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Repository Citation
(2002) "Medicare Reasonable and Medically Necessary Care: Skirmishes at the Front," Marquette Elder's Advisor: Vol. 4: Iss. 1, Article 8.
Available at: http://scholarship.law.marquette.edu/elders/vol4/iss1/8

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**Medicare Reasonable And Medically Necessary Care: Skirmishes at the Front**

By Journal Staff

Medicare covers health care costs for reasonable and necessary health care. In contrast, coverage excludes any care that is experimental, investigatory, or unproven. Coverage is also limited by the rules determining the scope of health care. For example, Medicare does not cover dental services or cosmetic surgery. These two examples are central to the controversies about coverage that mark the limits to Medicare and the numerous exceptions that authorize Medicare payment.

**Experimental, Investigative, Or Unproven**

These exclusions might apply to experimental, investigatory, or unproven care. Medicare carriers have discretion to authorize payment for treatment of complications arising from the use of such devices. In 2000, however, the Health Care Financing Administration (HCFA), renamed in 2001 the Center for Medicare and
Medicaid Services (CMS), published a change of policy that authorizes payment for many services provided in certain clinical trials conducted by government agencies including the National Institutes of Health, and under the auspices of the National Cancer Institute. This authorization may include new drugs or drug applications. Other trials might qualify if the researcher has furnished CMS the required information. The scope of coverage remains limited, in that the investigational item or service is not covered. Other noncovered items include tests conducted solely to determine statistical information for the purposes of the study, and anything furnished without charge by the researchers. Otherwise, Medicare covers all the health care items and services provided to such patients.

With regard to investigational medical devices, CMS generally follows the approval process of the Food and Drug Administration (FDA). However, the agency also authorizes payment for devices not approved by the FDA that it considers them to be “non-experimental, investigational” devices, provided they are used in clinical trials approved by the FDA.

A case illustrates the progress of a familiar technology from “experimental, investigative, and unproven” to “reasonable and necessary.” In Goodman v. Sullivan, the patient underwent an MRI (magnetic resonance imaging) procedure on February 8, 1985, to determine the cause of a speech impediment. He was aware at the time that the MRI was not approved for payment under Medicare for this purpose because it was considered to be experimental and unproven. In November of the same year, the Secretary of HHS approved coverage of the MRI procedure. Goodman brought a claim for recovery of $675 for his MRI.

Goodman argued that the Medicare program is required by law to cover all care that a physician determines to be medically necessary, citing statutory language that is phrased in the negative: Medicare need not cover items and services “not reasonable and necessary for the diagnosis or treatment of illness or injury.”

Goodman relied on a Medicaid case, Rush v. Parham, construing medical necessity in procedures relating to a sex-change operation. The court distinguished the two programs, and found that in any case, a regulation “may adopt a definition of medical necessity that places reasonable limits on a physician's discretion ... [such as] a ban against reimbursement for experimental forms of treatment...”

The court considered the impact of such a denial on health care and medical practice, in response to Goodman's argument that the decision conflicted with federal law: “Nothing in this subchapter shall be construed to authorize any Federal office or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided...” The court first observed that the statute did not control the practice of medicine; rather, it limited Medicare reimbursement. The purpose of the limitation, according to the court, was not to stifle technological change, to favor one procedure over another, or to influence the judgment of medical professionals.

The court observed that the date of the Secretary's approval, seven months after Goodman's MRI, was reasonable given the mandate to execute faithfully the mandates of the Medicare statute. It observed that the Secretary "necessarily must paint with a broad brush" in distinguishing reasonable and necessary from experimental. Thus, the Secretary had carried out her responsibilities and, implicitly, the date upon which HHS approved the payment is the date after which MRI procedures for Medicare beneficiaries are covered.

An analogous circumstance, with a twist, arose in Yale-New Haven Hospital v. Thompson, in which the hospital sought reimbursement for $1,500,000 in services the Secretary had denied pursuant to a superceded guideline. The hospital had provided surgical implantation of experimental medical devices provided by the hospital to Medicare beneficiaries. The hospital also sought invalidation of the guideline. The court refused to dismiss on the Secretary's motion claiming collateral estoppel on procedural grounds, and remanded to hear arguments on the merits of the hospital's claims.

