

PARTNERSHIP
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Better Lives for People with **Chronic Conditions**

*Medical Necessity Determinations in the Medicare Program:
Are the Interests of Beneficiaries With Chronic Conditions
Being Met?*

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PREFACE

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EXECUTIVE SUMMARY

Of the nearly 40 million Medicare beneficiaries, over three-quarters (78%) have at least one chronic condition which requires ongoing medical care and management. Almost two-thirds (63%) have two or more chronic conditions, and twenty percent of Medicare beneficiaries have five or more chronic conditions. Thus, access to medical services that addresses the needs of people with chronic conditions is critical for the majority of Medicare beneficiaries.

Medicare confers on its beneficiaries entitlement to broad categories of medical services. The program has developed a myriad of rules specifying particular medical items and services for which the program will or will not make payment, either for all beneficiaries or for beneficiaries in specific circumstances. Most of these rules are not found in the Medicare statute and regulations. They are set out in program manuals and National Coverage Determinations developed by the Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, or in local coverage policies, called Local Medical Review Policies (LMRPs) developed by CMS' local contractors. Where the Medicare statute is silent, an NCD may be developed to state, on a national basis, whether Medicare will cover a particular item or service, and the population for whom it may be covered. If no NCD has been issued, or an NCD requires further clarification, an LMRP may be developed to determine initial Medicare coverage for an item or service, or to determine medical necessity in an individual claim. An LMRP may also serve as a program integrity tool to prevent inappropriate payment of Medicare funds.

Medicare standards for making medical necessity determinations in individual cases do not always address the particular needs of beneficiaries with chronic conditions. Chronic care differs from acute care, where the treatment goal is improvement and/or cure, and end of life care, where the treatment goal may be palliation. The goal for a patient with chronic conditions may be to prevent deterioration and/or to maintain functioning. A patient with one or more chronic conditions may have a medical need for, and accepted medical and nursing practice may require, observation and assessment, therapeutic care, and care management on an on-going basis.

Nevertheless, for certain services, such as outpatient therapy services, Medicare's policies impose improvement standards that are inconsistent with the statute. The Medicare statute does not demand a showing of improvement to find services medically necessary or to cover treatment of an illness or injury. The statutory criterion for treatment of an illness or injury applies regardless of where the covered service is provided, be it in a skilled nursing facility, at home, or as an outpatient.

Even when Medicare rules currently address the treatment requirements of beneficiaries with chronic conditions, those rules and the language of the statute are not always followed. For example, Medicare regulations and policy manuals governing skilled nursing facility and home health care acknowledge that services may be required to maintain ability or prevent deterioration. Despite the clarity of the regulations, Medicare providers and contractors sometimes impose an improvement standard and deny care when the beneficiary's condition is stable or when maintenance services are needed.

Medicare policies concerning medical necessity determinations in individual claims should be revised to recognize that the overwhelming majority of beneficiaries have at least one chronic condition whose method of treatment and treatment goal are different from the method of treatment and treatment goal for an acute illness or injury. In this regard:

- Improvement should not be a medical necessity criterion used to determine a patient's claim unless the service at issue relates to a malformed body member.
- Maintenance of ability, prevention of deterioration, and patient education should be recognized as treatment goals for beneficiaries with chronic conditions.
- Beneficiaries with multiple chronic conditions should be allowed to demonstrate a need for ongoing services in order to obtain more services or services for a longer period of time than set forth in local policies.
- The medical necessity analysis should not be dependent upon payment policies.

To accomplish these goals, Medicare manuals and other policies need to be reviewed to assure that they meet the above criteria and that they do not conflict with the Medicare statute and regulations. Agency policies also need to be reviewed on a regular basis to assure that they comport with changes in medical knowledge and practice.

CMS is beginning to review local policies and to establish procedures to assure that they are consistent with current medical practice and knowledge as well as with agency regulations and guidance. CMS plans to improve beneficiary notices to include information about why a claim was denied. The agency also plans to establish a data system that allows it to track the reasons for a claims denial so that the agency can identify and address problem areas.

The Medicare statute provides coverage for an array of services to address many of the needs of beneficiaries with multiple chronic conditions. The services are available as long as they are reasonable and necessary for the diagnosis or treatment of the particular beneficiary's individual illness or injury. CMS needs to assure that the statute is interpreted properly so that Medicare beneficiaries with chronic conditions are able to obtain the medical care they require.

I. INTRODUCTION

Medicare is a federal program which provides health insurance to people age 65 and older who are eligible for social security benefits, people younger than age 65 who have received social security disability benefits for twenty-four months, people with end-stage renal disease (ESRD) and ALS. Of the nearly 40 million Medicare beneficiaries, over three-quarters (78%) have at least one chronic condition which requires ongoing medical care and management. Almost two-thirds (63%) have two or more chronic conditions, and twenty percent of Medicare beneficiaries have five or more chronic conditions.¹ Thus, access to medical services that address the needs of people with chronic conditions is critical for the majority of Medicare beneficiaries.

The Medicare program itself has a strong interest in the care provided to people with chronic conditions, since the program expends more funds per beneficiary as the number of chronic conditions increases. The Standard Analytic File (SAF), Centers for Medicare & Medicaid Services, 1999, indicates that the average per person cost to Medicare, taking into account all beneficiaries regardless of age and eligibility category, was \$4,200. Average costs per beneficiary ranged from \$160 for beneficiaries without chronic conditions, to \$13,700 for beneficiaries with five or more chronic conditions. Medicare expends 66% of its funds on the latter group, who comprise 20% of Medicare beneficiaries.²

The Medicare statute, 42 U.S.C. §§1395 et. seq., confers on its beneficiaries entitlement to a broad range of specific medical services. Medicare Part A, hospital insurance, provides coverage for in-patient hospital services, skilled nursing facility services, some home health care, and hospice services. Part B, "... the voluntary supplemental plan ...provide[s] protection that builds upon the protection provided by the hospital insurance plan. It cover[s] physicians' services, additional home health visits, and a variety of other health services, not covered under the hospital insurance plan."³

Although the statute generally discusses coverage of broad categories, some items and services are set forth with particularity.⁴ For example, the statutory definition of home health services refers to nursing care, physical or occupational therapy or speech-language pathology, medical social services, home health aides, and medical supplies.⁵ The statutory definition of durable medical equipment specifies that the term includes iron lungs, oxygen tents, hospital beds and wheelchairs, as well as blood-testing strips and blood glucose monitors for people with diabetes. The term includes the seat lift mechanism but not the seat-lift chair itself.⁶ Over the years, as

¹ Robert Berenson, Jane Horvath, *The Clinical Characteristics of Medicare Beneficiaries and Implications for Medicare Reform*, Coordinated Care Conference (Washington, D.C., March 22, 2002) at 4.

² Berenson and Horvath at 6,7.

³ Senate Report 89-404.

⁴ See 42 U.S.C. §§1395x,1395y.

⁵ 42 U.S.C. §1395x(m).

⁶ 42 U.S.C. §1395x(n).

medical care changed and the public began to focus on the need for preventive services, Congress expressly added coverage of mammography, prostate cancer and colorectal cancer screenings, and flu, pneumonia and hepatitis B vaccines.⁷

Medicare's statutory exclusions from coverage are well known. Medicare does not pay for routine physical checkups, regular eyeglasses, or hearing aids.⁸ It does not cover custodial care, cosmetic surgery, or routine dental care.⁹ Much attention has been focused over the last several years on Medicare's failure to cover out-patient prescription drugs, and whether and in what manner to include such coverage as a part of the Medicare benefit.

The most expansive exception to payment is found in the statutory prohibition of payment "for items and services... not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member".¹⁰ Congress did not give any specific mandate on how to decide what is "not reasonable and necessary." Instead, what Congress did was to "sketch Medicare benefits in broad brush strokes" and vest power in the Secretary of Health and Human Services to decide what is "medically necessary."¹¹ In other words, Congress was more concerned with what would be covered under the Medicare program rather than when the program would pay for the covered services enumerated in the statute.

As with all insurance programs, the distinction in Medicare between what is a covered service and when it is considered medically necessary is crucial. Not all covered services may be medically necessary for all Medicare beneficiaries at all times. For example, hospitalization is not medically necessary for a beneficiary exhibiting no acute medical symptoms. Medicare therefore will not pay for hospital services for that beneficiary even though Medicare Part A covers hospitalizations. The concept of medical necessity can be particularly problematic for beneficiaries with chronic conditions, especially when health coverage is designed in an acute care model that does not adequately consider preventive services or services designed to maintain health or functional status.

