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Executive Summary

Heart failure (HF) is a widespread and costly complex clinical syndrome that primarily affects the elderly. Although mortality has steadily declined, HF remains a progressive and ultimately fatal condition. With nearly 4 million beneficiaries, California is home to 10 percent of the nation’s Medicare population. Heart failure is the most common discharge diagnosis in this population, costing more than $19 billion annually. As the state’s population continues to age, it is expected that the incidence and prevalence of HF will continue to rise, straining both state and federal health care resources. The appropriate use of prescription medications in treating HF has been proven to slow disease progression, reduce hospitalizations and mortality, and improve the functional status of patients with HF. California, however, continues to lag behind the best performing states in the use of these drugs.

There are many barriers impeding the effective treatment of people with HF, including the lack of prescription drug coverage in Medicare fee-for-service, which covers an estimated 65 percent of Medicare beneficiaries in the state. Medicare+Choice plans, which historically included prescription drug coverage, are continuing to withdraw from service areas in the state due to medical cost increases that have exceeded Medicare’s annual capitation rates. Remaining Medicare+Choice plans have reduced or eliminated prescription drug benefits in recent years because of spiraling drug costs, as have many Medi-Gap plans as well.

Comprehensive disease management programs offered by Medicare-contracting HMOs have been shown to reduce costs and improve the quality of life for severely ill HF patients. Medicare+Choice plans also offer population-based disease management programs for enrollees in the early stages of HF, although the effectiveness of these programs is questionable. Many medium to large provider organizations in the state have also begun offering coordinated disease management services to HF patients, targeting only severely ill patients that are identified in the acute care setting and not patients presenting with the early signs and symptoms of HF.

The need to improve the quality of care for HF patients has been clearly discerned at both the state and federal level. The Centers for Medicare and Medicaid Services (CMS) has taken the lead in quality improvement efforts for both the Medicare fee-for-service and Medicare+Choice
populations. National programs are coordinated in California by CMRI, the Medicare Quality Improvement Organization in California. Both the fee-for-service and Medicare+Choice quality initiatives focus on improving the appropriate diagnosis of patients with HF and increasing the use of a specific class of drugs to treat the condition. Since the inception of the national fee-for-service initiative in 1998, CMRI has already documented improvements in both of these areas. The CMS improvement project for Medicare+Choice began in 2001. CMRI has provided extensive tools and resources to Medicare HMOs and provider organizations as this project has unfolded. Chart abstraction was completed late in 2001 to establish baseline measurements for the Medicare+Choice initiative.

As an organization that understands the goals and processes embedded in the national CMS quality improvements projects, CMRI provides the best opportunity for achieving significant, measurable improvements in heart failure care delivery across a wide cross-section of stakeholders in California. In addition to working with CMRI to expand its efforts to foster institutional change, other quality improvement areas for CHCF and others to consider include (1) participating with the California Heart Disease and Stroke Prevention (CHDSP) Program in the development of a state heart disease action plan, beginning with the creation of a statewide “resource map”; (2) partnering with the CHDSP Program to create a demonstration project for improving heart failure care for a targeted, high-risk geographic area or population in California; (3) assisting Sutter Health with further development of its HF initiative in order to export it to other hospital-based systems; (4) working with state and federal policymakers to find a creative solution to expanding drug coverage to HF patients enrolled in formalized disease management programs; and (5) exploring opportunities to better identify and educate underserved populations at risk for developing heart failure, such as African Americans and women.
I. Introduction

This paper is one of five white papers produced at the request of the California HealthCare Foundation (CHCF) by Powers & Associates. Besides heart failure, the other four topics are breast cancer, diabetes, end-of-life care, and pediatric asthma. The primary purpose of each paper is to assist CHCF staff in determining priority areas for investment in quality improvement in the state of California. Although each paper stands alone, together the five form an integrated body of work.

Each paper includes the following sections: the epidemiology of the disease/condition; costs; the state of knowledge on preventing, diagnosing, treating, and monitoring the disease/condition; the gaps between knowledge and treatment; current efforts to close the gaps; and opportunities and recommendations for potential investments by the Foundation and others. In order to preserve the readability of the paper and limit its length, most of the sections are illustrative, rather than exhaustive. Any omission of specific information or an initiative does not intentionally imply it has been deemed unworthy of acknowledgement.

As the team of authors writing these papers delved into opportunities for fundamentally improving quality of care, it became apparent that a coordinated approach to chronic care management is a common, critically needed element in improving care across all five diseases/conditions. Each paper includes a broad recommendation to implement a coordinated approach to caring for the chronically ill in partnership with the respective leading organizations devoted to each disease/condition. Other recommendations specific to priorities identified by key stakeholders within each disease/condition are included in the papers.
II. Epidemiology

Of the 60 million Americans who have one or more types of cardiovascular disease (CVD), an estimated 4.7 million people currently have heart failure. An estimated 10 percent of Medicare beneficiaries suffer from HF, putting the number of people 65 or older with heart failure in California at just under 400,000. Heart failure primarily affects the elderly and is the most common Medicare diagnosis-related group, with an incidence of nearly 10 per 1,000 of population after age 65. The American Heart Association (AHA) estimates that approximately 550,000 new cases of HF occur each year. The prevalence of HF increases with age and a two- to three-fold increase in prevalence is projected in the next decade as the baby boomer population ages. The annual nationwide number of hospitalizations with HF as the primary diagnosis increased nearly 64 percent in the last ten years to 978,000. According to CMRI, the Medicare QIO in California, HF is the most common hospital discharge diagnosis for people age 65 and older.

Mortality due to HF has been steadily declining since 1950 due to a better understanding of the disorder and improvements in treatment modalities, but HF is still a progressive and ultimately fatal syndrome. After diagnosis, the five-year mortality rate for HF is about 50 percent. Survival is poorer in men—on an age-adjusted basis, death rates for men of all races is higher than for women. Sudden cardiac death occurs in HF patients at a rate of 6 to 9 times the rate of the general population. From 1996 to 1998, California had lower rates of death for all heart disease, including heart failure, on an age-adjusted basis per 100,000 of population compared to the national average, except for African American women (Figure 1).

