

## REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4 - A-06  
(June 2006)

Subject: Update on Disease Management

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1 Council on Medical Service Report 3 (I-97), established a series of principles on the conduct of  
2 disease management programs (Policy H-285.944, AMA Policy Database). Since 1997, the House  
3 of Delegates has considered at least two reports that addressed disease management. Council on  
4 Scientific Affairs Report 11 (A-04) provided an in-depth analysis of disease management processes  
5 and efficacy, reaffirmed Policy H-285.944, and directed the American Medical Association to  
6 educate physicians on the impact of disease management programs on patients and their treating  
7 physicians (Policy D-285.976). In addition, Council on Medical Service Report 5 (A-05)  
8 established Policy H-155.995[3], which supports greater evaluation of the use of disease  
9 management, case management, pay-for-performance, and end-of-life care programs for high-cost  
10 patients, so that their cost-containment impact and projected future savings can be better assessed.

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12 In May 2004, the AMA Private Sector Advocacy unit created a pamphlet entitled “Demystifying  
13 Disease Management: What You Need to Know for Your Patients and Your Practice.” The  
14 pamphlet explores the potential impact of disease management, offers some interactive strategies,  
15 and is available to AMA members at <http://www.ama-assn.org/ama/pub/category/9368.html>.  
16 The Council initiated an update on disease management and presents its findings for the  
17 information of the House. This report discusses the evolution of the disease management industry;  
18 describes disease management initiatives in Medicare and Medicaid; summarizes findings on the  
19 return on investment; discusses the role of accreditation and regulation; notes the increasing  
20 importance of performance measures; and presents AMA policy related to disease management.

21

### 22 THE EVOLUTION OF DISEASE MANAGEMENT

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24 The evolution of the disease management industry since 1997 has been marked by rapid growth  
25 and consolidation. The Disease Management Association of America (DMAA) was founded in  
26 1999, two years after the recommendations contained in Council Report 3 (A-97) were adopted as  
27 Policy H-285.944. DMAA currently has 50 member disease management companies of the  
28 estimated 100 companies nationally. Disease management originally was a managed care tool  
29 focused on larger employers, and was something of a replacement for utilization management  
30 during the “managed care backlash” of the late 1990s.

31

32 Compared with the climate in 1997, disease management programs now rely less on  
33 pharmaceutical management and there are fewer single-disease vendors. The tendency now is to  
34 promote patient awareness and self-care, and to address multiple diseases or conditions. Acting in  
35 this capacity, disease management programs often provide education that physicians are not  
36 currently paid to provide. According to a September 2005 report in the trade publication “Inside  
37 Disease Management,” some disease management vendors are considering programs designed for  
38 the “middle market” of smaller employers and self-funded companies. As noted in the next  
39 section, Medicare is now funding disease management pilot projects for fee-for-service

1 beneficiaries. The growth of fee-for-service disease management is expected to continue as  
2 programs gain expertise.

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4 An August 2005 article in Managed Care Magazine, "12 DM Trends You Should Know About,"  
5 described key components of the evolution of disease management. According to the article, large  
6 disease management firms now offer to manage dozens, rather than a single or small number of  
7 diseases or conditions. In addition, disease management is often outsourced to specialized vendors.  
8 The article reported that a 2004 survey of health plans found that 63% use both in-house and  
9 outsourced disease management programs; 32% use only in-house programs; and 5% use only  
10 outsourced vendors. Increasingly, the article reported, employers are asking disease management  
11 programs to address wellness programs, such as smoking cessation and weight loss.

### 12 13 MEDICARE AND MEDICAID FEE-FOR-SERVICE

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15 As previously noted, disease management was originally a managed care construct. Both Medicare  
16 and Medicaid increasingly are focusing on managing the care of their fee-for-service beneficiaries  
17 who are known to have chronic or disabling conditions.

#### 18 19 Medicare Health Support

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21 In December 2004, the Centers for Medicare and Medicaid Services (CMS) defined a new strategy  
22 for Medicare fee-for-service patients with chronic illnesses. The new program, Medicare Health  
23 Support, replaced the Chronic Care Improvement Program (CCIP), although CCIP continues to be  
24 widely cited in industry literature. Medicare Health Support awarded nine well-established disease  
25 management vendors with contracts to conduct three-year pilot projects. The areas to be served  
26 have a high prevalence of diabetes and congestive heart failure among Medicare beneficiaries. The  
27 areas represent a mix of rural and urban areas and include ethnically and culturally diverse  
28 populations.

