

MINI-FOCUS ISSUE: SOCIOECONOMIC FACTORS AND HEART FAILURE

STATE-OF-THE-ART REVIEW

Heart Failure and the Affordable Care Act Past, Present, and Future



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HIGHLIGHTS

- The Affordable Care Act has affected heart failure patients through insurance regulation, coverage expansion, and delivery system reform.
- Some of these elements could have positive effects for heart failure patients.
- The benefit of value-based and alternative payment models for heart failure outcomes is less clear.
- Heart failure clinicians should be aware of how legislation affects clinical practice.

ABSTRACT

The Affordable Care Act (ACA) and other major health care legislative acts have had an important impact on the care of heart failure patients in the United States. The main effects of the ACA include regulation of the health insurance industry, expansion of access to health care, and health care delivery system reform, which included the creation of several alternative payment models. Particular components of the ACA, such as the elimination of annual and lifetime caps on spending, Medicaid expansion, and the individual and employer mandate, could have positive effects for heart failure patients. However, the benefits of value-based and alternative payment models such as the Hospital Readmissions Reduction Program and bundled payment programs for heart failure outcomes are less clear, and controversy exists regarding whether some of these programs may even worsen outcomes. As the population ages and the prevalence of heart failure continues to rise, this syndrome will likely remain a key clinical focus for policymakers. Therefore, heart failure clinicians should be aware of how legislation affects clinical practice and be prepared to adapt to continued changes in health policy. (J Am Coll Cardiol HF 2019;7:737-45) © 2019 by the American College of Cardiology Foundation.

Heat failure (HF) is a major medical and economic problem worldwide. In the United States alone, more than 5.7 million adults have prevalent HF, a figure that will continue to rise as the population ages (1). Costs for the care of HF patients have reached \$30.7 billion annually and are estimated to increase by 120% by 2030 (2). Given its clinical and financial footprint, many recent efforts

in health policy, including the Affordable Care Act (ACA), significantly affect HF patients and the clinicians who care for them. Passed in March 2010 and often referred to as “Obamacare” (Figure 1), the major provisions of the ACA went into effect in 2014 and can be divided into 3 categories: health insurance regulation, expansion of access to health care, and reform of delivery systems (Central Illustration). In each of these

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**ABBREVIATIONS
AND ACRONYMS****ACA** = Affordable Care Act**ACOs** = accountable care organizations**BPCI** = bundled payments for care initiative**HF** = heart failure**HRRP** = Hospital Readmissions Reduction Program**HVBP** = hospital value-based purchasing**MIPS** = merit-based incentive payment system**MSSP** = Medicare Shared Savings Program**PCORI** = patient-centered outcomes research institute**VM** = value (-based payment) modifier

areas, it is important for the HF community to understand what is in the ACA, as well as other health care legislation, and how it may affect the care of HF patients going forward.

**HEALTH INSURANCE REGULATION
AND ITS IMPACT ON HF**

The ACA resulted in numerous regulations for the health insurance industry. Health insurers were prevented from denying coverage based on pre-existing conditions and from dropping policy holders when they get sick. Annual and lifetime coverage caps were banned. Preventative care, vaccinations, and routine medical screening were not allowed to be subjected to copayments or deductibles. Notably, the percentage of profit earned on health insurance premiums was also effectively

capped, such that insurers were required to spend 80% to 85% of premiums on direct health care costs.

These changes have important implications for HF patients. In particular, the regulations imposed by the ACA to prevent insurers from denying coverage based on pre-existing conditions and from dropping policy holders when they get sick has been particularly relevant for patients living with HF, given its high morbidity, mortality, and costs. The 5-year mortality rate for patients with symptomatic HF approaches 50% (3). HF is also one of the most frequent causes of recurrent hospitalizations and the leading cause for admissions and readmission in patients older than 65 years of age (4,5). High mortality and hospitalization rates have driven extensive innovation in pharmacological and device therapies for HF patients (6). As a result, HF patients incur extraordinary expenses for health insurance companies and are consequently placed in “high-risk” categories. The protections afforded to HF patients as a result of new insurance regulations under the ACA are, thus, crucial.