Coronary artery disease is the leading risk factor for HF and is present in about two-thirds of patients with left ventricular systolic dysfunction, the most common type of HF in patients under 70. Hypertension is another common cause of HF. The third most common cause is dilated cardiomyopathy, damage to the heart that is usually caused by heart attack, although damage can also be caused by valvular disease, infection, substance abuse, or no apparent cause. The incidence of heart failure is five times greater in people who have had a heart attack compared to people who have not. Other risk factors include diabetes, thyroid disease, and kidney disease.
An estimated 20 percent to 40 percent of patients with HF suffer from diastolic dysfunction, a condition in which the ventricle is unable to relax and fill the heart with blood. Risk for diastolic dysfunction is mainly associated with elderly women (age 70 or older), an estimated 75 percent of whom have antecedent hypertension.\(^9\) Aging has a significant effect on diastolic function, and therefore it is anticipated that as the population continues to age, diastolic failure will become more common and may become responsible for 40 percent to 50 percent of all HF cases.\(^{10}\)

Women in California die in greater numbers than men from HF. Based on total deaths, women accounted for 62.7 percent of deaths as compared to men, who accounted for 37.3 percent of total heart failure deaths in 1999. State mortality rates by gender track closely with national mortality rates.\(^{11}\)

Heart failure is more prevalent in the African American population, affecting 3.5 percent of male African Americans and 3.1 percent of female African Americans as compared to 2.3 percent for Caucasian males and 1.5 percent for Caucasian women.\(^{12}\) In addition, the average age of onset in the overall population is 62 to 63 years of age; however, the onset of HF symptoms occurs at a
younger average age and disease progression is more rapid in the African American population. African American men have the highest estimated incidence of new or recurrent HF events in the 75 to 84 age range, the age range at which most patients manifest severe symptoms of HF, compared to Caucasians of either gender and African American women\(^\text{13}\) (Figure 2).

**Figure 2. Estimated Incidence of Heart Failure Events per 1,000 Population**

![Graph showing estimated incidence of heart failure events per 1,000 population by age range and gender.](image)

The leading risk factors for HF in the African American population are hypertension and diabetes, conditions that are more common in the general African American population. Higher risk for initial and recurrent hospitalization and death from HF is also present in this population.\(^\text{14}\) African Americans experience higher mortality rates than either Caucasians or Hispanics. In 1999, the age-adjusted death rate for non-Hispanic African Americans was 23.2 per 100,000 of population as compared to 20.8 for Caucasians and 9.2 for Hispanics.\(^\text{15}\) Although socio-economic status plays a part in high mortality rates among African Americans, early onset and disease progression in this patient population is still not well understood, in part because clinical trials for pharmacologic treatment of HF have traditionally focused on Caucasian male patients. New studies are underway that may improve both prevention and treatment of HF in the African American population.
III. Cost

Estimates on the direct costs to treat heart failure vary enormously according to experts, ranging from $8 billion to $400 billion annually.\textsuperscript{16} Estimates of direct costs to treat heart failure in 1993 were $17.8 billion.\textsuperscript{17} The indirect costs of HF due to lost productivity and mortality were estimated to be $1.6 billion nationally in 2001.\textsuperscript{18} The American Heart Association(AHA) estimates the direct costs to treat HF nationally in 2001 rose to $19.4 billion\textsuperscript{19} (Figure 3).

**Figure 3. Direct Treatment Costs (in billions of dollars) of Heart Failure, 2001**

More Medicare dollars are spent on the diagnosis and treatment of HF than for any other condition. Approximately $500 million is spent annually on drugs for treating heart failure. According to CMRI, annual Medicare fee-for-service hospitalizations in California cost an estimated $270 million. In 1997, $3.7 billion ($5,501 per discharge) was paid on behalf of Medicare beneficiaries for HF.

CMRI concluded in a 1999/2000 study that the increased use of angiotensin-converting enzyme (ACE) inhibitors would avoid an estimated 330 California hospital readmissions and save Medicare more than $1.4 million. The study also noted that survival rates would increase, with an additional 150 Medicare beneficiaries alive within 90 days of discharge.

Use of third-party disease management vendors by health plans to provide weight and symptom monitoring of patients with severe HF is becoming increasingly common in California because of the high overhead costs associated with providing these services using internal resources. The overriding goal of monitoring patients who are decompensating (that is, manifesting severe symptoms of heart failure, such as shortness of breath or edema, as the heart becomes less able to compensate for reduced pumping efficiency) is to catch and quickly address early changes in weight or symptoms. This approach avoids hospital services, which are the single largest component of medical costs for heart failure, accounting for about 75 percent of total direct costs.

Such third-party programs cost in the range of $500 to $2,000 per patient per year, depending on patient volume and the scope of services provided. Alere Medical, a third-party vendor used by both Health Net and PacifiCare for severely ill patients, reported a 90 percent reduction in HF hospitalization costs for all enrolled patients based on a national average of 2 admits per patient per year. In a comparison (which Alere expects to substantiate with the results of a clinical study to be completed in 2002 by the University of Pennsylvania) of an Alere cohort with a control group using all-cause hospitalizations, the Alere cohort had a 62 percent reduction in all-cause hospitalization costs, including emergency room visits. The return on investment of the cohort population was 175 percent. Third-party vendors are also used by health plans in California for population-based disease management programs that stratify populations by risk and conduct self-care education for patients with early stage heart failure. According to third-party vendor representatives, average costs for population-based disease management programs are about $200 per patient per year, depending on patient volume and the scope of services provided.
IV. State of Knowledge, Prevention, Diagnosis, Treatment, and Monitoring

Heart failure is a syndrome in which the ability of the ventricle to fill with or eject blood is impaired by functional or structural heart disorders. Such dysfunction can be caused by narrowing of the arteries that supply blood to the heart (coronary artery disease), damage to the heart muscle from a previous heart attack, high blood pressure, or disease or infection of the heart valves or heart muscle. Left-sided (systolic) HF occurs when the left ventricle loses its ability to pump enough blood into circulation. Right-sided (diastolic) failure occurs if the ventricle is unable to fill with blood during the resting period between each beat. As the heart loses pumping power, blood flow slows, causing fluid to collect in the tissues of the lower extremities or back up into the lungs and causing edema in either case. The heart then begins to compensate for reduced pumping power through a process called remodeling. This includes enlarging to pump more blood, developing more muscle mass and thickening, and pumping faster to increase blood output. The body also compensates in other ways, releasing neurohormonal factors that further damage the heart and cause heart failure to progress.