29  
30 Approximately 180,000 Medicare fee-for-service beneficiaries who have congestive heart failure  
31 and complex diabetes will be screened for participation. Targeted beneficiaries will be assigned  
32 randomly to either an intervention group or a control group. Those in the intervention group will  
33 be notified of the opportunity to participate through a letter from the Medicare program. The letter  
34 will describe the program and give the beneficiary the opportunity to decline to be contacted by a  
35 Medicare Health Support organization if he or she does not want to participate.

36  
37 The pilot projects, authorized by the Medicare Prescription Drug, Improvement and Modernization  
38 Act of 2003, are tasked with helping participating patients adhere to their physicians' plans of care  
39 and obtain the medical care they need to reduce their health risks. By better managing and  
40 coordinating the care of beneficiaries with chronic conditions, CMS hopes to help increase  
41 adherence to evidence-based care, reduce unnecessary hospital stays and emergency room visits,  
42 and help participants avoid costly and debilitating complications. The disease management  
43 organizations operating the programs are required to assist participants in managing all  
44 co-morbidities, relevant health care services, and pharmaceutical needs as well as unique individual  
45 needs and cognitive impairments.

46  
47 CMS has developed a "fact sheet" to inform physicians about the project, available on the Web at  
48 <http://www.cms.hhs.gov/CCIP/downloads/factsheet.pdf>. There is anticipation that the Medicare

1 pilot projects will accelerate the market consolidation and evolution of disease management over  
2 the next year or two. The Secretary of the Department of Health and Human Services is authorized  
3 to expand the program if the Secretary finds programs or program components that have proven to  
4 be successful in improving clinical outcomes, increasing beneficiary satisfaction, and meeting  
5 Medicare spending targets for their assigned populations.

6  
7 Medicaid  
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9 Disease management is used in many states as a way to improve care and reduce the significant  
10 expenditures of the Medicaid program on chronic illnesses and disabilities. The Kaiser Family  
11 Foundation (KFF) issued a report in September 2004 entitled “Medicaid Disease Management:  
12 Issues and Promises,” which highlighted the difficulty of documenting cost savings. The KFF  
13 report noted that Medicaid disease management programs typically do not address mental health  
14 issues and often exclude dual eligibles, despite their great need, because the cost savings would  
15 largely benefit the Medicare program rather than the Medicaid program. In addition, KFF  
16 indicated that commercial disease management vendors may need to take measures to ensure that  
17 they are sensitive to Medicaid enrollees, who may be more difficult to contact and have more  
18 mitigating factors that could prevent them from adhering to their treatment plans. According to the  
19 KFF report, most disease management programs operate independently of physicians to avoid  
20 being perceived as burdensome or interfering. KFF indicates that some states are seeking a more  
21 active role for physicians. The KFF report also found that states increasingly are targeting disease  
22 management to fee-for-service beneficiaries, in addition to those in capitated managed care plans.  
23 This shift has been accomplished by the rapid growth of stand-alone Medicaid disease management  
24 programs.

25  
26 RETURN ON INVESTMENT  
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28 The expectation of disease management is that it will improve care and save money. Improved  
29 patient compliance with treatment regimens is expected to prevent hospitalizations and other costly  
30 interventions. However, the evaluation of disease management remains elusive. The evaluation of  
31 disease management success is typically attempted by determining a “return on investment” (ROI).  
32 The ROI analysis of disease management emphasizes capturing the financial benefit that results  
33 from decreased use of health care resources, which in turn, results from the beneficial effects of  
34 disease management. Employers increasingly are using consulting firms to audit their contracted  
35 disease management programs for ROI. Information about patient satisfaction is used as a measure  
36 of the beneficial impact of disease management. In one meta-analysis, quality of care was  
37 measured using clinical, utilization, safety, and patient satisfaction indicators.

