



AN ANALYSIS OF LEADING CONGRESSIONAL HEALTH CARE BILLS, 2005–2007: PART II, QUALITY AND EFFICIENCY

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ABSTRACT: The U.S. health care system will become a high performance health system only with strong leadership from the federal government in partnership with the private sector. A prior report analyzed the likely effect on U.S. health system performance of congressional legislative proposals to extend health insurance coverage. This report addresses the major bills introduced over 2005–2007 designed to advance the quality and efficiency of the health system. The bills relate to: Medicare prescription drug coverage; Medicare payment reform; transparency; health information technology; patient safety; medical liability reform; and elimination of health disparities. Although they fall short of a comprehensive strategy for systemwide improvement, the legislative proposals potentially lay a foundation for more fundamental reforms.

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CONTENTS

List of Figures and Tables.....	iv
About the Authors.....	v
Acknowledgments.....	v
Executive Summary.....	vi
Introduction.....	1
Bills That Seek to Strengthen Medicare Prescription Drug Coverage.....	2
Bills That Propose Price Negotiation by HHS.....	3
Bills That Propose National Drug Plans Operated by Medicare.....	5
Bills That Would Simplify, Standardize, and Improve the Transparency of Medicare Part D.....	6
Bills That Would Reform Medicare Payment.....	8
Bills That Would Increase Transparency.....	12
Bills That Would Support the Spread of Health Information Technology.....	14
Bills Establishing Systems to Ensure Patient Safety.....	16
Bills to Reform Medical Liability.....	19
Bills Designed to Eliminate Disparities.....	20
Analysis of Congressional Bills to Improve Quality and Efficiency.....	21
Healthy Lives.....	22
Quality.....	23
Access.....	23
Efficiency.....	24
Equity.....	24
System Capacity to Innovate and Improve.....	24
What’s Missing in the Legislative Agenda?.....	25
Appendix. Tables.....	29
Notes.....	99

LIST OF FIGURES AND TABLES

Figure ES-1	Major Features of Quality and Efficiency Bills and Impact on Health System Performance	vii
Figure 1	Major Features of Quality and Efficiency Bills and Impact on Health System Performance	22
Table A-1	Side-by-Side Analysis of the Medicare-Guaranteed Prescription Drug Act of 2006 and the Medicare Accountability, Bargaining, and Compassion for Part D (ABC for D) Act	29
Table A-2	Side-by-Side Analysis of the Pharmacy Access Improvement (PhAIm) Act of 2006 and the Medicare Prescription Drug Simplification Act of 2006	33
Table A-3	Side-by-Side Analysis of the Medicare Value-Based Purchasing for Physicians’ Services Act of 2005 and the Medicare Value Purchasing Act of 2005	45
Table A-4	Side-by-Side Analysis of the VA Hospital Quality Report Card Act of 2006 and the Hospital Quality Report Card Act of 2006	59
Table A-5	Side-by-Side Analysis of the Medicare Payment Rate Disclosure Act of 2006 and the Hospital Price Reporting and Disclosure Act of 2005	62
Table A-6	Side-by-Side Analysis of the Wired for Health Care Quality Act and the Health Information Technology Promotion Act of 2006	64
Table A-7	Side-by-Side Analysis of the Safe Health Care Reporting Act of 2005 and the National Medical Error Disclosure and Compensation (MEDiC) Act	80
Table A-8	Analysis of the Fair and Reliable Medical Justice Act.....	88
Table A-9	Analysis of the Faircare Act	91

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EXECUTIVE SUMMARY

The U.S. health care system requires strong national leadership to become a high performance health system. The federal government, in partnership with the private sector, should set national goals and priorities, develop policies and practices to shape the delivery of health care services, and implement measures to track and improve provider performance. By focusing on quality improvement and efficiency gains, the government would get better value from its substantial investment in the system.

A prior report analyzed the likely effect on health system performance of congressional legislative proposals to extend health insurance coverage.¹ This report addresses the major bills introduced over 2005–2007 designed to advance the quality and efficiency of the health system. They include bills related to:

1. **Medicare prescription drug coverage**, including proposals for pharmaceutical price negotiation, creation of a national Medicare plan with comprehensive prescription drug benefits as an alternative to private drug plans, and simplification and standardization of prescription drug benefit packages;
2. **Medicare payment reform**, including proposals to dedicate part of Medicare provider payments for a pay-for-performance pool to be distributed to physicians (House bill) or to virtually all providers (Senate bill), with payments based on evidence of clinical quality, provision of patient-centered care, and benchmarks of efficiency—legislation enacted in the 109th Congress authorizes incentives to encourage physicians to report data on quality;
3. **Transparency**, including proposals to require price and quality reporting for individual hospitals and physicians;
4. **Health information technology**, including separate proposals passed by the House and Senate in the 109th Congress to establish a nationwide health information technology network and legislative authorization for the Office of the National Coordinator of Health Information Technology;
5. **Systems to ensure patient safety**, including proposals for medical error disclosure and expansion of the National Practitioner Data Bank to include all licensed health care practitioners and skilled nursing facilities;
6. **Medical liability reform**, a proposal to award grants to up to 10 state demonstration programs testing alternatives to current medical tort litigation; and

7. **Elimination of disparities**, a proposal to promote reporting of data on health care quality by patients’ race, ethnicity, education, and primary language and to provide financial incentives for hospitals and health centers that reduce disparities in care.

This report analyzes these proposals against the dimensions of performance included in The Commonwealth Fund Commission on a High Performance Health System’s *National Scorecard on U.S. Health System Performance*:² the health system’s support of healthy lives; health care quality, including the provision of the “right” care as well as safe, coordinated, and patient-centered care; access to care; efficiency; equity; and the system’s capacity to innovate and improve (Figure ES-1).

Figure ES-1. Major Features of Quality and Efficiency Bills and Impact on Health System Performance

	Strengthen Medicare Rx drug coverage	Reform Medicare payment	Increase transparency	Increase use of HIT	Ensure patient safety	Reform medical liability	Eliminate disparities
Long, healthy, and productive lives	X	X			X		X
Quality		X	X	X	X	X	X
Right care		X					
Coordinated care				X	X		
Safe care		X		X	X	X	
Patient-centered care		X	X				
Access	X						X
Efficiency	X	X	X	X		X	
Equity	X						X
Capacity to improve and innovate		X	X	X			

Although they fall short of a comprehensive strategy for systemwide improvement, the legislative proposals present an interesting set of approaches to address these dimensions of health system performance. Taken together, the proposals could lay a foundation for more fundamental reforms.

Healthy Lives

It is difficult to assess the effects the congressional proposals might have on health outcomes, or the ability of the system to support healthy lives. Bills that would expand

access to medications to control chronic conditions would likely make modest contributions toward extending patients' lives and improving their capacity to function. So, too, would proposals to offer financial incentives to providers that achieve better health outcomes for patients, investigate the causes of and seek to prevent medical errors, and eliminate disparities. To the extent that the proposals specifically make information on health outcomes transparent and assist providers in delivering care that yields better health outcomes, their impact could be more significant.

Quality

Important provisions for improving quality are those that would advance transparency in reporting quality and cost of care and provide financial incentives to hospitals, physicians, and other health care providers for delivering quality care. These build on the President's executive order promoting "four cornerstones" for health care improvement:

1) implementing standards for health information technology, so information can be securely shared with patients and providers; 2) reporting on quality-of-care measures; 3) providing information on prices and costs of health care services; and 4) promoting quality and efficiency through incentives. Legislation enacted in December 2006 would provide a 1.5 percent Medicare payment increase for physicians who report information on the quality of their care—adding public reports on physician quality to the current reports on hospital quality for Medicare beneficiaries.

The research literature suggests that most patients do not access quality and cost information when it is available, and even fewer alter their choice of provider based on the information. Making the information more consumer-friendly might increase its usefulness. Public release of quality information has been shown to spur providers to improve quality. Robust systems of reporting on quality along with modest financial incentives have been found to be effective in motivating hospitals and medical groups to improve care. Providers may respond to such information from a desire to see that patients obtain the best care, from professional pride in providing excellent care, or from the desire to avoid being publicly identified as outliers on poor quality or high cost. This research suggests that these legislative proposals may help improve U.S. health system performance and are important building blocks for other initiatives, such as payment reform or technical assistance to spread best practices among providers.

The House and Senate proposals to set aside payment pools in Medicare to offer pay-for-performance incentives are likely to have an effect on improving quality. Early evidence from Medicare pay-for-performance demonstrations indicates that even modest

financial incentives for hospitals contribute to improved quality. Inclusion of measures on patient experiences with care, as specified in the House and Senate Medicare payment reform bills, should facilitate providers' efforts to improve patient-centered care.

Legislative proposals to increase use of information technology could improve the coordination and safety of care, two important aspects of health care quality. The health information technology proposals would put in place mechanisms for setting standards, fund a national office for coordinating health information technology, and provide modest grant funding. Their potential effect is uncertain, given that there has been little research into the effectiveness of such efforts. More important, the provisions may be insufficient to promote the adoption of information technology.

Similarly, the patient safety proposals, which institute confidential reporting and a voluntary compensation system for those taking part, may not be sufficient to overcome provider resistance to transparency on this sensitive dimension of care.

Access

The legislative proposals discussed here are not primarily aimed at improving access to care. (For an analysis of congressional proposals to extend health insurance coverage, see the [earlier report](#) in this series.) However, the Medicare proposals that would improve the prescription drug benefit, including eliminating the “doughnut hole” in coverage, are likely to improve access to prescription drugs for chronically ill beneficiaries. Similarly, the legislative proposal targeting health disparities may lead to improved access for vulnerable populations by funding state coalitions that seek to improve minority health and by providing incentives to hospitals and health centers that reduce disparities in care among patients.

Efficiency

The legislative proposals with the greatest potential to achieve savings in the health system are those that would reform Medicare payment for prescription drugs and health care services. Several proposals call for the federal government to negotiate pharmaceutical prices for Medicare beneficiaries, and one proposal would offer a Medicare-administered alternative to private drug plans. The Congressional Budget Office has argued that private drug plans already have significant incentive to negotiate substantial discounts to attract beneficiaries, and therefore has not “scored” the bills as achieving additional Medicare savings. Yet, a recent study indicates that a Medicare program enrolling all Americans would yield savings through pharmaceutical price negotiations of an estimated \$33.9 billion,

or 15 percent of pharmaceutical spending. Negotiating for 43 million Medicare beneficiaries, however, might yield lower savings and might lead to higher prices for private payers. The potential for savings from bargaining with pharmaceutical companies would vary from drug to drug, depending on the availability of generic alternatives or other effective brand-name drugs for treating a specific condition. Lower prices, if achieved, could also affect future investment in research and development.

Proposals to reward hospitals, physicians, and other providers for providing high-quality and efficient care could add momentum to hospital and physician efforts to improve quality, reduce complications, and achieve greater efficiency. Would the pay-for-performance payments in the House and Senate bills be enough to affect provider behavior? Experience from the Medicare Hospital Quality Incentive Demonstration (sometimes referred to as the Medicare Premier Hospital Demonstration) suggests that bonuses of 1 percent to 2 percent of hospital diagnosis-related group (DRG) case payment can be a modest spur to improve quality and reduce costs. For hospitals with an average margin of 3 percent to 5 percent, bonuses of this magnitude might be attractive. Physicians might require a greater financial incentive, and the same might be true for nursing homes and home health agencies, which operate with margins of about 15 percent. The effects of the legislative proposals would need to be monitored and the rewards calibrated accordingly.

Equity

The Senate legislative proposal on “fair care” explicitly aims to improve equity in the health care system. It would require public reporting of quality data by patients’ race, ethnicity, education, and primary language in federally supported health programs. It also would ensure that quality metrics targeted health problems that disproportionately affect vulnerable populations and produce high rates of mortality or morbidity.

System Capacity to Innovate and Improve

Although these congressional legislative proposals may not have sweeping effects on health system performance in the near term, many of them put in place building blocks to support future innovation and improvement. Most important in this regard are efforts to promote a national health information technology network. Expanded quality measurement and reporting, as well as modest performance incentives, could give providers the encouragement and wherewithal to implement quality improvement processes and systems, or to adopt health information technology such as decision-support systems, patient reminders, and electronic health records.

What's Missing in the Legislative Agenda?

Health legislative proposals introduced over 2005–2007 embrace a number of strategies to improve health system performance, but they fall short of an overarching and coordinated policy strategy. Most notably missing are national goals to guide improvement efforts, establish priorities, ensure implementation of effective strategies, and monitor impact. Creation of a National Quality Coordination Board, as recommended by the Institute of Medicine, would help ensure that public and private efforts reinforce each other, rather than work at cross-purposes.

Other steps that are necessary to achieve an effective and vigorous agenda for change include:

- fundamental payment reform, moving away from fee-for-service payment to paying for care coordination and population- or episode-based care and reducing the differential between high payment for procedures and relatively low payment for primary care services;
- creation of a Center on Comparative Effectiveness and Evidence-Based Decision-Making to promulgate information on comparative effectiveness of prescription drugs, devices, and procedures as well as adequate funding of health services research through the Agency for Healthcare Research and Quality;
- engagement of patients in the provision of effective and efficient care by giving them access to their own medical records, tools for shared decision-making, and financial incentives, including value-based health benefit designs;
- reorientation of the health care system to encourage prevention, early primary care, and chronic disease management, including a medical home chosen by each patient and restructured financial incentives and quality standards that reward practices and organized care systems for providing accessible, effective, safe, well-coordinated, and efficient care;
- identification of superior models of quality and efficiency in federal health care delivery programs implementing known best practices and continuous quality improvement processes, building on the leadership of the Veterans Health Administration (VHA) and extending quality improvement techniques developed by the VHA to Defense Department health services, the Indian Health Service, and community health centers;

- better targeting or augmented funding of Medicare quality improvement organizations to provide technical assistance to health care providers, especially safety net providers; and
- refocusing of the grants programs of the Health Resources and Services Administration to ensure a high performance health workforce, trained to work in teams and use information technology and other tools to achieve high-quality care efficiently.

The federal government has a responsibility to ensure that the health system has the requisite research, knowledge, best practices, trained personnel, and capital infrastructure to ensure high-quality, efficient care. By doing so, the U.S. can attain what its public has a right to expect for the resources invested in health care—the best health system in the world. Further, the system should continuously improve and adapt to build on new knowledge and experience. Congressional legislative proposals introduced over 2005–2007 begin to address serious deficiencies in the U.S. health system, but the goal should be no less than the provision of accessible, high-quality, and efficient care to all.

AN ANALYSIS OF LEADING CONGRESSIONAL HEALTH CARE BILLS, 2005–2007: PART II, QUALITY AND EFFICIENCY

INTRODUCTION

U.S. health care costs, already the highest in the world, continue to rise, and strategies to shift and minimize costs have not been effective.³ The U.S. will have a high performance health system only when the federal government, in partnership with the private sector, exercises strong leadership by setting national priorities, developing policies and practices to shape the delivery of health care services, and implementing measures to track and improve provider performance. By focusing on quality improvement and efficiency gains, the government and private sector would get better value from their substantial investment in health care.⁴

This effort, however, would require a major rethinking of the role of federal involvement in health care. Numerous congressional bills introduced in recent years would enhance current federal programs and policies to achieve improved quality or greater efficiency in Medicare or the health system as a whole. This report summarizes the major bills that have been introduced over 2005–2007 and assesses the extent to which they would help to build a high performance health system.

The federal government can affect the health care system through public programs, for example, by covering prescription medications for Medicare beneficiaries or by creating incentives through Medicare payment policies for hospitals, physicians, and other providers. It can also establish policies that affect the entire health care system, such as mandating public reporting of information on quality, safety, disparities in care, and costs, or by funding initiatives to promote use of information technology or medical liability reform. Although the legislative proposals introduced over 2005–2007 take a number of different approaches, together they fall short of an overarching and coordinated strategy to improve health care quality and efficiency.

The bills are related to:

1. **Medicare prescription drug coverage**, including proposals for pharmaceutical price negotiation, creation of a national Medicare plan with comprehensive prescription drug benefits as an alternative to private drug plans, and bills that would simplify and standardize prescription drug benefit packages;

2. **Medicare payment reform**, including proposals for pay-for-performance rewards to be distributed to physicians (House bill) or to virtually all providers (Senate bill) based on evidence of clinical quality, provision of patient-centered care, and efficiency—legislation enacted in the 109th Congress authorizes incentive payments under Medicare to encourage physicians to report data on quality;
3. **Transparency**, including proposals to require price and quality reporting for hospitals and physicians;
4. **Health information technology**, including separate proposals passed by the House and Senate in the 109th Congress to establish a nationwide health information technology network and legislative authorization for the Office of the National Coordinator of Health Information Technology;
5. **Systems to ensure patient safety**, including proposals for medical error disclosure and expansion of the National Practitioner Data Bank to include all licensed health care practitioners and skilled nursing facilities;
6. **Medical liability reform**, a proposal to award grants to up to 10 state demonstration programs testing alternatives to current medical tort litigation; and
7. **Eliminating disparities**, a proposal to promote reporting of data on health care quality by race, ethnicity, education, and primary language and to provide financial incentives for hospitals and health centers that reduce disparities in care.

These proposals are assessed on their potential to achieve the major goals of a high performance health system: healthy lives; health care quality, including the provision of the “right” care as well as safe, coordinated, and patient-centered care; access to care; efficiency; equity; and the system’s capacity to innovate and improve.