The three most common symptoms of heart failure are shortness of breath, extreme fatigue, and excess fluid retention (edema). “Heart failure” is the preferred term rather than “congestive heart failure” in recognition of the fact that many patients do not experience the congestion associated with edema of the lungs. Heart failure is classified according to symptom severity using the New York Heart Association (NYHA) Functional Classification system, which assesses limitations to a patient’s physical activities. An explanation of the functional classes and percent of patients in each class is presented in the Appendix.

Guidelines and Measures

Updated treatment guidelines were published by a joint committee of the American College of Cardiology (ACC) and the AHA in collaboration with the International Society for Heart and Lung Transplantation in December 2001 and are endorsed by the Heart Failure Society of America (HFSA). The updated guidelines include a new staging system similar to that used in
cancer treatment. The goal of the staging system is to widen the treatment focus of HF to include prevention as well as early detection and treatment, beginning with the identification of patients at risk for developing heart failure. The stages are defined as follows:

- **Stage A**: Patients at risk for developing heart failure who have no structural disorder of the heart.
- **Stage B**: Patients with structural disorders of the heart but who have never developed symptoms of heart failure.
- **Stage C**: Patients have past or current symptoms of HF associated with underlying structural disorders of the heart.
- **Stage D**: End-stage patients who require specialized treatment strategies such as mechanical circulatory support, infusion therapy, or hospice care.

In addition to the updated ACC/AHA guidelines, treatment guidelines have also been promulgated by the Agency for Healthcare Research and Quality (AHRQ), and the Heart Failure Society of America (HFSA). The HFSA guidelines focus specifically on the pharmacologic treatment of systolic heart failure. There is strong consensus among the national entities that have developed guidelines, all of which identify assessment of ejection fraction as the critical diagnostic test in the evaluation of HF and recommend the use of ACE inhibitors in the treatment of systolic dysfunction. Among California provider organizations, health plans, and third-party disease management vendors, the AHRQ and ACC/AHA treatment guidelines are most commonly used as the primary resources in developing care management programs for HF. Although it is too early to predict when the updated ACC/AHA guidelines will be adopted or the extent to which they may be adapted by provider organizations, health plans, or third-party vendors, it is reasonable to assume that they will be widely used. A working group of the ACC and AHA has also reviewed national initiatives to measure and improve quality of care for patients with HF and developed recommendations for both structural and process-of-care measures to improve both quality of care and outcomes.

**Diagnosis**

Patients presenting with the signs or symptoms of HF are evaluated to diagnose the type of cardiac dysfunction, identify and treat any underlying causes of HF (such as coronary artery disease, hypertension, or diabetes), assess functional status, and determine prognosis. Echocardiography, which uses sound waves to create pictures of the heart’s walls, chambers, and valves, is the most common diagnostic test for assessing systolic function by measuring the heart’s ejection fraction (EF). Ejection fraction, a measure of how efficiently the heart is working, is the fraction of blood in the ventricle that is pumped out to the rest of the body each time the heart contracts. An EF of less than 40 percent indicates systolic dysfunction. A normal EF is in the range of 45 to 70 percent. Diastolic dysfunction is harder to pinpoint and is usually diagnosed when a patient presents with the signs and symptoms of HF but an echocardiogram reflects a normal EF.

Other diagnostic tests commonly performed in evaluating heart failure include coronary angiography in patients with chest pain to determine if there are blockages in the coronary
arteries; electrocardiogram (EKG), which may show evidence of a previous heart attack, thickening of the left ventricle, or an abnormal heart rhythm; chest x-ray to determine whether the heart is enlarged or if the patient’s lungs are congested; and blood tests to determine if liver and kidney function are normal.

**Treatment and Monitoring**

The overall goals of heart failure treatment are to slow disease progression, improve functional status and quality of life, and reduce hospitalizations and risk of sudden death. Medication is the foundation of treatment of HF, particularly ACE inhibitors; however, diastolic dysfunction is still not well understood and there are relatively few definitive studies to guide treatment of diastolic HF. Physicians treating patients with diastolic dysfunction therefore focus on managing heart rate, blood volume, and blood pressure, treating coronary artery disease and any other underlying conditions, and evaluating patients with heart disease for surgery (usually coronary artery bypass graft surgery or angioplasty).

**Medications**

Four classes of drugs are typically used to treat patients with systolic dysfunction whether or not they are symptomatic:

1. **Angiotensin-converting enzyme (ACE) inhibitors** are a form of vasodilator (drugs that dilate blood vessels) that work by blocking the formation of an enzyme that raises blood pressure, constricts blood vessels, and causes salt retention. ACE inhibitors are critical to the prevention and effective treatment of HF because they also slow disease progression by slowing the remodeling process, thus reducing morbidity and mortality. They are used in patients at risk for developing heart failure as well as for patients with HF. Eighty-five to ninety percent of HF patients are able to tolerate ACE inhibitors, although Asian patients have a nearly 50 percent risk of developing an ACE inhibitor-induced cough. New studies are underway to address doubts about the effectiveness of ACE inhibitors in African American patients.

2. **Beta-blockers** (beta-adrenergic blockers) are another type of vasodilator that reduces the heart's tendency to beat faster by blocking specific receptors ("beta receptors") located on heart cells. Beta-blockers are now considered standard therapy for stable patients with mild to moderate heart failure symptoms and for selected end-stage patients. Beta-blockers improve EF and reduce symptoms, hospitalizations, and mortality.

3. **Digitalis glycosides** are drugs that increase the heart’s ability to contract. Digoxin, a relatively inexpensive generic, does not reduce mortality but it has been shown to improve EF and functional status and to reduce hospital admission rates. Digoxin is usually used with other forms of standard therapy, such as ACE inhibitors, beta-blockers, and diuretics.

4. **Diuretics** are drugs that reduce fluid and are usually recommended in conjunction with ACE inhibitors to relieve edema. Diuretics are particularly important in the management of diastolic dysfunction because edema is common in these patients.
Surgery

Patients with coronary heart disease and HF may benefit from surgery, such as coronary artery bypass grafting (CABG) or angioplasty. CABG surgery is also recommended for patients with chest pain and moderate to severe HF. Pacemakers are recommended for some patients with arrhythmias. HFSA guidelines recommend the use of implantable cardioverter defibrillators (ICDs) as a first-line treatment for life-threatening arrhythmias rather than drug therapy. New trials that reflect a more than 30 percent drop in mortality associated with the use of ICDs in place of drug therapy are likely to fuel the debate surrounding costly evidence-based treatment options and Medicare funding constraints.