38  
39 An October 2004 report of the Congressional Budget Office (CBO), “An Analysis of the Literature  
40 on Disease Management Programs,” analyzed the cost effectiveness of disease management  
41 programs in an effort to determine how such programs could be applied to Medicare. Although,  
42 the CBO determined that it is inconclusive whether disease management programs pay for  
43 themselves, it noted that disease management may be worthwhile even if costs are not reduced.  
44 The Council believes that studies of ROI should not be limited to economic factors and should  
45 recognize non-economic factors, such as improvements in the quality of life. In addition, studies of  
46 ROI should compare disease management programs with physician offices, given comparable  
47 access to social services and tools. The pressure to demonstrate positive results for disease

1 management is likely to increase with Medicare Health Support. CBO indicated it would continue  
2 to monitor the disease management programs developed by CMS.

3  
4 The conclusion reached in Council on Scientific Affairs Report 11 (A-04) was that the ROI  
5 depends, in part, on the disease. By reviewing the medical literature, the report outlined the disease  
6 management process; presented the pros and cons of disease management services; and assessed  
7 the effectiveness of disease management for managing chronic diseases. The report indicated that  
8 poorly designed disease management programs can circumvent the treating physician, a practice  
9 opposed by AMA policy. For example, the report noted that some disease management programs  
10 might try to switch patients to less costly medical supplies or equipment, thus confusing patients.  
11 Patient confusion would be compounded if treating physicians are not notified of such changes.  
12 Furthermore, the report noted that disease management programs frequently use clinical practice  
13 guidelines to assess treatment plans. If the disease management program profiles individual  
14 physicians to create "report cards," physicians may be penalized if their practice patterns vary from  
15 the guidelines, even if equally effective.

16  
17 Council on Scientific Affairs Report 11 (A-04) also reviewed the chronic care model and compared  
18 it with disease management. The recommendations contained in the report reaffirmed Policy  
19 H-285.944, the principles established by Council on Medical Service Report 3 (I-97), and called for  
20 the AMA to continue to educate physicians on the impacts of disease management programs on  
21 patients and their physicians.

## 22 ACCREDITATION AND REGULATION

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25 Accreditation is a key component of the disease management industry. URAC (formerly known as  
26 the Utilization Review Accreditation Commission), the National Committee for Quality Assurance  
27 (NCQA), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have  
28 established principles for the accreditation or certification of disease management programs.  
29 JCAHO's principles are for hospital-based programs, NCQA's principles are for HMOs, and  
30 URAC's principles focus on private disease management vendors. Similar to the role of  
31 accreditation in other industries, accreditation for disease management programs is used to  
32 distinguish vendors.

33  
34 Accreditation also plays a role in the quality assessment of disease management programs. In  
35 January 2006, the DMAA announced that it would develop, by the end of the year, a uniform  
36 method for measuring and evaluating disease management outcomes. The DMAA hopes to  
37 establish "best practices" for evaluating disease management programs. Currently, URAC's  
38 standards contain variously weighted sets of measures for "Methodology for Outcomes  
39 Measurement," "Requirements for Measuring Program Performance by Clinical Condition," and  
40 "Consumer Reported Outcomes Measurement."

41  
42 According to the National Conference of State Legislatures (NCSL), 25 states have laws that  
43 specifically address disease management. The first year any of the laws listed on the NCSL Web  
44 site were enacted was 2002, with the majority of laws enacted in 2003 and 2004. Many of these  
45 laws establish task forces or panels to evaluate efficacy of a disease management program, or  
46 compel state agencies to establish or contract with disease management vendors. Others direct  
47 state departments of health to establish a disease management program for various specific  
48 conditions or diseases in their Medicaid programs.

1 Two states have laws that specify the financing of patient incentives to participate in disease  
2 management. New Hampshire and Rhode Island permit health insurers in the small group and  
3 individual markets to discount the premium rate for health benefit plans that include significant  
4 financial incentives for covered persons to participate in wellness or disease management  
5 programs. South Dakota requires health plans to include disease management programs that  
6 contain cost containment mechanisms. Enrollees who do not enroll in cost containment activities  
7 receive financial penalties in the form of higher out-of-pocket costs.  
8

9 Two other states have laws that appear to address issues pertaining to oversight of disease  
10 management. California requires disease management organizations to obtain physician prior  
11 authorization before providing services or medication management. California also prohibits the  
12 use of medical information to solicit, or to offer for sale, any products or services and specifies that  
13 disease management organizations are subject to confidentiality laws. Washington directs state  
14 purchased health care policies to be based on scientific and medical evidence, and to explore  
15 strategies for disease management and demand management programs.  
16