**EXPANSION OF ACCESS TO HEALTH CARE
AND ITS IMPACT ON HF**

The second major category of effects under the ACA was insurance expansion. The ACA sought to expand access to health care by multiple means and was largely successful in this, with an estimated 20 million additional individuals receiving health insurance, and has helped reduce the health insurance coverage disparities between whites and minorities (7). Most significantly, the law included an individual mandate for all individuals to purchase health care

insurance or to pay a penalty. Subsidies for health insurance for households between 100% and 400% of the federal poverty level were also included, as was expansion of Medicaid for residents with income up to 133% of the federal poverty level. Dependents were allowed to stay on their parent’s health insurance plan until their 26th birthday. The law also required employers of large businesses to provide health insurance to their full-time employees or to pay a tax penalty. Finally, the law established the creation of the health insurance exchange marketplaces for the individual insurance market, with the intention of promoting competition among insurance companies.

Since 2010, additional legislation has been passed that modifies some of the legislation passed originally. The Supreme Court ruled in 2012 as part of the case *National Federation of Independent Business v. Sebelius* that the language used in the ACA to expand Medicaid was coercive to states, and states were allowed to independently decide whether they would expand Medicaid in accordance with the ACA or to continue at pre-ACA levels of funding and eligibility. Ultimately, 36 states decided to adopt the Medicaid expansion proposed by the ACA, with 14 states opting out. The individual mandate was also eliminated as part of the Tax Cuts and Jobs Act of 2017, effective beginning in 2019. The consequences of removing the individual mandate are unclear, but the Congressional Budget Office estimated that by 2027, 13 million fewer Americans would have health insurance; they forecasted an associated increase in insurance premiums for individuals remaining in the market and an estimated cost savings of \$338 billion to the federal government (8).

These changes could affect HF patients in a number of ways. The most well-documented benefit of insurance is protection from financial hardship, which is a major issue for HF patients. In the United States, atherosclerotic disease, the most common cause of HF, is responsible for the highest health care costs of any single class of disease and is associated with a high prevalence of financial distress, food insecurity, and cost-related medication non-adherence (9-11). The burden of catastrophic expenditures, defined as out-of-pocket medical expenses exceeding 30% of income, is particularly high among uninsured patients, with rates as high as 85% for patients hospitalized for acute myocardial infarction (12). Health insurance has been shown to protect patients from financial hardship. A study from the 2008 expansion of Medicaid in Oregon, which allowed for a randomized, controlled trial of health insurance coverage, showed that obtaining health insurance significantly reduced out-of-pocket spending and