The policy memos, analyses, and court cases that consider coverage and medical necessity often blur the distinction. Coverage policies that address whether Medicare should pay for a specific item or service under a broader category of Medicare coverage may also include discussions of when the item or service would be reasonable and necessary in individual situations. For the Medicare beneficiary, the distinctions are often unknown and unclear.¹²

The Secretary of Health and Human Services delegated to the agency that administers the Medicare program, the Centers for Medicare & Medicaid Services (CMS), formerly called the

⁷ 42 U.S.C. §§1395y(a)(1), 1395x(s)(1).

⁸ 42 U.S.C. §1395y(a)(7).

⁹ 42 U.S.C. §§1395y(a)(9),(10), (12).

¹⁰ 42 U.S.C. 1395y(a)(1)(A).

¹¹ Bosko v. Shalala, 995 F.Supp.580, 583 (W.D. Pa. 1996).

¹² Coverage refers to policies affecting categories of services or patients. Medical necessity refers to decisions affecting the individual patient.

Health Care Financing Administration (HCFA), the authority to make both coverage and medical necessity determinations. CMS, in turn, has delegated some of its authority to its contractors that review initial claims—the fiscal intermediaries (FIs) that review Part A claims, the carriers that review Part B claims, the regional home health intermediaries (RHHIs) that review home health claims, and the durable medical equipment regional carriers (DMERCs) that review claims for durable medical equipment and supplies. Hospital utilization review committees determine whether a hospital stay remains medically necessary. In essence, when a contractor reviews a claim to determine whether the claim should be paid, the contracting entity first determines whether the service in question is a Medicare-covered service and then determines whether the service is medically necessary for the particular beneficiary.

In determining whether Medicare coverage for a category of services exists, the Medicare contractor looks to the statute and to other Medicare guidance, including the Medicare agency’s policy manuals and transmittals. Where the statute is silent, CMS may issue a National Coverage Determination (NCD) that states, on a national basis, whether Medicare will cover a particular item or service, and the population for whom it may be covered. An NCD may provide for Medicare coverage, and therefore payment, under all circumstances; preclude coverage, and therefore payment, in all circumstances; or provide coverage under specified situations delineated in the NCD. NCDs as statements of Medicare coverage have the same effect as the statements of coverage found in the Medicare statute. Once an NCD is issued, the policy is binding on all Medicare contractors.¹³

If no NCD has been issued, or an NCD requires further clarification, Medicare carriers and intermediaries may develop Local Medical Review Policies (LMRPs).¹⁴ LMRPs do not have the same legal effect as NCDs; they are not binding on administrative law judges (ALJs) in administrative appeals. They may be used as determinations of initial Medicare coverage for an item or service, as medical necessity determinants in individual claims, or importantly, as program integrity tools to prevent inappropriate payment of Medicare funds.

Thus, the Medicare program has developed a myriad of rules specifying medical items and services for which the program will or will not make payment, either for all beneficiaries or for beneficiaries in specific circumstances. Most of these rules are not found in the Medicare statute and regulations, but are set out in program manuals or in sporadic publications of local contractors. This paper reviews the standards and processes for making medical necessity determinations in the Medicare program. It begins with an overview of the national and local coverage determination process, and then addresses issues pertinent to Part A and Part B. The

¹³ 42 U.S.C. § 1395ff(f) .

¹⁴ The Beneficiaries Improvement and Protection Act of 2000 (BIPA) defined the local policies as local coverage determinations (LCDs). According to a proposed rule issued by CMS, LCDs are narrower than LMRPs in that they only address medical necessity determinations, and do not include the guidance on coding and payment also included in LMRPs. 67 Fed. Reg. 54534 (Aug 22, 2002). Most LMRPs, however, will fall within the statutory definition of LCD. 42 U.S.C. 1395ff(f)(2). This paper uses the term “LMRP” as that is the term used by local contractors for the policies they issue.

paper will address barriers to receipt of care and make recommendations on how to improve the system. Comments are based on the experiences of the Center for Medicare Advocacy, Inc., representing Medicare beneficiaries with chronic and other conditions who have been denied access to care.¹⁵

II. National and Local Coverage Determinations

As stated above, National Coverage Determinations (NCDs) are specific rules that have been adopted by the Medicare administration (now CMS) concerning items and services that will or will not be covered for all or specific populations of Medicare beneficiaries.¹⁶ NCDs may be initiated by carriers, intermediaries, CMS staff, members of the public, providers, and suppliers. When developing NCDs, CMS consults with medical specialists, literature, and health policy analysts. In 1998 the Medicare administration established the Medicare Coverage Advisory Committee (MCAC) to provide input from public experts concerning evidence-based medicine standard for coverage.¹⁷ CMS also must specifically afford the public the opportunity to comment before implementation of a new NCD.¹⁸

CMS bases its statutory authority to issue NCDs on the "reasonable and necessary" section of the statute, 42 U.S.C. § 1395y(a)(1)(A), S.S.A. § 1862(a)(1)(A).¹⁹ The only statutory definition of National Coverage Determination, recently added to a different section of the statute by the Medicare, Medicaid, SCHIP Benefits Improvement Act of 2000 (BIPA),²⁰ refers to coverage and not medical necessity. No reference is made to the authorizing statutory section:

the term 'national coverage determination' means a determination by the Secretary [of the Department of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under this subchapter, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this subchapter or a determination with respect to the amount of payment made for a particular item or service so covered.²¹

¹⁵ In its fiscal year ending June 30, 2001, the Center for Medicare Advocacy responded to 6439 inquiries from its "1-800" telephone number, and formally opened 275 new cases for Medicare beneficiaries who are not also eligible for Medicaid. In addition, Center staff gather information about beneficiary experiences through training, responses to direct inquiries from attorneys and other advocates, web site postings, and work with other advocacy organizations.

¹⁶ NCDs are indexed in the Coverage Issues Manual. See www.cms.hhs.gov/coverage_or_www.cms.hhs.gov/pubforms/progman.htm.

¹⁷ 63 Fed. Reg. 68780 (Dec. 14, 1998). MCAC was established in response to Congressional and public pressure for a more open process for making Medicare NCDs.

¹⁸ 42 U.S.C. §1395y(a).

¹⁹ Some NCDs, primarily those concerning medical equipment, are based on 42 U.S.C. § 1395x(n).

²⁰ Pub. L. 106-554, 114 Stat. 2763. (December 21, 2000).

²¹ 42 U.S.C. § 1395ff(f)(1)(B).

BIPA also added to the statute a definition of Local Coverage Determination (LCD). LCDs refer to portions of policy issuances more commonly known as local medical review policies (LMRPs).²² The definition indicates that the issuing Medicare contractors must look to the medical necessity section when promulgating such a determination:

the term ‘local coverage determination’ means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A) of this title.²³

The definitions were included in a new statutory section creating procedures to challenge NCDs and LCDs that was to have become effective on October 1, 2001 but will not become effective until final rules are published.²⁴ CMS issued proposed regulations to implement the new section on August 22, 2002.²⁵ The proposed regulations broaden the definition of NCD to include national coverage determinations issued pursuant to all sections of the Medicare statute, and not just the medical necessity section. The proposed rules also distinguish between LMRPs and LCDs. LCDs only address medical necessity determinations; those portions of an LMRP that address coding and payment issues would not be considered an LCD subject to review under the new procedure.

Coverage and subsequent medical necessity determinations are complicated and difficult to make. CMS has tried unsuccessfully over the years to issue regulations to establish a process for determining when and how NCDs and LMRPs should be issued. In 1987, pursuant to the settlement of a class action lawsuit,²⁶ the Medicare agency, then called HCFA, published a notice in the Federal Register describing the procedure then used to deny coverage of classes of services determined to be “not reasonable and necessary.”²⁷ In January 1989 HCFA issued a proposed regulation setting forth the standards that would be used in the future in making the reasonable and necessary determination.²⁸ The standards, which included safety and effectiveness, experimental or investigational status, appropriateness of the setting, and, for the first time, cost-effectiveness, generated such adverse reaction from beneficiaries, manufacturers and providers that the proposed rule was never made final.

Ten years later, in April 1999, HCFA published a description of the process it uses to make NCDs. HCFA also officially acknowledged that it was not going to adopt the proposed regulation of January 29, 1989, and that the agency intended to promulgate with public comment the substantive criteria that it would use for making NCDs. The agency published a Notice of

²² See footnote 15, *supra*.