BILLS THAT SEEK TO STRENGTHEN MEDICARE PRESCRIPTION DRUG COVERAGE

Following the difficulties with implementation of the Medicare prescription drug benefit, a number of bills have been introduced that would enhance the quality and efficiency of health care. They would give the Department of Health and Human Services authority to negotiate pharmaceutical prices, offer a national drug plan operated by Medicare to compete with private drug plans, and simplify and standardize private drug plan benefits to promote beneficiaries’ understanding of their choices and encourage greater competition among private plans.

Bills That Propose Price Negotiation by HHS

The most controversial provision of the Medicare Modernization Act of 2003, which established Medicare Part D and private prescription drug plan coverage, was the prohibition on pharmaceutical price negotiation by the federal government. This became a major issue in the congressional election of 2006 and resulted in prompt passage in the House of Representatives in the first weeks of the 110th Congress of H.R. 4, introduced by Rep. John Dingell (D–Mich.), requiring the secretary of the Department of Health and Human Services to negotiate pharmaceutical prices. Senate consideration is still pending as of March 2007. More detailed proposals, including one by Rep. Jerry Moran (R–Kan.), were introduced in the 109th Congress.

Medicare Prescription Drug Price Negotiation Act of 2007 introduced by Rep. Dingell (H.R. 4)

Overall approach: The measure, introduced by Rep. Dingell, would alter the Medicare Part D drug benefit (PL 108-173) by requiring the secretary of Health and Human Services (HHS) to negotiate prescription drug prices. Negotiation could entail securing discounts, rebates, and other price concessions. It also would bar the government from setting up a formulary or restricting access to drugs as a way of leveraging lower prices and would require the secretary to report on the results of the negotiations every six months to the Committees on Ways and Means, Energy and Commerce, and Oversight and Government Reform of the House of Representatives and the Committee on Finance of the Senate.

The Medicare Accountability, Bargaining, and Compassion for Part D (ABC for D) Act (H.R. 4796) (for more detail see [Table A-1](#))

Overall approach: This bill, introduced by Rep. Moran, permits the secretary of HHS to negotiate contracts with the manufacturers of prescription drugs covered by Medicare Part D. It also requires standalone prescription drug plan (PDP) sponsors offering coverage to beneficiaries in traditional fee-for-service Medicare to register with state insurance departments, lengthens the open enrollment period, and provides funds for outreach and education efforts to increase enrollment in Part D coverage.

Benefit design: HHS would be given authority similar to that held by the secretaries of Veterans Affairs and Defense to negotiate contracts with manufacturers of Medicare Part D–covered drugs. Outreach, education, and counseling with respect to enrollment in a PDP would be provided to Medicare beneficiaries. HHS would award grants to states for providing outreach and counseling, and the Social Security Administration would provide outreach and education through its regional offices. The period of open enrollment for PDPs and Medicare Advantage prescription drug plans would be extended to allow enrollment without a late penalty.

Affordability: Premium and cost-sharing requirements not discussed.

Financing: Outreach and education in 2006 would be financed by \$200 million from the existing Medicare Advantage or Preferred Provider Organization Stabilization Fund. Of this amount, \$100 million would be appropriated for HHS to provide grants to states, and \$100 million would be appropriated for the Social Security Administration's regional offices.

Impact on Health System Performance

With regard to health system performance, the key question to ask about these bills is whether they would achieve significant savings and, if so, whether the discounts would affect pharmaceutical research and development. Anderson and Reinhardt argue that a major reason health care costs in the U.S. are higher than in other countries is that we pay higher prices; there is a general reluctance to use the nation's purchasing power to negotiate reasonable rates.⁵ In one study, the average price in 2003 for 30 leading prescription drugs was 52 percent lower in Canada than in the U.S., 59 percent lower in France, and 47 percent lower in the United Kingdom.⁶ Further, there is evidence that as the U.S. permits drug companies to set their own prices while other countries negotiate prices, these differences widen and drug makers obtain an ever higher share of sales and profits in the U.S.⁷

These numbers indicate that there might be substantial opportunity for the market power of large drug purchasers such as Medicare to reduce prices and achieve savings. For example, the Veterans Administration (VA) obtained a discount of 24 percent off the manufacturer's favored commercial price for patented products.⁸ The VA's success may or may not apply to Medicare. The VA uses a somewhat restrictive formulary, and has statutorily specified discounts. The VA is able to take advantage of its ability to buy at the margin—that is, use its large purchasing power to negotiate more favorable prices without distorting the market for the drugs that it buys. Medicare, with its 43 million beneficiaries, might not be able to do so, but the program could wield substantially greater market power because of its size and thus may be able to extract reasonable price concessions without the overhead and profit of private pharmaceutical benefit managers. Moreover, Medicare could partner with other payers to put pressure on drug companies to reduce excessive prices and ensure that pharmaceutical companies don't offset Medicare savings with higher prices to those who are privately insured. However, the pharmaceutical industry has countered that any significant price discounts would come at the price of reduced funds for investment in research and development of new drugs.

The Congressional Budget Office has argued that private drug plans already have significant incentive to negotiate substantial discounts to attract beneficiaries, and thus has not “scored” the bills as achieving additional savings for Medicare.⁹ In an analysis of the Medicare for All bill—introduced by Rep. Pete Stark (D–Calif.)—the Lewin Group estimated that pharmaceutical price negotiations under a plan covering virtually all Americans would yield \$33.9 billion in health system savings.¹⁰ The Lewin model assumes the federal government could achieve pharmaceutical prices midway between rates paid by Medicaid and the Veterans Health Administration. Estimated savings represent 15 percent of all U.S. pharmaceutical spending.¹¹ Negotiating for 43 million Medicare beneficiaries, however, might yield different savings than negotiating for approximately 280 million people covered under Rep. Stark’s AmeriCare or Medicare for All bill. The potential for savings from bargaining with pharmaceutical companies would vary from drug to drug, depending on the availability of generic alternatives or other effective brand name drugs for treating a specific condition. Lower prices, if achieved, might also affect future investment in research and development.

Bills That Propose National Drug Plans Operated by Medicare

Another strategy for achieving greater value for the federal government’s considerable investment in pharmaceutical coverage for Medicare beneficiaries is to offer a drug plan through Medicare, thus expanding choices beyond the private drug plans authorized by the Medicare Modernization Act.

The Medicare-Guaranteed Prescription Drug Act of 2006 (S. 2342)

(for more detail see [Table A-1](#))

Overall approach: The Medicare-Guaranteed Prescription Drug Act of 2006, introduced by Sen. Debbie Stabenow (D–Mich.), establishes a new, federally sponsored Part D plan option, the Medicare-Guaranteed Prescription Drug Plan, which would offer revised standard prescription drug coverage and access to negotiated prices. It also revises requirements for the existing privately sponsored Medicare Part D standard prescription drug coverage option with respect to the annual deductible (making it equal to the deductible for Medicare Part B), reduced coinsurance, and the initial coverage limit (thereby eliminating the “doughnut hole”).

Benefit design: HHS would offer a new plan, the Medicare-Guaranteed Prescription Drug Plan. The Secretary of HHS would be permitted to negotiate contracts with the manufacturers of Medicare Part D–covered drugs. The benefit also would encourage the use of more affordable therapeutic equivalents and implement strategies used by other federal purchasers of prescription drugs (e.g., the Department of Veterans Affairs) to reduce the overall price of covered Part D drugs. With respect to the existing privately sponsored Medicare Standard Part D benefit option, the initial coverage limit would be eliminated—removing the “doughnut hole.” Cost-sharing above the annual out-of-pocket threshold would be prohibited, thereby eliminating the current 5 percent cost-sharing for

beneficiaries for catastrophic drug costs. There would be no late enrollment penalty applicable to the Medicare-Guaranteed Prescription Drug Plan.

Affordability: The monthly premium for the Medicare-Guaranteed Prescription Drug Plan would be uniform throughout the country and equal to the base premium calculated for purposes of the existing Medicare Standard Part D benefit. For the Medicare Part D coverage standard option, the annual deductible would be equal to the deductible for Medicare Part B, and coinsurance for costs above the annual deductible would be reduced from 25 percent to 20 percent, or from 15 percent to 10 percent for individuals with income below 150 percent of the federal poverty level.

Financing: General revenues would be used to pay for the expenses incurred in the operation of the new plan.

Impact on Health System Performance

Like H.R. 4 and the Moran bill, the Stabenow bill would permit pharmaceutical price negotiation by the government. It goes further, however, in establishing an option for Medicare beneficiaries to obtain the prescription drug benefit directly from Medicare rather than through private drug plans, effectively having Medicare compete with private drug plans. The major question is whether, in doing so, it might exert downward pressure on premiums offered by private drug plans or reduce overhead administrative costs. If so, it could achieve savings for beneficiaries selecting it and for those continuing to enroll through private plans. However, it might also lead to risk segmentation, with private drug plans encouraging sicker beneficiaries who are higher users of pharmaceuticals to obtain coverage from Medicare.

Improving the prescription drug benefit also could affect access to prescription medications. The research literature demonstrates that higher out-of-pocket costs or gaps in insurance coverage contribute to beneficiaries not filling prescriptions written by physicians or not taking medications as prescribed, for example, skipping doses to make a supply of pills last longer.¹² Lowering the deductible and coinsurance in the prescription drug benefit, eliminating the doughnut hole, and making special provisions for low-income beneficiaries could expand access to prescription drugs and potentially improve health outcomes through better medication adherence and better control of chronic conditions.

Bills That Would Simplify, Standardize, and Improve the Transparency of Medicare Part D

Medicare Part D has been sharply criticized for its complexity, which contributes to higher administrative costs and confusion for beneficiaries. Several bills have been introduced that seek to achieve administrative simplification of the prescription drug benefit by standardizing

benefit packages and ensuring an adequate network of participating pharmacies. The rationale for the bills introduced is to reduce beneficiary confusion, ensure access to prescription drugs, and promote effective competition among private drug plans.

**The Pharmacy Access Improvement (PhAlm) Act of 2006 (S. 2664)
and the Medicare Prescription Drug Simplification Act of 2006 (S. 2665)**
(for more detail see [Table A-2](#))

Overall approach: These bills, introduced by Sen. Max Baucus (D–Mont.), would make several changes to the Medicare Part D benefit, including standardization of benefit packages and requirements for sponsors of standalone prescription drug plans (PDPs) and sponsors of Medicare Advantage prescription drug (MA–PD) plans to improve access, transparency, and protection for beneficiaries.

Benefit design: Under the Simplification Act, HHS would establish five national uniform benefit packages for drug coverage other than standard prescription drug coverage as described in the Medicare Modernization Act. These benefit packages would be updated at least once every three years. Three of the uniform benefit packages would provide “basic” prescription drug coverage, and two would be “supplemental” prescription drug coverage consisting of reductions in cost-sharing and/or coverage of optional drugs. In 2007 and 2008, plans would be required to include on their formulary all or substantially all available drugs in the following categories: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.

The bills also would allocate funding to assist beneficiaries in enrolling in Part D plans. PDP sponsors would be required to provide a pharmacy network that included a sufficient number of pharmacies accessible to the general public. The set of bills would establish a series of beneficiary and provider protections by requiring that: plan sponsors demonstrate performance quality; PDPs and MA–PD plans provide prompt payment of claims to pharmacies; HHS establish hotlines to provide Part D information to pharmacists and pharmacy staff; dispensing fees be established for covered Part D drugs; and PDP sponsors encourage generic drug utilization by paying an increased dispensing fee for generic drugs.

Affordability: The five national uniform benefit packages for drug coverage created by the Simplification Act would be either “basic” or “supplemental.” The three “basic” benefit packages are actuarially equivalent, but vary in their cost-sharing structure. Lower cost-sharing would require the tradeoff of higher premiums. Option 1 has no coinsurance, while options 2 and 3 do. HHS would ensure that the actuarial and unsubsidized value of the three “basic” benefit packages equals that of the standard prescription drug coverage option. The two “supplemental” prescription drug coverage benefit packages would have reduced cost-sharing and/or coverage of optional drugs: one package would provide for coverage of costs incurred within the “doughnut hole,” and the other package would increase the initial coverage limit to equal the annual out-of-pocket threshold.

Financing: Financing for the PhAlm Act is not discussed. Financing for the Prescription Drug Simplification Act includes up to \$120 million appropriated to the Centers for Medicare and Medicaid Services (CMS) to provide grants to state health insurance counseling programs and to allow states to conduct innovative programs to help individuals enroll in Part D and the low-income subsidy.

Impact on Health System Performance

The “basic” national uniform benefit packages created by the Baucus Simplification Act would have either no deductible or a deductible equal to the standard coverage deductible. The Stabenow bill also would revise requirements for Medicare Part D: the deductible would be equal to the deductible for Medicare Part B, plans would have reduced coinsurance, and the initial coverage limit (the “doughnut hole”) would be eliminated. The key question is whether a range of benefit packages would enhance Medicare beneficiaries’ ability to make informed choices among private drug plans. Medicare has considerable prior experience with this under the 1990 Omnibus Budget Reconciliation Act legislation sponsored by Sen. Baucus, which created standardized benefit packages for Medigap, or private coverage to supplement Medicare. This legislation helped beneficiaries make choices among plans based on premiums rather than among complex benefit options, and contributed to more effective price competition among plans and concentrated enrollment in a few plan types.¹³

The two Baucus bills are primarily aimed at improved access, transparency, and protection for beneficiaries. Sen. Baucus’s Simplification Act requires the proposed five uniform drug benefit packages to include on their formularies all available drugs in certain categories. The Stabenow bill establishes a federally sponsored Part D plan option, which offers standard prescription drug coverage and access to negotiated prices. Additionally, the Baucus bill requires private drug plan sponsors to ensure that pharmacies are accessible to beneficiaries. There is support to provide funding for outreach/education efforts and to assist beneficiaries in enrolling in Part D plans; both the Baucus and Moran bills provide for this. Some bills propose to simplify benefit design by streamlining the benefit packages. This support and simplification should help beneficiaries make more informed choices that best fit their circumstances and spare them time and anxiety in obtaining desired information.

BILLS THAT WOULD REFORM MEDICARE PAYMENT

Leaders of the 109th Congress introduced bills to change the way Medicare pays health care providers to reward higher quality and greater efficiency. These “value-based purchasing” proposals include:

- the Medicare Value-Based Purchasing for Physicians’ Services Act of 2005 (Rep. Johnson);
- the Medicare Value Purchasing Act of 2005 (Sens. Grassley and Baucus); and
- the Tax Relief and Health Care Act of 2006, enacted into law at the end of the 109th session.

Medicare Value-Based Purchasing for Physicians' Services (H.R. 3617)

(for more detail see [Table A-3](#))

Overall approach: Under this proposal, introduced by Rep. Nancy Johnson (R–Conn.) and 46 cosponsors, Medicare Part B would establish a pay-for-performance payment system for physician services based on quality and efficiency measures.

The new Medicare payment system would replace the Sustainable Growth Rate (SGR) formula that is currently scheduled to lead to a reduction in physician fees. It would provide for increases of 1.5 percent in 2006, and the Medicare Economic Index less one percentage point thereafter. It would provide an additional allowance of 1.0 percent for providers reporting quality data in 2007 and 2008, and an additional 1.0 percent for physicians and groups that both report quality data and achieve performance objectives in 2009 and beyond.

Providers affected: Physicians

Performance measures: Measures would include a mix of outcome, process, and structural quality measures, patient assessment of care, and efficiency measures including relative use of resources, services, or expenditures. A process is outlined for adoption of measures, including submission of proposed measures by physician specialty organizations to a consensus-building body such as the National Quality Forum (NQF) and then selection by the U.S. Department of Health and Human Services (HHS).

Financing: The bill does not specify how the additional expenditures would be financed.

Medicare Value Purchasing Act of 2005 (S. 1356)

(for more detail see [Table A-3](#))

Overall approach: Through this proposal, introduced by Sen. Chuck Grassley (R–Iowa) and Sen. Baucus (D–Mont.), Medicare would reward quality and efficiency for virtually all participating Medicare providers. Two percent of Medicare outlays for a type of provider would be placed in a fund to reward providers that substantially improve or exceed a threshold on performance measures related to health outcomes, quality of care, patient-centered care, efficiency, and use of information technology.

Providers affected: Hospitals, physicians and practitioners, Medicare Advantage managed care plans, end-stage renal disease providers and facilities, and home health agencies. The proposal also authorizes studies by the Medicare Payment Advisory Commission for other entities, including prescription drug plans and nursing homes.

Performance measures: Measures target process, structure, outcomes, beneficiary experience, efficiency, equity, and overuse/underuse of health care items and services, as well as health information technology use. It also specifies a process involving advice and recommendations from a nonprofit entity (most likely NQF) and wide consultation with nationally recognized provider organizations, quality measurement organizations, and researchers. It gives HHS somewhat greater latitude than does the House bill to make final decisions on the measures.

Financing: The proposal does not address the SGR formula, and specifies that the pay-for-performance bonuses would be budget-neutral, financed by gradually placing 2 percent of all scheduled payments in a pool to be allocated predominantly to providers meeting threshold quality and efficiency standards, with some payments as well to those improving performance.

