “[d]epending upon one’s viewpoint, this process has either developed into an effective means of preventing the entry of charlatans and opportunists into the program, or it has stood in the way of making vital, new health care technologies available for the nation’s elderly and disabled.” Id.

139. See Susan Bartlett Foote, Focus on Locus: Evolution of Medicare’s Local Coverage Policy, 22 HEALTH AFF. 137, 138 (2003), available at http://content.healthaffairs.org/cgi/content/full/22/4/137. Unlike the “all-or-nothing national decisions made by a large federal bureaucracy,” a favorable local decision allows the device industry multiple points of entry into the market, allowing the manufacturer of the new technology to begin to market the product as it pursues coverage in other geographic areas. Id. at 144.

140. Id. at 138.

141. Thompson & Dahl, supra note 31, at 144. See also GENERAL ACCOUNTING Office, supra note 136, at 45 (2003) (HHS reply comment) (“[A]llowing contractors to develop local coverage policies gives Medicare the opportunity to test new, experimental treatments before enough clinical evidence is available to warrant national coverage” and allows the Medicare program “the flexibility to address needs that are not national in scope.”).
Local coverage also provides manufacturers with an opportunity to obtain clinical data needed to identify limited subsets of patients who have better outcomes.\textsuperscript{142} With respect to the national process, stakeholders had for some time lobbied legislators to require CMS to allow input from interested parties, and to make its coverage process more open and transparent. Device manufacturers, in particular, had become increasingly frustrated with their inability to more wisely allocate their resources in planning investment strategies, to better focus their research and development efforts, and to develop strategies for marketing and diffusing clinical information.\textsuperscript{143} Thus, interested stakeholders continued to press CMS for sector-specific guidance as to the level and character of evidence required in order to meet the reasonable and necessary requirement.\textsuperscript{144}

\textsuperscript{142} Thompson & Dahl, \textit{supra} note 31, at 144.

\textsuperscript{143} See Procedure for Producing Guidance Documents Describing Medicare’s Coverage Process, 69 Fed. Reg. 57,325, 57,326 (Sept. 24, 2004) (“Guidances may be useful in certain cases to help plan investment strategies, research and development efforts, and marketing and clinical diffusion strategies.”).

\textsuperscript{144} See Bagley, \textit{supra} note 41, at 23 (noting that sector-specific guidance is important because different technologies require different evidentiary approaches, and that the “level and character of evidence needed are issues of major controversy that remain to be addressed”). For example, Bagley explains that diagnostic techniques for medical devices undergo a different clinical trial process than do drug therapies, principally because it is not practical to use the double-blind randomized trials for devices that are commonly used for drugs. \textit{id.} at 37. One long-running point of contention was whether HCFA (now CMS) was required to engage in the rule-making and public comment procedures required by the Administrative Procedures Act. This statute requires administrative agencies to publish in the Federal Register general notice of proposed rule-making, and to engage in a period of public comment before promulgating final rules. 5 U.S.C. § 553(c) (2000). An exception exists, however, when the rules are not substantive, but instead are “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.” 5 U.S.C. § 553(b)(A) (2000). Whether Medicare rules are substantive or interpretive is not always clear. A coverage policy that describes several examples of items or procedures that may or may not be reasonable and necessary is interpretive in the sense that it illuminates agency thinking on the subject. On the other hand, a beneficiary may be substantially impacted by a policy that restricts an item or service that one would reasonably believe ought to be “reasonable and necessary.” A good argument may be made in this instance that the policy is substantive, and subject to notice and comment procedures. See Eleanor D. Kinney, \textit{National Coverage Policy Under the Medicare Program; Problems and Proposals for Change}, 32 St. Louis U. L.J. 869, 943 (1988). HCFA consistently took the position that its coverage criteria was a matter of internal procedure and practice that did not involve substantive, legislative decision-making; thus, it was not legally required to engage in the notice and comment procedure, even though it had attempted to do so on several occasions. \textit{See} Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,620-21 (Apr. 27, 1999). A good argument exists, however, that in order to implement the Congressional directive to pay for reasonable and necessary care, Congress has delegated to CMS the authority to create substantive rules that may change an existing law or policy, which would require CMS to comply with the Administrative Procedures Act. \textit{See} Linoz v. Heckler, 800 F.2d 871, 876-77 (9th Cir. 1986) (holding that a national coverage policy that excluded payment to ambulance service to another hospital “solely to obtain the services . . . of a physician in a specific specialty” was invalid because it was a substantive rule, and the Secretary had failed to conform with the administrative notice and comment procedures) (footnote omitted).
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Congress addressed several stakeholder concerns in a head-on manner in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Although Congress did not eliminate the local coverage process, the MMA directed CMS to develop a plan to achieve greater consistency among local coverage determinations, and to consider which local decisions should be adopted nationally. Furthermore, the MMA spoke to the concerns of interested stakeholders by establishing an expedited time frame for making national coverage determinations, requiring opportunity for public comment on draft decisions, and requiring consultation with outside experts on national coverage determinations not referred to MCAC. Most importantly for purposes of this Article, the MMA also required CMS to develop and make available to the public guidance documents explaining the factors CMS considers in determining whether an item or service is reasonable and necessary.

This statutory mandate places CMS in a challenging position. Its 1989 attempt at rule-making—designating cost-effectiveness as an explicit coverage criterion—was soundly opposed, and ultimately abandoned. Yet, CMS has been able to control the cost of expensive new technology, at least implicitly, either by claiming some other reason for limiting beneficial new technology, as it did in the case of heart transplantation, or by opening an NCD and designating the technology for external technology assessment, thereby slowing the coverage process. Given the lack of statutory and popular support for considering cost-effectiveness in its decision-making, CMS surely cannot again openly designate cost, or cost-effectiveness, as a factor.