FIGURE 1 Major Events in Health Care Policy Between 2008 and 2019

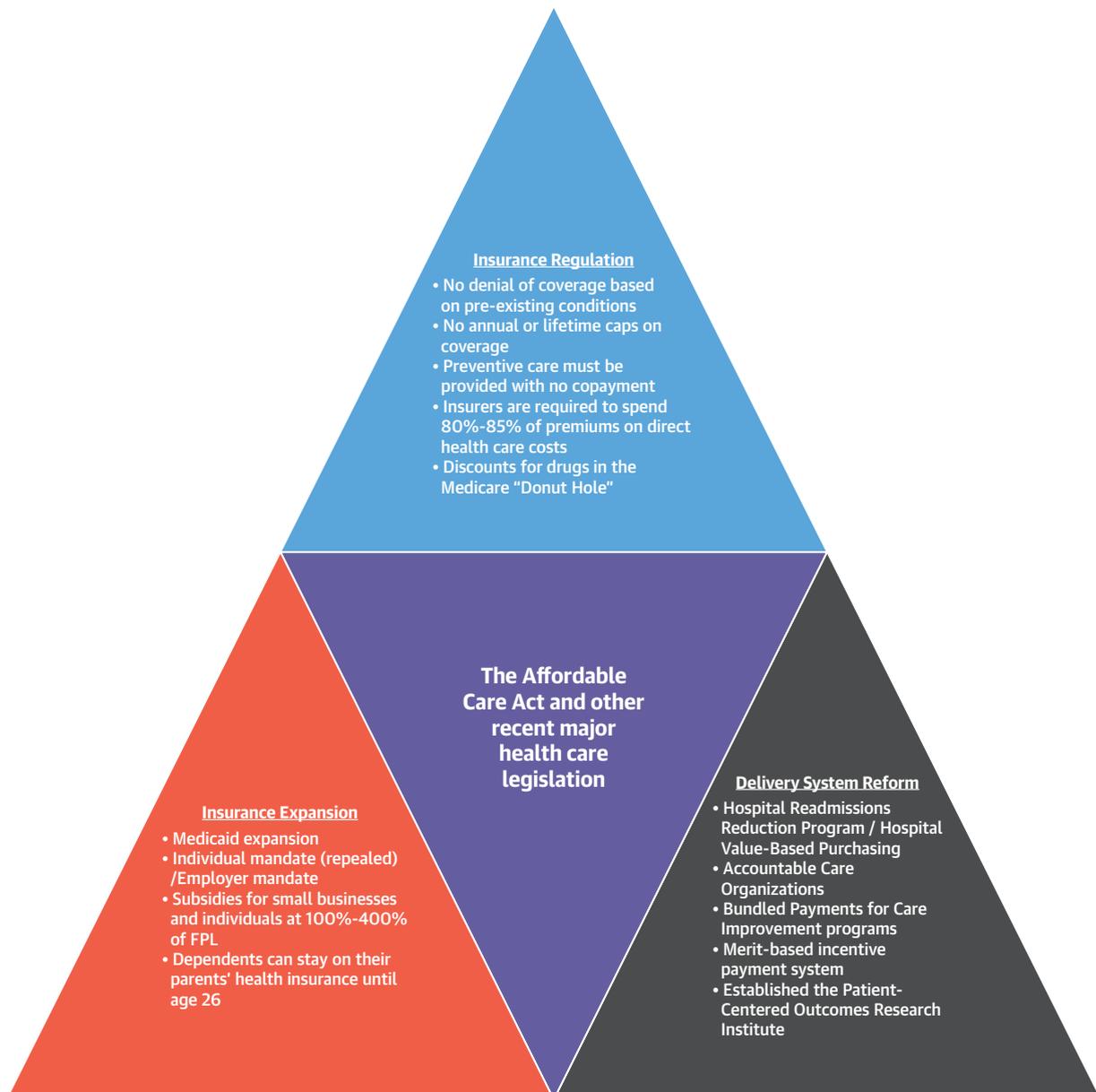


Timeline of major events in health care policy, with a focus on political events that shaped policy legislation between 2008 and the present.
ACA = Affordable Care Act.

virtually eliminated catastrophic expenditures for health care (13). A study looking at the ACA's dependent coverage provision allowing young adults to stay on their parent's plan until 26 years of age showed similar reductions in out-of-pocket expenditures (14).

Increased insurance coverage may also affect HF patients by allowing more patients access to preventive care. In 2001, the American Heart Association (AHA) and American College of Cardiology (ACC) jointly developed a new classification system for HF patients that emphasized both the development and

progression of disease. ACA/AHA Class A patients had no symptoms but were at high risk for HF, and ACC/AHA Class B patients had no symptoms but had some structural heart disease (15). Estimates of HF prevalence in the United States include symptomatic patients, but the rates of ACC/AHA Class A and B patients are unknown but much higher (16). Preventative care for these patients is crucial to prevent the development or progression of structural heart disease. Results of studies that evaluated the Massachusetts health care reform, the ACA Medicaid

CENTRAL ILLUSTRATION Major Components of the Affordable Care Act and Other Recent Health Care Legislation

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Major components of the Affordable Care Act and other recent health care legislation are grouped into 3 broad areas: regulation of the health insurance industry, broadening access to health care through insurance expansion, and health care delivery system reform. FPL = federal poverty level.

expansion, and the Oregon Health Study have suggested that increased access to health care leads to high rates of preventative care visits, increased rates of screening for diabetes, hyperlipidemia, HIV, and some types of cancer. Similar studies have also indicated that improving coverage has led to increased

access to high-value types of surgical care (13,17-19). Therefore, insurance expansion under the ACA may facilitate better preventative care for HF, and tracking its impact on early-stage HF patients and preventing the transition to symptomatic disease will be important going forward.