The Tax Relief and Health Care Act of 2006

Overall approach: At the close of the 109th Congress, the Tax Relief and Health Care Act of 2006 was enacted into law. It builds on the House and Senate bills and, among other things, eliminates the reduction in physician fees in 2007, rather than the reduction called for by the SGR factor formula, and provides a 1.5 percent increase in July 2007 for those physicians reporting data on quality.

Providers affected: Physicians

Performance measures: The initial set of measures includes those already in use by the Physician Voluntary Reporting Program, with additional measures to be determined throughout 2007. To qualify for that boost, doctors must report data on at least three quality measures. The measures must be from a list produced through a consensus-setting process involving doctors and Medicare officials. If three measures haven't been approved for a particular specialty, doctors will receive the payment for meeting existing measures for that type of care.

E-prescribing: The legislation includes language by Sens. Richard Lugar (R–Ind.) and Evan Bayh (D–Ind.) that recommends e-prescribing as one of several potential safety measures to help prevent hospital medication errors. The legislation calls on HHS to develop standards, including medication safety measures, to improve hospital quality. Hospitals that do not disclose whether they have adopted the new standards will be penalized through reduced Medicare payments.

Financing: For operational reasons, physicians will receive the bonus payments in early 2008, when the payments will be issued in the form of a lump-sum payment. The provisions were financed by using a portion of the stabilization fund for Preferred Provider Organization plans created by the Medicare Modernization Act of 2003.

Impact on Health System Performance

Aligning financial incentives so that health systems, hospitals, and physicians benefit financially from doing the right thing—as these proposals would do—is essential for strengthening health system performance. The fee-for-service payment system rewards doing more, and in so doing contributes to wide variations in quality and costs related to overuse of services and duplicative or wasteful care.¹⁴

In a report by the Institute of Medicine (IOM) requested by Congress in the Medicare Modernization Act, the IOM recommended aligning provider incentives to reward high-quality, patient-centered care, and providing care more efficiently.¹⁵ In particular, the IOM recommended creating a bonus pool largely from existing funds by dedicating a portion of payments to a pool to be distributed to providers with high performance on clinical quality, patient-centered care, and efficiency—the approach taken in the Senate bill. Bonuses would be provided both to high performers and those who improve as specified in the Senate bill. Also consistent with the IOM recommendations, the House and Senate bills call for all performance information to be publicly reported

after one year of confidential feedback. Most important, the IOM recommends basing pay-for-performance on measures of efficiency as well as quality, as would the House and Senate bills.

The IOM report noted the limited evidence base on pay-for-performance and questions related to the feasibility of implementation, magnitude of rewards sufficient to influence provider behavior, and possibility of unintended consequences.¹⁶ Given the considerable uncertainties, the report recommended that implementation proceed gradually, first with public reporting, then with modest rewards based on a limited set of scientifically valid measures. At each stage, the system should be monitored and informed by an ongoing evaluation and timely information on consequences, both intended and otherwise. All of these recommendations are also features of the House and Senate bills.

Would the incentives in the House and Senate bills be sufficient to encourage real change in provider behavior? Experience from the Medicare Hospital Quality Incentive Demonstration (sometimes referred to as the Medicare Premier Hospital Demonstration) suggests that bonuses of 1 percent to 2 percent of hospital diagnosis-related group (DRG) case payments can be a modest spur to improve quality and lower costs.¹⁷ Efficiency gains might have been greater if hospitals had been required to meet cost thresholds to be eligible for quality bonuses, or if individual physicians caring for patients with the selected conditions in high-performing hospitals had been given bonuses as well. Provisions to tailor payments in these ways are made in the House and Senate bills,

Given this experience, the legislative proposals, even with the proposed modest bonuses, might be expected to add momentum to hospital and physician efforts to improve quality, reduce complications, and achieve greater efficiency. However, given the limited evidence base, it would be important to implement an ongoing monitoring and assessment initiative to derive early feedback and make modifications as appropriate. The demonstration efforts do not provide information on how different patient populations are affected, in particular whether quality improvement extends to racial and ethnic minority Medicare beneficiaries. These dimensions of performance would benefit from scrutiny as well.

In the longer term, more sweeping payment reform may well be required to achieve high levels of quality and efficiency. Pay-for-performance systems, if properly designed, can serve as a transition to fundamental payment reform. For example, payment ultimately might be based on episodes of care or patient populations.¹⁸ But reducing variation in cost and quality would make it easier for providers to adapt to uniform payment for treatment of a given condition. Reform of fee-for-service to correct the

imbalance in payment for specialty procedures and primary care, as well as encouragement of more rapid adoption of risk-adjusted episode-based or capitation-based payment for selected conditions, is likely to have more fundamental effects.

BILLS THAT WOULD INCREASE TRANSPARENCY

Several proposals were introduced over 2005–2007 to improve public reporting of prices and quality of care:

- federal agency quality reporting (Sen. Obama); and
- Medicare price reporting (Sens. Brownback and DeMint).

Federal Agency Quality Reporting (S. 2358 and S. 2359)

(for more detail see [Table A-4](#))

Overall approach: Sen. Barack Obama (D–Ill.) introduced bills in the Senate to require semiannual reports by the Veterans Administration (S. 2358) and by HHS (S. 2359) with individual hospital data on effectiveness, safety, timeliness, efficiency, patient-centeredness, and equity. The Veterans Administration and HHS would report information on nurse and other staffing levels, rates of nosocomial infections, volume of procedures, hospital accreditation and sanctions or violations found by accreditation or state licensing boards, quality of care for special populations including racial and ethnic minorities, and availability of on-site interpreter services.

Quality improvement: Both bills also authorize funds for organizations to assist hospitals with quality improvement, and require reports on the effectiveness of the initiatives to be submitted to Congress by the Agency for Healthcare Research and Quality.

Medicare Price Reporting (S. 2606 and S. 1827)

(for more detail see [Table A-5](#))

Overall approach: Sen. Sam Brownback’s (R–Kan.) Medicare Payment Rate Disclosure Act of 2006 (S. 2606) would post Medicare payment rate information on hospital inpatient, hospital outpatient, and physician services, including at least 30 of the most frequently provided services and eventually on at least 100 such services. Sen. Jim DeMint’s (R–S.C.) Hospital Price Reporting and Disclosure Act of 2006 (S. 1827) would have HHS post on its Web site hospital-reported data on charges for certain hospital inpatient services, hospital outpatient services, and hospital-administered drugs, including the 25 most frequently performed hospital inpatient services, the 50 most frequently administered drugs in the hospital inpatient setting, and the 25 most frequently performed hospital outpatient services.

Impact on Health System Performance

Quality information and patient reports on their experiences, as called for in Sen. Obama's proposal, are likely to be particularly helpful to patients and providers, especially if physician-level information is made available. Information on charges for individual services as called for in the Brownback and DeMint proposals may not be relevant to patients, who may be more interested in their total projected out-of-pocket costs for care over an episode of illness. Further, there is often a discrepancy between charges and actual prices, given the pervasiveness of price discounts in the health sector. However, for uninsured patients or patients with high deductibles, prices of homogeneous services such as mammograms or MRIs may be helpful, and private payers may find it instructive to have more detailed information on Medicare payment rates. As noted above, information on quality and efficiency is essential for new payment systems that reward providers for excellence and efficiency.

These legislative proposals would build on the President's Executive Order promoting "Four Cornerstones" for health care improvement: 1) implementing standards for health information technology, so information can be securely shared with patients and providers; 2) reporting on quality of care measures; 3) providing information on prices and costs of health care services; and 4) promoting quality and efficiency through incentives.¹⁹ Legislation enacted in December 2006 provides a 1.5 percent increase in fees for physicians participating in Medicare, effective July 2007, conditional on reporting information on quality of care. This would add public reporting on physician quality to the current system of reports on hospital quality for Medicare beneficiaries.

The research literature suggests that most patients do not access quality and cost information when it is available, and even fewer alter their choice of provider based on the information.²⁰ Making the information more accessible for consumers might increase its usefulness. Public release of quality information has been shown to spur provider quality improvement.²¹ Robust systems of quality reporting along with modest financial incentives have been found to be effective in motivating hospitals and medical groups to improve care.²² Providers may respond to such information from a desire to see that patients obtain the best care, from professional pride in providing excellent care, or from the desire to avoid being publicly identified as outliers on poor quality or high cost. This research suggests that these legislative proposals may help improve U.S. health system performance and are important building blocks for other initiatives, such as payment reform or technical assistance to spread best practices among providers.

BILLS THAT WOULD SUPPORT THE SPREAD OF HEALTH INFORMATION TECHNOLOGY

Among the bills introduced in the 109th Congress to promote the spread of health information technology are:

- S. 1418 and H.R. 4726, the Wired for Health Care Quality Act (Sen. Enzi and Rep. Issa); and
- H.R. 4157, the Health Information Technology Promotion Act of 2005 (Reps. N. Johnson and N. Deal).

Wired for Health Care Quality Act (S. 1418 and H.R. 4726)

(for more detail see [Table A-6](#))

Overall approach: The Wired for Health Care Quality Act, introduced by Sen. Mike Enzi (R–Wyo.) with 38 cosponsors, passed the Senate and was introduced in the House by Rep. Darrell Issa (R–Calif.) in the 109th Congress. It would establish a nationwide health information technology (HIT) infrastructure, including HIT collaboratives, uniform standards, and funding of the Office of the National Coordinator of Health Information Technology within HHS. It would provide legislative authorization for the Office of the National Coordinator. It would also establish a public–private American Health Information Collaborative to recommend uniform policies and standards in an effort to develop a nationwide interoperable health information infrastructure. It would provide grants and funds for state loan programs to assist in adoption and use of HIT.

Functions of HIT Office: The Office of the National Coordinator of Health Information Technology would be responsible for advising the President and the HHS secretary on the development, application, and use of HIT and on facilitating the adoption of a nationwide interoperable system for the electronic exchange of health information as well as on the adoption and implementation of HIT standards to reduce costs and improve quality.

Quality measures: The proposal also calls for HHS to develop risk-adjusted measures of patient care quality, including measures of clinical processes and outcomes, patient experience, efficiency, and equity as well as measures of underuse and overuse.

Grants: HHS could award competitive grants to facilitate purchase and utilization of technology systems targeted on not-for-profit hospitals, community health centers, and small practices. In addition, it would fund states' establishment of HIT loan programs, and support development of regional or local health information networks.

Funding: The proposal calls for appropriation of \$5 million in FY 2006 and \$5 million in FY 2007 for the Office of the National Coordinator; \$4 million for the American Health Information Collaborative in each of those years; \$116 million in FY 2006 and \$141 million in FY 2007 for competitive grants; and sums as necessary for FY 2008 through 2010.

Health Information Technology Promotion Act of 2005 (H.R. 4157)

(for more detail see [Table A-6](#))

Overall approach: The Health Information Technology Promotion Act of 2005, sponsored by Rep. Johnson (R–Conn.) and 58 cosponsors, passed the House with amendments in July 2006. It would establish an Office of the National Coordinator for Health Information Technology. It would provide legislative authorization for the Office of the National Coordinator, headed by the National Coordinator of Health Information Technology, and charge it with overseeing a strategic plan for national HIT implementation. It would provide a series of grants for integrated health systems and small physician practices to use HIT to improve care for medically underserved populations. It calls for a public–private American Health Information Community to provide consultation on a strategic plan and recommend uniform policies and standards in an effort to develop a nationwide interoperable health information infrastructure.

Functions of HIT Office: The National Coordinator of Health Information Technology would work to develop a nationwide interoperable HIT infrastructure, serving as principal advisor to HHS on development and use of HIT and providing a strategic plan for the nationwide implementation of interoperable HIT in the public and private health care sectors.

Safe harbors: It would create safe harbors and an exception related to certain HIT and training services to the existing anti-kickback law and physician referral prohibitions.

Demonstration grants: HHS could establish demonstration programs to improve care for vulnerable populations through HIT, including grants to integrated health care systems and small physician practices in rural or medically underserved urban areas or states, to determine the impact of HIT on disease management for Medicaid-eligible individuals.

Funding: The proposal would provide \$15 million in FY 2007 and FY 2008 for grants to integrated health systems and \$5 million in those years for grants to physician practices.

Impact on Health System Performance

Electronic information systems show considerable promise for enhancing efficiency, eliminating duplication and waste, reducing medical errors, assisting physicians, nurses, pharmacists, and other health professionals in delivering and coordinating the best care, and ensuring that patients are informed, active partners in their care. Yet, such systems are costly, and the benefits often accrue to the payers rather than the providers who adopt such systems. Further, in order for the health system to maximize benefits from these individual systems, innovation must focus on linking all pieces into an information exchange network.

The U.S. lags behind leading nations in use of health information technology. Fewer than 30 percent of U.S. physicians use electronic health records, compared with 90 percent or more in several countries, including the Netherlands, New Zealand, and the United Kingdom.²³ Furthermore, fewer than 10 percent of U.S. hospitals use a robust health information system with physician order-entry capabilities and electronic clinical

documentation of patient characteristics and demographics.²⁴ There is also an uneven distribution of health information technology: larger medical groups are more likely to use electronic records, but most Americans get their care from smaller physician practices.

The research literature is not sufficiently well developed to know whether health information technology would actually reduce overall medical care expenditures for the U.S. health care system. However, there seems little question that such technology would improve health system performance and could potentially reduce overall costs, depending on how well it is managed. Just a few of the advantages include legibility, which can improve communication among providers and reduce medical errors; decision support, including reminders and prompts to help clinicians make the most appropriate diagnoses, choose tests efficiently, and prescribe and apply appropriate treatments; and the ability to aggregate patient information and reduce duplicate testing.

To achieve these benefits, however, there must be upfront investments and centralized functions, including setting standards so that information can be exchanged easily and patient data from multiple sources (e.g., physicians, hospitals, pharmacies, laboratories, nursing homes, and home health nurses) may be aggregated, shared, and analyzed (with appropriate privacy protections). The investment to achieve this type of interoperability in the health care system has been estimated to be on the order of \$150 billion initially, with an annual maintenance cost of \$50 billion—a large sum, but still a small fraction of our total health care expenditures.²⁵ These costs do not include the acquisition and maintenance of technologies by providers.

None of the bills would commit the funds and central leadership required to realize the potential benefits of a health information system. Instead they constitute modest building blocks and experimentation. If the U.S. is to close the health information technology gap with other leading countries, it will need a strategy and commitment of requisite funds to achieve its promise.

BILLS ESTABLISHING SYSTEMS TO ENSURE PATIENT SAFETY

Following on the heels of enactment of the Patient Safety and Quality Improvement Act of 2005, patient safety legislation in the 109th Congress focused on broadening requirements for reporting. Legislative proposals introduced in the 109th Congress included:

- H.R. 2006 and S. 948, the Safe Health Care Reporting Act of 2005 (Rep. Pallone and former Sen. Corzine); and
- S. 1784, the National Medical Error Disclosure and Compensation Act (Sen. Clinton).

The Safe Health Care Reporting Act of 2005 (H.R. 2006 and S. 948)

(for more detail see [Table A-7](#))

Overall approach: The Safe Health Care Reporting Act of 2005, introduced by former Sen. John Corzine (D–N.J.) and Rep. Frank Pallone (D–N.J.), expands the requirements for reporting information from the National Practitioner Data Bank to include information on skilled nursing facilities and all licensed health care practitioners, not just physicians.

Affected entities: State licensing boards and health care entities including hospitals, skilled nursing facilities, health maintenance organizations, group medical practices, physicians, and licensed health care practitioners.

Information to be reported: State licensing boards would have to report to the Data Bank sanctions taken against all health care practitioners, not just physicians, including revocation or suspension of license and censures or other reprimands for reasons relating to professional competence or conduct. Health care entities would report to the state licensing board professional review actions taken against physicians and licensed health care practitioners.

Incentives and penalties: Civil penalties would be permitted for health care entities that fail to comply with reporting requirements. Health care entities reporting required information would be immune to civil liability for disclosure. Employers could not discriminate against health care practitioners who report conduct that results in a professional action against an individual.

The National Medical Error Disclosure and Compensation Act (S. 1784)

(for more detail see [Table A-7](#))

Overall approach: Sen. Hillary Clinton's (D–N.Y.) bill calls for more extensive reporting, creates a national patient safety database, and would establish a voluntary mechanism for negotiated compensation for injuries.

The proposal would create an Office of Patient Safety and Health Care Quality within the Agency for Healthcare Research and Quality to improve patient safety and reduce medical errors across the health care system. It would establish a National Medical Error Disclosure and Compensation (MEDiC) program that requires reporting, investigation, and communication of medical errors and other patient safety events to a national database and to the affected parties. Patients injured in a reported event could elect to enter into negotiations for compensation through the MEDiC program. It also would establish a National Patient Safety Database for the collection and study of non-identifiable data on medical errors and patient safety events.

Voluntary compensation system: In exchange for agreeing to report any incident involving a patient thought to be a medical error or patient safety event and any legal action related to the medical liability of a health care provider, providers would have access to the MEDiC program, which would negotiate with the patient for fair compensation, working to ensure communication and resolution without legal proceedings and saving providers legal costs.

Grants: The bill would provide grants to health care entities, providers, and medical liability insurers to develop the capacity to meet the MEDiC reporting requirements, and grant to patient safety organizations and researchers to analyze the database and develop training and educational patient safety materials for providers.