²³ 42 U.S.C. § 1395ff(f)(2)(B).

²⁴ CMS Ruling 01-01 (Sept. 2001).

²⁵ 67 Fed. Reg. 54534 (Aug. 22, 2002).

²⁶ *Jameson v. Bowen*, [1987 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 36,703 (E.D.Cal. 1987).

²⁷ 52 Fed. Reg. 15560 (April 29, 1987).

²⁸ 54 Fed. Reg. 5302 (Jan. 30 1989).

Intent to Publish a Proposed Rule on May 16, 2000, describing the criteria for developing both NCDs and LMRPs.²⁹ Instead of focusing as it had done previously on whether a service is experimental, investigational, or not generally accepted, HCFA proposed focusing on evidence of the effectiveness of the item or service. The Notice of Intent raised the issue of cost-effectiveness again by looking at “added value.” The agency proposed that where the new treatment does not represent an improvement in treatment effectiveness, then the new treatment would be covered only if it will result in equivalent or lower total costs than covered alternative treatments of equal or better effectiveness. Finally, the notice discussed a new “medical benefit” criterion, and the need for information about how an item or service “improves” diagnosis or treatment, “improves” function, and results in “improved” health outcomes.

The 1999 approach raised questions for beneficiaries with chronic conditions. These beneficiaries require therapeutic services to maintain functioning or to prevent deterioration. How would such services be evaluated under a medical benefit criterion that looked at improvement? Would the added value to the beneficiary of a service that enables her to maintain her independence be considered in the same light as a new, less costly treatment for an acute condition?

No proposed rule has yet been issued to follow up on the May 2000 Notice of Intent. Recognizing the need for further clarification, CMS issued policy guidance through its manual provisions that helps explain the relationship between NCDs and LMRPs in making coverage determinations for categories of items and services and medical necessity determinations for individual beneficiaries. According to the Local Medical Review Policy Chapter of the Medicare Program Integrity Manual (PIM),

NCDs are developed by CMS to describe the circumstances for Medicare coverage for a specific medical service, procedure or device. NCDs generally outline the conditions for which a service is considered to be covered (or not covered) under § 1862(a)(1) [the reasonable and necessary section] of the Act or other application provisions of the Act.³⁰

An LMRP, on the other hand,

specifies under what clinical circumstances a service is covered (including under what clinical circumstances it is considered to be reasonable and necessary) and correctly coded. If a contractor develops an LMRP, its LMRP applies only within the area it services.³¹

The PIM also provides guidance to contractors in developing LMRPs. It suggests that contractors describe in the proposed LMRP the circumstances under which the service meets the reasonable and necessary requirement of the Medicare statute. A contractor may consider a service to be reasonable and necessary if the service is: 1) safe and effective; 2) not experimental or

²⁹ 65 Fed. Reg. 31124 (May 16, 2000).

³⁰ PIM, Chapter 13, §1.1 (Rev. April 5, 2002).

³¹ PIM, Chapter 13, §1.3 (Rev. April 5, 2002.)

investigational; and 3) appropriate: i.e., furnished in accordance with accepted medical standards, furnished in a setting appropriate to the patient's medical needs and condition, ordered and/or furnished by qualified personnel; meets but does not exceed patient's medical need, and at least as beneficial as an existing and available medically appropriate alternative.³²

Thus, the NCD addresses coverage of items and services under the Medicare statute. The LMRP specifies the particular clinical circumstances under which the item or service will be covered and/or the circumstances when the covered service will be deemed reasonable and necessary, and therefore paid for, by Medicare for a particular person within the area overseen by the contractor which issued the LMRP.

The agency issues National Coverage Determinations that are compiled in the Medicare Coverage Manual and on the agency web site. CMS utilizes its contractors and its program manuals to set the standards under which care will be paid for once it is provided. In issuing these standards, CMS and its contractors go through a much less formal process than used in rule making, in the past issuing guidelines without public input. Several standards may not take into account the special needs of people with chronic conditions. Some may not comport with language of the statute, and may in effect result in the denial of payment for items and services needed by these beneficiaries.

III. RESTORATION POTENTIAL

Claims for services that patients with chronic but stable conditions need to maintain their current capabilities may be denied as not reasonable and necessary because the patient is not expected to improve or has reached a plateau. Yet the Medicare statute, regulations and policy manuals allow for the provision of care in certain situations and in certain settings where the potential for restoration does not exist.

A. The Medicare Statute, Regulations, and Policy Manuals

The Medicare statute distinguishes between items and services for diagnosis and treatment of an illness or injury, on the one hand, and items and services to improve functioning of a malformed body member, on the other:

....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...*³³

Thus, in order for Medicare to pay for an item or service, it must be either: 1) reasonable and necessary for the diagnosis or treatment of illness or injury or 2) reasonable and necessary to improve the functioning of a malformed body member. The improvement standard applies only

³² PIM, Chapter 13, § 5.1C (Rev. April 5, 2002).

³³ 42 U.S.C. § 1395y(a)(1)(A).

in the second clause of the sentence, to those items or services that address the functioning of a malformed body member, for example, a club foot. Other items and services fall within the first clause, and must be measured in terms of their reasonableness and necessity for diagnosis or treatment.

Diagnosis and treatment are broad related medical concepts that connote more than just “improvement.” Diagnosis considers the nature of the disease or condition. A diagnosis involves the weighing of the probabilities of one disease versus another with similar symptoms, and it helps determine the cause or causes of the problem presented by the patient.³⁴ Before a treatment plan can be devised, the treating physician must first make a diagnosis.

Treatment involves the medical and/or surgical management of a patient in terms of medicines, surgeries, appliances, and remedies. The concept pertains to more than a plan to improve the condition or status of the patient; treatment must look at the disease and the patient as a whole.³⁵ Treatment strategies may differ based on the age and medical condition of the patient, patient preferences, and the stage and aggressiveness of the underlying medical disease or illness. They may involve the use of drugs or surgery, be symptomatic to relieve symptoms without curing the underlying disease. Treatment strategies may also be “supportive, building the patient’s strength.”³⁶ Because the majority of Medicare beneficiaries have multiple chronic conditions, treatment strategies that address their medical needs must take into account all of their illnesses and conditions, and may differ from individuals with fewer or different chronic conditions. Some of these strategies will be supportive and/or symptomatic, rather than curative, and aimed at maintaining health status or slowing the progression of the disease.

The application of the appropriate standard, incorporating the definitions of diagnosis and treatment, is crucial for people with chronic conditions. A chronic disease or condition is one that is expected to last a year or more, limit what one can do, and may require ongoing medical care.³⁷ Among the goals for chronic disease control are the alleviation of the severity of the disease and the prolongation of the patient’s life.³⁸ Treatment strategies should be designed to reduce the consequence of the disease, to prevent its progression, or to provide for some restoration of health or abilities.³⁹ “Improvement”--other than in terms of complete prevention of diseases caused by such lifestyles as smoking or unhealthy eating--is typically not feasible given the nature of chronic conditions.

³⁴ *Mosby’s Medical Dictionary* (4th Ed. 1994); Webster’s Encyclopedic Unabridged Dictionary of the English Language (1996); *Online Medical Dictionary* (2002) at <http://cancerweb.ncl.ac.uk/omd/index/html>.

³⁵ *Online Medical Dictionary* (2002) at <http://cancerweb.ncl.ac.uk/omd/index/html>.

³⁶ *Mosby’s Medical Dictionary* (4th Ed. 1994).

³⁷ Robert Berenson and Jane Horvath, *The Clinical Characteristics of Medicare Beneficiaries and Implications for Medicare Reform*, *supra*, note 1.

³⁸ Ross C. Brownson, Patrick L. Remington, James R. Davis, ed., *Chronic Disease Epidemiology and Control* at 3 (2d Ed. 1998) at 5.

³⁹ *Id.* at 8.