On April 11, 2006, in response to the mandates of the Medicare Modernization Act, CMS published two guidance documents that illustrate CMS’s desire, yet its inability, to consider cost in making coverage determinations. In the first document, “Factors CMS Considers in Opening a National Coverage Determination,” CMS avows that, even though it may choose for NCD consideration technology that is “likely to have a significant programmatic impact,” which would include a significant financial impact, it would not consider the cost-effectiveness of the particular technology in

150. 42 U.S.C.A. § 1395y(b)(1) (West Supp. 2006) ( “The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph . . . ”).
determining whether it should be covered through an NCD.\textsuperscript{151} The process by which CMS internally generates an NCD is not transparent, however, and may itself be the equivalent of considering cost-effectiveness outright. Similarly, in “Factors CMS Considers in Commissioning External Technology Assessments,” CMS is less than clear with respect to whether cost considerations will be part of the “reasonable and necessary” inquiry.\textsuperscript{152} In that document, CMS admits that “economic considerations may be a factor discussed in a technology assessment,” but that “cost is not a factor in our review or decision to cover a particular technology.”\textsuperscript{153}

Technologies that have a significant financial impact on the Medicare program, as well as technologies that may require an external technology assessment, are just the types of interventions that may be designated for Coverage with Study Participation.\textsuperscript{154} A CSP designation would effectively control costs by delaying NCD consideration indefinitely, likely for years, until clinical trials could be established and completed, and the research analyzed and published. Quite possibly, CMS could send technology it is considering for an NCD first to outside technology assessment and, following that, to CSP for clinical trials, thereby pushing a possible NCD even further into the future.

Assuming that one could prove that Coverage with Study Participation was a means of implicit cost control, CMS may not fare well in the event of a court challenge to its authority to consider cost in making coverage decisions. The Supreme Court’s opinion in \textit{FDA v. Brown & Williamson Tobacco Corp.}\textsuperscript{155} provides insight as to how a reviewing court might analyze whether CMS has the administrative authority, under the administrative deference doctrine, to consider cost in making coverage decisions. In determining the limits of agency authority, the Court stated that the first inquiry is whether Congress has directly addressed the scope of the agency’s authority.\textsuperscript{156} If not, a court should consider whether Congress has subsequently taken actions regarding the specific topic at hand, thereby indicating its intent to control the area.\textsuperscript{157} The final inquiry is whether the

\textsuperscript{151} See CTRS. FOR MEDICARE & MEDICAID SERVS., \textit{supra} note 42, at pt. IV.C.

\textsuperscript{152} CTRS. FOR MEDICARE & MEDICAID SERVS., \textit{supra} note 46.

\textsuperscript{153} Id. at pt. III.

\textsuperscript{154} Examples of the type of technology likely to have significant financial impact on Medicare policy may include the use of FDG-PET scans for suspected dementia, and the use of implantable cardioverter defibrillators for certain indications. See Tunis & Pearson, \textit{supra} note 9, at 1222-23. CMS, after initial resistance, agreed to cover these interventions subject to beneficiary participation in prospective clinical trials or registries. \textit{Id.} at 1222-24.

\textsuperscript{155} \textit{FDA v. Brown & Williamson Tobacco Corp.}, 529 U.S. 120 (2000). The issue in \textit{Brown & Williamson} was whether the FDA had authority to regulate tobacco products under its authority to regulate drugs and devices, under the theory that cigarettes and smokeless tobacco were “combination products” that delivered nicotine to the body. \textit{Id.} at 125.

\textsuperscript{156} Id. at 132.

\textsuperscript{157} Id. at 133 ("[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand."). In \textit{Brown & Williamson}, the Court reviewed numerous instances where Congress had acted to regulate the

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The topic involves a “policy decision of such economic and political magnitude” that Congress would not likely have delegated the area to an administrative agency.158

Since Congress has not specifically stated whether CMS can consider cost in making coverage decisions, the analysis turns on the latter two inquiries. First, Congress has, on several occasions, indicated its intent to control Medicare program costs. The most striking example of congressional intervention to address and restrain rising program costs is the enactment in 1983 of the prospective hospital payment legislation, followed in 1989 with a new fee schedule for physicians, the Resource-Based Relative Value Scale.159 One reason for congressional action was to keep disputes over cost control out of the political process.160 Interesting to note is the proximity in time of the 1989 physician fee schedule legislation to Medicare’s 1989 failed attempt to use the administrative rule-making process to institute cost-effectiveness analysis into its coverage criteria.161 Clearly, congressional implementation of the prospective payment system and physician fee schedule indicates that Congress, not CMS, is the proper vehicle for addressing rising health care costs.

The second inquiry necessary to determine whether Congress intended CMS to consider cost in its coverage criteria is whether the topic involves a “policy decision of such economic and political magnitude” that Congress would not likely have delegated the area to an administrative agency.162

Congress has given CMS the authority to consider the cost of new services and technologies when it sets payment rates, which is accomplished in a process that is separate and apart from the coverage process.163 Congress’s explicit grant of permission to consider costs in the payment process, and the lack of any such permission respecting the coverage process, indicates that Congress intended to keep that authority for itself.

Moreover, cost control in the coverage process is synonymous with rationing tobacco industry, noting that these actions by Congress precluded the FDA from claiming jurisdiction to regulate tobacco products. Id. at 143-55.

158. Id. at 133.

159. MARMOR, supra note 81, at 108 (describing the prospective hospital payment legislation and the physicians fee schedule as “effective in achieving the overarching goal of restraining the growth of Medicare expenditures”).

160. Id. at 109.

161. See discussion supra at Subsection III.B.3.

162. Brown & Williamson, 529 U.S. at 133.

163. See 42 U.S.C.A. § 1395ww(d)(5)(K)(i)-(ii) (2003) ("[T]he Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system . . . . The mechanism . . . shall . . . apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG [diagnosis-related group] prospective payment rate otherwise applicable to such discharges under this subsection is inadequate . . . .").

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care. The term "health care rationing" is itself politically charged, raising issues of economic and political magnitude. The Court in *Pegram v. Herdrich* made it clear that health care rationing is an area that Congress would not likely delegate to an agency. In that case, the Court noted that Congress is better equipped than the courts to make health care rationing decisions, given the comprehensive investigations and social value judgments that would be required to balance optimal treatment levels against health care expenditures.\(^{164}\) Certainly, Congress would not likely delegate health care rationing decisions to an administrative agency.

Implicit rationing, however, is less noticeable and far more politically acceptable than explicit rationing. Perhaps CMS, facing the inability to overtly use cost in its decision-making, yet possessed of the practical reality that not all beneficial technology can be paid for indefinitely, has devised a means of implicit rationing by slowing down the coverage process, perhaps for years, through Coverage with Study Participation.