Financing: A portion of the savings to medical liability insurers would be dedicated to reducing premiums for health care providers and a portion of savings to health care entities and providers would be used for activities to reduce medical errors and improve patient safety.

Impact on Health System Performance

Substantial gains in health system performance could be achieved if all providers were to adopt proven systems to ensure patient safety. These include use of evidence-based medicine, “reengineering” delivery within and among provider organizations to improve safety and reliability, and ensuring care coordination across sites of care, especially when transitioning from a hospital to other settings.

The Pallone/Corzine proposal is narrowly focused on improved reporting of actions and sanctions against physicians and other licensed practitioners. The Clinton proposal is more far-reaching and would encourage better communication with patients in exchange for a negotiation process aimed at reducing litigation costs. It also would initiate a data bank that would make it possible to learn more about the incidence of medical errors and their root causes. By making information available on the major causes of medical errors, it would be possible for hospitals, physicians, and policy officials to take corrective actions and reduce their incidence, contributing to improved patient safety and health system performance. Effective prevention of medical errors and lower litigation costs could contribute to lower health system costs.

While they are steps in the right direction, these proposals do not embrace the comprehensive recommendations of the Institute of Medicine report, *To Err Is Human*.²⁶ The report lays out a four-tiered approach, including: 1) establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety; 2) identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts; 3) raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and 4) creating safety systems inside health care organizations through the implementation of safe practices at the delivery level.

BILLS TO REFORM MEDICAL LIABILITY

The 109th Congress actively considered medical liability reform, including extensive hearings in the Senate. The major focus was on:

- S. 1337, the Fair and Reliable Medical Justice Act (Sens. Enzi and Baucus).

The Fair and Reliable Medical Justice Act (S. 1337)

(for more detail see [Table A-8](#))

Overall approach: Sen. Enzi (R–Wyo.), the ranking Republican on the Senate Health, Education, Labor, and Pensions (HELP) Committee, and Sen. Baucus (D–Mont.), the ranking Democrat on the Senate Finance Committee, cosponsored the Fair and Reliable Medical Justice Act, intended to fund state demonstrations of alternative dispute resolution mechanisms.

The proposal would authorize the secretary of HHS to award up to 10 demonstration grants to states to develop, implement, and evaluate alternatives to current medical tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.

Health system improvement requirements: To receive a grant, states would be required to develop an alternative to tort litigation and promote reduced health care errors through collection and analysis of patient safety data related to disputes resolved by the alternative processes. HHS would provide technical assistance in development of a defined payment schedule for noneconomic damages and set forth three standard models that states could use to automatically meet HHS standards for approval: 1) early disclosure and compensation; 2) administrative determination of compensation; and 3) a special health care court.

Financing: The bill would authorize the appropriation of funds necessary to carry out the Act.

Impact on Health System Performance

State demonstrations of alternative dispute resolution mechanisms along the lines contained in the Fair and Reliable Medical Justice Act were recommended by an Institute of Medicine report, *Fostering Rapid Advances in Health Care*.²⁷ The three models proposed in the legislation build on the IOM analysis, and offer the prospect of reduced litigation costs and fairer compensation to injured patients. Given the absence of evidence on which to assess alternative resolution mechanisms, systematic testing is desirable. The demonstrations should yield essential information on the effectiveness of different strategies as regards prevention of medical errors and reduced litigation costs, both of which could contribute to lower health system costs.

BILLS DESIGNED TO ELIMINATE DISPARITIES

The major focus on eliminating racial and ethnic disparities in health care in the 109th Congress was on:

- S. 1929, the Faircare Act (Sen. Lieberman).

The Faircare Act (S. 1929) (for more detail see [Table A-9](#))

Overall approach: Sen. Joe Lieberman (Ind.–Conn.) introduced the Faircare Act to promote data collection by race, ethnicity, education, and primary language among federally supported health programs, and to support development of a new set of quality measures. The Act would require federal agencies to collect demographic data on participants in HHS-funded health-related programs by race, ethnicity, and primary language and provide grants to assist hospitals and federally qualified health centers to collect the required data. It also would authorize the Agency for Healthcare Research and Quality (AHRQ) to develop quality measures.

Quality measures: AHRQ would be charged with developing quality measures for each of the most common treatment settings, including those specific to hospitals and outpatient facilities, based on health care priority areas determined by the Institute of Medicine, the National Quality Forum, the Quality Initiative, and other health care quality and minority health organizations. These would include health problems that produce a high level of mortality or morbidity; have the potential for improvement; and disproportionately affect populations for whom there are demonstrated disparities in health care or health status.

Financial incentives: Financial incentives would be provided to hospitals and federally qualified health centers that demonstrate decreases in disparities in care among patients, with up to four percentage-point bonuses for Medicare hospital payment and up to \$500,000 per health center.

State coalitions: The Act would require the Centers for Disease Control and Prevention to expand the Racial and Ethnic Approaches to Community Health Programs (REACH 2010) to all 50 states to fund coalitions to eliminate disparities in the health status of ethnic minorities in six key health areas.

Impact on Health System Performance

Research has demonstrated that collection of data on health care quality by race and ethnicity is feasible and facilitates quality improvement efforts.²⁸ The Faircare Act would accelerate such quality improvement efforts by requiring public reporting and awarding significant financial incentives for progress in reducing disparities. Implementation of reporting requirements and incentives to improve care for disadvantaged populations could make a contribution to improving access to care and improved health outcomes.

ANALYSIS OF CONGRESSIONAL BILLS TO IMPROVE QUALITY AND EFFICIENCY

The bills designed to improve quality and efficiency in the U.S. health system introduced over 2005–2007 would be important building blocks in creating a higher performance health system. Yet, taken as a whole, they would leave important gaps. The Commonwealth Fund Commission on a High Performance Health System has set forth a framework for a high performance health system and identified seven strategies for transforming the health system:²⁹

- extend health insurance to all;
- increase transparency and reward quality and efficiency;
- organize the care system to ensure coordinated and accessible care for all;
- pursue excellence in provision of safe, effective, and efficient care;
- expand the use of information technology and exchange;
- develop the workforce to foster patient-centered primary care; and
- encourage leadership and collaboration among public and private stakeholders.

A recent report, *An Analysis of Leading Congressional Health Care Bills, 2005–2007, Part I, Insurance Coverage*, explores how recent health care bills would address the first of these seven interlocking strategies.³⁰ This report examines how recent legislative proposals might move the nation closer to achieving the other key strategies for improving health system performance (Figure 1).

Figure 1. Major Features of Quality and Efficiency Bills and Impact on Health System Performance

	Strengthen Medicare Rx drug coverage	Reform Medicare payment	Increase transparency	Increase use of HIT	Ensure patient safety	Reform medical liability	Eliminate disparities
Long, healthy, and productive lives	X	X			X		X
Quality		X	X	X	X	X	X
Right care		X					
Coordinated care				X	X		
Safe care		X		X	X	X	
Patient-centered care		X	X				
Access	X						X
Efficiency	X	X	X	X		X	
Equity	X						X
Capacity to improve and innovate		X	X	X			

Although they fall short of a comprehensive strategy for systemwide improvement, the legislative proposals present an interesting set of approaches to addressing these dimensions of health system performance. Taken together, the proposals could lay a foundation for more fundamental reforms.

The following sections explore the potential of the legislative proposals to improve health system performance in the following six dimensions: the ability to promote healthy lives; health care quality; access to care; efficiency; equity; and the capacity to innovate and improve.

Healthy Lives

It is difficult to assess the effects the congressional proposals might have on health outcomes, or the ability of the system to support healthy lives. Bills that would expand access to medications to control chronic conditions would likely make modest contributions toward extending patients' lives and improving their capacity to function. So, too, would proposals to offer financial incentives to providers to achieve better health outcomes for patients, proposals to investigate the causes of and seek to prevent medical errors, and proposals to eliminate disparities. To the extent that the proposals specifically make information on health outcomes transparent and assist providers in delivering care that yields better health outcomes, their impact could be more significant.

Quality

Important provisions for improving quality are those that would advance transparency in reporting quality and cost of care, and provide financial incentives to hospitals, physicians, and other health care providers for delivering quality care. Legislation enacted in December 2006 would provide a 1.5 percent Medicare payment increase for physicians who report information on the quality of their care—adding public reports on physician quality to the current reports on hospital quality for Medicare beneficiaries.

The House and Senate proposals to set aside payment pools in Medicare to offer pay-for-performance incentives are likely to have an effect on improving quality. The research literature suggests that adding financial incentives to quality reporting has at least a modest effect on improving quality.³¹ Early evidence from Medicare pay-for-performance demonstrations involving hospitals indicates that even modest financial incentives contribute to improved quality.³²

Some legislative proposals are intended to help patients make more informed choices in selecting providers by providing them with information about the costs and quality of care—a service that the public says it desires and values highly.³³ Inclusion of measures on patient experiences with care, as specified in the House and Senate Medicare payment reform bills, should facilitate providers' efforts to improve patient-centered care.

Legislative proposals to increase use of information technology could improve the coordination and safety of care, two important aspects of health care quality. The proposals would put in place mechanisms to set standards for health IT, fund a national office for coordinating its use, and provide modest grant funding. Their potential effect is uncertain, given that there has been little research into the effectiveness of such efforts. More important, the provisions may not be sufficient to promote the adoption of information technology.

Similarly, the patient safety proposals, which institute confidential reporting and a voluntary compensation system for those taking part, may not be sufficient to overcome provider resistance to transparency on this sensitive dimension of care.

Access

The legislative proposals discussed here are not aimed primarily at improving access to care. (For an analysis of congressional proposals to extend health coverage, see the [earlier report](#) in this series.³⁴) However, the Medicare proposals that would improve the

prescription drug benefit, including eliminating the “doughnut hole” in coverage, are likely to improve access to prescription drugs for chronically ill beneficiaries. Similarly, the legislative proposal targeting health disparities could lead to improved access for vulnerable populations by funding state coalitions that seek to improve minority health and by providing incentives to hospitals and health centers that reduce disparities in care among patients.

Efficiency

The legislative proposals most likely to achieve savings in the health system are those that would reform Medicare payment for prescription drugs and health care services. Several such proposals call for the federal government to negotiate pharmaceutical prices, and one would offer a Medicare-administered alternative to private drug plans. As discussed above, the Congressional Budget Office has not “scored” the bills as achieving additional Medicare savings, arguing that private drug plans already have incentives to negotiate price discounts in order to attract beneficiaries.³⁵ Yet, a recent study indicates that a Medicare program enrolling all Americans would yield savings through pharmaceutical price negotiations of an estimated \$33.9 billion, or 15 percent of pharmaceutical spending.³⁶ Negotiating for 43 million Medicare beneficiaries would be different; the potential savings would likely vary from drug to drug, depending on the availability of generic alternatives or other brand-name drugs. Lower prices, if achieved, could also affect future investment in research and development.

Efforts to reward hospitals, physicians, and other providers for providing high-quality and efficient care could add momentum to hospital and physician efforts to improve quality, reduce complications, and achieve greater efficiency. Experience from the Medicare Hospital Quality Incentive Demonstration suggests that even small performance incentive outlays can spur quality improvements and at the same time reduce costs.³⁷

Equity

The Senate legislative proposal on “fair care” is explicitly aimed at improving equity in the health care system. It would require public reporting of quality data by patients’ race, ethnicity, education, and primary language in federally supported health programs. It also would ensure that quality metrics targeted health problems that disproportionately affect vulnerable populations and lead to high rates of mortality or morbidity.

System Capacity to Innovate and Improve

Although the congressional legislative proposals may not have sweeping effects on health system performance in the near term, many of them put in place building blocks to

support future innovation and improvement. Most important in this regard are efforts to promote a national health information technology network. Expanded quality measurement and reporting, as well as modest performance incentives, could give providers the encouragement and wherewithal to implement quality improvement processes and systems, or to adopt health information technology such as decision-support systems, patient reminders, and electronic health records.

What's Missing in the Legislative Agenda?

Health legislative proposals introduced over 2005–2007 embrace a number of strategies to improve health system performance, but they fall short of an overarching and coordinated policy strategy. Most notably missing are national goals to guide improvement efforts, establish priorities, ensure implementation of effective strategies, and monitor impact. The formation of national aims has been repeatedly recommended, first by the President's Commission on Quality and on several occasions by the Institute of Medicine.³⁸ Most recently the Institute of Medicine recommended the creation of a National Quality Coordination Board to establish national aims, reach consensus on quality measures, ensure the creation of multipayer data systems that measure provider performance, and urge all payers, public and private, to incorporate such measures in incentive systems.³⁹ The promulgation of national goals would ensure that public and private efforts reinforce each other, rather than work at cross-purposes.

In addition, federal action on payment reform of the current fee-for-service payment system is urgently needed.⁴⁰ Fee-for-service payments create perverse financial incentives to provide more care, though not necessarily effective and appropriate care. On the other hand, capitation payments that provide a fixed amount for each patient for which a delivery system or provider group is accountable could contribute to underutilization of services and lower-quality, if cheaper, care. Further, there are few integrated delivery systems and large group practices that could assume accountability for all of the care required by patients with complex conditions. Greater attention should be given to development, testing, and evaluation of systems that combine per-patient and per-service fees, or population- and episode-based systems of payment that provide financial incentives for greater productivity, higher quality, and more efficient care. In addition, the fee-for-service physician payment system needs to be recalibrated to improve payment for primary care, and eliminate the strong incentives for overutilization of specialized procedures.

Unlike other countries, the U.S. does not have a government entity charged with assessing the comparative effectiveness or cost-effectiveness of new technologies. The Agency for Healthcare Research and Quality has a limited budget for health services and effectiveness research, but does not have a mandate for generating the kinds of information that policymakers need to make informed decisions about covering new technologies, drugs, devices, and procedures under public or private insurance programs, or designing patient incentives to encourage use of effective services while reducing possible overuse of marginally beneficial services.⁴¹

In addition, efforts are needed to engage patients to ensure the most effective and efficient care. Patients should have easy access to their own medical records and be given tools to help them understand the benefits and risks of alternative therapies and help them be actively engaged in their own care. Financial incentives, such as value-based benefit designs, could encourage patients to seek preventive and early primary care services and take medications to control chronic conditions.⁴² Currently, high deductibles in health insurance plans can deter patients from seeking preventive care or adhering to recommended care.⁴³

Reorienting the health care system to encourage prevention, early primary care, and chronic disease management would be facilitated by having patients designate a “medical home.” The four major primary care specialty organizations, the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), the American Academy of Pediatrics (AAP), and the American Osteopathic Association (AOA), have advocated the creation of medical homes. The ACP defines the advanced medical home as “a physician practice that provides comprehensive, preventive, and coordinated care centered on their patient’s needs, using health information technology and other process innovations to assure high-quality, accessible, and efficient care.”⁴⁴ In order for these types of practices to succeed, changes in workforce and training policies as well as payment reforms are needed. For example, instead of fee-for-service payments, a payment structure based on a monthly fee for every patient enrolled in the medical home could support health care teams and new practice arrangements. Such a payment system also could provide incentives for desired behaviors, such as care coordination, preventive services, and investment in advanced information systems.⁴⁵ Payment reform could increase the primary care workforce and strengthen primary care practice. There are some signs of interest among policymakers in the medical home model. For example, the Tax Relief and Health Care Act of 2006 calls for a Medicare Medical Home Demonstration

Project, which would offer management fees to clinicians who serve as personal physicians and incentive payments to physicians in practices that provide medical home services.

The federal government has a special responsibility to ensure that best practices for safe, effective, and efficient care are implemented in public health care delivery programs. The Veterans Health Administration has been a national leader in quality improvement, but those efforts also need to spread to the Defense Department, the Indian Health Service, and community health centers. The federal government could also assist safety-net providers nationwide, including public hospitals and clinics, in the adoption of information technology and cutting-edge quality improvement practices and systems.

For example, as recommended by the Institute of Medicine, the work of Medicare quality improvement organizations (QIOs) could be expanded. QIOs could focus especially on safety net providers, which often cannot afford to hire private consultant services or establish their own internal quality improvement units, and on providers needing special assistance in reaching high levels of performance.⁴⁶ QIOs can also play a useful role in spreading information on best practices that lead to excellence in safe, effective, and efficient care.

The Health Services and Resources Administration provides some support for training health professionals. However, there is a need for a systematic effort to assess the health care workforce supply and consider the skills required to deliver safe, effective, and efficient care. A team approach to care, for example, will undoubtedly be needed as the U.S. experiences serious shortages of skilled personnel. Changing demographics—an aging population, a shrinking supply of professionals to care for this aging population, and increasing reliance on a more diverse workforce, including immigrants—obviously have major implications for the U.S. health system. In the future, finding opportunities to increase productivity by substituting capital for labor, through use of information technology and other forms of automation, and ensuring that all highly trained health professionals' skills are used to their maximum advantage will have even greater urgency.