Medicare regulations make some mention of treatment requirements of people with chronic conditions. For example, the need for skilled nursing care provided in a skilled nursing facility or by a home health agency must be based solely on the unique condition of the patient, without regard to the patient's diagnosis, and whether the illness or injury being treated is acute, chronic, or terminal.⁴⁰ Similarly, agency guidance says that a patient's diagnosis should never be the sole factor in a medical necessity determination for services in these settings. In the context of home health services, the determination should consider whether the service is consistent with the nature of the illness or injury, the beneficiary's particular medical needs, and accepted standards of medical and nursing practice.⁴¹ The regulations and guidance also recognize the importance of care management as a part of treatment. Medicare coverage in a skilled nursing facility or for home health services is available for a beneficiary who needs and receives skilled observation, assessment, management of a care plan, or patient education services.⁴²

The Medicare regulations also provide that restoration or the need to show improvement should not be the determining factor for entitlement to coverage of therapy services in a skilled nursing facility or in a home care setting. In fact, they specifically provide for coverage of a maintenance program as a skilled service if it is necessary to prevent further deterioration or to preserve current capabilities. Coverage includes visits by the therapist to provide or supervise a maintenance program.⁴³ "The deciding factor is not the patient's potential for recovery, but whether the services needed require the skills of a therapist or whether they can be carried out by nonskilled personnel."⁴⁴

The Medicare policies concerning therapy services in an out-patient setting do not recognize the needs of people with chronic conditions as do the policies that apply to skilled nursing facilities and to home health care. Policies applicable in the out-patient setting may specifically look to the potential for improvement. They may not differentiate based on whether the services need to be provided by skilled personnel.

And even in the context of skilled nursing facility and home health care, providers and Medicare contractors sometimes do not follow the policies described above when determining whether to provide covered services to individuals with chronic conditions. They may not look at the unique condition of the individual, or they may apply an improvement standard, even where a beneficiary requires skilled care.

Chronic care differs from acute care, where the treatment goal is improvement and/or cure, and end of life care, where the treatment goal may be palliation. A patient with one or more chronic conditions may have medical need for, and accepted medical and nursing practice may require, observation and assessment, therapeutic care, and care management on an on-going basis.

⁴⁰ 42 C.F.R. §§ 409.32(b),(c); 409.44(a),(b)(3)(iii).

⁴¹ Pub. 11, Medicare Home Health Manual § 205.1 A.4.

⁴² 42 C.F.R. §§ 409.32, 409.33(a), 409.44(b). See, also, Pub. 11, Medicare Home Health Manual § 205.1 B.2.

⁴³ 42 C.F.R. § 409.44(c), Pub. 11, Medicare Home Health Manual § 205.2

⁴⁴ Pub. 12, Skilled Nursing Facility Manual, §§ 214.1, 214.3.A.

Medicare in some settings accommodates the treatment requirements of beneficiaries with chronic conditions. The accommodations need to be applied more consistently.

B. What Happens in Real Life

Despite the policy and legal directives, beneficiaries with chronic conditions may not get therapy and other services needed to maintain their functioning or to prevent further deterioration. People with such chronic conditions as multiple sclerosis, Alzheimer's disease and other dementias, and quadriplegia are particularly vulnerable to a denial of care. If their skilled therapy or nursing services are found to be "not reasonable and necessary," then these individuals lose access to medical care the physician who ordered the service believes to be medically necessary. They may also lose access to Medicare coverage, and therefore payment, for skilled nursing facility or home health care.

The experiences of beneficiaries who have contacted the Center for Medicare Advocacy, the Alzheimer's Association, and other organizations that represent Medicare beneficiaries demonstrate the problems encountered by people with chronic conditions. Many of these people have difficulty getting care they need at home or in a skilled nursing facility. For example:

- X A woman with Alzheimer's disease who resides in Houston is told that she cannot receive additional therapy because she is not improving. Her physical therapist, who believes the therapy helps maintain the woman's ability to walk and prevents deterioration, files a Medicare appeal on the woman's behalf.
- X A doctor ordered physical therapy for an individual with Alzheimer's disease in Illinois who had gait problems. When the therapist came to evaluate the individual, she determined that Medicare would not cover the therapy because of his dementia. As a result, the man lost the ability to walk and must use a wheelchair.
- X A 74 year old Massachusetts resident had a history of lumbar disc excision, eye surgery, circulatory problems with her legs resulting in amputation, and congestive heart failure. Her physician ordered home health aide visits and skilled nursing visits to assess her cardiovascular and circulatory status, medical compliance and safety at home. The intermediary found some of the visits to be covered but denied others as not requiring skilled care. After several years of appeal, an administrative law judge found that the services were skilled and needed to maintain the beneficiary's health and to prevent deterioration.
- X A 32-year old man with quadriplegia in Connecticut was denied coverage of skilled nursing visits ordered by his doctor to assess his cardiopulmonary, gastrointestinal and genitourinary status, as well as his self-care plan, his medication regimen and his mental status. Again, after numerous years of appeal, an administrative law judge determined that the services provided were skilled care and should have been covered. Although the man's condition had periodically stabilized, he required skilled intervention to prevent further deterioration in his overall health status. The ALJ stated that the fiscal

intermediary had ignored the great potential for rapid deterioration and the need for continuity of care.

- X The fiscal intermediary found some skilled nursing visits reasonable and necessary for a 90 year old Connecticut resident with senile dementia, residuals attributable to a stroke and incontinence, but denied other services during an approximate three week period when it deemed the man's condition to be stable. An administrative law judge stated that, while the man's condition had stabilized during the time frame, there was great potential for rapid deterioration due to the beneficiary's age and nature of his impairments, and the need for continuity of care made the skilled nursing services reasonable and necessary.

Beneficiaries who seek therapy services in an out-patient setting also may encounter difficulties. Often, Medicare contractors in denying claims for services rely on LMRPs that incorporate restoration requirements. For example, a New York LMRP that applies to physical medicine and rehabilitation modalities and procedures (PMM & R) provided in office or home settings (when the patient does not have Medicare home health services) contains the following standards in its General PMM&R Guidelines:

There must be an expectation that the condition or level of function will improve within a reasonable and generally predictable time, or the services must be necessary to establish a safe and effective maintenance regimen required in connection with a specific illness. If the patient's expected restoration potential would be insignificant in relation to the extent and duration of physical therapy services required to achieve such potential, the therapy would not be considered reasonable and necessary.⁴⁵

The next section of the LMRP further indicates that restoration potential is a factor in the establishment of a safe and effective maintenance regimen:

1. Periodic evaluations of the patient's condition and response to treatment may be covered when medically necessary if the judgment and skills of a professional provider are required.

The following are examples of covered services:

- a. The design of a maintenance regimen required to delay or minimize muscular and functional deterioration in patients suffering from a chronic disease;
- c. The infrequent reevaluations required to assess the patient's condition and adjust the program.

⁴⁵ New York State Medicare Local Medical Review Policy PM0030E00, Phys. Medicine & Rehab., Eff. 8/331/02, www.lmrp.net/lmrp/carrier/2/00803/physicalmedicineandrehabilitation.htm.

2. Physical/occupational therapy that does not restore function, but is aimed primarily at maintaining function level does not meet Medicare's criteria for reimbursement. These situations include:

- b. Repetitive exercises to maintain gait or maintain strength and endurance, and assisted walking such as that provided in support for feeble or unstable patients; and,
- c. Range of motion and passive exercises that are not related to restoration of a specific loss of function, but are useful in maintaining range of motion in paralyzed extremities.
- d. Maintenance therapies rendered after the patient has achieved therapeutic goals or for patients who show no further meaningful progress. (emphasis added)⁴⁶

As a result, individuals with multiple sclerosis, who require therapy to maintain, rather than restore, functioning during the progress of their degenerative disease, have been denied access to physical therapy services in New York.

Organizations that represent or advocate for Medicare beneficiaries encounter similar problems on an on-going basis. The Medicare statute does not demand a showing of improvement to find services medically necessary and to provide for coverage when treating an injury or illness. The statutory criteria apply regardless of whether the covered service is provided in the skilled nursing facility, at home, or as an out-patient. Medicare regulations governing skilled nursing facility and home health care acknowledge that services may be required to maintain ability or prevent deterioration. Nevertheless, Medicare contractors may impose an improvement standard and deny care when the beneficiary's condition is stable or when maintenance services are needed. Beneficiaries who need such care must resort to the time-consuming appeals process to assure that the proper medical necessity criteria are applied to their claims for coverage.

IV. ITEMS AND SERVICES COVERED UNDER MEDICARE PART A

A. Skilled Nursing Facility Care

The Medicare statute and regulations are prescriptive in their description of coverage for skilled nursing facility (SNF) care. Coverage is limited to SNF admissions that follow a hospital stay of three days and extends no more than 100 days for each benefit period. The individual must require daily skilled nursing and/or rehabilitation services, and the skilled care must relate to the condition for which the patient was hospitalized.⁴⁷ Skilled nursing services include observation and assessment, overall management and evaluation of a patient's care plan, and patient education. Skilled rehabilitation services include ongoing assessment of rehabilitation needs and

⁴⁶ *Id.*

⁴⁷ 42 U.S.C. §§ 1395x(i), 1395d(a)(2).

potential, therapeutic exercises, range of motion exercises, and maintenance therapy.⁴⁸ If an individual is receiving one or more of the services listed in the Medicare regulations and policy manuals on a daily basis, the requirement for receiving daily skilled care is met per se.