### III. PROBLEMS WITH INCLUDING MEDICARE BENEFICIARIES IN CLINICAL TRIALS

Coverage with Study Participation (CSP) restricts payment for the items and services provided in a study to those Medicare qualified patients who are subjects in the study.\(^ {165}\) Several concerns surface with respect to the difficulty of achieving "qualified trial" status to meet CMS's stated goals, the challenges of including elderly and disabled persons in clinical trials, and the troubling issue of obtaining the voluntary consent of research subjects in the CSP context.

#### A. Meeting CMS Goals and the "Qualifying Trial" Standard

Providers have expressed concern over the increasing weight CMS is giving to randomized, double-blinded, peer-reviewed clinical trials in making coverage decisions for the Medicare population, some claiming that proof in the scientific literature of the effectiveness of the vast majority of Medicare-covered procedures can not be found.\(^ {166}\) The primary purpose of a CSP clinical trial is to

\(^{164}\) See *Pegram v. Herdrich*, 530 U.S. 211, 221 (2000) (stating that "such a debatable social judgment [is] not wisely required of courts unless for some reason resort cannot be had to the legislative process, with its preferable forum for comprehensive investigations and judgments of social value, such as optimum treatment levels and health care expenditure"); see also Fox, supra note 81, at 624.

\(^{165}\) CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. VI.B.

\(^{166}\) Letter from E. Ratcliffe Anderson Jr., on behalf of the American Medical Association, to Hugh M. Hill, Acting Director, Coverage and Analysis Group, Health Care Financing Administration (May 9, 2000), available at http://www.incontinent.com/ama2mcac.doc. In opposing MCAC's alleged over-reliance on peer-reviewed scientific journals to determine the effectiveness of a medical intervention, to the exclusion of clinical guidelines that reflect the standard of care, Mr. Anderson stated that "[t]he effectiveness of the vast majority of procedures that are covered by
test whether the intervention potentially improves the participants’ health outcomes.  

Yet providers are concerned that, although clinical trials can provide valuable information, they often do not produce data regarding health outcomes. Moreover, given that a large percentage of Medicare beneficiaries have poor health, and for other reasons that will be discussed later in this Part, they typically are not recruited for randomized, double-blinded clinical trials. In order to limit variability within a trial, only those Medicare patients with limited co-morbidities would likely be recruited, and the trial results would be skewed toward this limited subset of patients. Studying outcomes data is often prohibitive in such size-limited studies. Thus, CMS may have difficulty meeting its goals of generating sufficient outcome data to support a national coverage determination through its CSP initiative.

Moreover, CMS will only provide payment for clinical research that meets the standards of a qualified trial. These standards are outlined in its Clinical Trial Policy, which CMS is revising to encompass CED. One of the requirements of a CSP qualified trial will be that the trial should include a representative sample of Medicare beneficiaries with the health condition being researched. CMS engages in circular reasoning here. Trial data cannot be generalized to the Medicare population unless a significant number of Medicare beneficiaries with the condition are enrolled in the trial. Yet the trial will not be covered unless it ultimately recruits the requisite number of Medicare beneficiaries. How likely is it that a Medicare beneficiary will enroll in a clinical trial unless coverage is assured? Not very.

Medicare today for its aged and disabled beneficiaries has not been demonstrated in peer-reviewed scientific literature.”

167. CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. VI.B.
168. Rachel F. Ochs-Ross & Thomas A. Connaughton, The Perspective of Providers, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, supra note 30, at 105, 115 (“While many experts agree that the standard of controlled randomized clinical trials generally provides valuable information, data from these trials that include health outcomes often do not exist, either for most of the therapies currently in use or for new treatments.”).
169. See HENRY J. KAISER FAMILY FOUND., MEDICARE CHART BOOK 2, 5 (3d ed. 2005), available at http://www.kff.org/medicare/upload/Medicare-Chart-Book-3rd-Edition-Summer-2005-Report.pdf (reporting that 90% of Medicare beneficiaries have one or more chronic illnesses; 60% have hypertension; 58% have arthritis, and 25% have a cognitive or mental impairment).
170. Ochs-Ross & Connaughton, supra note 168, at 115 (“Results from clinical trials, by necessity, are limited to the patient base studied in the trial and, because of the need to limit variability within a clinical trial, skewed to patients with limited co-morbidities.”).
171. Id. (“[S]ize limitations often make the study of outcomes data prohibitive, not just because of cost, but because of recruitment difficulties and the long time periods often required to adequately assess large numbers of patients.”).
172. CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. VI.B (“The sample of study subjects in the trial should include individuals representative of the Medicare population with the condition described in the NCD.”).
Although the elderly are the chief consumers of medical services, they are typically under-represented in clinical trials. The standard Phase I drug trial consists of subjects aged between eighteen and forty-five,173 despite federal guidelines for clinical trials that require new drugs to be studied in all age groups, including the geriatric group if they are the group who will most benefit from the drug.174 Nevertheless, most clinical trials seek healthy, younger subjects, and typically exclude subjects over sixty-five. For example, according to the National Institute on Aging, most tumors are diagnosed in persons ages seventy to seventy-four, and information on the safety and effectiveness of treatments is badly needed for this elderly population.175 Patients in this age group, however, seldom meet the eligibility criteria for clinical trials, and so tend not to be referred to these trials. To the contrary, clinical researchers typically recruit younger individuals who represent the minority of persons with the particular disease. The unfortunate result is data that cannot be generalized to the over-sixty-five (i.e. Medicare) population as a whole.176

B. The Difficulty of Including Medicare Beneficiaries in Clinical Trials

Many reasons exist for the lack of Medicare beneficiary participation in clinical trials. Although Medicare beneficiaries include many under-sixty-five disabled persons, most of the literature pertains to the significant majority of beneficiaries who are elderly. Thus, this Section focuses on the difficulty of including the elderly in clinical trials, although many of the basic principles apply to other beneficiaries as well. The aging process leads to changes in physical, mental, hormonal and metabolic conditions that may cause many elderly persons to be excluded from trials.177 Elderly persons may have decreased bone mass, muscle strength, and immune response to infection. They may be more susceptible to heat and cold, and have increased sensitivity to medications.178 Elderly persons may be excluded from trials because the researcher is concerned that these conditions may interfere with trial objectives.