In short, steps to achieve a balanced and vigorous agenda for health system improvement include:

- fundamental payment reform, moving away from fee-for-service payment to paying for care coordination and population- or episode-based care;⁴⁷

- creation of a Center on Comparative Effectiveness and Evidence-Based Decision-Making to promulgate information on comparative effectiveness of prescription drugs, devices, and procedures, as well as adequate funding of health services research through the Agency for Healthcare Research and Quality;
- engagement of patients in the provision of effective and efficient care by giving them access to their own medical records, tools for shared decision-making, and financial incentives, including value-based health benefit designs;
- reorientation of the health care system to encourage prevention, early primary care, and chronic disease management, including patient designation of a medical home and restructured financial incentives and quality standards that reward practices that meet high standards of accessible, effective, safe, well-coordinated, and efficient care;
- identification of superior models of quality and efficiency in federal health care delivery programs implementing known best practices and continuous quality improvement processes, building on the leadership of the Veterans Health Administration and spreading its quality improvement techniques to Defense Department health services, the Indian Health Service, and community health centers;
- better targeting or augmented funding of Medicare quality improvement organizations' efforts to provide technical assistance to health care providers, especially safety net providers; and
- refocusing of the grants programs of the Health Resources and Services Administration to ensure a high performance health workforce, trained to work in teams and use information technology and other tools to achieve high-quality care efficiently.

The federal government has a responsibility to ensure that the health system has the requisite research, knowledge, best practices, trained personnel, and capital infrastructure to ensure high-quality, efficient care. By doing so, the U.S. can attain what its public has a right to expect for the resources invested in health care—the best health system in the world. Further, the system should continuously improve and adapt to build on new knowledge and experience. Congressional legislative proposals introduced over 2005–2007 begin to address serious deficiencies in the U.S. health system, but the goal should be no less than the provision of accessible, high-quality, and efficient care to all.

APPENDIX. TABLES

Table A-1. Side-by-Side Analysis of the Medicare-Guaranteed Prescription Drug Act of 2006 and the Medicare Accountability, Bargaining, and Compassion for Part D (ABC for D) Act

Bill name	Medicare-Guaranteed Prescription Drug Act of 2006	Medicare Accountability, Bargaining, and Compassion for Part D (ABC for D) Act
Bill number(s)	S. 2342	H.R. 4796
Bill sponsor(s)	S. 2342 is sponsored by Senator Stabenow and has eight cosponsors.	H.R. 4796 is sponsored by Representative Moran and has five cosponsors.
Latest Congressional action	S. 2342 was referred to the Senate Committee on Finance on March 1, 2006.	H.R. 4796 was referred to the House Committee on Ways and Means on Feb. 16, 2006, and the House Committee on Energy and Commerce, Subcommittee on Health on February 17, 2006.
Basic structure of changes to Part D	<p>Establishes a new, federally sponsored Part D plan option, the Medicare-Guaranteed Prescription Drug Plan. The secretary of Health and Human Services (HHS) would be permitted to negotiate contracts with the manufacturers of Medicare Part D-covered drugs for the new benefit option.</p> <p>Also changes requirements for the existing privately sponsored Medicare Part D standard benefit option with respect to the annual deductible, coinsurance, and the initial coverage limit (eliminating the “doughnut hole”).</p>	<p>Permits the secretary of Health and Human Services (HHS) to negotiate contracts with the manufacturers of Medicare Part D-covered drugs.</p> <p>Requires standalone prescription drug plan (PDP) sponsors offering coverage to beneficiaries in fee-for-service Medicare to register with state insurance departments.</p> <p>In addition, the open enrollment period would be lengthened and funds provided for outreach and education efforts to increase enrollment of eligible individuals in Part D coverage through PDP plans or Medicare Advantage prescription drug (MA-PD) plans.</p>
Eligibility/enrollment criteria	Not discussed.	Not discussed.
Benefit design/coverage requirements	<p>HHS would offer a new benefit, the Medicare-Guaranteed Prescription Drug Plan. This new Part D benefit option would be offered nationwide. In establishing this new benefit option, HHS would:</p> <ul style="list-style-type: none"> • Negotiate rates for covered Part D drugs; • Encourage the use of more affordable therapeutic equivalents; and • Implement strategies used by other federal purchasers of prescription drugs (e.g., the Department of Veterans Affairs) to reduce the overall price of covered Part D drugs. <p>With respect to the existing, privately sponsored Medicare Standard Part D benefit option, the requirements for plans offering the standard benefit option would change as follows:</p> <ul style="list-style-type: none"> • The initial coverage limit on costs (\$2,250 in total drug expenditures in 2006) would be eliminated, removing the “doughnut hole”; and 	<p>HHS would be given authority similar to that of the secretaries of Veterans Affairs and Defense to negotiate contracts with manufacturers of Medicare Part D-covered drugs to ensure that individuals enrolled in PDPs and MA-PD plans pay the lowest possible price for their medications.</p>

Bill name	Medicare-Guaranteed Prescription Drug Act of 2006	Medicare Accountability, Bargaining, and Compassion for Part D (ABC for D) Act
	<ul style="list-style-type: none"> The imposition of cost-sharing above the annual out-of-pocket threshold would be prohibited, eliminating the 5 percent cost-sharing for beneficiaries that currently exists for catastrophic drug costs. 	
Pharmacy network requirements	Not discussed.	Not discussed.
Premium and cost-sharing requirements	<p>The monthly premium for the Medicare-Guaranteed Prescription Drug Plan would be uniform throughout the country and equal to the base premium calculated for purposes of the existing Medicare Standard Part D benefit.</p> <p>For the Medicare Part D coverage standard option, the annual deductible amount would be equal to the deductible for Medicare Part B (which would be, for 2006, \$124). Additionally, the coinsurance for costs above the annual deductible would be reduced from 25% to 20%, and for individuals with income below 150% of the federal poverty level, the coinsurance would be reduced from 15% to 10%.</p>	Not discussed.
Administration and oversight	HHS would be responsible for administering the new Medicare-Guaranteed Prescription Drug Plan and overseeing changes to the existing Medicare Part D standard benefit option.	<p>Would require PDP sponsors to register with the state insurance department in each state in which the sponsor offers a PDP by submitting:</p> <ul style="list-style-type: none"> A certified copy of the sponsor's charter or deed of settlement; A statement including the name of the sponsor, location, and amount of capital; and A copy of the sponsor's last annual report. <p>HHS would be given authority to negotiate contracts with manufacturers of Medicare Part D-covered drugs for individuals enrolled in PDPs and MA-PD plans.</p>
Payment and reimbursement policies	Not discussed.	Not discussed.

Bill name	Medicare-Guaranteed Prescription Drug Act of 2006	Medicare Accountability, Bargaining, and Compassion for Part D (ABC for D) Act
Beneficiary protections	There would be no late enrollment penalty applicable to the Medicare-Guaranteed Prescription Drug Plan.	<p data-bbox="959 260 1430 373">Outreach, education, and counseling with respect to enrollment in a PDP or MA-PD would be provided to Medicare beneficiaries as follows:</p> <ul data-bbox="959 415 1458 594" style="list-style-type: none"> <li data-bbox="959 415 1442 499">• HHS would award grants to states for the purpose of providing outreach and counseling; and <li data-bbox="959 506 1458 594">• The administrator of the Social Security Administration (SSA) through its regional offices would provide outreach and education. <p data-bbox="959 632 1430 867">The period of open enrollment for PDP and MA-PD plans would be extended to allow enrollment without a late penalty through December 31, 2006. Individuals making an election between November 15, 2006, and December 31, 2006, would be required to specify whether the election is effective for 2006, 2007, or both.</p> <p data-bbox="959 905 1463 1325">Coverage elections would not take effect for 14 days if made during the initial enrollment period (i.e., when a beneficiary first becomes eligible for the Medicare program) or during continuous enrollment (i.e., when beneficiaries may switch coverage elections at any time, a feature granted to dual-eligible beneficiaries, who are permitted to make changes to their coverage selection on a monthly basis). To allow for this 14-day delay, for 2007 and succeeding years, the annual coordinated election period would be shortened so that it would begin on November 15 and extend through December 15.</p> <p data-bbox="959 1362 1463 1598">Adequate notice would be given to affected MA-PD sponsors of any election or change of coverage made during a special election period (i.e., time periods in which beneficiaries may switch coverage elections without any penalties, based on a limited number of reasons, e.g., status under the low-income subsidy or as a Hurricane Katrina-affected beneficiary).</p>
Evaluations, studies, and reports	Not discussed.	Not discussed.
Financing/funding	General revenues would be used to pay for expenses incurred in the operation of the new plan.	<p data-bbox="959 1667 1458 1780">The existing Stabilization Fund (of \$10 billion) would be reduced to offset the \$200 million appropriated by the Act for outreach and education in 2006:</p> <ul data-bbox="959 1818 1463 1934" style="list-style-type: none"> <li data-bbox="959 1818 1409 1875">• \$100 million would be appropriated for HHS to provide grants to states; and <li data-bbox="959 1881 1463 1934">• \$100 million would be appropriated for SSA regional offices.

Bill name	Medicare-Guaranteed Prescription Drug Act of 2006	Medicare Accountability, Bargaining, and Compassion for Part D (ABC for D) Act
Key implementation dates	<p>The provisions establishing the Medicare-Guaranteed Prescription Drug Option would take effect on the date of the Act's implementation.</p> <p>The provisions making changes to the existing Medicare Standard Part D benefit option would take effect on January 1, 2007.</p>	<p>Provisions requiring PDP sponsors to register with the state insurance department would apply to PDPs offered on or after January 1, 2007.</p> <p>Changes made to the initial and continuous enrollment periods would not apply to elections of coverage made prior to the Act's implementation, or to elections made in the month in which the Act is enacted, if enactment occurs during the last 14 days of that month.</p> <p>Changes to the annual, coordinated enrollment period would apply to such periods beginning on or after November 15, 2006.</p> <p>The provisions requiring notice of election changes to affected providers would apply to special enrollment periods as specified by HHS.</p>
Other key elements of the bill	<p>With the establishment of the Medicare-Guaranteed Prescription Drug Option, existing requirements related to access to a choice of coverage and application of limited risk and fallback plans (which are designed to ensure access to a choice of at least two plans in each area) would sunset at the end of 2006.</p>	<p>Not applicable.</p>

Table A-2. Side-by-Side Analysis of the
Pharmacy Access Improvement (PhAIm) Act of 2006 and the
Medicare Prescription Drug Simplification Act of 2006

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
Bill number(s)	S. 2664	S. 2665
Bill sponsor(s)	S. 2664 is sponsored by Senator Baucus and has three cosponsors.	S. 2665 is sponsored by Senator Baucus and has four cosponsors.
Latest Congressional action	S. 2664 was referred to the Senate Committee on Finance on April 27, 2006.	S. 2665 was referred to the Senate Committee on Finance on April 27, 2006.
Basic structure of changes to Part D	<p>Makes a number of changes to the Medicare Part D benefit, including requirements for: (1) sponsors of standalone prescription drug plans (PDPs) used by beneficiaries in traditional, fee-for-service Medicare; and (2) sponsors of Medicare Advantage prescription drug (MA-PD) plans for beneficiaries in Medicare managed care.</p> <p>These changes include:</p> <ul style="list-style-type: none"> • Requiring that PDP sponsors provide beneficiaries with convenient access to a sufficient number of pharmacies accessible to the general public; • Requiring that PDPs and MA-PD plans provide prompt payment of clean claims to pharmacies; • Requiring that PDPs and MA-PD plans pay a minimum reasonable dispensing fee for covered Part D drugs; • Requiring the secretary of Health and Human Services (HHS) and PDP sponsors to establish hotlines to provide Part D information to pharmacists and pharmacy staff; • Imposing restrictions on plans' marketing and cobranding (e.g., relationships between PDPs and other entities aimed at enhancing plan enrollment); and • Requiring that PDP sponsors increase the dispensing fee for generic drugs to encourage the use of generics. 	<p>Makes a number of changes to the Medicare Part D benefit, including requirements for: (1) sponsors of standalone prescription drug plans (PDPs) used by beneficiaries in traditional, fee-for-service Medicare; and (2) sponsors of Medicare Advantage prescription drug (MA-PD) plans for beneficiaries in Medicare managed care.</p> <p>These changes include:</p> <ul style="list-style-type: none"> • Establishing five national uniform benefit packages; • Requiring that plan sponsors cover (i.e., include on their formulary) six specific categories of drugs; • Requiring that plan sponsors demonstrate satisfactory performance quality; and • Establishing a series of beneficiary protections, including protections relating to the use by plans of cost or utilization management tools and the format of information provided to enrollees about non-covered drug requests for reconsideration of denied claims and marketing. <p>Studies relating to formulary requirements, cost and utilization management tools, and value-based purchasing programs (i.e., programs providing payments to providers and entities for improved quality of care) would be conducted by governmental and non-governmental entities.</p> <p>Also, allocates funding to assist beneficiaries in Part D plans.</p>
Eligibility/enrollment criteria	Not discussed.	<p>The secretary of Health and Human Services (HHS) could waive the application of the late enrollment penalty for eligible individuals who have not enrolled in Part D because of exceptional circumstances (e.g., receiving erroneous information about the plan).</p> <p>HHS would collaborate with the commissioner of the Social Security Administration (SSA) to integrate processes for individuals applying for subsidies available to low-income beneficiaries and enrolling in a Part D plan.</p>

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
Benefit design/coverage requirements	Not discussed.	<p data-bbox="927 254 1481 436">HHS would establish five national uniform benefit packages for drug coverage other than standard prescription drug coverage (e.g., “alternative prescription drug coverage”). These uniform benefit packages would be updated at least every three years.</p> <p data-bbox="927 470 1481 558">Three of the uniform benefit packages for alternative coverage would provide “basic” prescription drug coverage:</p> <ul data-bbox="927 592 1481 961" style="list-style-type: none"> <li data-bbox="927 592 1481 680">• One package would have no annual deductible or coinsurance for costs up to the initial coverage limit (e.g., \$2,250 for 2006); <li data-bbox="927 680 1481 863">• One package would have the deductible applicable to standard coverage (e.g., for 2007, \$250 plus the annual percentage increase) and would require copayments for costs above that deductible, up to the initial coverage limit; and <li data-bbox="927 863 1481 961">• One package would have no deductible and would require copayments for costs up to the initial coverage limit. <p data-bbox="927 995 1481 1325">HHS would ensure that the actuarial and unsubsidized value of the three “basic” uniform benefit packages equals that of the standard prescription drug coverage option. HHS also would ensure that the average enrollee cost for coverage is equal to the product of: (1) the amount by which the initial coverage limit for the standard drug coverage exceeds the annual deductible (e.g., \$2,000 for 2006); and (2) 100 percent minus the applicable coinsurance percentage.</p> <p data-bbox="927 1358 1481 1478">Two of the uniform benefit packages would be “supplemental” prescription drug coverage consisting of reductions in cost-sharing and/or coverage of optional drugs:</p> <ul data-bbox="927 1512 1481 1755" style="list-style-type: none"> <li data-bbox="927 1512 1481 1661">• One package would provide for coverage of costs incurred within the “doughnut hole” (i.e., after the initial coverage has been reached but before the annual out-of-pocket threshold has been reached); and <li data-bbox="927 1661 1481 1755">• One package would increase the initial coverage limit to equal the annual out-of-pocket threshold. <p data-bbox="927 1789 1481 1929">HHS would ensure that the two “supplemental” uniform benefit packages have an actuarial value greater than that of the standard prescription drug coverage option.</p>

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
		<p>In establishing the five uniform benefit packages, HHS would balance various objectives such as simplifying the benefit structures, avoiding adverse selection (e.g., comprehensive plans attracting the sickest patients with the most to gain from such coverage), and promoting competition among plans. Specifically, HHS would be required to develop standardized language, nomenclature, definitions, and format to be used by plans when providing beneficiaries with information about the plans. This standardized language and format would clearly distinguish between the various types of plans, both for benefit packages newly established by the Act and plans currently in existence.</p> <p>The uniform benefit packages would be prohibited from including more than three levels/tiers of cost-sharing unless such a level/tier is used for specialty or high-cost covered drugs where the Part D plan has an exceptions process (i.e., a non-preferred drug could be covered as a preferred drug in certain instances) as to that level/tier.</p> <p>For 2007 and 2008, plans would be required to include on their formulary all or “substantially all” (as defined in the Act) available drugs in the following six categories:</p> <ul style="list-style-type: none"> • Immunosuppressants; • Antidepressants; • Antipsychotics; • Anticonvulsants; • Antiretrovirals; and • Antineoplastics. <p>A PDP sponsor could not use a utilization management tool (e.g., prior authorization) for a drug in these six categories for enrollees who were taking the drug prior to the implementation of the tool.</p> <p>For 2009 and subsequent years, HHS could promulgate regulations requiring that Part D plan formularies include coverage of drugs within certain categories.</p>

Bill name	Pharmacy Access Improvement (PhAIM) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
Pharmacy network requirements	<p>PDP sponsors would be required to provide a pharmacy network that includes a sufficient number of pharmacies accessible to the general public (e.g., not including pharmacies dispensing drugs by mail order only or pharmacies located in a hospital or nursing home). In determining whether PDP sponsors meet HHS rules for convenient access to in-network pharmacies, only in-network preferred pharmacies (those offering drugs at a lower copay) would be considered (not non-preferred pharmacies that, while in-network, require higher copays from beneficiaries).</p> <p>PDP sponsors could not exclude a pharmacy from participation in the PDP's pharmacy network for either of the following reasons:</p> <ul style="list-style-type: none"> • The pharmacy has previously refused an offer to participate in the plan's network; or • The pharmacy is a "covered entity" under §340B of the Public Health Service Act, which provides discounted drug pricing for specified entities (e.g., certain disproportionate share hospitals, AIDS/HIV and tuberculosis clinics, and federally qualified health centers). <p>Additionally, §340B-covered entities would be allowed to demand modifications to contracts with PDP sponsors in the following ways:</p> <ul style="list-style-type: none"> • If the entity requests that the terms of the Model Safety Net Pharmacy Addendum to Pharmacy Contract (which applies special terms and conditions to an agreement between a PDP sponsor and a provider) govern a contract with a PDP to dispense covered drugs, those terms would govern; or • If the entity requests that the contract with a PDP permit the pharmacy to waive or reduce cost-sharing, such terms also would be included in the contract. <p>In establishing rules for beneficiary access to in-network pharmacies, HHS would include standards with respect to enrollees in long-term care facilities.</p>	Not discussed.
Premium and cost-sharing requirements	Not discussed.	Not discussed.