Insurance coverage may also have a clinical benefit for patients with more advanced disease. There has been a national debate regarding whether expanding health care coverage for Americans leads to better health outcomes. Some have suggested that the number of people with health insurance is not a useful metric and that “nobody dies because they don’t have access to health care” (20). However, growing evidence suggests that such a statement is untrue and that in fact health insurance may be associated with lower mortality rates (21).

The data are less clear, however, as to how these gains are achieved for patients with chronic diseases. One study showed that after 2 years of coverage for patients with diabetes, there were no statistically different changes in hemoglobin A_{1c} levels, blood pressure, or cholesterol levels, leading critics to suggest that expanding access to care is not helpful (13). However, the rate of diagnosis of diabetes was increased, and the use of diabetes medications has nearly doubled. A different study of post-ACA Medicaid expansion recipients found that Medicaid expansion was associated with better blood pressure control among community health-center patients (22). For cancer patients, it has been hypothesized that improved access to health care may result in increased cancer screening in order to diagnose cancer at an earlier stage, resulting in more timely or effective care. A post-ACA study showed that ACA-dependent coverage was associated with earlier diagnosis and treatment of cervical cancer among young women (23). However, a study of Massachusetts health care reform did not find any changes in the stage of breast cancer at diagnosis (24).

Data evaluating the implications of health care coverage for HF patients are not yet available. However, existing data for other chronic conditions suggest that there may be some benefit for improvements in chronic disease outcomes by expanding coverage. Whether these improvements are cost-effective is a matter of some debate and represents an important area for future research (25).

DELIVERY SYSTEM REFORM AND ITS IMPACT ON HF

The ACA reformed the health care delivery system in multiple ways in an effort to improve health care quality. Hospitals had incentives to adopt electronic medical records and to discourage hospital-acquired conditions and readmissions through payment penalties. The ACA also promoted moving away from a fee-for-service model to a pay-for-performance

model with the development of alternative payment models. These alternative payment models have included episode-based, or “bundled,” payments and the creation of Accountable Care Organizations, which assume responsibility for the total costs of care and quality metrics for a population of patients annually. These changes have driven clinical innovation but have also proven to be a significant challenge to health care providers and hospitals.

HOSPITAL READMISSIONS REDUCTION PROGRAM.

Of the changes that the ACA has made to the health care delivery system, none has created more controversy related to the care of HF patients than the Centers for Medicare and Medicaid Services (CMS) Hospital Readmissions Reduction Program (HRRP). The program was established to incentivize hospitals to improve care transitions and readmission rates due to the perception among clinicians and policymakers that readmissions are a correctable source of poor quality care and excessive spending. In fact, at the program’s inception, readmission rates for HF patients within 30 days of hospital discharge were as high as 23% in the Medicare population (26). The HRRP calculates risk-standardized 30-day readmission rates for 6 conditions including acute myocardial infarction, chronic obstructive pulmonary disease, pneumonia, coronary artery bypass graft surgery, total hip and total knee arthroplasty, and HF (27). CMS then levies penalties on hospitals with higher-than-expected readmission rates that are capped at 3% of a hospital’s total Medicare payments. Payment penalties went into effect in 2013 and have been driven largely by excess HF readmissions (28).

Some have argued that the HRRP has had a positive impact on patients. Risk-standardized readmission rates have decreased since the policy’s announcement (29,30), and the increased focus on quality improvement for HF has driven extensive innovation. Although the effective strategies to prevent or reduce readmissions have not reached consensus (31), surveys of hospitals suggest that changes to discharge processes, post-discharge follow-up, and care pathways have been significant (32).

On the other hand, the HRRP has been the source of significant controversy for a number of reasons. First, triggers for readmissions are diverse, and the degree to which readmissions are avoidable is unclear (33,34). Health system strategies and disease management systems to prevent readmissions include patient education, discharge planning, medication reconciliation, home care, scheduling follow-up before discharge, telehealth, and invasive and noninvasive monitoring. Reviews of these

interventions suggest that no single strategy alone is effective at reducing readmissions, and a meta-analysis of readmissions suggests that fewer than 1 in 4 readmissions may be avoidable (35-37).