To a significant extent, the hesitation of the elderly to enroll in clinical trials is due to their perceived, as well as actual, health condition. Medicare beneficiaries total 41.8 million persons, with 35.4 million age sixty-five or over,

176. Id.
177. See Kosling, supra note 173.
178. Id.
and 6.3 million under sixty-five with permanent disabilities. When non-institutionalized beneficiaries were asked to self-report their general health condition, 28% reported being in fair or poor health, with a considerably higher proportion of poor beneficiaries reporting being in poor health than their wealthier counterparts. Over half of non-institutionalized Medicare beneficiaries report living with chronic conditions such as hypertension and arthritis. In addition, functional impairment resulting in difficulty with bathing, eating, and other activities of daily living affects one third of all beneficiaries. Aside from health concerns, many elderly persons may have difficulty participating in clinical trials due to lack of social support, difficulty in obtaining transportation to and from the trial site, or lack of caregiver assistance. Some may simply be unwilling to participate because the trial is perceived as too much effort, or because they are afraid of possible risks.

Another concern is the ability of some elderly persons to give truly informed consent to participate in a clinical trial. An older person may not completely understand the implications of a research protocol, and the quality of informed consent forms varies from institution to institution. Although the federal regulations that protect human subjects in clinical trials provide special protections for “vulnerable populations” such as children, prisoners, persons with mental disabilities, pregnant women and the economically or educationally disadvantaged, they provide no additional protections for elderly subjects who participate in clinical trials. Vulnerability, however, is sensitive to situational context, and elderly persons may be vulnerable in one situation, but not in another. For example, some elderly persons may regularly put aside their own concerns to defer to the wishes of their adult children. Others may feel

179. HENRY J. KAISER FAMILY FOUND., supra note 169, at 3 (figures based on 2004 research). While most beneficiaries are between ages 65 and 74, 12% are age 85 and above. Id. at 3.
180. Id. at 2. (noting that 43% of those with incomes less than 100% of the federal poverty guideline reported their health to be fair or poor, but only 17% with incomes at 300% or above the poverty line report their health as fair or poor).
181. Id. at 2 (noting that 60% reported living with hypertension and 58% reported living with arthritis).
182. Id. at 5.
183. Nat’l Inst. on Aging, supra note 175.
184. See Kosling, supra note 173.
185. See 45 C.F.R. § 46.111(3) (describing “vulnerable populations” as children, prisoners, pregnant women, mentally disabled persons, or the economically or educationally disadvantaged).
186. See NAT’L BIOETHICS ADVISORY COMM’N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 85 (2001), available at http://bioethicsprint.bioethics.gov/reports/past_commissions/nbac_human_part.pdf (“[V]ulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in ethically inappropriate ways in research.”).
187. Id. at 89.
pressured to defer to their physicians' suggestion that they enroll in a clinical trial, and they wish not to disappoint their physicians, or they may be concerned that their refusal may negatively affect their care.\footnote{188}

\textit{C. CSP May Violate HHS Protection of Human Subject Regulations}

Perhaps the most serious objection to CSP is that it runs afoul of federal regulations designed to protect human subjects who participate in medical research.\footnote{189} Without question, federal regulations would apply to the research contemplated by the CSP arm of CED, since regulations broadly define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."\footnote{190} Research conducted or supported by a federal department or agency must comply with federal regulations outlining basic policy for the protection of human subjects.\footnote{191}

At the heart of human subject protection is the principle of informed consent.\footnote{192} Human beings may be used as research subjects only if they are

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\item 188. Id.
\item 189. The term "subject" is used to describe persons who participate in medical research in order to distinguish them from patients who are receiving medical treatment or therapy, even though an individual may be both a patient and a research subject. Medical ethicist Jay Katz notes that it is "imperative to view clinical research as a distinct category, sharply delineated from clinical practice." Jay Katz, \textit{Human Experimentation and Human Rights}, 38 \textit{St. Louis U. L.J.} 7, 17 (1993).
\item 190. 45 C.F.R. § 46.102(d) (2006).
\item 191. Research involving human subjects conducted by the Department of Health and Human Services (HHS) is governed by 45 C.F.R. Part 46, and research conducted by the Food and Drug Administration (FDA) involving drugs and devices regulated by the FDA is governed by 21 C.F.R. Parts 50 and 56. 45 C.F.R. § 46.101(a) (2006) provides that federal policy "applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research." The regulations further provide that "[r]each work that is conducted or supported by a federal department or agency... must comply with all sections of this policy." 45 C.F.R. § 46.101(a)(1) (2006).
\item 192. The principle of informed consent developed in response to the atrocities committed by Nazi doctors and scientists under the guise of medical research during World War II and the subsequent 1946 Nuremberg Military Tribunal, which brought these war criminals to justice. \textit{See generally, The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation} (George J. Annas & Michael A. Grodin eds., 1992). Part of the Tribunal's decision included what has become known as the Nuremberg Code. The first principle of the Nuremberg Code is "[t]he voluntary consent of the human subject is absolutely essential." \textit{Nuremberg Code, in 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council No. 10, 181-82} (U.S. Gov't Printing Office 1949) [hereinafter Nuremberg Code],
\end{itemize}
legally competent to consent to participate, and only after the details of the research have been explained, including the purpose of the research and any potential risks or benefits involved in the research.\footnote{35}

Most pertinent to CSP, however, is the principle that the subject’s informed consent must be voluntary.\footnote{36} The Nuremberg Code, which provides the historical basis for federal regulations requiring the informed consent of research participants, described voluntary consent as being “without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form