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
Administration and oversight	Not discussed.	<p>HHS would establish a 15-member Benefit Advisory Committee, with specified membership composition, to advise HHS on the development of the five uniform benefit packages.</p> <p>The Act would limit the ability of HHS to grant a waiver of licensure (requiring a sponsor to be licensed in the state in which it offers a PDP) to instances in which HHS has received a certification from the state insurance commissioner that the PDP has a substantially complete application pending in that state. Similarly, HHS would revoke such waivers if the certification indicates that the recipient:</p> <ul style="list-style-type: none"> • Committed fraud or abuse; • Failed to make a good-faith effort to satisfy state licensing requirements; or • Was found ineligible for licensure by the state. <p>As of January 1, 2007, the PDP and PDP sponsor would be required to demonstrate satisfactory performance quality, as determined by HHS taking into consideration the following:</p> <ul style="list-style-type: none"> • Indicators of consumer service; • Indicators of compliance with pharmacy service standards; • The plan’s incorporation of treatment effectiveness reports developed by the Agency for Healthcare Research and Quality; • Adverse consequences to enrollees’ health due to formulary, utilization management, or transition policies; • Indicators from the MedPAC study regarding alignment of payments to plans with performance; • The negligent provision of inaccurate formulary information; and • Clinical quality indicators as determined by HHS.
Payment and reimbursement policies	<p>PDPs’ and MA-PD plans’ contracts with pharmacies would require the plan sponsor to issue, mail, or transmit payment for “clean claims” (claims with no defects or improprieties) within 14 days of receipt for electronically submitted claims and within 30 days of receipt for all other submitted claims.</p> <p>If payment is not issued in accordance with the new time requirements for a clean claim, interest would be paid equal to the weighted average of interest on three-month marketable Treasury securities determined for such period, increased by 0.1 percentage points beginning on the day after the required payment date.</p>	

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
	<p>Part D plan sponsors' contracts with pharmacies also would require the sponsor to acknowledge receipt of a clean claim within 10 days of the submission of the claim. A claim would be deemed clean if the sponsor did not provide notice of any deficiency during that period.</p> <p>If the Part D plan sponsor determines a claim is not clean, the sponsor would be required to issue a notice within 10 days of receipt of the claim that specifies the defects and lists the additional information necessary to correct the claim. If the claimant provides the requested additional information and the sponsor does not provide notice of defect, the claim would then be deemed clean.</p> <p>Plan sponsors would be required to pay claims submitted electronically by electronic transfer of funds if requested by the pharmacy.</p> <p>Beginning January 1, 2008, PDP and MA-PD sponsors' contracts with pharmacies would require the plan sponsor to pay pharmacies a reasonable dispensing fee based on considerations related to costs incurred by pharmacists in filling prescriptions for covered drugs. These considerations include:</p> <ul style="list-style-type: none"> • Costs associated with a pharmacist's time in determining an individual's coverage status and performing clinical review and quality assurance activities; • Costs associated with measuring or mixing a drug, filling the actual container, providing the completed prescription to an enrollee, delivery, special packaging, facility overhead, maintenance (e.g., salaries of pharmacists), and geographic factors impacting operational costs; and • Costs associated with filling a prescription based on whether the pharmacist is dispensing a standard or extended supply of the drug. <p>For PDP and MA-PD sponsors with disparate rates for preferred and non-preferred pharmacies, the dispensing fee established for a non-designated pharmacy must be at a rate not less than that for designated pharmacies.</p> <p>If the PDP or MA-PD sponsor uses a standard for reimbursement based on the cost of the drug, the sponsor would be required to update that standard at least every seven days.</p>	

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
	<p>After 2008, PDP and MA-PD sponsors would be required to pay a reasonable minimum dispensing fee in accordance with regulations specified by HHS for covered drugs dispensed through a participating pharmacy.</p> <p>HHS would annually review and revise the required minimum dispersing fee based on considerations relating to costs incurred by pharmacists in filling prescriptions for covered drugs and the National Industry-Specific Occupational Employment and Wage Estimates.</p> <p>PDP sponsors also would be required to encourage the use of generic rather than brand-name drugs by paying an increased dispensing fee for prescriptions for generic drugs filled on or after January 1, 2008.</p>	
Beneficiary protections	<p>HHS would establish and staff a 24-hour toll-free phone number dedicated to providing information about the Part D benefit for pharmacists and pharmacy staff.</p> <p>PDP sponsors also would be required to establish and staff a 24-hour toll-free phone number dedicated to providing information about the Part D benefit for pharmacists and pharmacy staff as well as for physicians and providers.</p> <p>PDP sponsors' participation cards (for use by enrollees to access negotiated prices) could not display the name or logo of any pharmacy. In addition, marketing materials distributed by a PDP sponsor that has a co-branding relationship with a pharmacy (e.g., a relationship between a PDP and pharmacy whereby the PDP displays the name of the pharmacy on marketing materials to signify a business arrangement as a way to promote enrollment) would be required to include a disclaimer acknowledging the availability of other pharmacies in the network.</p>	<p>PDP sponsors could only remove a covered drug from the plan formulary, apply a cost or utilization management tool restricting or limiting the coverage of a drug, or increase cost-sharing of a drug on the date sponsors begin marketing their plans. This restriction would not apply to a covered drug that is:</p> <ul style="list-style-type: none"> • A brand-name drug for which there is an approved generic placed on the market during a period in which removals or changes in the formulary are limited; • A drug for which the commissioner of the Food and Drug Administration (FDA) issues a safety warning that imposes a restriction on the drug; • A drug that the Pharmacy and Therapeutic Committee of the Part D plan sponsor determines has a lower safety profile than is appropriate; or • One for which HHS establishes a specific exception. <p>PDP sponsors would be required to provide appropriate notice of any permitted change in formularies to HHS as well as affected enrollees, physicians, pharmacies, and pharmacists. Additionally, each PDP sponsor would be required to furnish to each enrollee a notice of any changes in the formulary (that will take effect for the applicable plan year) at the time of each annual coordinated election period. With respect to drugs excluded under Part D, HHS would be required, on an annual basis, to publish a list of the excluded drugs in the Federal Register and to inform eligible individuals of the types of drugs excluded in conducting information dissemination activities.</p>

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
		<p data-bbox="943 258 1425 407">In disseminating comparative information to beneficiaries about PDPs and MA-PD plans, HHS would ensure that the information provided distinguishes between the following types of plans:</p> <ul data-bbox="943 443 1468 653" style="list-style-type: none"> <li data-bbox="943 443 1468 499">• Plans that offer basic drug coverage and plans that offer supplemental drug coverage; <li data-bbox="943 506 1468 562">• Plans that offer coinsurance and plans that offer flat copayments; and <li data-bbox="943 569 1468 653">• Plans that cover all drugs that may be provided under Part D drugs and plans that do not cover all Part D drugs. <p data-bbox="943 688 1430 806">In addition, PDP sponsors would be required to include the following information when disseminating information regarding each plan to the public:</p> <ul data-bbox="943 842 1468 1150" style="list-style-type: none"> <li data-bbox="943 842 1468 961">• A description of how any cost and utilization management tools are used to impose restrictions or limitations under the plan's formulary; <li data-bbox="943 968 1468 995">• Beneficiary cost-sharing requirements; <li data-bbox="943 1001 1468 1087">• Information concerning the plan's benefit process and contact information (e.g., toll-free customer call line, Web site); and <li data-bbox="943 1094 1468 1150">• A description of the specific information an enrollee can request of the PDP sponsor. <p data-bbox="943 1186 1468 1486">HHS would standardize the format of information provided by PDP sponsors to enrollees (e.g., a listing of the covered drugs and the use of cost and utilization management tools). Specifically, HHS would develop a standard definition for any cost and utilization tools used as well as a standard nomenclature for distinguishing between drugs excluded from the definition of a covered drug under the Part D benefit and drugs not included on the plan's formulary.</p> <p data-bbox="943 1522 1458 1759">HHS would develop a standardized notice for pharmacies to distribute when a Part D-covered drug prescribed for the enrollee is (1) not covered; (2) restricted by the plan; or (3) on a nonpreferred or specialty tier (e.g., subject to a higher cost-sharing). Pharmacies would be reimbursed for providing these notices. The notice would include:</p> <ul data-bbox="943 1795 1468 1946" style="list-style-type: none"> <li data-bbox="943 1795 1468 1822">• An explanation of the coverage decision; <li data-bbox="943 1829 1468 1885">• Information on requesting a reconsideration and exception and filing an appeal; and <li data-bbox="943 1892 1468 1946">• Contact information for the PDP or MA-PD plan sponsor.

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
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HHS also would develop:

- Standardized forms to be used by an enrollee to request a reconsideration of a coverage determination or an exception to the tiered cost-sharing structure; and
- A standardized process for reconsiderations and exceptions with explicit requirements regarding the bases for determinations regarding medical necessity and the submission of additional information.

HHS would request that the National Association of Insurance Commissioners (NAIC) develop standardized marketing requirements for PDPs and MA-PD plans and submit a report describing these requirements by April 1, 2007.

In particular, the report should prohibit the following marketing activities: cross-selling non-Medicare products/services with those offered by a PDP or MA-PD plan; “upselling” from PDPs to MA-PD plans; and telemarketing conducted by a PDP or MA-PD plan.

The conduct of agents engaged in on-site promotion at an organization with which the PDP or MA-PD plan has a cobranding relationship also would be addressed by the marketing requirements.

HHS would promulgate regulations for standardized marketing requirements (based on the NAIC report or, if NAIC declines to issue a report, prohibiting the activities described above) to take effect no later than July 31, 2007 (and to apply to contracts with sponsors of PDPs and MA-PDs beginning January 1, 2008).

If a state adopts these marketing requirements, the state may provide for the enforcement with respect to agents of PDPs or MA-PDs licensed in the state.

Regardless, HHS could enter into a memorandum of understanding with a state providing for state enforcement of the marketing requirements.

HHS would request that states report violations of marketing requirements to CMS and would submit an annual enforcement report to Congress including a list of any alleged violations as well as the disposition of these violations.

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
Evaluations, studies, and reports	<p>The Office of Inspector General (OIG) for HHS would analyze the cost of dispensing covered drugs, taking into consideration costs incurred by pharmacists in filling prescriptions for covered drugs, and report its findings to HHS by March 1, 2007. The report would include recommendations regarding the minimum reasonable dispensing fee, as well as the extent to which the fee could be increased when an extended supply of a covered drug is dispensed.</p>	<p>Within two months of the Act's implementation, HHS would conduct a study, in collaboration with the Institute of Medicine (IOM) of the National Academy of Sciences, with respect to requiring that Part D formularies cover certain categories or classes of drugs.</p> <p>The study would include an evaluation of whether requiring certain categories of drugs is necessary to protect enrollees from undue medical risk and complication as well as options to allow the reevaluation of coverage requirements on an ongoing basis. Additionally, in conducting the study, IOM would be required to consider:</p> <ul style="list-style-type: none"> • The existing framework for beneficiary protections; • The role of the Pharmacy and Therapeutic Committees (entities with which sponsors are required to collaborate in developing drug formularies) in selecting drugs for inclusion on Part D formularies; and • The implications of those choices on Medicare spending. <p>The committee appointed to conduct the study would comprise individuals with expertise in economics, clinical pharmacology, actuarial sciences, pharmacy benefit design, and medicine. Within 12 months of HHS collaboration with IOM, IOM would be required to submit a report on the study to HHS and Congress.</p> <p>The Government Accountability Office (GAO) would conduct a study on plans' use of cost and utilization management tools to impose restrictions or limitations on formulary drug coverage. The study would include:</p> <ul style="list-style-type: none"> • A comparison of PDPs and MA-PD plans regarding the range and extent of cost and utilization management tools; • A comparison of these tools with those used by private insurance plans and plans under the Federal Employees Health Benefits Program (FEHBP); • An assessment of the impact of these tools on enrollee access to needed medications, enrollee health, providers, and pharmacists; • An assessment of the cost-effectiveness of these tools; and • An assessment of the feasibility, advantages, and disadvantages associated with implementing these tools.

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
		<p>The GAO would submit its report to Congress by September 1, 2007, including recommendations for legislation.</p> <p>The Medicare Payment Advisory Committee (MedPAC) would conduct a study on the establishment and implementation of a value-based purchasing program regarding the provision of prescription drug coverage. The study would analyze potential clinical quality indicators and options for aligning payment to plans with performance regarding the provision of prescription drug coverage. MedPAC would submit its report to Congress, including recommendations for legislation and administrative actions, by June 1, 2007.</p>
Financing	Not discussed.	<p>Funds necessary for the IOM study would be authorized to be appropriated as needed.</p> <p>The Act would appropriate an amount not to exceed \$120 million to CMS for the purpose of ensuring that individuals have access to objective advice and assistance in enrolling in the Part D benefit. In particular, the funds would be used to provide grants to state health insurance counseling programs and to allow states with Part D enrollment below the national average to conduct innovative programs to help individuals enroll in Part D and/or an available low-income subsidy. Amounts appropriated for these purposes would remain available until December 31, 2010.</p>
Key implementation dates	<p>Unless indicated otherwise below, all provisions would apply to plan years beginning on or after January 1, 2007.</p> <p>Provisions regarding the use of standardized technology would apply to communications or transactions conducted beginning 60 days after the Act instatement.</p> <p>Provisions regarding plan sponsors' participation cards and marketing materials would apply to cards and materials distributed beginning 60 days after the Act instatement.</p> <p>HHS would establish reasonable dispensing fee rates on an expedited rulemaking process. In setting these rates, HHS would:</p> <ul style="list-style-type: none"> • Consider recommendations issued by the OIG; • Publish a notice (after consultation with interested parties) of rulemaking within 60 days of the Act's implementation; • Provide for a shortened comment period of 15 days. 	<p>Unless indicated otherwise below, all provisions would apply to plan years after January 1, 2007.</p> <p>The provisions establishing the new uniform benefit packages would be implemented beginning January 1, 2008.</p> <p>The requirement of annual notice of changes in the formulary would apply to coordinated election periods beginning on or after November 15, 2006.</p> <p>The provisions waiving the late enrollment penalty in exceptional circumstances and requiring integrated processes for application of the low-income subsidy would take effect on the date of the Act instatement.</p>

Bill name	Pharmacy Access Improvement (PhAIm) Act of 2006	Medicare Prescription Drug Simplification Act of 2006
	<p>HHS would appoint a negotiated rulemaking committee within 20 days of the end of the comment period. The committee would report to HHS on its progress in reaching consensus on the rulemaking process by December 1, 2007.</p> <p>HHS would publish an interim, final rule in the Federal Register by March 1, 2008, which would be subject to change and revision after a period of public comment.</p>	
Other key elements of the bill	<p>PDP sponsors would be required to use standardized technology for communications and transactions between the plan and participating pharmacies.</p> <p>PDPs and MA-PD plans' contracts would have to allow pharmacies in long-term care facilities at least 30 days (but not more than 90 days) to submit claims for reimbursement.</p>	<p>Effective November 1, 2006, the Pharmacy and Therapeutic Committee would be required annually to disclose to HHS (and, upon request, to the public) any conflict of interest its members might have with a pharmaceutical company, an insurer, a PDP sponsor or MA organization, or other relevant entity. The Committee also would disclose to HHS (and, upon request, the public) the decisions, and bases for such decisions, made with regard to the formulary for plan years beginning on or after January 1, 2007.</p> <p>With respect to the appeals process in place for nonformulary drugs, an individual could only appeal a plan's denial of coverage for a covered Part D drug if the prescribing physician has determined that: (1) all covered drugs on any tier of the formulary would not be as effective for the individual; (2) all covered drugs on any tier would have adverse effects for the individual; or (3) the prescribed drug is the most effective for the individual.</p> <p>HHS would distribute comparative information about PDPs and MA-PD plans that included the following information:</p> <ul style="list-style-type: none"> • The number of enrollees; • The percentage of drugs dispensed that were generic; • The number of grievances received; • The number of appeals received and the percentage of successful appeals; • The number of calls to customer service call centers; • The average hold time at such centers; • The percentage of drugs dispensed requiring prior authorization; • The percentage of drugs requiring step therapy; and • Any additional information deemed appropriate.