Second, the HRRP has been controversial in the area of social determinants of health. Initial studies showed that safety-net hospitals were disproportionately receiving penalties (38). In response, Congress passed the 21st Century Cures Act, which required that CMS take into account the proportion of low-income patients cared for by hospitals when evaluating readmissions and assess hospitals relative to their peer facilities instead of judging each hospital against all others (39,40). The impact of this policy change remains to be seen.

Third, there have been concerns that the HRRP may be associated with higher mortality among HF patients. A number of recent studies have shown that although the HRRP was associated with lower 30-day readmission rates, it may also be associated with increased 30-day mortality (41,42). Although the mechanism for this rise is unknown, some have postulated that hospitals may be incentivized to reduce admissions by inappropriately triaging emergency care, delaying hospital readmissions beyond day 30, or increasing observational stays without admitting patients (43). These findings, although controversial and contested, may prompt reconsideration of the HRRP for HF (44,45).

HOSPITAL VALUE-BASED PURCHASING. Hospital Value-Based Purchasing (HVBP) is another program introduced by CMS as part of efforts to promote high-value care that impacts HF patients (46). Through the program, hospitals receive fee-for-service reimbursement with adjustments based on value metrics. HVBP is budget neutral. Overall Medicare payments are cut by 2%, and this reduction is paid back to participating hospitals in the form of bonuses. The program evaluates hospitals for their performance in 4 domains, including safety, clinical care, efficiency and cost reduction, and patient- and caregiver-centered experience. The clinical care domain includes 30-day mortality rates for acute myocardial infarction, pneumonia, and HF (47). In 2019, the program will affect 2,800 hospitals across the country, and for fiscal year 2019, 1,550 hospitals will receive bonuses, and 1,250 hospitals will receive penalties (48). However, there is no evidence that HVBP has had a positive impact on patient outcomes; a study evaluating the impact of HVBP on mortality for 2,919 participating hospitals more than 3 years into the program found no effects (49). Additional studies are anticipated, and the program's currently neutral effect on HF mortality may change.

MERIT-BASED INCENTIVE PAYMENT SYSTEM. In the outpatient setting, value-based payment models may affect HF patients as well. The Merit-based Incentive Payment System (MIPS) adjusts payment to providers based on performance in 4 performance categories: quality, cost, promotion of interoperability, and improvement activities. Each of these categories carries different weights that shift as the program progresses. Under the quality performance category, the highest weighted category, which requires reporting of 6 measurements; measurements that are particularly relevant for HF patients include functional status assessments, all-cause hospital readmissions, and the percentage of patients with systolic HF prescribed angiotensin-converting enzyme inhibitors or angiotensin receptor blockers and beta-blockers. The maximum MIPS penalty in 2019 is 4% of Medicare part B payments but will increase to 9% by 2021. Given that MIPS is a relatively new program, little is known about how it will affect outpatient clinicians. However, initial data from the Physician Value-Based Payment Modifier, a precursor to MIPS, suggested that it disproportionately penalized practices caring for highly medically complex patient populations, which likely includes HF patients (50). This is an area that bears close observation as MIPS launches and expands.

BUNDLED PAYMENTS FOR CARE IMPROVEMENT AND ACCOUNTABLE CARE ORGANIZATIONS. Beyond value-based payment models, there are 2 new alternative payment models that may impact HF patients. The CMS Bundled Payments for Care Improvement (BPCI) program was launched in 2013 and is a voluntary program in which hospitals choose to accept bundled payments to cover the cost of care for patients with 1 of 48 different primary diagnoses, including HF. Under BPCI, hospitals select from 4 different reimbursement models, although most hospitals have chosen model 2. Under model 2, hospitals assume the cost of care for 30, 60, or 90 days after hospitalization. If cost targets are achieved, participating hospitals can keep a portion of the savings. If costs are exceeded, participating hospitals reimburse CMS for part of the difference. An early study evaluating the BPCI program for joint replacement showed a reduction in Medicare payments and no change in any quality measurements, suggesting the program may help promote cost savings (51). However, a later study evaluating the 5 most commonly selected medical conditions in BPCI, HF, pneumonia, chronic obstructive pulmonary disease, sepsis, and acute myocardial infarction, showed that BPCI was not associated with a difference in Medicare payments, clinical complexity, length of

stay, emergency department use, hospital readmissions, or mortality (52). CMS reorganized the BPCI model and released BPCI Advanced in January 2019, which will test a new iteration of bundled payments for 32 clinical diagnoses. The effects of this reorganization remain to be seen.