\footnote{35} available at http://ohsr.od.nih.gov/guidelines/nuremberg.html. This principle was modified in 1964 by the Declaration of Helsinki, which allows a legally authorized representative to consent for legally incompetent persons who are physically or mentally incapable of giving consent. WORLD MED. ASS’N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (adopted 1964, amended 1975, 1983, 1989, 1996, and 2000), available at http://www.wma.net/e/policy/b3.htm. Medical research practice in the United States was surprisingly unchanged by the Nuremberg Trials and the ensuing world attention on the use of humans in medical research. It was not until 1966, when a highly controversial article by Dr. Henry K. Beecher provided twenty-two examples of unethical research, that the federal government focused on the need to regulate medical research. The FDA and the National Institutes of Health (NIH) developed internal guidelines providing rudimentary subject protections that were codified as federal regulations in 1974. See Harold Y. Vanderpool, Introduction and Overview, in THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS FACING THE 21ST CENTURY 1, 10 (Harold Y. Vanderpool ed., 1996). Also in 1974, the newly formed National Commission for the Protection of Human Subjects of Biomedical Research and Behavioral Research (National Commission) was given the task of identifying the ethical principles underlying biomedical research involving human subjects and instructed to develop federal guidelines. See William J. Winslade & Todd L. Krause, The Nuremberg Code Turns Fifty, in ETHICS CODES IN MEDICINE 150 (Ulrich Trohler & Stella Reiter-Theil eds., 1996). Among the seventeen reports produced by the National Commission was the Belmont Report, which served as the basis for our current federal regulations. The Belmont report provided a framework for solving the ethical problems that arise in human subject research, and sheds light on the application of ethical principles in the clinical setting. See Nat’l Comm’n for the Prot. of Human Subjects of Biomedical & Behavioral Research, The Belmont Report: Ethical Principles & Guidelines for Research Involving Human Subjects, 44 Fed. Reg. 23,192 (Apr. 18, 1979), available at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm [hereinafter Belmont Report]. The Belmont Report identified and enumerated three fundamental ethical principles necessary for the protection of human subjects in medical experimentation: respect for persons; beneficence; and justice. Id.

\footnote{36} See 45 C.F.R. § 46.116(a)(1)-(8) (2006). The basic elements of informed consent include an explanation of the purpose of the research, the duration of the subject’s participation, an explanation of each step of the research procedure, a description of the risks, discomforts, or benefits that might reasonably be expected from the research, alternatives available should the subject choose not to participate in the research, a description of how records will be kept confidential, and other protections. Id.

\footnote{35} See Nuremberg Code, supra note 192 (“The voluntary consent of the human subject is absolutely essential.”). The Nuremberg Code was drafted during the Nuremberg War Crime Tribunals as a set of principles, or standards, for judging those physicians and scientists who had conducted medical experimentation on concentration camp prisoners during World War II.

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of constraint or coercion . . . "  

Similarly, the Belmont Report, which provides a framework for solving the ethical problems that arise in medical research on human subjects, explains that in order for consent to be truly voluntary, it must be "free of coercion and undue influence."

Coercion occurs when the potential research subject is threatened with harm in order to obtain compliance with the research protocol. Undue influence occurs when an excessive reward or incentive is offered to gain subject participation, or when an inducement is offered to a potential subject who is particularly vulnerable. These basic ethical principles are also embodied in HHS and FDA regulations, which require that investigators seek the consent of potential subjects only under circumstances that "minimize the possibility of coercion or undue influence."

If a particular intervention is approved for payment under Coverage with Study Participation, only Medicare beneficiaries who agree to participate in the research will have access to the service. Payment for the items and services provided in the clinical trial is restricted to those services provided to Medicare beneficiaries who are enrolled in the study. Thus, the cost to the patient of choosing not to participate in research is that the service would be prohibitively expensive. A decision to participate in medical research cannot be truly voluntary, however, when participation is the only way to receive the service. This is particularly troublesome in light of the fact that the particular intervention has likely already been FDA-approved as safe and effective, deemed appropriate

195. Id.
196. Belmont Report, supra note 192. The Belmont Report analyzes the consent process as containing three elements: information (disclosure of all aspects of the research); comprehension (the information must be conveyed in a manner that is understandable to the subject, given the subject’s intelligence, maturity, and language comprehension); and voluntariness (consent to participate in research must be free from coercion, undue influence). Id.
197. The Belmont Report defines coercion as occurring "when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance." Id.
198. The Belmont Report defines undue influence as occurring "through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance." Id. The report adds that "inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable." Id.
199. 45 C.F.R. § 46.116 (2006) ("An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."). The FDA regulations governing research on human subjects involving drugs or devices contain identical language. See 21 C.F.R. § 50.20 (2006). HHS regulations regarding informed consent and other subject protections are found in Subpart A of 45 C.F.R. Part 46. Subpart A is typically referred to as the Common Rule because it incorporates the Federal Policy for the Protection of Human Research Subjects. This Federal Policy is also reflected in the regulations for an additional fourteen government departments that conduct research using human subjects. See, e.g., Protection of Human Subjects, 45 C.F.R. Part 46 (2006) (regulating research of HHS); Protection of Human Subjects, 7 C.F.R. § 1c (2006) (regulating research of Department of Agriculture); Protection of Human Subjects, 10 C.F.R. § 745 (2006) (regulating research of Department of Energy).
200. CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. VI.B.
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for the patient by the patient’s treating physician, and considered by CMS to be sufficiently reasonable and necessary to be approved for Medicare beneficiaries, but only so long as they agree to participate in research. CMS may be engaging in coercion or undue influence in violation of federal regulations in the sense that coverage of the service is essentially the patient’s reward for enrolling in the trial.

Theoretically, a Medicare beneficiary could bypass CSP and privately pay for the intervention, receiving it through a provider who has opted out of the Medicare program.201 For the most part, CSP will involve new technology that has been FDA-approved as safe and effective, and may well be publicly available outside the Medicare program. The practical reality, however, is that the cost would be prohibitive for a significant majority of Medicare beneficiaries. Most Medicare beneficiaries rely on their Social Security checks for living expenses and non-covered health care services. A Kaiser Family Foundation study reveals that in 2003, 10% of Medicare beneficiaries over sixty-five had incomes below $8825.202 In 2004, nearly four in ten elderly Medicare beneficiaries had incomes below $18,120 for individuals and $22,836 for couples.203 Similarly, most Medicare beneficiaries have minimal assets. In 2002, the most recent year for which data is available, more than half of non-institutionalized Medicare beneficiaries had assets of $20,000 or less.204 Given the high cost of new health care technology, no realistic possibility of private purchase exists.205 The effect

201. See 42 U.S.C.A. § 1395a(b) (West Supp. 2006) (allowing a physician to enter into a private contract with a Medicare beneficiary, provided no claim for payment is submitted and no reimbursement is received from Medicare); 42 U.S.C.A. § 1395a(b)(2) (West Supp. 2006) (requiring physician’s private written contract with beneficiary to state that the physician’s charges are not limited by the Medicare rules, and that the beneficiary may not submit any claim for reimbursement to Medicare); 42 U.S.C.A. § 1395a(b)(3)(B) (West Supp. 2006) (requiring the physician to file an affidavit with the Secretary affirming the physician will not submit any claim for any service provided to any Medicare beneficiary, or receive reimbursement for any service for a two year period).