Table A-3. Side-by-Side Analysis of the
Medicare Value-Based Purchasing for Physicians' Services Act of 2005
and the Medicare Value Purchasing Act of 2005

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
Bill number(s)	H.R. 3617	S. 1356
Bill sponsor(s)	H.R. 3617 is sponsored by Representative Nancy Johnson and has 46 cosponsors.	S. 1356 was introduced by Senator Grassley and has five cosponsors.
Latest Congressional action	H.R. 3617 was referred to the House Committee on Energy and Commerce, Subcommittee on Health on August 5, 2006.	S. 1356 was referred to the Senate Committee on Finance on June 30, 2005.
Basic structure of health system improvement	<p>Amends Medicare Part B to establish a payment program for physicians' services based on quality and efficiency measures.</p> <p>Revises the current Medicare payment system for physicians. Updates for the Medicare physician fee schedule in 2007 and beyond would provide an additional 1.0 percent to providers and groups providing physician services that report quality data. In 2009 and beyond, the updates would provide an additional 1.0 percent to those providers and groups that both report quality data and achieve certain performance objectives.</p> <p>The sustainable growth rate (SGR) formula currently used to update physician payments annually would be replaced by a new payment system.</p>	<p>Establishes quality measurement systems for the following health care entities participating in the Medicare program: hospitals; physicians and practitioners; Medicare Advantage (MA) managed care plans; end-stage renal disease (ESRD) providers and facilities; and home health agencies.</p> <p>Creates a Medicare payment program for health care entities based on new quality measurement systems. Payments would reflect improvements in quality of care or the delivery of care that exceeds an established threshold for quality.</p> <p>Establishes a variety of demonstration and pilot projects related to: chronic kidney disease; the exchange of clinical claims and outcomes data; the value associated with delivering high-quality care; the aggregation of data regarding quality of care; and the use of health information technology for data coordination.</p> <p>Directs the Medicare Payment Advisory Committee (MedPAC) to conduct a variety of studies relating to: the effect of implementing value-based purchasing programs, and the advisability of establishing a value-based purchasing program for critical-access hospitals, prescription drug coverage (Medicare Part D plans), pediatric renal dialysis facilities, and skilled nursing facilities (SNFs).</p>
Description of affected entities	Physicians participating in the Medicare Part B program would be affected by this Act.	Hospitals; physicians and practitioners (including physical therapists, occupational therapists, and qualified speech-language pathologists); MA plans; ESRD providers and facilities; and home health agencies participating in the Medicare program would be affected by this Act.
Health system improvement requirements	The secretary of Health and Human Services (HHS) would establish a value-based purchasing program for physician services. In doing so, HHS would oversee the selection of quality and efficiency measures (Q & E measures) to be used in assessing the quality and efficiency of physician services for Medicare beneficiaries. These Q & E measures would:	<p>The secretary of Health and Human Services (HHS) would develop quality measurement systems to provide value-based payments to hospitals, physicians and practitioners, MA plans, ESRD providers and facilities, and home health agencies.</p> <p>In developing and updating each quality measurement system, HHS would:</p>

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
	<ol style="list-style-type: none"> 1. Include a mix of outcome, process, and structural measures; 2. Include efficiency measures related to clinical care; 3. Include measures of care furnished to frail individuals over the age of 75 and to individuals with multiple complex chronic conditions; 4. Be evidence-based (if pertaining to clinical care); 5. Be consistent, valid, practicable, and not too burdensome to collect; 6. Be relevant to physicians, enrollees, and the source for Medicare Part D funding (i.e., the Federal Supplementary Medical Insurance Trust Fund); 7. Provide a balanced measure of performance; 8. Capture individuals' assessments of care (e.g., patient satisfaction information); and 9. Assess relative use of resources, services, or expenditures. <p>In designing, implementing and applying the measures, attention would be paid to differences in patients' health status and compliance with physicians' orders, ensuring that providers and groups/practices do not select healthier patients or deselect unhealthy patients, reducing health disparities, and using appropriate statistical techniques.</p> <p>To select the Q & E measures, HHS would request that each physician specialty organization (including organizations representing non-physician practitioners or groups that furnish and bill for physician services) submit proposed measures (described in 1 through 7 above) to a consensus-building organization by March 1, 2006, that are applicable to clinical care. If the specialty organization failed to meet this deadline, HHS itself would submit the proposed measures to a consensus-building organization by April 1, 2006.</p> <p>The consensus-building organization would be an entity (e.g., the National Quality Forum) that HHS identifies as having experience in using a process for reaching group consensus regarding performance measures. The consensus-building organization would include the following individuals:</p> <ul style="list-style-type: none"> • HHS representatives; • Practicing physicians (and nonphysicians and suppliers who furnish physicianlike services); 	<ul style="list-style-type: none"> • Take into account quality measures developed by nationally recognized quality measurement organizations, researchers, and provider organizations; • Consult and enter into an arrangement with a private nonprofit entity, as required by the Act; • Consult with provider-based groups and clinical specialty societies; • Take into account existing quality measurement systems; and • Take into account the MedPAC reports and demonstrations required under this Act, as well as the applicable report by the Institute of Medicine (IOM) required by the Medicare Modernization Act (MMA). <p>HHS also would enter into an arrangement with a private nonprofit entity for advice and recommendations regarding the development and updating of quality measurement systems. The entity would have to meet specified membership requirements, as well as the following requirements:</p> <ul style="list-style-type: none"> • The entity must not charge a fee for allowing members to participate in the work with HHS; • The entity must permit any member to vote on matters related to the arrangement with HHS and ensure that members have an equal vote on such matters; • The entity must conduct its business in an open and transparent manner; and • The entity must operate as a voluntary consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 2005. <p>The quality measurement systems developed by HHS would include:</p> <ul style="list-style-type: none"> • Measures that are evidence-based, reliable and valid, and feasible to collect and report; • Measures of process, structure, outcomes, beneficiary experience, efficiency, equity, and overuse/underuse of health care items and services; • At least one measure of health information technology (HIT) enabling the provision of high-quality care (such as the use of a qualified health information system) for the first year of implementation, with additional HIT measures included in subsequent years;

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
	<ul style="list-style-type: none"> • Practitioners with experience caring for the frail elderly and individuals with complex chronic conditions; • Entities and individuals representing the specialty involved; • Enrollees; • Experts in quality and efficiency; and • Individuals with experience in the delivery of care in urban, rural, and frontier areas, and to underserved populations. <p>The consensus-building organization would submit recommendations regarding Q & E measures (described in 1 through 7 above) to HHS by July 1, 2006.</p> <p>Based on the consensus-building organization's recommendations, HHS would select the Q & E measures to be used for its value-based purchasing program. HHS could only select measures relating to clinical care that had been submitted by a physician specialty organization and recommended by the consensus-building organization. If there were no, or insufficient, recommendations regarding Q & E measures, HHS could select certain Q & E measures that do not relate to clinical care (selected from 1 through 9 in the list above) by regulation.</p> <p>HHS would use the selected Q & E measures to rate each provider or group that bills for physicians' services under the Medicare fee schedule based on its performance relative to the performance of its peers.</p> <p>The actual rating of each provider or group would only be made available to the relevant group. However, beginning in 2009, HHS would make information publicly available regarding whether the provider or group (1) was new or had insufficient data to provide for a measurement of its performance or (2) met performance objectives. Before disseminating this information, HHS would notify the group of its performance (in general and relative to its peers) and give the provider's or group the opportunity to provide written comments. HHS would be required to respond in writing to these comments. In the event of continued disagreement about the group's performance, HHS would establish a formal appeals process. At the end of this process, HHS would disclose the provider's or group's comments with disclosure of the provider's or group's performance. To be eligible for the higher payment update</p>	<ul style="list-style-type: none"> • For value-based payments to hospitals, at least 5 measures by January 1, 2008, that take into account the unique situation of small hospitals in rural and frontier areas; and • Measures that assess the quality of care furnished to frail individuals over 75 years old with multiple complex chronic conditions. <p>HHS could make adjustments to the measures for each type of provider based on the following variables:</p> <ul style="list-style-type: none"> • Hospitals: by the volume and scope of services provided by the hospital; • Physicians and practitioners—by specialty of physician/type of practitioner or volume of services furnished; • ESRD providers and facilities: by type, volume, and scope of services provided; and • Home health agencies—by volume and scope of services provided. <p>HHS would assign weights to the measures to be used in evaluating overall performance. Measures of clinical effectiveness would be weighted more heavily than measures of beneficiary experience, and measures of risk-adjusted patient health outcomes would be weighted more heavily than measures of process.</p> <p>HHS also would establish risk adjustment procedures to control for differences in performance between health care entities due to the health status and characteristics of the entities' patient population.</p> <p>In implementing each quality measurement system, HHS would consult with entities that had come together to develop strategies for quality measurement and reporting and that involved representatives of providers, plans, consumers, employers, purchasers, quality experts, agencies, and other individuals interested in quality of care.</p> <p>HHS would collect data on a proposed measure for at least 12 months before the measure could be used to determine value-based payments.</p> <p>HHS would use the most recent quality data with respect to the relevant provider. In the case of providers with insufficient data because of a low number of services, HHS could aggregate data across more than one year.</p>

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
	<p>available in years 2007 and 2008, a provider or group would submit information on performance of the selected Q & E measures to HHS according to the form, manner, and time specifications identified by HHS. During these years, reimbursement would be based merely on reporting the required data rather than on performance under the Q and E measures.</p> <p>In 2009 and subsequent years, HHS would establish performance standards for the Q & E measures. To be eligible for the higher conversion factor update provided in 2009 and subsequent years, the provider or group would have to meet these performance objectives, as demonstrated by clear improvement in performance (in accordance with improvement standards established by HHS) or by meeting/exceeding performance thresholds (established by HHS).</p>	<p>Each quality measurement system would be updated by HHS at least annually with emphasis on the addition of more accurate and precise measures, the refinement of assigned weights, and the refinement of risk adjustment procedures.</p> <p>The Act also would change the existing quality data submission requirements for health care entities. In addition, these revised requirements would apply to entities reporting data using the newly developed quality measurement systems.</p> <p>For PPS hospitals and home health agencies, data submission requirements would change as follows:</p> <ul style="list-style-type: none"> • For 2007 and subsequent years, each entity would be required to submit to HHS data deemed appropriate for the measurement of health care quality; • For 2007 and subsequent years, for entities not submitting data as required, the applicable percentage increase in Medicare payment rates would be reduced by 2 percentage points for the fiscal year involved; and • HHS would develop procedures to make such data available to the public in a clear and understandable form and to ensure that the entity has the opportunity to review the data prior to its being made public. <p>For SNFs, the same changes in data quality reporting discussed above would apply except that these changes would not be effective until 2009. SNFs also would be required starting October 1, 2006, to report to HHS on the functional capacity of each resident at the time of admission and at the time of discharge (reporting would be due within 10 days).</p> <p>The quality data submission requirements also would be subject to the following special adjustments based on the provider type:</p> <ul style="list-style-type: none"> • For physicians and practitioners, HHS would establish exceptions to the data submission requirements that take into account the size and specialty representation of the practice. • For MA Plans, the two-percentage-point payment reduction for entities not submitting data would not apply. Additionally, HHS would only be permitted to change the types of data required for submission after submitting a report to

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
		<p>Congress on the reasons for such changes. These requirements would apply to MA plans, Medicare fee-for-service plans, and entities with reasonable cost-reimbursement contracts.</p> <ul style="list-style-type: none"> For ESRD providers and facilities, HHS would, by July 31, 2006, establish procedures providing for the voluntary submission of quality data. However, beginning in 2007, ESRD facilities receiving Medicare payments under the prospective payment system would be required to submit quality data to be eligible for a value-based payment. HHS would establish procedures for making the submitted data available to the public after ensuring the provider or facility had an opportunity to review the data. <p>Using the newly developed quality measurement systems and the data collected through these systems, HHS would establish value-based purchasing programs to provide value-based payments for the provision of high-quality care to Medicare beneficiaries (discussed below).</p>
Federal incentives and penalties	Not applicable.	<p>HHS would establish value-based purchasing programs to provide value-based payments for the provision of high-quality care to the following health care entities participating in the Medicare program:</p> <ul style="list-style-type: none"> Hospitals paid by Medicare under the prospective payment system (PPS); Physicians and practitioners; MA plans; ESRD providers and facilities; and Home health agencies. <p>Among these health care entities, HHS would make a value-based payment to those that have, with regard to the quality of care provided (1) substantially improved over the prior year or (2) exceeded a threshold established by HHS.</p> <p>In determining which entities qualify for value-based payments, HHS would use the quality measurement system developed according to this Act. HHS would determine the amount of a value-based payment. The total payments made in a fiscal year would be equal to the total amount of available funding for such payments for the year.</p> <p>A majority of the amount available for value-based payments would be provided to entities that exceed established thresholds, and the</p>

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
		<p>percentage of payments made to these entities for exceeding the threshold would increase each year.</p> <p>To be eligible for a value-based payment, the health care entity must have complied with the quality-of-care data submission requirements for the applicable year and the entity must have provided an attestation that the data are complete and accurate.</p> <p>In addition, aspects of the value-based program would vary for each of the following five types of health care entities as described:</p> <p>(1) PPS hospitals providing care to Part A-eligible inpatient beneficiaries could receive value-based payments beginning in 2007. Payments to eligible hospitals for performance during the year would be made by the close of the following fiscal year.</p> <p>(2) Physicians and practitioners could receive value-based payments beginning in 2008.</p> <p>In addition to the quality measurement system, HHS would develop a comparative utilization system for determining which physicians and practitioners qualify for a value-based payment. Under the comparative utilization system, HHS would select measures of efficiency based on claims data regarding services furnished or ordered.</p> <p>Beginning in 2006, HHS would provide physicians and practitioners with annual reports regarding their performance on measures of efficiency. These reports would remain confidential (and unavailable to the public) in 2006 and 2007.</p> <p>Payments to eligible physicians for the preceding year's performance would be made no later than December 31 of the subsequent year.</p> <p>(3) MA plans would be eligible for value-based payments beginning in 2009.</p> <p>MA plans could only use value-based payments to (a) invest in quality improvement programs and (b) enhance beneficiaries' benefits. The MA plan would be required to submit a description (for a plan year beginning on or after January 1, 2011) of how any payments received would be used.</p>

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
Administration and oversight of the health system improvements	HHS would provide for the periodic revision and selection of Q & E measures.	<p>To be eligible for value-based payments, the MA plan would have to collect, analyze, and report the required data for the two-year period preceding the year for which a payment is made. In addition, the MA plan would have to provide HHS with an attestation that the value-based purchasing program had no effect on the integrity and actuarial soundness of the bid submitted for the plan for the relevant year.</p> <p>Payments to eligible MA plans would be made no later than March 1 of each year for the preceding year's performance.</p> <p>(4) ESRD providers and facilities providing care to beneficiaries under Medicare Part B would be eligible for value-based payments beginning in 2007.</p> <p>However, pediatric renal dialysis facilities and providers or facilities currently participating in the bundled case-mix adjusted payment system for the ESRD demonstration project would not be included in the program. HHS would implement a separate value-based purchasing program, beginning January 1, 2007, for these facilities and providers participating in the ESRD demonstration project.</p> <p>For 2007, the entire amount available for value-based payments would be used to make payments to providers or facilities exceeding an established threshold.</p> <p>Payments to eligible ESRD providers and facilities for performance during the year would be made by the end of the calendar year (December 31st of each year).</p> <p>(5) Home health agencies providing care to beneficiaries under Medicare Part A or enrolled under Part B would be eligible for value-based payment beginning in 2008.</p> <p>Payments to eligible home health agencies would be made by December 31 for the preceding year's performance.</p> <p>HHS would develop the quality measurement systems and establish and administer the value-based purchasing program, including determining which entities would receive increased payments and the amounts of these payments for eligible health care entities.</p>

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
Technical assistance, grants and demonstration programs	Not discussed.	<p data-bbox="943 258 1455 342">HHS would establish six demonstration projects related to value-based purchasing programs and improvements in quality of care.</p> <p data-bbox="943 380 1455 709">One demonstration project would focus on physicians and practitioners. Within six months of the Act's implementation, HHS would collaborate with the National Coordinator for HIT to establish a three-year demonstration project to determine the amount of technology connectivity necessary to improve the ability of physicians and practitioners in rural and frontier areas to collect, report, and maintain data on quality of care and to use such data as a resource for improving quality and efficiency of care.</p> <p data-bbox="943 747 1455 863">HHS would report to Congress on the physicians and practitioners demonstration project within six months of the project being completed. The report would include:</p> <ul data-bbox="943 900 1455 1146" style="list-style-type: none"> <li data-bbox="943 900 1455 957">• The information accessed, transferred, and exchanged; <li data-bbox="943 961 1455 1018">• The characteristics of models successful at improving information flow; <li data-bbox="943 1022 1455 1079">• The barriers to widespread adoption of such models; and <li data-bbox="943 1083 1455 1140">• Any recommendations for legislation, as appropriate. <p data-bbox="943 1178 1455 1423">A second demonstration project would focus on critical-access hospitals (i.e., rural community hospitals receiving cost-based reimbursement). Within six months of the Act's implementation, HHS would establish a two-year value-based purchasing demonstration program to test innovative methods of measuring and rewarding quality care for these hospitals.</p> <p data-bbox="943 1461 1455 1661">HHS would report to Congress on the critical-access hospital demonstration project within six months of the project's completion. This report would include recommendations regarding the establishment of a permanent value-based purchasing program for critical-access hospitals and for other actions as deemed appropriate.</p> <p data-bbox="943 1698 1455 1814">A third demonstration project would focus on chronic kidney disease. By January 1, 2007, HHS would establish chronic kidney disease demonstration projects to:</p> <ul data-bbox="943 1852 1455 1934" style="list-style-type: none"> <li data-bbox="943 1852 1455 1934">• Increase public awareness about the causation, prevention, and treatment of kidney disease;