When a guideline is valid and applicable, it is most likely to determine the outcome, though the distinction between covered and noncovered services is slight. In Matthews v. Shalala, the plaintiff-patient sought review of denial of her claim for coverage of home oxygen therapy. Her doctor had prescribed home oxygen therapy to alleviate her medical condition, known as multiple chemical sensitivity syndrome. The Medicare insurance carrier terminated the
benefit pursuant to a national coverage decision made pursuant to a federal rulemaking procedure. The court found that the drafters of the national coverage determination intended to reimburse oxygen therapy costs only for those persons suffering from hypoxemia, and that the rulemaking was not promulgated in an arbitrary manner. Thus, coverage was effectively limited though the plaintiff's condition had not been specifically considered, and her motion for remand to the commissioner to supplement the rulemaking was denied.

**Services Not Normally Covered and Exceptions**

Certain classes of care, such as dental care, lie outside the scope of Medicare coverage. However, some such services might be covered if they are necessary in order to provide safe and effective care that is covered by Medicare.

In *Wood v. Shalala*, the patient-plaintiff required heart valve replacement. His infected teeth presented a threat to health if the surgery proceeded without removal and cure of the condition. Wood had fourteen of his teeth removed by his dentist in an office procedure. Shortly thereafter, Wood underwent heart valve replacement surgery. His surgeon stated that he would not have done the valve surgery if the teeth had not been removed, because of the risk of infection. The bill for the tooth extractions was $1,156. The Secretary denied coverage and the District Court affirmed.

The court of appeals decision is a catalog of exceptions, both general and specific, that relate to such ancillary services and can trigger Medicare coverage despite the general prohibition on dental coverage. The court agrees with plaintiff Woods that the interpretation of the Medicare statute is ambiguous because the Secretary gives no reasons for the exceptions. There it considers the list in order to determine whether the Secretary's interpretation is reasonable, in light of the plaintiff's arguments that the interpretation in his case is inconsistent with prior interpretation; and that the rationale behind prior exceptions, to decrease the chance of infection and increase the chance of successful surgery, applies here.

The first exception plaintiff put forward is the "same physician rule" that authorizes payment for services by an oral surgeon during the course of a covered surgery, though the specific services would not normally be covered. Clearly, Wood did not have his extractions done by the same surgeon. Under a factual variation on the "same physician rule" identified by the Court of Appeals, the patient might receive services performed by a dentist "at the same time as the surgical removal of a tumor" and "the totality of the surgery would be a covered service. The court finds, in agreement with the administrative law judge (ALJ), that the exception does not apply in Wood's case, in which two physicians, a dentist and a surgeon, did separate procedures at separate times in separate locations.

Two corollaries to the "same physician" rule take into account work by another physician in association with some covered physician service. One is dental care in preparation for radiation of the jaw. Another is inpatient dental examination conducted in preparation for kidney transplant surgery. The ALJ held that neither exception applied to the facts of the case, both being specific to an identified procedure and, for the second, also limiting the service to examination only. The Court of Appeals concurred, noting that ESRD is a special case among all Medicare services.

Wood also argued that Part B pays for "otherwise covered services" furnished by a doctor of dental surgery or dental medicine if those services would be covered as physician services when provided by a doctor of medicine. The court notes the Secretary's argument that interpreting the "otherwise covered" provision as Wood suggests might allow coverage of many dental services that might be covered if provided by a medical doctor. Also, the court notes that the provision expressly states that the exclusion of dental services remains in effect. Without endorsing all the Secretary's arguments as effective, the court nevertheless concludes that the "otherwise covered" provision does not extend to Wood's dental extractions.

The specific exceptions argued by attorneys of the Wisconsin Coalition on Aging become increasingly interesting in their number and variety. A federal program of Rural Health Clinics and Federally Qualified Health Centers defines an exception for dental services in its manual: "A dental examination for patients requiring certain complex surgical procedures may be covered. To date, the only identified procedures for which dental examinations are covered are kidney transplants and heart valve
replacements.” The court notes that Wood was not a patient of the programs covered by the manual. The specific reference to heart valve replacement prompts the court’s comment:

…the reference to heart valve replacements indicates their specific inclusion within the general exception to the exclusion for examinations in connection with surgical procedures. While this reference lends some weight to Wood’s argument, it appears in an isolated corner of the administrative provisions and is not strong enough to prevail over the authority to the contrary.20

Further, notes the court, only examination, not treatment, is authorized.