In determining the medical necessity of SNF care, the Medicare agency must make an individualized assessment of the beneficiary's need for care based on the facts and circumstances of her particular case. Coverage cannot be denied on the basis of "arbitrary rules of thumb."⁴⁹ The total condition of the beneficiary must be taken into consideration. The regulations state clearly that restoration potential of the patient is not the deciding factor in determining whether skilled services are needed; skilled services may be required to prevent further deterioration or preserve current capabilities.⁵⁰

Nevertheless, individuals with chronic conditions may be more vulnerable to a denial of SNF coverage than individuals who require SNF care after hospitalization for an acute episode. As discussed in Section III, some beneficiaries who require rehabilitation services are inappropriately denied continued coverage of their SNF care if it is determined that their restoration potential is insufficient or that they have "plateaued." Also, Medicare may be reluctant to find that observation, assessment, and care plan management received by a patient with chronic conditions falls within the definition of skilled nursing services, even though those services are clearly identified in the regulations as skilled care. A patient's age, co-morbidities, mental impairment, safety, as well as professional staff involvement, are critical to a determination that the services received are skilled services. In addition, when treatment of a condition ordinarily does not require skilled services, the regulations state that Medicare may still find that skilled services are required because of a patient's special medical complications.⁵¹

The switch in 1999 to a prospective payment system (PPS) for SNF care adds another dimension to the medical necessity determination process. Although reimbursement policy is separate from medical necessity, reimbursement may play a role in both access to services and the amount of services a skilled nursing facility provides. In terms of access to services, the report by the Office of Inspector General in 2001 found, for example, that individuals requiring kidney dialysis, chemotherapy or radiation therapy were vulnerable to SNF denials because of PPS classification.⁵² When a skilled nursing facility denies admission to an individual based on the services she needs or her classification under PPS, she is also denied her right to an individualized assessment of the medical necessity of the SNF care ordered by her physician. More recently, in regard to the amount of services provided, the General Accounting Office (GAO) found that more patients' are classified into high and medium rehabilitation payment

⁴⁸42 C.F.R. §§ 409.33(a), (b), (c). The regulations also include examples of items that are personal care or custodial care services which do not satisfy the requirement that the services provided be skilled. 42 C.F.R. § 409.33(d).

⁴⁹ *Fox v. Bowen*, 656 F.Supp. 1236 (D.Conn. 1986).

⁵⁰ 42 C.F.R. § 409.32(c).

⁵¹ 42 C.F.R. § 409.32(b).

⁵² Office of Inspector General, *Medicare Beneficiary Access to Skilled Nursing Facilities 2001* (OEI-02-01-00160, July 2001).

categories because reimbursement in these categories is more favorable than in other payment groups. The GAO also found, however, that patients in all rehabilitation categories, including the two most common, received less therapy than was provided in 1999, before PPS went into effect. The amount of care declined 22 percent for those in the high and medium categories.⁵³

B. Home Health Services

Home health services are among the most critical services covered under Medicare for people with chronic conditions. Many home health users have multiple chronic conditions, requiring a multiplicity of services.⁵⁴ Unlike hospital and SNF care, there is no durational limit on the time for receiving home health services. A beneficiary may continue to be certified for home care under Medicare as long as she continues to meet the eligibility criteria.⁵⁵ Thus, when delivered appropriately, home health services provide the monitoring, the maintenance, the patient education, and the on-going care required by people with chronic care needs.

Medicare covers medically necessary home health services when: 1) the individual is confined to the home; 2) the individual needs skilled nursing care on an intermittent basis, or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need, but no longer needs such nursing care or therapy, the individual continues to need occupational therapy; 3) a plan for furnishing the services has been established and is periodically reviewed by a physician; and 4) such services are furnished by or under arrangement with a Medicare certified home health agency.⁵⁶

It is important to note at the outset that one of the biggest impediments to receipt of Medicare-covered home health services is caused by the homebound requirement⁵⁷ and not by a determination that services are not reasonable and necessary for the particular beneficiary. This is an important limitation for people with chronic conditions who could benefit from home health services to prevent deterioration to the point of becoming homebound.⁵⁸

⁵³ GAO, *Skilled Nursing Facilities: Providers Have Responded to Medicare Payment System by Changing Practices*, pg 3 (GAO-02-841, August 2002).

⁵⁴ GAO, *Medicare Home Health Care: Prospective Payment System Could Reverse Recent Declines in Spending* (GAO/HEHS-00-176, Sept. 2000) at 9.

⁵⁵ 42 C.F.R. § 424.22 (b). Recertification of the plan of care is required every 60 days.

⁵⁶ 42 U.S.C. § 1395f.

⁵⁷ In order to be homebound, the individual must not be able to leave the home without the assistance of another individual or a supportive device or leaving home must be contraindicated for her condition. Leaving home must require a considerable and taxing effort, and absences must be infrequent and of relatively short duration or to receive medical treatment. 42 U.S.C. §§ 1395f(a)(8), 1395(n)(a)(2)(F). Recently, Congress has added that a beneficiary may leave home to attend adult day care or religious services and still be considered homebound.

⁵⁸ Comments concerning the experiences of beneficiaries who require home health services are based on information developed by the Center for Medicare Advocacy from its own case records and from the records of other organizations that represent Medicare beneficiaries. Between April 1, 1986 and February 28, 2002, the Center for Medicare Advocacy closed 45,438 cases involving

Another eligibility barrier relates to the amount of services an individual beneficiary requires. The need for too much care can result in a determination of ineligibility for home health services because the beneficiary needs more than “intermittent” skilled nursing services. Yet the limitations on Medicare payment of SNF care - the three-day prior hospitalization requirement and the cap on the number of covered days - may preclude a beneficiary with chronic conditions from receiving Medicare covered services in an alternative setting as well.⁵⁹ Those who seek home health services because they require physical or speech therapy are not subject to the “intermittent” basis requirement.⁶⁰

Once eligibility has been established, the home health benefit may include: 1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse; 2) physical, occupational, or speech therapy; 3) medical social services under the direction of a physician; and 3) part-time or intermittent services of a home health aide. Medical supplies such as catheters and catheter supplies and ostomy bags, and durable medical equipment may also be provided.⁶¹

The skilled services available through the Medicare home health benefit parallel the services available in a skilled nursing facility; the regulatory provisions defining the benefit are related.⁶² Examples included in the Medicare Home Health Manual also help determine whether an individual requires skilled care and provide important parameters for making the medical necessity determination. According to the Manual, the beneficiary’s diagnosis should never be the sole factor in deciding that a service the beneficiary needs is either skilled or nonskilled. The determination of whether a beneficiary needs skilled nursing care should be based solely upon the beneficiary’s unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal or stable.⁶³

In regard to the service of a physical, speech, or occupational therapist, the Manual explains that the service is skilled if its inherent complexity is such that the service can be performed safely and or effectively only by or under the supervision of a skilled therapist. To be reasonable and necessary, the therapy must be consistent with the nature and severity of the illness or injury and the beneficiary’s particular needs. The amount, frequency, and duration of the services must be

claims for Medicare home health services for Medicare beneficiaries who were also eligible for Medicaid.

⁵⁹ 42 USC §§1395f(a); 1395n; 1395x(m); *Duggan v. Bowen*, 691 F.Supp. 1487 (D.D.C. 1988).

⁶⁰ The intermittent requirement also serves as a limitation on the number of hours of nursing and aide services a person may receive. 42 USC §§1395f(a); 1395n; 1395x(m); Medicare Home Health Agency Manual, § 206.7 A (HCFA Pub. 11). Though the statute defines the maximum number of hours of services available, some home health agencies attempt to put arbitrary caps on the amount of aide or other services a beneficiary may receive.

⁶¹ 42 U.S.C. § 1395x(m).

⁶² 42 C.F.R. §§ 409.33(c), 409.44(b).