Other Measures

Reducing dietary salt, cardiac rehabilitation, reducing fluid intake, avoiding alcohol, reducing weight, and receiving smoking cessation counseling are recommended for patients with current or prior symptoms of HF. Follow-up programs, usually performed by a nurse or physician assistant, that monitor changes in weight and symptoms and compliance with diet and drug therapy can help reduce emergency room use and hospitalization in patients with moderate to severe HF. Patient education on the progressive nature of heart failure and the consequent importance of compliance with drug therapy and dietary restrictions are essential self-management tools recommended for all HF patients. Compliance with medication and diet is likely the single greatest hurdle to overcome in the area of patient management, particularly in the case of patients with no symptoms. Studies have shown that effective patient education strategies that include both inpatient and outpatient components can be expensive and typically lack adequate support within the health delivery system. Noncompliance with both diet restrictions and drug therapy are common results of ineffective patient education efforts.

Specialized treatment strategies for end-stage HF include mechanical circulatory support (such as left ventricular assist devices (LVADs), IV therapy, and evaluation for heart transplantation, or hospice care. Close monitoring of symptoms is especially critical in end-stage HF patients because many suffer greatly from shortness of breath and edema. A comprehensive HF treatment plan also includes consideration of end-of-life issues. Both the patient and family should receive ongoing education regarding prognosis, including the course of treatment and the progressive and ultimately fatal nature of this condition. It is important for patients to consider final treatment options and preferences, advance directives, and living wills.

Improving Quality of Care for Californians with Heart Failure
The gaps between knowledge and treatment is quite wide in California, as evidenced by a national study based on 1998 patient data that ranked California 34th (80 percent) among states in the use of ACE inhibitors and 33rd (65 percent) in assessing left ventricular ejection fraction (LVEF). In contrast, the best-performing state achieved rates of 88 percent and 79 percent respectively. According to a 1996 CMRI study, only 57 percent of eligible CHF patients were prescribed an ACE inhibitor at hospital discharge.

Women and non-Caucasians are less likely to receive ACE inhibitors than Caucasian males, although the prevalence of HF is highest among African Americans, and women have the highest total deaths from HF. Other studies suggest that ACE inhibitors are not prescribed in high enough doses to be most effective and that most clinical trials for ACE inhibitors and beta-blockers were predominantly based on Caucasian male patient populations. As diastolic dysfunction is becoming more prevalent, the dearth of clinical trials for treatment of this disorder is finally being corrected with recent trials; however, current guidelines for treating diastolic dysfunction rely mainly on clinical judgment in the absence of randomized, controlled studies.

Many of the deficiencies that exist between the state of knowledge concerning heart failure and the delivery of care to patients result from a traditional emphasis on treatment of acute stages only. Instead, heart failure should be recognized as a chronic condition with a coordinated approach to prevention, education, and management of the disease as it progresses. The barriers to closing the gaps between knowledge and treatment have been loosely grouped into structural, process-of-care, and reimbursement policy categories below.

**Structural Barriers**

- Provider organizations and hospitals lack the infrastructure, such as decision support systems that are built on evidence-based treatment guidelines, to systematically monitor patient care and outcomes, especially on a timely basis.
A lack of coordination across care settings (common to most chronic disease states) makes it difficult to smoothly transfer patients to the appropriate care setting as the disease progresses. Patients who lack regular access to care are particularly affected by this barrier and, in California, experience higher emergency room and hospitalization rates.30

Patients commonly do not receive optimal drug titration, which is critical to efficacy, particularly women and minorities (due in part to the lack of clinical studies). This is also true for patients not followed by a cardiologist. Dosage issues often arise when patients are shifted from brand-name to generic ACE inhibitors and beta-blockers in response to health plan formulary requirements or because the patient is unable to afford brand-name drugs.

A lack of clinical expertise in heart failure forms another structural barrier. Many patients are followed by general practitioners, rather than cardiologists, often because they lack access to specialty care, or experience difficulties obtaining required referrals from PCPs. Many also lack access to disease management programs that provide nurse specialists trained in monitoring HF patients. Most of these patients are not assessed for functional status, nor are they evaluated for satisfaction or overall health status.

Disease management programs at both the health plan and provider organization level generally focus on Class III and IV patients (those who are symptomatic and likely to deteriorate). Little or no attention, beyond passive intervention strategies, such as population-based educational materials, is given to patients at high risk for developing HF or those with a depressed ventricular function but no symptoms. Coordinated disease management programs for heart failure have typically been developed in response to CMS requirements and are seldom offered or available to people who are under age. In some cases telephonic monitoring programs are only available to Medicare+Choice enrollees.

**Process of Care**

- Physicians do not follow guidelines despite the fact that general consensus exists around proper management of HF patients among the major authorities on heart failure.

- Under-prescribing of both ACE inhibitors and beta-blockers for HF patients and those at risk of developing HF is widespread, despite overwhelming evidence for the use of both classes of drugs in slowing disease progression, improving functional status, and decreasing the risk of sudden cardiac death.31

- Failure to evaluate and document left ventricular ejection fraction in patients discharged from the hospital with a heart failure diagnosis continues to be widespread.32

- There exists a lack of evidenced-based pharmacologic treatment for diastolic function, which is quickly approaching systolic dysfunction in prevalence and incidence. A statewide sample of community hospitals in California revealed that diastolic dysfunction is associated with high morbidity and mortality; treatment with ACE inhibitors did not appear to confer comparable benefits to these patients as to patients with systolic dysfunction.33
Reimbursement Policies

- Medicare fee-for-service does not include an outpatient prescription drug benefit, a critical shortcoming in medical coverage for patients with a condition that is primarily treated by prescription drugs. Evidence suggests that Medicare beneficiaries who lack prescription drug coverage do not fill all prescriptions written\textsuperscript{34}, often split pills inappropriately, and skip doses. This problem is likely to be exacerbated in 2002 by the further reduction of drug benefits by some of the state’s largest Medicare+Choice plans in selected services areas.