A Wisconsin program initiated in 1996 also would have brought Wood’s dental extractions under Medicare, since the program specifically provides “Medicare coverage of dental extractions due to infections prior to heart valve replacement surgeries.” The court observes that Wood received care in Michigan, not Wisconsin, and that, in any case, he had the procedure before the implementation of the Wisconsin coverage.21

Wood argues a Social Security decision that seems to support his claim, in which the patient had to have all his infected teeth removed prior to implantation of a defibrillator. The court quotes the ALJ’s holding that the extractions were covered by Medicare because of “an exception to the dental services exclusion in the regulations because the dental work was required secondary to a severe heart condition.”22

Wood argues the legislative history of the Medicare provisions, citing the committee bill that makes a specific exclusion of dental services. Wood notes, however, that the committee intended that only “complex surgical procedures” should be covered. The court rejects the idea that Wood’s extractions, at least in themselves, amount to a complex surgical procedure. Wood has finally exhausted his quiver of arguments and his claim is denied because Medicare does not cover dental services.

The road to coverage for a service typically excluded from Medicare coverage seems to be paved with quite specific language. However, not all cases are as resistant as Wood’s. In Stein v. Secretary of HHS,23 the patient was denied coverage for her inpatient hospital rehabilitation program because it was not reasonable and necessary. The applicable rule 85-2 states that a patient in need of inpatient hospital rehabilitation requires all of the following:

1. close medical supervision by a physician with specialized training or experience in rehabilitation;
2. twenty-four-hour rehabilitation nursing;
3. a relatively intense level of physical therapy or occupational therapy and, if needed, speech therapy, social services, psychological services, or prosthetic-orthotic services;
4. a multi-disciplinary team approach to the delivery of the program;
5. a coordinated program of care;
6. significant practical improvement;
7. realistic goals; and
8. a properly terminating program.

On appeal, the district court reversed the agency determination, holding that the rule was a factor to be considered if the attending physician and the Utilization Review Committee were not in agreement. In Mrs. Stein’s case, the physician and utilization review committee agreed on the appropriateness of in-patient care. Finally, the court vacated and remanded the decision to the district court because it had not applied the rule to the facts of the case, providing the court of appeals an inadequate basis for review.

On the other hand, in Chipman v. Shalala,24 the patient had jaw bone augmentation surgery, which later permitted the placement of porcelain veneer crowns. The claimant submitted Medicare claims for payment of both the surgery and the crowns. The ALJ concluded that payment for the bone augmentation surgery was covered by Medicare but that the porcelain veneer crowns were not. Chipman filed a complaint in federal district court, which affirmed the agency’s decision. On appeal, the federal district court affirmed, holding that there was no evidence that the crowns were medically necessary.

Endnotes

1. 42 U.S.C. § 1395y(a). The phrase often used is “reason-able and medically necessary”.
2. 42 U.S.C. § 1395hh(a) (authorizing the Secretary of Health

3. 42 C.F.R. § 405.207.


5. Coverage Issues Manual Sec. 30-1. The original rules with regard to clinical trials of medical devices, which apply to all that do not qualify under the exception, are found at 42 C.F.R. §§ 405.201 - 405.215, 411.15(o).

6. 891 F.2d 449 (2nd Cir. 1990).

7. Note that this phrase represents the justification for Medicare's failure to provide any preventive services unless specifically authorized by law.

8. 625 F.2d 1150 (5th Cir. 1980).

9. Id. at 1154-55.


11. Such rhetoric might be less persuasive today, when reduced fee for service and prospective payment are, at least in part, intended to influence the physician recommendations and patient choices.


14. Other classes of services not normally covered include routine physical checkups and examinations for insurance and employment, eye exams and glasses, hearing aids, immunizations (except for certain authorized services for pneumonia, influenza and sometimes hepatitis B), orthopedic shoes (except for some shoes for persons with diabetes), cosmetic surgery (except in cases of accidental injury or in order to improve the function of the affected body member), and routine foot care.

15. 246 F.3d 1026 (7th Cir. 2001).


17. Id. at 1029.

18. A third exception, a covered medical procedure performed by the same physician doing the dental work, is noted by the court, but seems entirely inapplicable to the facts.

19. Id. at 1032.

20. Id. at 1033.

21. Id.

22. Id. at 1034.

23. 924 F.2d 431 (2nd Cir. 1991).

24. 90 F.3d 421 (10th Cir. 1996).