⁶³ Medicare Home Health Agency Manual, § 205.1 A.4 (HCFA Pub. 11).

reasonable, and the services must be considered, under accepted standards of medical practice, to be specific and effective treatment for the patient's condition.⁶⁴

Advocacy organizations report that their clients who are deemed chronic, stable, in need of care to "maintain" their conditions, or who otherwise are not getting better or worse at a rapid pace may be told by their home health agency or by the regional home health intermediary (RHHI) which administers the claims that their home health services are not medically necessary. Under the regulations and the Manual, however, home health services may be medically necessary for an individual who is confined to the home and in need of intermittent nursing care or physical or speech therapy even if the individual is chronically ill or in need of care over an extended period of time.⁶⁵ Beneficiaries who require skilled therapy services are the most vulnerable to a charge that the services they need are not reasonable and necessary because of the beneficiary's failure to "improve." Such a determination may not be sustainable, however, under the Medicare statute, regulations, and manual provisions, as discussed previously in Section III.

As in other settings, the physician plays a pivotal role in the creation and delivery of Medicare home health services. Medicare law requires that home health services be furnished pursuant to a Plan of Care established and periodically reviewed by a physician.⁶⁶ Because beneficiaries with chronic conditions are more likely to need home health services for extended periods of time, they are more vulnerable when changes to care are made without physician concurrence.⁶⁷ The Center for Medicare Advocacy, Inc., and other beneficiary representatives have encountered the following situations:

- X home health agencies that terminate services that the physician believed to be medically necessary;
- X home health agencies that tell beneficiaries that services would not be provided even if re-ordered by the physician;
- X home health agencies that tell beneficiaries that their physician had changed the Care Plan or had signed a discharge order when they had not done so;
- X home health agencies that advise physicians that Medicare would not pay for covered services for patients who met the eligibility criteria;
- X home health agencies that discharge an eligible patient against the physician's orders and then represent to Medicare that the physician approved the discharge.⁶⁸

For these individuals, even though their physicians determined that home health services were still medically necessary for them, the home health agencies did not follow the physicians' orders.

⁶⁴ Medicare Home Health Agency Manual, § 205.2 B.1 (HCFA Pub. 11).

⁶⁵ 42 C.F.R. § 409.44(b)(3)(iii), Medicare Home Health Manual, § 205,1 A.4 (HCFA Pub. 11).

⁶⁶ 42 U.S.C. §§ 1395f(a)(2)(C); 1395x(m); 42 C.F.R. § 409.42(b), (d).

⁶⁷ Barbara Smith, Kathleen Maloy, Daniel Hawkins, *An Examination of Medicare Home Health Services: A Descriptive Study of the Effects of the Balanced Budget Act Interim payment System on Access to and Quality of Care* (George Washington University September 1999).

⁶⁸ See affidavits, amicus brief filed in *Healey v. Thompson*, 186 F.Supp.2d 105 (D.Conn. 2001), on appeal to the Circuit Court for the Second Circuit.

Home health agencies that are reluctant to provide home health services a physician determines to be medically necessary may fear a potential fraud investigation of certain types of claims, typically those involving continuing care. In the mid-1990's, as a result of a dramatic increase in the amount of home health claims, the Office of Inspector General (OIG) conducted intensive reviews of home health claims and reported substantial numbers of them to be fraudulent.

The home health agencies' reluctance to provide physician-ordered services may also result from the change to a prospective payment reimbursement system (PPS). PPS is based on the functional limitations, care needs, and severity of the patient's condition.⁶⁹ Because the home health agency is paid a set amount for each patient, based on the PPS criteria, there are incentives to provide fewer services than are medically necessary in order to minimize costs and maximize profits. As the OIG recently explained, "...under PPS physicians are expected to ensure that the patient is not short-changed with regard to the services that Medicare is paying the agency to provide."⁷⁰ But, as previously discussed, physicians may be unaware of the services being provided or Medicare coverage criteria.

One further concern about the impact of PPS on medical necessity determinations involves the use of the Outcome and Assessment Information Set (OASIS) for home health patients.⁷¹ OASIS was designed as a patient assessment tool. The current version of OASIS results from years of research to determine the questions most effective in determining patient care needs and in measuring outcomes. The intent was to give CMS and home health agencies a uniform tool by which they can evaluate and improve the quality of home health care received by patients. OASIS can also be used to help develop normative guidelines for determining the medical necessity of home health services.⁷² Twenty-three of the questions in the OASIS assessment tool are used to establish the proper payment level for patients under PPS. Recommendations have been made to CMS that OASIS be limited to those twenty-three questions. If the recommendations are accepted, the distinction between an assessment for care planning and quality needs and an assessment for payment purposes will be lost, calling into question whether payment will further drive the medically necessity determination for home health care services.

V. ITEMS AND SERVICES COVERED UNDER MEDICARE PART B

The majority of Medicare-covered services are paid for under Medicare Part B. These include doctor's visits, some home health services, ambulance services, preventive services, laboratory tests and services, durable medical equipment, and some drugs and pharmaceuticals. As with in-

⁶⁹ 42 U.S.C. § 1395fff

⁷⁰ DHHS, Office of Inspector General, *The Physician's Role in Medicare Home Health 2001*, p.4 (OEI-02-00620 Dec. 2001).

⁷¹ 42 C.F.R. § 484.55.

⁷² The Balanced Budget Act of 1997, Pub. Law 105-33, added a requirement that the Secretary develop through regulations normative guidelines for the frequency and duration of home health services. Services in excess of the guidelines would not meet the medical necessity standard of the Act. 42 U.S.C. § 1395y(a)(1)(I). The Secretary has yet to develop such guidelines.

patient hospital utilization, the number of physician visits increases dramatically as the number of chronic conditions increases. People with no chronic conditions average two physician visits per year; those with five or more average 37 visits.⁷³

The Medicare Coverage manual contains updates and modifications to Medicare coverage policy for specific items and services.⁷⁴ Coverage for other items and services may be subject to local medical review policies established by Medicare contractors and fiscal intermediaries. Again, LMRPs may include medical necessity standards that are stricter than the statutory and regulatory requirements and so result in denials of care. This is particularly true for certain identified chronic conditions and for therapeutic services.

A. Utilization screens

Utilization screens set numerical parameters for certain procedures based on a comparison of the frequency of the service to the time period the service is provided. LMRPs may be based on utilization during a calendar month, a quarter, or a year. Beneficiaries who need more services than the LMRP provides should have the opportunity to present additional evidence to support the medical necessity of the more frequent services. For example, a court ruled that an LMRP could contain a utilization screen concerning frequency of coverage of manual manipulation for subluxation of the spine, a service covered by Medicare, since beneficiaries had the opportunity to explain why more frequent service was required in their case.⁷⁵

Some LMRPs, though, use criteria “.... not supported or authorized by any applicable law or regulations to deny what otherwise might be meritorious claims...”⁷⁶, that do not allow for individualized assessment or review of the beneficiary’s medical condition. They may be disguised as codes for certain diagnoses or illnesses, the ICD-9 diagnosis codes, which establish when a service is or is not medically necessary. Depending on how the LMRP is drafted, it might provide coverage only for certain diagnosis codes that are listed in the LMRP, or it might list the codes for which the item or service is never reasonable and necessary. A beneficiary whose code does not fall within the parameters of the LMRP does not have the opportunity to submit information as to why the service is medically necessary based on her condition and medical needs; payment for her care is simply denied as never reasonable and necessary.

The American Bar Association’s Commission on Law and Aging (formerly the Commission on Legal Problems of the Elderly) (ABA) and the Alzheimer’s Association documented the use of the ICD-9 code for Alzheimer’s disease, code 311, in LMRPs to deny Medicare covered services to people with Alzheimer’s disease. This criterion was found in LMRPs addressing a wide variety of services, including a blood test used in the diagnostic process to diagnose Alzheimer’s

⁷³ Berenson and Horvath, *The Clinical Characteristics of Medicare Beneficiaries and Implications for Medicare Reform*, *supra* at 9.

⁷⁴ Medicare Coverage Issues Manual (Pub. 6) § 59 (services); § 60 (durable medical equipment), available at www.hcfa.gov/pubforms.

⁷⁵ *Vorster v. Bowen*, 709 F.Supp.934 (C.D.Cal. 1989).

⁷⁶ *Fox v. Bowen*, 656 F. Supp. 1236, 1248 (D.Conn.1987).

disease itself. Other LMRPS denied all psychiatric services,⁷⁷ regardless of the stage of illness. Still others denied physical, occupational or speech therapy, failing to recognize that therapy may be needed to maximize functioning of the individual patient. Many of the LMRPs did not take into account the research studies that substantiate the benefit to someone with Alzheimer's disease of the services presumed to be not reasonable and necessary for that population.