- Medicare fee-for-service lacks a billing code for daily weight monitoring, leaving Class III and IV patients with a critical gap in covered services because providers are unable to bill for services rendered. Education on self-care techniques, including nutrition counseling and other lifestyle changes, is also not covered under Medicare fee-for-service, although many provider organizations in the state provide self-care information to all heart failure patients, regardless of the patient’s Medicare status.
VI. Current Efforts to Close the Gaps

The most comprehensive national initiatives to improve quality of care for heart failure patients are the CMS-sponsored National Heart Failure (NHF) project and the CHF Quality Assessment and Performance Improvement (QAPI) project, which was the Quality Improvement System for Managed Care (QISMC) topic designated by CMS for 2001. Launched in 1999, the NHF project is hospital-based and focuses on the fee-for-service Medicare population. The QAPI project for heart failure began in 2001 and focuses on the Medicare+Choice population. Both projects are coordinated statewide by California Medical Review, Inc. (CMRI), the Medicare QIO in California.

The main objective of the NHF project is to reduce morbidity and mortality associated with HF in Medicare beneficiaries through the improvement of two process measures: (1) increased evaluation of left ventricular systolic function, and (2) increased use of ACE inhibitors for heart failure patients. In the QAPI project, Medicare+Choice plans are required to demonstrate improved quality of care by reporting on the same two quality indicators: (1) the proportion of CHF patients with assessment of left ventricular function, and (2) the proportion of CHF patients with left ventricular systolic dysfunction who have been prescribed an ACE inhibitor or have a documented reason for not using ACE inhibitors. Medicare+Choice plans must achieve a 10 percent reduction between the threshold (75 percent for the EF evaluation and 80 percent for ACE inhibitor use) and individual plan performance. While the NHF program is relatively limited because it is aimed only at patients who require hospitalization, the Medicare+Choice project includes patients in both the ambulatory and hospital settings who are appropriate for EF evaluation and ACE inhibitor use.

Other national level HF quality improvement studies and efforts include: (1) the Veterans Administration CHF Quality Enhancement Research Initiative (QUERI), which began in 1998 and funded a wide range of research topics on HF treatments and care management; (2) the Institute for Healthcare Improvement’s (IHI) Breakthrough Series Collaborative to Improve Care for People with CHF, which was conducted from May 1999 to January 2000 (participants from California were limited to several VA facilities, a hospice, and Kaiser Permanente); and (3) the ACC/AHA Heart Failure Working Group, which conducted an extensive review of interventions.

JCAHO (Joint Commission on Accreditation of Healthcare Organizations) has established a set of core measures for patients admitted with an HF diagnosis, which include evaluation of EF, the use of ACE inhibitors and beta-blockers, and smoking cessation counseling (new for 2002). The National Committee for Quality Assurance (NCQA) is currently developing Health Plan Employer Data and Information Set (HEDIS) measures for managing HF for Medicare+Choice plans. HEDIS measures for managing antecedent conditions to HF, such as controlling high blood pressure and high cholesterol, have been measured in California for several years through the California Cooperative Health Care Reporting Initiative (CCHRI).

The AHA’s national “Get With The Guidelines” program is a hospital-based coronary heart disease prevention program that, while not specific to heart failure, supports all of the JCAHO and CMS core measures for HF and helps manage associated risk factors. The program emphasizes an interdisciplinary approach between cardiologists, neurologists, primary care physicians, nurses, and pharmacists and features a decision support system based on the ACC/AHA guidelines. In California the AHA collaborated with a variety of stakeholders, including the Department of Health Services and CMRI, to begin an extensive campaign in 2001 to introduce the program to all public and private hospitals in the state. The program is free of charge and can be conveniently downloaded by hospitals from the AHA Web site, along with the decision support tool, for which there is an annual charge of less than $1,000.35

In 1999, the California state legislature attempted to broadly address the lack of prescription drug coverage for Medicare beneficiaries with the Prescription Drug Discount Program for Medicare Recipients, which became operational in February 2000. The program allows Medicare patients to purchase prescription drugs for the same cost that Medi-Cal reimburses Medi-Cal pharmacy providers, plus a 15-cent processing fee for each prescription filled. There are no formulary restrictions and no prior authorizations required. Most of the pharmacies in California (more than 5,000) participate in Medi-Cal, making the discount program, in theory, easily accessible to Medicare beneficiaries. However, seniors often do not receive the discount unless it is specifically requested. In addition, a significant number of individually owned pharmacies, which often are located in the poorest neighborhoods, do not participate in Medi-Cal, leaving many low-income seniors without easy access to the discount.

Several pharmaceutical manufacturers have also introduced Medicare discount programs to assist seniors who lack prescription drug coverage. However, these programs are often means-tested and provide discounts only for the manufacturer’s products. Seniors who “spend down” their resources can qualify for prescription drug coverage under Medi-Cal, but the requirements for qualification are punitive and cause many seniors to lose what financial independence they have.

Over the past ten years, stakeholders in the California health care delivery system have initiated efforts to improve the quality of care for heart failure patients. As is true for other conditions, care largely depends upon where financial responsibility for the delivery of health services rests. There are approximately 4 million Medicare beneficiaries statewide; about 1.4 million people were enrolled in Medicare+Choice plans as of 2001.36 Enrollees in Medicare+Choice plans generally have access to comprehensive care management programs offered by either the
Medicare contracting health plan or by the at-risk provider organization. These programs typically include a weight and symptom monitoring component managed by registered nurses for Class III and IV patients. Often these disease management (DM) programs incorporate many of the structural elements critical to high-quality chronic care, such as integrated practice teams, patient education programs, nurse managers to coordinate delivery of services across the care continuum, feedback mechanisms to measure changes in patient satisfaction and health status, and reductions in hospital admissions and lengths of stay. Examples of these programs are described below.

**Health Plans**

By virtue of its unique structure as a group model HMO, Kaiser Foundation Health Plan has achieved a level of coordination for HF patients that is unparalleled by its network model competitors. Kaiser’s comprehensive HF care management program was internally developed by its Care Management Institute (CMI) and incorporates the elements of the Chronic Care Model promoted by the Institute for Healthcare Improvement (IHI). The program was launched nationally in 1998 through the Permanente Medical Groups to all enrollees affected with or at risk for developing HF. It includes an integrated electronic medical record (EMR), online decision support and case management tools, and interdisciplinary practice teams.