203. Id. at i.

204. Id. at 2.

205. After publication of CMS’s CED Draft Guidance, many stakeholders questioned whether a national coverage determination designating a service for CED (now CSP) would preclude them from seeking a local coverage determination. CMS responded to this and other concerns in a follow-up fact sheet. See SCRUTINIZING THE CED - DEFINITION AND PROCESS FOR NON-INSTITUTIONALIZED MEDICARE BENEFICIARIES REGARDING COVERAGE DECISIONS WITH A PRELIMINARY 7-9-05 COVERED DECISION HIGHLIGHTS (2005), available at http://www.cms.hhs.gov/coverage/download/guidfactsheet.pdf. CMS indicated that, although an NCD supersedes any inconsistent local decision, the local carriers could “continue to make independent medical decisions while CMS is considering a new NCD.” Id. at 2. Under these circumstances, however, local coverage for subjects who are unable or unwilling to participate in CED research is not likely to happen. Carriers are typically unwilling to cover a new item or service once CMS has indicated its intention to subject it to a national coverage decision. See, e.g., Letter from Laura Thevenot, Executive Director, American Society for Therapeutic Radiology & Oncology, to Steve Phurrough, Director, CMS Coverage and Analysis Group, (June 6, 2005) (on
of non-coverage outside of CSP is that patients unable or unwilling to enroll in research will not have access to the service.

IV. RECOMMENDATIONS

Medicare began as a politically acceptable compromise for its architects, who had expected it to be the first step toward universal national health insurance. The expectation was that Medicare patients would receive the same level of care as was enjoyed by other paying or insured patients, and that hospitals and physicians would be paid their full costs. What soon became apparent, however, was that after-the-fact reimbursement for hospital costs and physician services was flawed, creating considerable incentive for over-utilization, and that government intervention would be required to rein in costs that were rapidly approaching crisis proportions. To address rising hospital costs, in 1982 Congress implemented a prospective payment system based on diagnostic related groups for hospitals, followed in 1989 by similar cost-saving measures for Part B physician services.

Today, it is commonly accepted that changes in medical technology account for a significant portion of health care costs, which are again approaching crisis levels. Not only is it costly to bring new technology through the extensive

file with author) (public comment on CED policy, stating that many carriers are unwilling to cover a new item or service once CMS is considering it for NCD). Moreover, in CMS's subsequent CED Guidance Document, CMS has apparently backed off its earlier response, since the new document does not mention local coverage. In any event, a local carrier would not likely cover an item or service designated for CSP, since CMS has indicated that those interventions are not (yet) "reasonable and necessary."

206. See Ball, supra note 80, at 62-72. Ball, who served as commissioner of Social Security under Presidents Kennedy, Johnson, and Nixon, explained that the Medicare bill likely would never have passed had the architects created a more prominent role for the government. Id. at 67.

207. Id. at 67. Ball writes that "the aged, who were mostly poor, were usually treated in hospital wards where their care was often left to interns and medical students." Id. at 68. To be treated the same as paying patients meant being treated in a two-bed, semi private room, with respect, and without discrimination on the basis of race. Id.; see also Marian Gornick et al., Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures. 6 HEALTH CARE FIN. REV. 13, 14 (Supp. 1985) (indicating that in 1963, only about half of the over-sixty-five population had hospital insurance, in contrast to about three-fourths of the under-sixty-five population).

208. Ball, supra note 80, at 68. That the government was originally slated for a hands-off role is reflected in the first section of the Medicare Act, which provides a "prohibition against any federal interference . . . [or the] exercise [of] supervision or control over the practice of medicine . . . [or over] any such institution, agency or person" providing health services. 42 U.S.C. § 1395 (2000).

209. See FURROW ET AL., supra note 45, at 373 (noting that between 1967 and 1983, hospital expenditures increased eleven times, from $3 billion to $33 billion).
FDA approval process, but costs multiply when the technology leads to many more people being treated for diseases that, for better or worse, were not treatable on the same level prior to the advent of the new technology.\textsuperscript{211} The prospective payment system is of limited utility in addressing the cost of new technology because a reimbursement rate set too low not only discourages innovation, but essentially is a de facto non-coverage decision.

It appears that CMS is using Coverage with Study Participation as a cost-cutting initiative, achieved by tying up expensive technology in clinical trials for which financing is uncertain and recruiting is slow, and thereby delaying diffusion of the technology into the marketplace for an indefinite period of time. CMS predicts, without commitment, that at some undetermined point down the road it will analyze the data to determine whether the technology merits a national coverage decision.\textsuperscript{212} Meanwhile, CMS contends that CSP is a means of enhancing access to promising new medical technology that otherwise would not be covered. That such services would be non-covered seems disingenuous, however, since CMS is covering the service for those Medicare beneficiaries enrolled in trials.

The more likely explanation is that the evidence is sufficient to support a national coverage determination, but the financial impact on the program would be too great if the service was implemented nationally. This rationale is supported by CMS's original Draft Guidance position that it could cover certain technology linked to clinical trials because the available evidence indicated that the technology was "reasonable and necessary."\textsuperscript{213} Only when doubt arose as to

\footnotesize{http://www.citizenshealthcare.gov/healthreport/healthreport.php (reporting total health care spending will increase to $4 trillion by 2015, with Medicare spending becoming an increasingly large percentage of overall spending). According to CMS 2005 statistics, the United States spent $6697 per person on health care, totaling $2 trillion. Although the rate of increase was somewhat less than in previous years, health care spending overall grew to 16\% of the gross domestic product in 2005. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE DATA, http://cms.hhs.gov/nationalhealthexpenddata/Downloads/highlights.pdf (last visited May 3, 2007). The Medicare program is the dominant source of public spending, with $342 billion spent in 2005. In 2005 alone, Medicare spending rose 7.8\%, due primarily to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which increased payments for capitated health plans and rural providers, and home health and physician services. \textit{Id.} This growth represents a 2\% rise over 2003 spending. \textit{Id.}}

\textsuperscript{211} See Cutler & McClellan, \textit{supra} note 210, at 12 (describing the "treatment expansion effect" as a "major factor in the benefits and failures of technological innovation").