#### 17 DEVELOPMENT OF PERFORMANCE MEASURES

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19 There is a growing link between disease-based performance measures and quality improvement  
20 (QI) programs. These links are seen in private sector programs, such as Bridges to Excellence,  
21 and in public sector pilot projects sponsored by Medicare. The Council believes that the Physician  
22 Consortium for Performance Improvement convened by the AMA with participation by a large  
23 number of specialty and state medical societies, CMS, NCQA, and others, should play an important  
24 role in these efforts. The Consortium's rigorously reviewed performance measures are often  
25 derived from generally accepted disease management guidelines. These measures are emerging as  
26 useful tools to assist physicians and other clinicians in efforts to assess clinical performance and QI  
27 progress using a standards and consensus-based approach. The need for simple, affordable  
28 information technology tools (e.g., disease and patient registries and new electronic health record  
29 functionality) to document and aggregate data and easily display reports of these measures, is also  
30 becoming more apparent in the overall disease management process.  
31

#### 32 AMA POLICY RELATED TO DISEASE MANAGEMENT

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34 AMA policy related to disease management is largely supportive of its use, if conducted in a  
35 manner consistent with AMA policy. A number of policies emphasize the need to measure the  
36 efficacy of disease management, which has resulted in recent reports from AMA councils. Taken  
37 together, AMA policy addresses the critical issue facing disease management: measuring the value  
38 of disease management and maintaining physician control of the process.  
39

40 Policy H-285.944, which was established with the adoption of the recommendations in Council on  
41 Medical Service Report 3 (I-97), contains principles related to both disease management and  
42 demand management. The principles related to disease management strongly encourage health  
43 insurance plans and managed care organizations that provide disease management to involve the  
44 patient's physician in the disease management process as much as possible, and to minimize  
45 arrangements that may impair the continuity of a patient's care across different settings. Policy  
46 H-285.444 supports the development of disease management systems that adhere to the following  
47 principles, and encourages any public or private entities that evaluate such programs for purposes  
48 of certification or accreditation to utilize these principles in conducting their evaluation:

- 1 (1) The primary goal of both disease management should be as follows: (a) to improve  
2 outcomes by providing timely and appropriate preventive, therapeutic and restorative  
3 services. Cost savings and care efficiencies resulting from such services are a secondary but  
4 legitimate objective. (b) To promote cooperation between primary care and specialty care  
5 physicians to provide a continuum of care for specific health care needs.
- 6 (2) Disease management should continue to place major emphasis on educating and empowering  
7 patients to more successfully manage their own health and intelligently use care resources.
- 8 (3) The clinical practice guidelines used in disease management should be developed by  
9 physicians knowledgeable in dealing with the conditions addressed, and should be updated  
10 regularly.
- 11 (4) The decision to participate or not participate in a disease management program should  
12 always be the prerogative of the patient, who should be fully informed of any plan coverage  
13 conditions attendant on such decisions.
- 14 (5) Physicians should be able to deviate from disease management practice guidelines without  
15 incurring sanctions or jeopardizing coverage for services, when in their judgment such  
16 deviation is indicated by the medical needs or desires of individual patients.
- 17 (6) Attention to the performance of physicians in disease management programs should be  
18 triggered by concern with a physician's overall practice patterns rather than by deviation  
19 from practice guidelines in a single case. Emphasis in remedial activities should be on  
20 helping the practitioner to correct any overall performance problems identified by peer  
21 review, rather than on sanctions.
- 22 (7) Non-physicians who function as care coordinators in disease management programs should  
23 be certified or licensed as physician assistants or nurse practitioners, or have at least a  
24 comparable level of training.
- 25 (8) The overall authority for decisions to use or not use specialized care and ancillary or  
26 supportive services or products for patients enrolled in a disease management program  
27 should rest with the primary or principal care physician providing care in the program.
- 28 (9) The primary or principal care physician in a disease management program should strive to  
29 assure effective collaboration among the different programs and personnel needed for care of  
30 patients with comorbidities, and should be routinely informed by such personnel of the  
31 services they provide.
- 32 (10) Physicians who provide care in disease management programs should be fully licensed to  
33 practice medicine in the jurisdiction of the program's location, and should be professionally  
34 and legally accountable for any adverse patient events resulting from that care.
- 35 (11) In disease management programs conducted by drug manufacturers, the choice of  
36 pharmaceuticals used in program formularies and for care of individual patients should not  
37 be restricted to those of the sponsoring manufacturer, but should be based on the clinical  
38 judgment of participating physicians and validated outcome studies.