Originally most heart failure disease-management programs were internally developed and administered by the health plans sponsoring the programs. However, several now use third-party disease-management vendors to deliver services to Class III and IV HF patients. Because of the high costs associated with such programs, for a relatively small number of patients, vendors have been found to be efficacious.

Three of the four largest health plans in California (Blue Cross, Health Net, and PacifiCare) deliver disease management programs through a combination of third-party vendors and in-house staff. Blue Cross, and PacifiCare internally identify and stratify Medicare+Choice patients using inpatient, ambulatory, lab, and pharmacy data. As of July 2000, Health Net began using a third-party vendor, Landacorp, to identify and stratify HF patients using a health risk assessment tool in addition to claim data. The triggers used by plans to identify HF patients for population-based and specialty case management programs (such as number of HF admits per patient per year, use of ACE inhibitors) are generally very similar.

All three plans use third-party vendors to provide telephonic monitoring and case management services to Class III and IV patients, finding these vendors to be more cost-effective than using internal resources. Blue Cross has worked with Patient Information Systems since 1998 to manage severely ill heart failure patients. Blue Cross has conducted a longitudinal analysis of the population enrolled in this program, beginning with a baseline of 1,700 patients in 1998. At the end of year two, 1,457 of the original baseline members remained. Results have been impressive, with the greatest improvements seen at the end of the first year and incremental improvements across all measures continuing into year two. Since the program’s inception, Blue Cross internal claims data show that admits per 1,000 members have declined 49 percent in the baseline population, while hospital days per 1,000 have decreased 54 percent. Emergency room visits have decreased 9 percent and adherence to ACE inhibitor therapy has increased 24 percent.
Between the population-based and case management components of its HF initiative, Blue Cross managed care for an estimated 7,000 to 8,000 members in 2000-01.

PacifiCare turned to Alere Medical for management of Class III and IV patients in late 2000. Health Net followed suit in 2001. Both of these programs have yet to report results. In all plans that use third-party vendors to manage severely ill heart failure patients, the feedback loop between the vendor and health plan includes monthly reports with data on medication compliance, hospital and emergency room data, and information on patient health status and satisfaction. Most PPO plans provide case management services to severely ill Class III and IV patients, but generally lack the patient data necessary for implementing the formalized disease-management programs found in managed care plans.

Across all of these plans, low-risk patients (Class I and II) are passively enrolled in population-based disease-management programs. These programs attempt to change behavior by educating patients on the nature of heart failure, appropriate medications for treating heart failure, the importance of diet and lifestyle changes, etc. Providers receive reports detailing patients with HF and reminders on how to manage heart failure, including the use of ACE inhibitors. PacifiCare’s pharmacy benefit management subsidiary provides physician groups with a list detailing patients with an HF diagnosis not on ACE inhibitors.

**Physician Organizations**

The use of a mixture of in-house staff and third-party vendors has also been adopted by a number of physician organizations in the state, most of which initially identify HF patients in the acute care setting. Most care management programs offered by medium to large physician organizations incorporate patient education programs (on diet, weight management, medication, etc.) that are typically offered through classes or via the Internet. Telephonic monitoring of severely ill heart failure patients is also widespread among most of the medium to large provider organizations in the state, including academic teaching centers. Several of the larger, more organized integrated provider organizations, such as Sutter Health, Scripps Health System, and Sharp HealthCare have developed comprehensive, high-quality care management programs using in-house staff and resources.

Sutter Health is one of the largest health systems in the state, with 26 hospitals, 7 foundation medical groups, and 5 affiliated IPAs delivering services to 1 million patients covered by capitation arrangements and to another estimated 1 million fee-for-service patients. Sutter Health provides an interesting case for improving the quality of care for HF patients at the health system level. Sutter’s Clinical Integration Department identified an opportunity to improve the quality of care for heart failure patients based on the understanding that (1) HF is a common diagnosis, (2) clear and consistent guidelines exist for managing patients with this condition, and (3) wide variability had been documented in how heart failure was being managed across the system.

The Clinical Integration Department determined that third-party vendors were effective in managing extremely ill patients, but were not as effective in managing early presenters, a population important to the system. In 1998, Sutter began developing a coordinated inpatient and outpatient initiative for all of its hospitals and its foundation medical groups. Implementation of the initiative began in 1999 with the adoption of many CMRI, ACC/AHA, and Institute for
Clinical Systems Integration (ICSI) recommendations. Prior to the start of the program, the overall ACE inhibitor usage rate was 70 percent, and an aggressive target rate of 90 percent was set (the IHI Collaborative goal is 85 percent). Goals were also set for reductions in admission rates and lengths-of-stay. Since implementation, the program has had annual participation of 5,000 inpatients and 2,250 outpatients. According to Clinical Integration Department staff at Sutter, overall ACE inhibitor usage has increased to 86 percent and readmission rates dropped while average lengths-of-stay remained stable.

Key elements of the program that have contributed to its success mirror many of the goals and elements of the IHI Collaborative to Improve Care for People with CHF. For example, by relying on the larger community of contracting health plans for prescription drug data reporting resources, Sutter has been able to match inpatient and ambulatory heart failure diagnoses with claims data on ACE inhibitors and beta-blockers to benchmark usage rates for quality improvement and to identify patients not on the appropriate medications for follow-up for about 70 percent of its managed care patient base. Sutter demonstrated its commitment to improving care for its patients by funding the entire cost of the HF initiative internally. Opinion leaders were recruited, including both consulting and local cardiologists from within each facility, to train physicians on the guidelines and associated critical pathways to redesign hospital practices and improve the process of care. Support for developing patient self-management skills has been enhanced through the use of discharge orders that require documentation of self-care education for patients prior to discharge. The expanded use of home health agencies for follow-up self-management education has helped ensure that patients understand diet and medication regimens and have clear instructions on when to call the doctor.

Sutter has found the use of trained nurse specialists both to reinforce patient education aimed at behavior change and to conduct telephonic monitoring of severely ill patients to be one of the most effective components of the initiative. The initiative incorporates a decision support system that uses the AHRQ and ACC/AHA treatment guidelines. Sutter is moving toward an electronic medical record (EMR) that is coordinated between the outpatient and inpatient settings systemwide. The outpatient EMR is already in place at four Sutter foundation medical groups (Palo Alto, Sutter West, Sutter Sacramento, and Sutter Gould) and can send alerts to admitting physicians with a copy of the pre-printed (standing) admission orders used in all Sutter hospitals for HF patients. A research team at the Palo Alto Medical Foundation is currently developing an algorithm that will allow Sutter to build HF patient rosters at all of the system’s medical groups.