Accountable Care Organizations (ACOs) were created as part of the ACA. Much like Health Maintenance Organizations that emerged in the 1970s, ACOs assume responsibility for the total costs of care for a population of patients annually. To become eligible, certain criteria must be met, which include accountability for a minimum of 5,000 beneficiaries and a minimum 3-year commitment. ACOs provide reimbursement under 3 practice models: the Medicare Shared Savings Program (MSSP), the Pioneer ACO model, and the Advance-Payment ACO model. Under the MSSP and Pioneer ACO models, ACOs receive a fee-for-service billing approach but also receive bonus payments for minimizing costs and achieving quality metrics. The Advance-Payment ACO model focuses on rural areas and provides advanced payments to invest in infrastructure to improve patient care. Early results from the Pioneer ACO model showed the program was associated with a modest reduction in Medicare spending (53). A later study of the MSSP model showed reductions in post-acute spending without change in quality of care (54). Early after initiation, ACOs focused primarily on consolidating primary care and only later expanded to specialty providers (55). Data for HF are consequently sparse. However, a recent study comparing patients within ACOs to patients outside of ACOs hospitalized with acute myocardial infarction or HF showed no changes in spending for patients within the first 90 days but significant savings between 90 days and 1 year (56). Late spending reductions were driven by lower payments for readmissions.

BILLING CODES. New billing codes intended to improve care coordination for complex patients may be beneficial for HF patients, who often have a high number of comorbidities as well as many social needs. CMS's recognition in 2017 that HF specialists are a distinct specialty may also have implications for the care of HF patients. Medicare had previously denied HF specialist payments when a general cardiologist in the same practice made a claim for the same patient. The impact of this change on the care of HF patients has not been evaluated, but it is anticipated to incentivize HF involvement in patients with complex heart disease.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.

The ACA established the Patient-Centered Outcomes Research Institute (PCORI), which helps fund research with the goal of helping patients and clinicians make better informed health care decisions. This is done predominantly through comparative effectiveness research. The PCORI has funded extensive research in cardiovascular disease. PCORI-funded research related specifically to HF is limited but includes methods of caring for minorities with HF and decision support guides for patients with advanced heart disease considering left ventricular assist devices (57,58).

THE FUTURE OF HEALTH CARE AND THE ACA

The ACA has faced significant criticism since its onset. There were recurrent efforts made on a partisan basis to repeal the ACA between 2012 and 2016 that were vetoed by former President Barack Obama. With the election of President Donald Trump in 2016, along with Republican control of both the legislative and executive branches, renewed efforts began to repeal the legislation. However, due in part to growing public pressure to keep the ACA, full repeal efforts were ultimately abandoned. Subsequently, the individual mandate, one of the most significant features of the ACA, was repealed through the Tax Cuts and Jobs Act. Ongoing lawsuits, including one in Texas in which a judge declared the ACA to be unconstitutional, remain unresolved.

Health care was a major issue in the 2018 midterm elections (59). The idea of "Medicare-for-all" has gained popularity and was endorsed by several candidates. The 2018 election also saw popular votes in 5 additional states to expand Medicaid, including Idaho, Nebraska, Utah, Kansas, and Maine (60). It is likely that all major party candidates in the 2020 election will present health policy proposals as key components of their campaigns, although details of these proposals are not yet available. Professional societies and clinician groups are also increasingly involved in advocacy efforts around health policy, particularly in areas of insurance coverage, pharmaceutical costs, and alternative payment models.

CONCLUSIONS

HF care accounts for billions of dollars of health care spending in the United States and is expected to increase. Developed to combat the rising costs of care in the current system as well as heterogeneous health care quality, the ACA has substantially changed the current health care system. Given its prevalence and associated expenditures, HF will likely remain central

to health policy efforts going forward. Therefore, cardiologists and HF physicians need to be aware of how legislation effects clinical practice and be prepared to adapt to and help shape a landscape of continual changes in policy.

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