\textsuperscript{212} See CMS, CED GUIDANCE DOCUMENT, \textit{supra} note 6, at pt. V.B.

\textsuperscript{213} See CMS, DRAFT GUIDANCE, \textit{supra} note 58, at 4. This Draft Guidance was CMS's first public explanation regarding a new coverage category that linked coverage decisions to the collection of additional data. CMS clearly stated that the statutory authority for this type of coverage was the "reasonable and necessary" provision. \textit{Id.} With its July 2006 CED Guidance Document, CMS did a complete about face, announcing that this coverage category would include services that were \textit{not} "reasonable and necessary," but that CMS had the statutory authority to
whether CMS had the statutory authority to limit coverage in this manner did it do an about face and declare that this category of coverage would actually involve services that did not meet the “reasonable and necessary” standard for national coverage purposes.214 The inference is that CMS, under extreme pressure to contain program costs, yet aware that some expensive technology holds promise for beneficiaries, has discovered a means of slowing national availability of new technology through implicit cost-cutting maneuvers. Absent congressional direction, responsibility for controlling costs has been a burden assumed by CMS, but CMS can address cost issues only when setting payment for services, since it does not have the legislative authority to consider cost, or engage in cost-effectiveness analysis, when making coverage decisions.215

In light of stakeholder opposition, the lack of statutory support, and the political unpopularity of cost-cutting that might be construed as health care rationing, CMS has resorted to implicit cost control, most recently through its Coverage with Study Participation policy. The reality, however, is that broad national coverage of items or services designated for CSP may be delayed for a significant time, first in the technology assessment process, and later in CSP. Even after a service is designated for CSP, delay may be indefinite because at this point many details of the policy remain unclear, such as who will pay for the costs of structuring the trials. After trials have “qualified” for CSP via a process that has yet to be defined, items or services could be delayed for years, during which time Medicare beneficiaries outside of trials will be denied services that their physicians deem beneficial.216 Add to this undesirable state of affairs the proposition that CMS may not have the statutory authority to restrict new technology as it proposes in CSP, coupled with the likelihood that CSP violates the federal regulations for the protection of human subjects, and it becomes clear

cover the services in clinical trials pursuant to it authority to conduct quality control research. See CMS, CED GUIDANCE DOCUMENT, supra note 6. CMS’s original plan to link coverage with additional data collection was to apply to services that met the statutory reasonable and necessary standard, but CMS simply wanted more and better evidence before granting national coverage. Only when CMS had doubts about its statutory authority to do so did it change its position and state that services designated for trials were not reasonable and necessary. This supports the position that services designated for CSP would more likely merit a decision of coverage rather than non-coverage, and CSP is in reality a means of cutting costs by projecting into an indefinite future the point at which a national decision is made.

214. CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. V.B (stating that “CSP will allow coverage of certain items or services for which the evidence is not adequate to support coverage under” the reasonable and necessary provision).

215. See discussion supra Part II.

216. Although CMS has indicated that the end-point for CED research studies is predetermined in the study protocol, this does not address the fact that it may take years before a statistically significant number of Medicare beneficiaries are enrolled, given that many elderly and disabled persons may meet exclusion criteria. See CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt. VIII.A (2006) (stating that the end to data collection in research studies is predetermined in the study protocol).
that CSP is not the best means of achieving CMS's goals.

To the extent that data obtained from clinical trials provides the most meaningful evidence of outcomes, one obvious solution would be to encourage more Medicare beneficiaries to participate in clinical trials on a truly voluntary basis, without linking coverage of the item or service to the trial. Although it may appear that trial enrollment incentive is lacking where the service is available outside of the trial, one recent study indicates that elderly people may be more willing that previously believed to consider participation in a clinical trial.\textsuperscript{217} The study indicates that elderly patients do not actively seek clinical trials, and that they are often not informed about such trials by their physicians. Given the opportunity, however, three-quarters of the cancer patient respondents in the study indicated that they would participate in a trial to prevent or screen for cancer, just over half would enroll in a trial comparing a new drug to a standard drug, and 70\% would agree to test a new drug where no standard drug was available.\textsuperscript{218} Keep in mind, this research concerned the inclination of elderly cancer patients to enroll in clinical trials of cancer drugs that were not yet FDA-approved. Interventions that CMS would designate for Coverage with Study Participation, however, would be those that have already been FDA-approved and that the physician has indicated are medically necessary for the patient. Under these circumstances, the rate of voluntary participation in clinical trials should be significantly higher. With this recommendation, however, coverage of the intervention would not be linked to a clinical trial, but would be available outside of the trial context for those who require it. This would include those persons identified earlier, for whom participation in a trial is not possible due to medical conditions, transportation or logistic impediments, lack of necessary social support, or simple disinclination.\textsuperscript{219}

CMS could also achieve its goal of generating additional data by enhancing its traditional relationship with the AHRQ. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 specifically directs the Secretary of Health and Human Services to use the AHRQ to conduct and support outcomes, effectiveness, and appropriateness research to improve the quality of health care for Medicare beneficiaries.\textsuperscript{220} AHRQ is the lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. Its mission is to improve the quality, appropriateness, and

\textsuperscript{218} Id.
\textsuperscript{219} See discussion supra Section III.B.
effectiveness of health services. To that end, AHRQ conducts research regarding all aspects of health care, including research on the cost-effectiveness of health care practices, and the costs of health care. Since 1997, AHRQ has conducted research to promote evidence-based practice through its twelve Evidence-based Practice Centers located throughout the United States and Canada. CMS can use the services of AHRQ, as it has been doing for many years, to serve the needs of the Medicare program without restricting present coverage to Medicare beneficiaries in clinical trials.

Another organization that is ideally situated to address CMS concerns is the Centers for Education and Research on Therapeutics (CERTs) program, which is administered in cooperation with AHRQ, and in consultation with the Food and Drug Administration. CERTs is a research and educational program aimed at improving quality in the use of therapeutics, a category that includes drugs, medical devices, and biological products.

Coverage with Appropriateness Determination (CAD) presents perhaps the best opportunity for CMS to obtain the additional data it desires, without restricting coverage to clinical trials. CAD, as explained earlier, is the first arm of CMS’s Coverage With Evidence Development (CED) policy. CAD is designed to allow for payment of items or services that meet the statutory “reasonable and necessary” standard, but for which CMS would like to obtain additional clinical data. Essentially, services designated for CAD would be

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221. See 42 U.S.C. § 299(b) (2000) ("The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions.").