Sutter continues to struggle with significant barriers to closing the gaps between knowledge and treatment, such as data collection problems (chart review is still used, however it is costly and time-consuming), lack of data standardization (the pharmacy claims reported by contracting health plans come in different formats that are difficult to reconcile), and HIPAA requirements (privacy regulations make the sharing of data among Sutter affiliates more difficult). Although the initiative is available to all Sutter patients with HF, the system lacks good information on its Medicare fee-for-service patients who make up a large component of the overall heart failure patient population. Sutter expanded its cardiac rehabilitation program, previously available only to heart attack patients, to heart failure patients in 2000, but the system is struggling financially to keep the program afloat. In 2001 use of beta-blockers was added to the performance measures, and smoking cessation counseling will be added in 2002 to meet the new JACHO measure as Sutter works to continuously improve care delivery to its heart failure patients.
Employers have also taken steps to close the gaps between knowledge and treatment in California. The California Public Employees Retirement Systems (CalPERS), the largest employer in the state, initiated a heart failure treatment program in December 1999 for early retirees, active employees, and retirees not eligible for Medicare and enrolled in one of two employer-funded PPO plans. The initiative is a joint effort between CalPERS, Blue Cross, and Merck-Medco, which manages the carve-out pharmacy benefit plans associated with the PPO plans. This initiative is noteworthy because it was initiated by an employer rather than a health plan or health system, was designed for a non–Medicare-eligible fee-for-service population, and incorporates many of the goals embodied in the IHI Chronic Illness Collaborative, including reductions in medical utilization (hospital admits, hospital days, emergency room visits), adherence to ACE inhibitor and beta-blocker medications, evaluation of quality of life (using the Minnesota Living with Heart Failure Questionnaire) and patient satisfaction. Preliminary results were measured in the third quarter of 2001 based on an enrollment of 937 patients and showed promising improvement in all but one performance area (emergency room visits).
VII. Opportunities and Recommendations

Since 1998, the Centers for Medicare and Medicaid Services has taken a strong lead on quality improvement efforts related to HF. As described in the previous section on efforts to close the gaps, CMS’s programs for both Medicare fee-for-service patients as well as those enrolled in Medicare+Choice plans are managed by CMRI, the Medicare QIO in California. Preliminary data from the fee-for-service program show promising results. In addition, several vendor-contracted health plan programs, along with that of Kaiser Foundation Health Plan and those of leading hospital-based organizations, such as Sutter Health and several Sharp-affiliated entities, offer excellent models that can be expanded and shared with other delivery system stakeholders. Opportunities for CHCF, as well as other organizations seeking to improve quality in this area, include:

**Recommendation #1:** Partner with CMRI to expand CMS initiatives, specifically at the hospital level for fee-for-service Medicare populations, and among provider organizations generally, to create lasting change by implementing a systematic, coordinated approach to managing patients with HF.

Although CMRI does not yet utilize the IHI heart failure collaborative, the interventions promoted thus far by the organization to help provider organizations improve diagnosis and treatment of heart failure have been based on a rigorous literature review on the effectiveness of various intervention strategies and reflect many of the IHI strategies.

CMRI has experience collaborating with most of the key stakeholders involved in managing heart failure, including CMS, AHRQ, the California Department of Health Services, California hospitals and physician groups, the ACC, and the AHA. The CMRI Web site contains numerous tools and resources for improving the management of HF, including the updated ACC/AHA guidelines and an easy-to-use online decision algorithm for the use of ACE inhibitors based on AHRQ guidelines. In December 2001, CMRI convened a focus group of physician organizations to evaluate effective interventions for improving the quality of care for HF patients; it also has a number of other projects underway to assist hospitals and Medicare+Choice plans meet CMS-mandated quality measures. Of particular note is CMRI’s collaboration with the AHA “Get with the Guidelines” hospital-based program. While it is just getting underway in California, this
program promises to put a powerful, effective tool for improving the treatment of a wide variety of cardiovascular disorders, including heart failure patients, into the hands of public and private hospitals.

Recommendation #2: Participate with the California Heart Disease and Stroke Prevention (CHDSP) Program to develop a state heart disease action plan, beginning with a “resource map” to pinpoint what heart disease care programs are available to whom across the state.

Under the aegis of the state Department of Health Services, the CHDSP Program office is developing a statewide action plan to improve care for cardiovascular disease (CVD), the number-one cause of death in the state. The first step in developing the action plan is the creation of a resource map that identifies what programs are available to serve Californians with CVD. This effort will inform the state’s efforts to create a comprehensive policy for improving CVD care, including care for HF. Participating in this effort will not only keep CHCF abreast of programs currently underway or planned but may also provide CHCF with an opportunity to shape policy as it is formed.

Recommendation #3: Partner with the CHDSP on a demonstration project for improving HF care for a targeted, high-risk geographic area in California.

As of 1999 and for the several immediately preceding years, San Bernardino County had the highest rate of death from cardiovascular disease, including heart failure, in the state. CHDSP is currently working with Loma Linda University Medical Center on a demonstration project to evaluate adherence to secondary prevention guidelines (smoking cessation, cardiac rehabilitation, weight and blood pressure control, and use of beta blockers, ACE inhibitors, anticoagulants, and lipid-lowering drugs) in coronary artery disease patients who receive intensive outpatient follow-up care compared to coronary artery disease patients who receive usual care from their primary care physicians. A cardiac rehabilitation project focused on HF patients or a project aimed at working with primary care physicians to improve HF care are examples of demonstration projects that could be designed with Loma Linda or other interested provider partners. Another potential demonstration project aimed at working with primary care physicians to improve HF care for African Americans could be created in Los Angeles County around King/Drew Medical Center, which sees a high number of African American patients suffering from HF and other cardiovascular disorders.

Recommendation #4: Export model hospital system-based quality improvement programs to other hospital system in the state.

The Sutter Health HF quality initiative is primarily based on using data and information to identify opportunities to improve the delivery of care across the system’s care settings. Although the initiative faces obstacles, such as the lack of standardized data from health plans and inadequate funding for its successful cardiac rehabilitation program, the core components of this program could be replicated by other hospital-based systems in the state.