39  
40 Policy D-285.979 calls for the AMA to: (1) reevaluate the concept of disease management as a  
41 way to provide more cost effective delivery and improved quality of medical care to patients with  
42 chronic disease involving cooperation between physicians and teams of allied health care workers,  
43 including pharmacists, registered nurses, benefit managers, home health care, etc.; and (2) educate  
44 physicians about the benefits of properly designed and implemented disease management programs  
45 that are consistent with AMA policy. In response to Policy D-285.979, Council on Scientific  
46 Affairs Report 11 (A-04) evaluated disease management programs and recommended the  
47 reaffirmation of Policy H-285.944, and established a directive to educate physicians on the impact  
48 of disease management programs on patients and their treating physicians (Policy D-285.976).

1 Similarly, Council on Medical Service Report 5 (A-05) established Policy H-155.995[3], which  
2 supports greater evaluation of the use of disease management, case management, pay-for-  
3 performance, and end-of-life care programs for high-cost patients, so that their cost-containment  
4 impact and projected future savings can be better assessed. Policy H-290.982[17] supports case  
5 management and disease management approaches to the coordination of care, in the Medicaid  
6 managed care and the fee-for-service environments. Policy H-285.956[5] supports a disease  
7 management approach to the care of behavioral health problems. Policy H-285.931[3] supports  
8 physician involvement in the development of clinical practice guidelines and disease management  
9 protocols, and Policy H-285.921 calls on Managed Behavioral Health Organizations to share their  
10 written disease management protocols with primary care and other treating physicians. Policy  
11 H-140.919[2] states that any health plan communications to patients promoting improved outcomes  
12 through evidence-based approaches (e.g., promotion of preventive measures or disease  
13 management programs) should be designed to reinforce the primacy of the patient-physician  
14 relationship, and be sensitive to confidentiality issues and patients' concerns about their health  
15 status. Policy H-315.983[20] supports privacy standards that would prohibit pharmacies from  
16 using prescription refill reminders or disease management programs as an opportunity for  
17 marketing purposes.

18  
19 DISCUSSION

20  
21 The disease management industry is undergoing tremendous growth and change, and is likely to  
22 become much more sophisticated in the near future. In 2005, URAC completed a study of the  
23 medical management industry and concluded that many medical management firms integrate their  
24 disease management function with their utilization management and case management functions.  
25 In late 2005, the CMS initiated Medicare Health Support, a three-year disease management project  
26 for Medicare fee-for-service patients with chronic illnesses. In 2006, the DMAA announced plans  
27 to develop standards for measuring and evaluating disease management outcomes.

28  
29 The Council believes disease management programs should focus primarily on patient education  
30 and supporting the patient/physician relationship, and should not interfere with physician practices.  
31 However, with the continued lack of accurate evaluative methodologies, physicians can expect  
32 increased pressure to report on disease management performance measures and clinical outcomes.  
33 This pressure may be particularly strong as Medicare Health Support enters its evaluative phase.  
34 Already, there is pressure to link physician participation in disease management with pay-for-  
35 performance efforts. In a 2005 article, *Managed Care Magazine* described Medicare Health  
36 Support as the "event of the decade," which it predicted will catalyze disease management industry  
37 consolidation.

38  
39 AMA policy related to disease management remains germane. For example, Policy  
40 H-285.944[5,6] states that physicians should be able to deviate from disease management practice  
41 guidelines without incurring sanctions when in their judgment such deviation is indicated by the  
42 medical needs or desires of individual patients, and that attention to the performance of physicians  
43 in disease management programs should be triggered by concern with a physician's overall practice  
44 patterns rather than by deviation from practice guidelines in a single case. The Council will  
45 continue to monitor the evolution of the disease management industry.

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47 References for this report are available from the AMA Division of Socioeconomic Policy  
48 Development.