222. See id.; id. § 299(b)(1)(B)-(D) (2000) (stating that the AHRQ shall promote health care quality improvement by conducting and supporting . . . research that develops and presents scientific evidence regarding all aspects of health care, including . . . (B) the outcomes, effectiveness, and cost-effectiveness of health care practices . . . (D) the costs and utilization of, and access to health care.").

223. See Agency for Healthcare Research & Quality, Evidence-based Practice Centers, http://www.ahrq.gov/clinic/epc/ (last visited May 3, 2007) (stating that the EPCs conduct a "rigorous, comprehensive syntheses and analyses of the scientific literature" and produce reports for use by CMS, as well as other governmental and private entities that make health care organization and delivery decisions).

224. See AGENCY FOR HEALTHCARE RESEARCH & QUALITY, CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS: OVERVIEW (2007), available at http://www.ahrq.gov/clinic/certserv.htm. CERTs have eleven research centers and a coordinating center, and CERT programs represent collaborations with other public and private organizations concerned about health care quality and safety. Id.

225. CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt V.A.

226. See id.

227. Id. CMS deems items or services designated for CAD to be "reasonable and necessary," but that "additional clinical data is needed that is not routinely available on claims forms to ensure that the item or service is being provided to appropriate patients in the manner described in the NCD." Id.
covered so long as physicians submit additional clinical data with the claims forms used for reimbursement of the service.\textsuperscript{228} Such data is to be put into a database or registry for research purposes.\textsuperscript{229} Since data collection would place an additional burden on providers, CMS should consider payment to providers to secure their participation in CAD, and to assure that physicians would not hesitate to recommend CAD for their patients where appropriate. Surely any additional cost to CMS would be significantly less than what would be required in CSP, which involves clinical trials.

The solution to controlling Medicare program costs is not simple. A way for our nation to keep its promise to provide high quality health care to its elderly and disabled citizens, but at the same time protect the Medicare trust is far from obvious. Should the present rate of growth continue, Medicare Part A will be depleted by the year 2018.\textsuperscript{230} And, even though Part B is funded out of the general tax, a large portion of our taxes already go toward financing a system that will become increasingly difficult to maintain as baby boomers reduce their incomes and retire from the workforce in greater numbers.\textsuperscript{231}

Realistically, no one believes that Medicare can continue indefinitely to pay for all promising medical technology, no matter how high the cost. The alternative, of course, is that either cost-sharing must be increased or benefits for very expensive technology must be rationed. Some commentators would like clear authority to include cost-effectiveness analysis in coverage determinations,\textsuperscript{232} even though using economic analysis in medical decision-

\textsuperscript{228} Id. ("The extra data supplements the information gathered routinely through claims for services rendered and is collected by providers when the service is provided."). CMS has long understood the value of using administrative or claims data in health care research. Claims data is obtained from the process of billing insurance carriers for medical care, and it allows researchers to analyze patient histories and accumulated claims for services, including diagnoses and procedures, over time. See Medical Technology & Practice Patterns Inst., An Opportunity To Improve Quality of Care in the Medicare Program Using Enhanced Administrative Data (2004), http://www.mtppi.org/physiosymp_comments.asp.

\textsuperscript{229} CMS, CED GUIDANCE DOCUMENT, supra note 6, at pt V.A ("[P]roviders will submit extra data to databases or registries specifically designed for collecting data specified in the NCD in question.").


\textsuperscript{231} See id. (reporting that Part B financing, although adequately financed at present, would have to increase rapidly to meet expected future needs, and to keep assets at an appropriate level).

\textsuperscript{232} See Sean R. Tunis, Economic Analysis in Healthcare Decisions, 10 AM. J. MANAGED CARE 301, 304 (2004) ("A decision-making framework that explicitly includes economic analysis would enable us to adopt explicit and consistent reimbursement guidelines that link healthcare benefits to the amount paid."); see also Fox, supra note 81, at 632 (2005) (calling for congressional action to
making as it relates to individual patients is problematic. Yet, it is incumbent upon Congress, after robust public debate, to address the issues of cost and cost-effectiveness, and not for CMS to implicitly ration care by restricting coverage of certain expensive technology to clinical trials, as it is doing with CSP. Rationing may well be unavoidable if we are to preserve Medicare, but Congress, not CMS, bears responsibility for bringing the issues to the forefront for public debate. Congress, and not CMS, must face the hard question of how to pay for our future.

guide Medicare as to “how Congress expects it to grapple with extremely expensive, medically effective technology,” including the role of cost-effectiveness as well as the absolute costs of new technology in its coverage process; Alan M. Garber, Cost-Effectiveness and Evidence Evaluation As Criteria for Coverage Policy, HEALTH AFF., W4-284 (May 19, 2004), http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.284v1. One expert notes that cost-effective analysis is actually a significant influence on health care policy, but in a manner characterized as “cost effectiveness once removed.” Peter J. Neumann, Why Don’t Americans Use Cost-Effectiveness Analysis?, 10 AM. J. MANAGED CARE 308, 311 (2003) (stating that cost-effectiveness analysis is used “only at a safe distance,” and that “rationing is permitted under the radar”).

233. Tunis, supra note 232, at 304. Dr. Tunis explains that when applied to an individual patient, such as someone’s child or other loved one, cost-effectiveness analysis is problematic because the underlying logic of a decision based on medical necessity is that the benefits for the patient will outweigh the risks, but the underlying logic of cost-effectiveness analysis is that a patient may be denied a potentially beneficial intervention because the procedure is simply too expensive. Certainly several high-cost medical procedures that today are covered by Medicare would likely not have been covered were CMS to weigh cost-effectiveness analysis in its coverage criteria. See Gillick, supra note 117, at 2199. In her article, Dr. Gillick looks at the actual cost of three procedures that were ultimately covered by Medicare—lung-volume-reduction surgery, implantable cardioverter-defibrillators, and left ventricular assist devices. She then applied standard cost-effectiveness analysis to each of the three procedures, concluding that under this analysis, CMS would not have approved coverage of either lung-volume-reduction surgery or implantation of the left-ventricular assist device. Id. at 2202.