Recommendation #5: Work with state and federal policymakers to explore ways to expand drug coverage for seniors with this disease.

As congressional debate over prescription drug coverage for Medicare beneficiaries continues, the opportunity exists for CHCF to influence the debate with a creative approach that ties expansion of drug coverage to improved quality of care for HF. For example, beneficiaries who
demonstrate compliance with an HF disease management program would receive credits for the
drugs needed to treat the condition. In this way, patients would be both motivated and
empowered to improve their own quality of care. Rather than advocating for a large increase in
overall entitlements, CHCF could partner with Medicare QIOs to document expected savings in
overall health expenditures through reductions in hospitalizations and emergency room visits
based upon data from the NHF quality initiative already underway.

**Recommendation #6: Explore opportunities to better identify and educate underserved
populations with heart failure, including those with Class I and II diagnoses, African
Americans, and women.**

Understanding of what heart failure is, among patients with the syndrome as well as the general
public, is very low, in part because of the term used to describe the condition. General public
health messages and targeted messages for at-risk populations about how widespread and
treatable the condition is would raise the level of awareness and understanding of HF and
encourage people with underlying conditions, such as hypertension, diabetes, high cholesterol,
and previous heart attacks, to seek assistance in managing these conditions before they lead to
heart failure as well as encouraging those with the signs or symptoms of HF to seek medical
care. In addition, public health messages targeted to specific populations, such as African
Americans, regarding the effectiveness of drug therapy in controlling the condition and slowing
disease progression would help people with HF understand the necessity of complying with HF
treatment regimens.
VIII. Conclusion

Heart failure is a widely prevalent and costly disorder, both nationally and in California, that disproportionately affects people 65 and older. The state is currently home to 10 percent of the nation’s Medicare beneficiaries—a population that is expected to more than double in the next 20 years. As the population ages, the incidence and prevalence of heart failure will continue to increase. Growing numbers of people affected with HF combined with new and more costly treatment modalities for the disorder will strain state and national health care resources.

Effective treatments are available for slowing disease progression and improving the functional status and overall health status of patients with HF. However, studies have shown that a wide gulf exists between the theory and actual practice of managing these patients. Comprehensive disease management programs for people with HF can close the gaps between knowledge and practice and reduce overall health care costs, yet delivery of these programs is fragmented between stakeholders in the delivery system. From 1998 to 2000, California improved its usage of ACE inhibitors from 80 percent to 83 percent and assessment of ejection fraction from 65 percent to 73 percent, yet the state continues to lag behind the best performing state in both areas. Stakeholders in the delivery system, including the Medicare QIO in California, provider organizations, and health plans, have attempted to improve HF care. However, better coordination of efforts and changes to the delivery system itself are needed before lasting change can occur.
## Appendix: New York Heart Association Functional Classification System

<table>
<thead>
<tr>
<th>Stage</th>
<th>Class</th>
<th>Estimated Percentage of Patients in Category</th>
<th>Functional Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>B,C</td>
<td>I</td>
<td>35%</td>
<td>No symptoms and no limitation in ordinary physical activity.</td>
</tr>
<tr>
<td>C</td>
<td>II</td>
<td>35%</td>
<td>Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.</td>
</tr>
<tr>
<td>C</td>
<td>III</td>
<td>25%</td>
<td>Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.</td>
</tr>
<tr>
<td>D</td>
<td>IV</td>
<td>5%</td>
<td>Severe limitations. Experiences symptoms even while at rest.</td>
</tr>
</tbody>
</table>

*Source: ACC/AHA Guidelines for the evaluation and management of chronic heart failure in the adult.*
Glossary

**ACE inhibitor** – Angiotensin-converting enzyme inhibitor, a class of vasodilators (drugs that dilate blood vessels) that work by blocking the formation of angiotensin II, an enzyme that raises blood pressure, constricts blood vessels, and causes salt retention.

**Age-adjusted death rate** – Used to compare the rates of two or more specific communities, or the nation as a whole, over time.

**Angiography** – A diagnostic test used to detect diseases of the blood vessels, such as narrowing or blocking of the arteries, using radioactive dye that is injected into the blood vessels in order to take an x-ray.

**Angioplasty** – A revascularization procedure in which a physician reopens blocked coronary arteries using a hollow needle (catheter).

**Arrhythmia** – An irregular heartbeat.

**Beta-blocker** – A class of vasodilators that work by reducing the heart's tendency to beat faster by blocking specific receptors ("beta receptors") on the cells that make up the heart.

**Cardiomyopathy** – A weakening or deformity of the heart muscle that can impair the heart’s ability to circulate blood efficiently.

**Coronary artery bypass graft (CABG) surgery** – Surgery to bypass clogged coronary arteries to improve the supply of blood and oxygen to the heart using a blood vessel taken from another part of the body and grafted onto the diseased artery, bypassing the blocked portion.

**Coronary artery disease** – A condition caused by the thickening of the walls of coronary arteries that supply blood to the heart muscle. If the arteries become blocked, the heart becomes deprived of oxygen from reduced blood flow, resulting in ischemia, a condition in which the heart is damaged by an inadequate supply of oxygen and nutrients.

**Diastolic pressure** – The pressure of blood inside arteries when the heart is at rest.

**Dyspnea** – Shortness of breath.

**Edema** – Abnormal fluid accumulation in body tissues. Pulmonary edema is fluid accumulation in the lungs.

**Hypertrophy** – A thickening of the muscle fibers to strengthen the heart muscle, allowing the heart to contract more forcefully and pump more blood.

**Implantable cardioverter defibrillator (ICD)** – Implantable device that provide automatic electrical therapy for patients with certain kinds of arrhythmias.

**Sudden cardiac death** – Cardiac arrest caused by an irregular heartbeat.

**Systolic pressure** – The pressure of blood inside arteries when the heart contracts.

**Ventricle** – One of the two lower chambers of the heart. The right ventricle pumps blood to the lungs; the left ventricle pumps blood to the rest of the body.
Endnotes


16 CMS (formerly HCFA). “Heart Failure National Project Overview” (originally published as part of HCFA Pub. No. 10156).


21 CMS (formerly HCFA). “Heart Failure National Project Overview.” (Originally published as part of HCFA Pub. No. 10156.)


32 Jencks, Cuerdon “Quality of Medical Care Delivered to Medicare Beneficiaries.”