As a result of advocacy by the ABA and the Alzheimer's Association, CMS issued a program memorandum to address the problem. Effective September 1, 2001, Medicare contractors were told to stop using the dementia diagnostic codes alone as a basis for determining whether Medicare covered services are reasonable and necessary.⁷⁸ The ABA reports that carriers are changing LMRPs in response to the program memorandum and beneficiaries are starting to receive therapy and other services that had previously been denied them. The Florida carrier revised its LMRP to cover the blood test. A Florida nursing home resident who was hospitalized with pneumonia three times after his physical therapy was terminated now receives therapy services as ordered by his doctor, and he has not subsequently been hospitalized.⁷⁹

The CMS program memorandum addressed only the diagnostic code for Alzheimer's disease. LMRPs may still exist that use diagnostic codes for other diseases and illnesses, including several mental illnesses, as absolute bars to services. These LMRPs presume that, by nature of the disease or illness alone, a person cannot benefit from the service in question, without providing the opportunity for the beneficiary to submit information to explain why the service is necessary in her particular situation.

B. Mental Health Services

The fifteen most prevalent chronic conditions in the Medicare population include senility and organic mental disorders (including Alzheimer's disease), affective disorders (including depression), and schizophrenia and related disorders. Senility and organic mental disorders are more prevalent among beneficiaries aged 85 and over, while other chronic mental health conditions are more common among beneficiaries under age 65.⁸⁰ A Surgeon General's report from 1999 found that about 20% of Americans aged 55 and older have mental disorders that are not part of normal aging. The report further estimated that 40% of Medicare beneficiaries who are eligible based on disability are diagnosed with mental illness or substance abuse.⁸¹

⁷⁷ See, also, comments of the American Association for Geriatric Psychiatry, Office of Inspector General, *Medicare Carriers' Policies for Mental Health Services*, p. 31 (OEI-03-99-00132 May 2002).

⁷⁸ Program Memorandum AB 01_135, *Medical Review of Services for Patients with Dementia*.

⁷⁹ Telephone conversation with Leslie Fried, ABA Commission on Law and Aging, June 24, 2002.

⁸⁰ Berenson and Horvath, *The Clinical Characteristics of Medicare Beneficiaries and Implications for Medicare Reform*, *supra* at 3.

⁸¹ *Mental Health: A Report of the Surgeon General* (1999), www.surgeongeneral.gov/library/mentalhealth/toc.

Medicare pays for an array of mental health services, including psychiatric diagnostic or evaluative interview procedures, individual psychotherapy, group psychotherapy, family psychotherapy, psychoanalysis, psychological testing, and pharmacologic management. Partial hospitalization services that are expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization are also covered.⁸²

Beneficiaries have raised concerns that utilization screens in LMRPs for mental health services act as a complete bar to receipt of psychotherapy services. For example, LMRPs may set a cap for the number of treatments, after which the treatments are subject to medical review. Beneficiaries have found that some psychiatrists and psychologists are unwilling to provide more treatments than the number identified in the LMRP, regardless of whether the patient still requires more treatments, for fear of fraud and abuse investigations. Other providers require the beneficiary to pay out of pocket for treatments in excess of the number established in the LMRP, pending carrier review of the claims. Many beneficiaries with chronic mental health conditions are unable to pay privately, and so effectively are denied continued treatment. Those that do pay privately may wait years for a decision on coverage as they wind their way through the appeals process.⁸³ Finally, providers may, in accordance with standard medical practice, prescribe medications as a way to keep the frequency of office visits within utilization screens. Unfortunately, because Medicare does not cover prescription drugs, beneficiaries may not be able to afford the cost of the medications.

The Office of Inspector General (OIG) found in a recent report that about two-thirds of the LMRPs reviewed included utilization screens for individual psychotherapy services, specifying generally that prolonged treatment is more than 20 sessions. The OIG also noted that one LMRP included additional criterion in its utilization screen for psychotherapy, wanting to know whether a patient's illness is chronic or acute.⁸⁴ The report did not indicate the reason for the additional criterion.

Among the recommendations made by the OIG in its report was a recommendation that LMRPs contain "specific utilization guidelines such as those pertaining to a reasonable number of services that may be billed per year."⁸⁵ Both the American Association for Geriatric Psychiatry (AAGP) and the American Psychiatric Association (APA) expressed concern about this recommendation in their comments to the report. The APA reinforced the complaints from beneficiaries about utilization screens, and stated that guidelines "... should serve to permit the exercise of medical judgment as to the medical necessity of specific mental health services to Medicare patients rather than as cutoff points where there is a presumption against medical necessity. Our experience with such guidelines is that they are usually construed to mean that

⁸² 42 C.F.R. § 410.43(a).

⁸³ It currently takes, on average, 1265 days for a Medicare Part B claim to complete the Medicare appeals process. Presentation of Michele Edmonson, Director, Division of Appeals Policy, CMS, National Medicare Education Partnership meeting, October 23, 2002.

⁸⁴ Office of Inspector General, *Medicare Carriers' Policies for Mental Health Services*, p. 5 (OEI-03-99-00132 May 2002). The OIG received LMRPs from 53 out of 57 carriers.

⁸⁵ *Id.* at 8.

services beyond the limit are de facto unnecessary.”⁸⁶ The AAGP noted that its patients often suffer from co-morbidities, many of which are chronic conditions that require on-going care. The AAGP raised concerns that utilization guidelines would result in denial of care for “the sickest patients for whom more frequent, intensive, or ongoing services are medically necessary.”⁸⁷

The OIG concurred in the concerns of the provider organizations that utilization guidelines not be used to deny access to medically necessary care. However, the OIG also expressed concern that the overall lack of comprehensive guidance in LMRPs could result in inappropriate payments for mental health services.⁸⁸ The OIG thus identified a basic policy issue for CMS and its contractors. Policies and guidance must assure that Medicare dollars are not misspent but, at the same time, they must not preclude payment when treatment and services are required. The LMRPs reviewed in the OIG report, like others referred to in this paper, did not satisfy their dual role.

C. Durable Medical Equipment

Coverage is available under Part B for the rental, purchase, or lease of durable medical equipment (DME) for use in the home. The statute gives as examples of DME such items as iron lungs, oxygen tents, wheelchairs, and hospital beds.⁸⁹ The Medicare Coverage Issues Manual contains the most up-to-date coverage listing.⁹⁰ To be classified as DME, the equipment must be able to withstand repeated use, must be used primarily and customarily to serve a medical purpose and not generally be useful in the absence of an illness or injury, and must be appropriate for use in the home.⁹¹ A beneficiary must have a physician’s order to obtain DME.⁹²

Items that serve a medical purpose for some individuals are not covered as DME if they generally are used more broadly than for medical purposes. Thus, items for environmental control, such as air conditioners, heaters, humidifiers and dehumidifiers, are not covered as DME even though some patients with cardiac or respiratory illnesses may benefit from their use. Items deemed to be for the comfort of the patient or care giver--elevators, stairway elevators, and posture chairs--are excluded, as are physical fitness equipment, first-aid or precautionary-type equipment, and items such as grab bars that are deemed to be self-help devices.⁹³

A beneficiary who wants a customized item, including a customized wheel chair, must demonstrate how the item is uniquely designed to meet the needs of the particular beneficiary. The customization must be pursuant to the order of a physician and make the item different from

⁸⁶ *Id.* at 36.

⁸⁷ *Id.* at 31.

⁸⁸ *Id.* at 8, 9.

⁸⁹ 42 U.S.C. §§ 1395m(a); 1395x(n).

⁹⁰ Pub. 6, Coverage Issues Manual, § 60.

⁹¹ 42 C.F. R. § 414.202.

⁹² 42 U.S.C. §§ 1395m(a)(11)(B).

⁹³ Medicare Carriers Manual § 2100.1

another item used for the same purpose.⁹⁴ Under the Medicare Coverage Manual, all claims for power wheelchairs or wheelchairs with special features are referred for medical review, since payment for special features is limited to features that are medically required because of the patient's condition.⁹⁵ A customized item designed solely for the convenience of the beneficiary is not covered as medically necessary.

The Medicare Carriers Manual indicates that DME will not be found to satisfy the reasonable and necessary requirement if the equipment cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case. Stated the other way, items such as gel pads and water and pressure mattresses generally serve a preventative purpose, and Medicare will not pay for them when used for that purpose. However, they will be treated as DME when prescribed for a patient with bed sores, or where there is medical evidence that the patient is highly susceptible to ulceration.⁹⁶ Partial payment may be authorized if the Medicare contractor determines that the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.⁹⁷ Interestingly, the Manual separates the analysis into a discussion of the necessity for the equipment and a discussion of the reasonableness of the equipment. Necessary equipment is expected to contribute meaningfully to the treatment of the patient's illness or injury or to the improvement of the patient's malformed body member. The physician's prescription and other medical information are sufficient to establish necessity.⁹⁸ For example, a blood glucose monitoring system designed for home use may be necessary for an insulin-dependent beneficiary with diabetes who is capable of being trained to use the system at home. A special blood glucose monitoring system designed for people with visual impairments may be reasonable for that same beneficiary, but only if the physician certifies that he is visually impaired.

The issue of reasonableness addresses whether Medicare should pay for the prescribed item, even where the item may serve a useful medical purpose. The Manual identifies the following questions as assisting in the determination:

- X Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
- X Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
- X Does the item serve essentially the same purpose as equipment already available to the beneficiary?⁹⁹

⁹⁴ 42 C.F.R. § 414.224.

⁹⁵ Medicare Coverage Manual, Durable Medical Equipment List § 60-9. Note that the manual also states that a narrow wheelchair that is ordered specially because of the patient's slender frame or because of narrow doorways in the patient's home is not considered a deluxe item subject to additional review. *Id.* at § 60-6.

⁹⁶ Medicare Carriers Manual, § 21001.

⁹⁷ Medicare Carriers Manual, § 2100.2.

⁹⁸ *Id.*

⁹⁹ *Id.*

The Manual also admonishes that where “a medically appropriate and realistically feasible alternative pattern of care” exists, payment may be based on the charge for the alternative, rather than denied in full.¹⁰⁰ Thus, the Carriers Manual adds a cost-based analysis, not found in the statute, to the determination of the reasonableness of prescribed DME.

The reasonableness analysis contained in the Manual raises further questions for individuals with chronic conditions. How will the therapeutic benefit of a requested item be evaluated? Will an item used for monitoring a condition be viewed differently from an item used to improve functioning? What role will beneficiary preference play in determining whether a medically appropriate alternative pattern of care is realistically feasible and available? Will a beneficiary whose condition deteriorates during the regular course of his illness automatically be denied an item such as a power wheelchair because he already has a standard wheelchair, without evaluation of his current need for the power wheelchair?

How the reasonableness analysis is applied to items requested by a beneficiary with chronic conditions may depend on where he lives. The Center for Medicare Advocacy compared the standards for payment for canes, crutches, walkers and wheelchairs in the manuals developed by each of the four Durable Medical Equipment Regional Carriers (DMERCs).¹⁰¹ The difference in the detail and organization of the DMERC manuals and their guidance about how to determine whether canes, crutches, walkers or wheelchairs are reasonable mirrors the differences found by the OIG in its study of LMRPs concerning coverage of mental health services, discussed above. For example, the DMERC Region A Manual goes into great detail and relies on the Medicare Carriers Manual analysis. The Region B Manual, on the other hand, refers to neither the Medicare statute’s reasonable and necessary requirement nor to the Medicare Carrier Manual definition. It does not provide an overview of what constitutes medical necessity or an explanation of how medical necessity should be determined for individual items of DME. Such differences may result in disparate treatment of claims for the same items in different localities.

VI. CONCLUSION AND RECOMMENDATIONS

The Medicare program was designed in 1965 to protect older people against episodes of acute illness or injury. The program included coverage for hospitalization and for doctors visits, but only if the doctor visits were to address illness and not prevention. Medicare Part A services are designed to pay for a spell of illness or an episode of care, all of a short duration.¹⁰² Utilization screens to establish frequency and duration of Part B services are included in LMRPs. Medical necessity determinations in individual claims follow that model, and are oriented towards

¹⁰⁰ *Id.*

¹⁰¹ Congress ordered the Medicare Agency to establish a system of Durable Medical Equipment Regional Carriers (DMERCs) to process claims for DME on a regional basis. 42 U.S.C. § 1395m(a)(12).

¹⁰² Bruce Vladek, *You Can’t Get There From Here: Obstacles to Improving Care of the Chronically Ill*, 20 Health Affairs 175, 178 (Nov./Dec. 2001).

episodic care: a determination of the medical problem, the most efficacious treatment, and the period of time over which treatment will be provided.

Today, however, the most frequent users of Medicare services--and the majority of the Medicare population--are people with multiple chronic conditions. They visit doctors more frequently, have more episodes of inpatient care, and are more costly to the Medicare program. They require on-going, rather than episodic, medical treatment and services, including monitoring of their condition and education on how best to care for themselves. Their treatment goal is to maintain their condition and to prevent deterioration, not to improve an illness or injury.

As pointed out throughout this paper, even when the Medicare statute and regulations include a framework to evaluate needs of those with chronic conditions, LMRPs often contain standards that are inconsistent with the Medicare statute and regulations. They may deny services where there is no improvement, although regulations and even other policy guidance allow coverage where services are needed for maintenance or for observation and assessment. They may add a cost-based analysis, though none exists in the statute, without considering how value will be determined for someone who has no expectation of improvement. Most beneficiaries do not even know that LMRPs exist, that they may apply standards inconsistent with the statute and regulations, or that they are being used to deny care that a physician has ordered.

Another consideration involves the conflict between providing people with chronic conditions the care they need and the fiscal integrity function of the federal government.¹⁰³ Do utilization screens establish well-recognized norms or care, or do they set payment caps? Are LMRPs program integrity tools, or do they provide guidance for medical necessity determinations? What effect do fraud and abuse investigations have on a provider's willingness to deliver services to someone with chronic conditions whose treatment falls outside the norm for delivery of care?

Medical necessity determinations in individual claims should no longer follow the acute care model. They should be revised to recognize that the overwhelming majority of beneficiaries have at least one chronic condition whose method of treatment and treatment goal is different from the method of treatment and treatment goal for an acute illness or injury. In this regard:

- Improvement should not be the sole medical necessity criterion used to determine a patient's claim.
- Maintenance of ability, prevention of deterioration, and patient education should be recognized as treatment goals for beneficiaries with chronic conditions.
- Beneficiaries with multiple chronic conditions should be readily allowed to demonstrate a need for ongoing services in order to obtain more services or services for a longer period of time than set forth in an LMRP.

¹⁰³ Barbara Cooper asks, "What is the **principal** purpose of the care-management benefit – to save Medicare money or maximize beneficiary quality of life?: Barbara Cooper, *Issues in Designing a Care-Coordination Benefit for Medicare*, Coordinated Care Conference (Washington, D.C., March 22, 2002) at 2.

- Utilization screens should include specific ‘safe harbors’ for beneficiaries with multiple conditions, and should incorporate mechanisms to allow practitioners and beneficiaries to expeditiously appeal denials of care based on the screens.
- Diagnostic codes for conditions and illnesses should not be used arbitrarily as the code for Alzheimer’s disease was used, to deny access to care that a treating physician believes is medically appropriate.
- Payment policies should be separated from assessment mechanisms. The medical necessity analysis should not be dependent upon a PPS classification or reimbursement system.

To accomplish these goals, NCDs, LMRPs, Medicare manuals and other policies need to be reviewed to assure that they meet the above criteria, and that they do not conflict with the Medicare statute and regulations. Agency policies also need to be reviewed on a regular basis to assure that they comport with changes in medical knowledge and practice.

Medicare contractors also need to distinguish between medical necessity determinations and program integrity functions. They should:

- X Require adequate documentation for claims.
- X Review for proper coding of services.
- X Report separately denials based on inappropriate or insufficient documentation, failure to meet eligibility standards, and practices that demonstrate true fraud.

CMS has already begun to implement a number of these recommendations. The agency is reviewing LMRPs and establishing procedures to assure that LMRPs are consistent with current medical practice and knowledge as well as with agency regulations and guidance. CMS plans to improve beneficiary notices to include information about why a claim was denied. The agency also plans to establish a data system that allows it to track the reasons for a claims denial so that the agency can identify and address problem areas.

Medicare covers an array of services that are available to a Medicare beneficiary as long as they are reasonable and necessary for the diagnosis or treatment of the particular beneficiary’s individual illness or injury. The determination in each case must be made in the context of each individual’s unique situation. Given the vast range in age of Medicare beneficiaries and the vast differences in their medical conditions, “one size fits all” medical necessity determinations fit no one.