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
		<ul style="list-style-type: none"> • Enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease; and • Evaluate approaches for providing outreach and education to groups with a high incidence of such disease. <p>The chronic kidney disease projects would be conducted over a three-year period and would include at least three states (selected by HHS) as project sites. Within six months of the project's completion, HHS would report to Congress on the project and provide recommendations for action.</p> <p>A fourth demonstration project would focus on the exchange of clinical and outcomes data. Within six months of the Act's implementation, HHS would consult with the National Coordinator for HIT to establish a three-year information exchange pilot project to facilitate the exchange of clinical claims and outcomes data regarding Medicare and Medicaid beneficiaries, as well as clinical research findings and practice guidelines. After conducting the information exchange pilot project for at least two years, HHS could expand the project and implement it on a national basis.</p> <p>The information exchange pilot project would be conducted in four regions to include at least three distinct health care markets and specified participants that would be required to:</p> <ul style="list-style-type: none"> • Comply with interoperability standards and certification requirements; • Use existing resources, such as the Internet, in carrying out the project; and • Incorporate data systems and software from more than one competing vendor. <p>HHS would report to Congress on the information exchange pilot project within six months of the project's completion. The report would include:</p> <ul style="list-style-type: none"> • An analysis of the methodologies for building a National Health Information Infrastructure and the impact of the project on beneficiaries, providers, and the Medicare Trust Funds; • Findings regarding access to care, quality of care, efficiency of resource use, volume and utilization rates, and the projected impact on the Medicare Trust Funds if the pilot were expanded; • A description of issues related to expansion of the program; and

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
		<ul style="list-style-type: none"> • Recommendations for legislation and administrative actions. <p>A fifth demonstration project would focus on health care value. Within six months of the Act's implementation, HHS would establish a one-year demonstration project to document, track, and quantify the value created by delivering high-quality care to Medicare beneficiaries.</p> <p>The project would be conducted at six sites, including two community-based settings and two rural or frontier health care facilities.</p> <p>For the health care value project, HHS would assign to each site a team comprised of process engineers, health care providers, and cost accountants charged with performing observations on health care delivery, process analysis and improvement, and financial analysis. HHS would make Medicare claims data available to the teams to provide for a more complete analysis of the total costs and value of care.</p> <p>HHS could make incentive payments at a site to encourage health care entities and persons to participate in the health care value project where HHS determines the project will result in reduced expenditures under the Medicare Trust Funds.</p> <p>Within 18 months of the Act's implementation, HHS would submit a report on the health care value project to Congress, which would include a description of the findings from each of the six project sites as well as recommendations for action.</p> <p>A sixth demonstration project would focus on the aggregation data. Within six months of the Act's implementation, HHS would be required to establish a two-year demonstration project to evaluate the process, costs, and benefits of aggregating data on quality of care across all payers of health care costs. In selecting data to be aggregated, HHS would prioritize measures with the most potential to inform health care decisions, improve quality and efficiency of care, and achieve functionality in a timely manner.</p> <p>The data aggregation project would be conducted in three health care delivery markets or geographic areas, with participants to include health information networks, plans, self-insured employers, state health programs, and other entities. Participants would be required to comply with interoperability and certification standards.</p>

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
Financing	Not discussed.	<p data-bbox="943 260 1403 373">HHS would report to Congress on the data aggregation project within one year of the project's completion. The report would include:</p> <ul data-bbox="943 415 1451 592" style="list-style-type: none"> <li data-bbox="943 415 1451 562">• An analysis of the methodologies for data aggregation, privacy and security issues, the cost-effectiveness of alternative methods for data aggregation, and the effects of aggregation on the information; and <li data-bbox="943 569 1305 592">• Recommendations for action. <p data-bbox="943 600 1464 806">To carry out the provisions regarding the creation of quality measurement systems, \$3 million would be appropriated for both 2006 and 2007. For 2008 and each subsequent year, that amount would be increased by the growth in the Consumer Price Index (CPI) for all urban consumers since 2006.</p> <p data-bbox="943 842 1425 989">Payments for the value-based purchasing program would be budget-neutral. The funds used to make value-based payments to health care entities would come from reductions in Medicare payment rates as follows:</p> <ul data-bbox="943 1024 1464 1915" style="list-style-type: none"> <li data-bbox="943 1024 1451 1268">• For PPS hospitals, HHS would reduce Medicare payments by (1) reducing the average standardized amounts paid for outlier (e.g., high cost/long stay) patients and (2) instituting a graduated, overall reduction in PPS payments up to a maximum of 2.0 percentage points in 2011 and each subsequent year; <li data-bbox="943 1274 1451 1421">• For physicians and practitioners, Medicare payments to physicians would be reduced on a graduated basis up to a maximum of 2 percentage points in 2012, and each subsequent year; <li data-bbox="943 1428 1451 1541">• For MA plans, Medicare payments would be reduced on a graduated basis beginning in 2009 up to a maximum of 2 percentage points in 2013 and each subsequent year; <li data-bbox="943 1547 1451 1728">• For ESRD providers and facilities, payments for items or services furnished on or after January 1, 2007, would be reduced on a graduated basis up to a maximum of 2 percentage points in 2011 and each subsequent year; <li data-bbox="943 1734 1451 1915">• For home health agencies, Medicare payments under the PPS would be reduced annually beginning in 2008 and on a graduated basis up to a maximum of 2 percentage points in 2012 and each subsequent year;

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
Key implementation dates	<p>Physicians would begin reporting Q & E measures and begin receiving increased payment updates related to the reporting of these parameters in 2007.</p> <p>Other implementation dates are discussed elsewhere in this chart.</p>	<p>Funding as necessary would be authorized to be appropriated for HHS to carry out each of the six demonstration programs. In addition, funds as necessary would be transferred from the Federal Hospital Insurance Trust Fund to pay for value-based purchasing program established as part of the critical care hospital demonstration program.</p> <p>The value-based payments would be made to eligible entities according to the following schedule:</p> <ul style="list-style-type: none"> • PPS hospitals, 2007; • Physicians and practitioners, 2008; • MA plans, 2009; • ESRD providers and facilities, 2007; and • Home health agencies, 2008. <p>Other implementation dates would vary and are discussed elsewhere in this chart.</p>
Evaluation of health system improvements	<p>By May 1, 2008, HHS would report to Congress on the extent to which the submission of performance information by providers or groups in 2007 and/or 2008 results in increased administrative work and expenses for the provider or group.</p> <p>HHS would evaluate the value-based purchasing program during its initial five years of operation, focusing on the impacts of the program in improving quality and efficiency of services, access to such services, and the fairness of the program's implementation. HHS would report on this evaluation to Congress by September 30, 2011.</p> <p>Annually, HHS would report to the Medicare Payment Advisory Committee (MedPAC) and Congress (by April 1 of each year) information on the growth in volume of services per enrollee and growth in expenditures per enrollee. The information reported would: (1) be disaggregated by service type, area, and specialty; (2) distinguish between growth in expenditures due to price change and growth due to volume and intensity changes; and (3) identify types of services or areas where changes in volume or expenditures are inappropriate or unjustified.</p> <p>The reports also would include recommendations (regulatory and/or legislative) to respond to inappropriate growth in service volume.</p> <p>MedPAC would review each report and accompanying recommendations and include an analysis of these reports as part of MedPAC's annual report to Congress each June.</p>	<p>MedPAC would conduct an initial study of how the Medicare value-based purchasing programs created by the Act will impact beneficiaries, providers, and the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. MedPAC would submit to Congress and HHS a report on the study, with specified contents, by March 1, 2008.</p> <p>Following this initial study, no later than March 1, 2011, and June 1, 2012, MedPAC would submit an interim and final report on the 2008 study. These studies would update the findings of the 2008 study, analyze the impact of payment changes on providers, and provide recommendations.</p> <p>MedPAC also would conduct a study of the implementation of the ESRD provider and facility value-based purchasing program. The report would include a description of issues for HHS to consider in operating the program and recommendations for action. In preparing the report, MedPAC would take into account the results of the bundled case-mix adjusted payment system for ESRD services demonstration. This study would be due to Congress and HHS by June 1, 2008.</p> <p>The Government Accountability Office (GAO) would conduct a study of the implementation of data submitted under the value-based payment program. This report would look at the accuracy and completeness of data submitted by the affected health care entities and the appropriateness of value-based payments to such</p>

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
		<p>entities based on those data submissions: Within two years of the implementation of the value-based purchasing programs for the entities described above, the GAO would report to Congress and HHS on the data used for the purchasing programs, together with recommendations for action.</p> <p>MedPAC would conduct four studies into the advisability and feasibility of establishing value-based purchasing programs for selected health care entities. These reports and any recommendations for action would be due for the following entities on the accompanying dates:</p> <ul style="list-style-type: none"> • The study on critical-access hospitals would be due to Congress and HHS on March 1, 2007; • The study on Medicare Part D plans would be due to Congress on March 1, 2007; • The study on pediatric renal dialysis facilities would be due to Congress and HHS by June 1, 2007; and • The study on SNFs would be due to Congress and HHS on March 1, 2009. <p>HHS would conduct two studies:</p> <ul style="list-style-type: none"> • A study to determine the appropriate measures to be used to evaluate the quality of care provided by SNFs to Part A-eligible individuals, with results and recommendations due to Congress by July 1, 2008; and • A study examining: (1) the variation among state laws regarding licensure of physicians and practitioners; (2) how such variation impacts the electronic exchange of health information; (3) how such variation impacts the quality and safety of care of, and the cost incurred by, individuals in underserved areas; and (4) the potential for interstate coordination between state licensure boards in regulating the practices of physicians and practitioners. For this study, which HHS could conduct or contract with a private entity to conduct, any recommendations would be due to Congress within one year of the Act's implementation.

Bill name	Medicare Value-Based Purchasing for Physicians' Services Act of 2005	Medicare Value Purchasing Act of 2005
Other key elements of the bill	<p>The Sustainable Growth Rate (SGR) formula currently used to annually update physician payments would be replaced by a new payment system. The conversion factor used for determining Medicare payment updates for physician services would change in the following ways:</p> <ul style="list-style-type: none"> • For 2006, the update to the conversion factor would be 1.5 percent; • For 2007 and 2008, the update to the conversion factor would be the percentage increase in the Medicare Economic Index (MEI) for the year involved minus 1 percentage point. For services furnished by a provider or group that is new or that complies with the information submission requirements for 2007 or 2008, the update would be the full MEI percentage increase; • For 2009 and succeeding years, the update to the conversion factor would be the percentage increase in the MEI for the year involved minus 1 percentage point. For services furnished by a provider or group that is new or that complies with the information submission requirements and meets applicable performance objectives, the update would be the MEI full percentage increase. <p>During 2006, HHS would establish a program to educate providers/groups and enrollees about the value-based purchasing program, including information about the associated financial incentives.</p> <p>The Act would end the application of the Sustainable Growth Rate, effective November 1, 2005.</p>	<p>For each entity eligible to receive value-based payments, HHS would provide a description of how the entity's payments would have been affected for items and services furnished in the year prior to the Act's implementation had the value-based purchasing program been in effect for that year.</p> <p>Creates a new exception to the federal anti-kickback and physician self-referral laws for the provision of permitted support. Permitted support would be defined as the provision of any equipment, item, information, right, license, intellectual property, software, training, or service used for developing, implementing, operating, or facilitating the use of systems designed to improve the quality of health care and to promote the electronic exchange of information. Permitted support would not include the following:</p> <ul style="list-style-type: none"> • Support related to the volume or value of referrals generated between parties for which payment may be made under a federal health care program; • Support having more than incidental value to the recipient; or • Any HIT system or service not capable of exchanging information in compliance with interoperability standards. <p>HHS also would issue an interim final rule with a comment period within 180 days of the Act's implementation and a final rule within 180 days of the issuance of the interim final rule to carry out these amendments to the anti-kickback and self-referral laws.</p> <p>In establishing regulations regarding interoperability, HHS would consider whether the HIT system or service is widely accepted within the industry to ensure successful implementation and whether the system or service improves quality of care, enhances patient safety, or provides administrative efficiencies.</p>

Table A-4. Side-by-Side Analysis of the
VA Hospital Quality Report Card Act of 2006
and the Hospital Quality Report Card Act of 2006

Bill name	VA Hospital Quality Report Card Act of 2006	Hospital Quality Report Card Act of 2006
Bill number(s)	S. 2358	S. 2359
Bill sponsor(s)	S. 2358 is sponsored by Senator Obama and has no cosponsors.	S. 2359 is sponsored by Senator Obama and has no cosponsors.
Latest Congressional action	S. 2358 was referred to the Senate Committee on Veterans' Affairs on March 2, 2006.	S. 2359 was referred to the Senate Finance Committee on March 2, 2006.
Basic structure of health system improvement	The secretary of the Department of Veterans Affairs (VA) would collect data on health care quality factors from VA hospitals. The VA would provide reports to Congress and to the public on VA hospital quality on a semiannual basis.	The secretary of the Department of Health and Human Services (HHS), in consultation with the director of the Agency for Healthcare Research and Quality (AHRQ), would collect data on health care quality from hospitals participating in the Medicare program. HHS would provide reports to Congress and to the public on hospital quality on a semiannual basis. A Hospital Quality Advisory Commission also would be established to advise HHS on the submission, collection, and reporting of quality measures data.
Health system improvement requirements	At least twice a year, the VA would publish reports on VA hospital quality for six aspects of patient care: <ul style="list-style-type: none"> • Effectiveness; • Safety; • Timeliness; • Efficiency; • Patient-centeredness; and • Equity. <p>In addition, the semiannual reports would contain hospital-specific information for nine aspects of patient care:</p> <ul style="list-style-type: none"> • Staffing levels for nurses and other health professionals; • Rates of nosocomial infections (i.e., infections that originate or occur in a hospital setting); • Volume of procedures performed; • Hospital sanctions or other violations; • Quality of care for different subpopulations, including women, the elderly, the disabled, those living in rural areas, the mentally ill, and racial and ethnic minorities; • Availability of emergency rooms, intensive care units, maternity care, and specialty services; • Quality of care in various hospital settings; • Ongoing patient safety initiatives; and • Other measures determined by the VA. 	At least twice a year, HHS would publish reports on hospital quality for six aspects of patient care: <ul style="list-style-type: none"> • Effectiveness; • Safety; • Timeliness; • Efficiency; • Patient-centeredness; and • Equity. <p>In addition, the semiannual reports would contain hospital-specific information for 11 aspects of patient care:</p> <ul style="list-style-type: none"> • Staffing levels for nurses and other health professionals; • Rates of nosocomial infections (i.e., infections that originate or occur in a hospital setting); • Volume of procedures performed; • Hospital accreditation, and sanctions or violations found by accreditation or state licensing boards; • Quality of care for different subpopulations, including women, the elderly, the disabled, those living in rural areas, the mentally ill, and racial and ethnic minorities; • Availability of emergency rooms, intensive care units, maternity care, and specialty services; • Quality of care in various hospital settings;

Bill name	VA Hospital Quality Report Card Act of 2006	Hospital Quality Report Card Act of 2006
	<p>The VA would provide reports to the public in an understandable and electronic format that would permit quality comparisons among hospitals. Non-electronic copies of the report would be made available to the public upon request.</p> <p>In its reports, the VA would be permitted to risk-adjust quality measures to account for differences relating to the characteristics of the reporting hospital (e.g., size, geography, and status as a teaching hospital) and the characteristics of the patient population (e.g., health status, illness severity, and socioeconomic status). The VA would be required to make non-adjusted data available to the public as well.</p>	<ul style="list-style-type: none"> • Ongoing patient safety initiatives; • Use of health information technology, telemedicine, and electronic medical records; • The availability of on-site interpreter services; and • Other measures determined by HHS. <p>HHS would provide reports to the public in an understandable and electronic format that would permit quality comparisons to be made among hospitals. Non-electronic copies of the reports would be made available to the public upon request.</p> <p>In its reports, HHS would be permitted to risk-adjust quality measures to account for differences relating to the characteristics of the reporting hospital (i.e., size, geography, and status as a teaching hospital) and the characteristics of the patient population (i.e., health status, illness severity, and socioeconomic status). HHS would be required to make nonadjusted data available to the public as well.</p> <p>HHS also would be required to issue reports comparing among hospitals the average cost of treatment for each medical condition for which quality data are collected.</p>
Federal incentives and penalties	None provided.	None provided.
Administration and oversight of the health system improvements	<p>The VA would verify the data reported by VA hospitals to ensure its accuracy and would be required to disclose the methodology for reporting of data.</p> <p>The VA would compare quality measure data among VA hospitals at least once a year to identify any hospital practices or activities that could artificially inflate a hospital's quality measurements.</p> <p>The VA also would establish safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate, or subjective VA hospital data.</p>	<p>HHS would verify the data reported by hospitals to ensure their accuracy and would be required to disclose the methodology for reporting the data.</p> <p>HHS would compare quality measure data among hospitals at least once a year to identify any hospital practices or activities that could artificially inflate a hospital's quality measurements (e.g., practices that discourage patients with severe illness from seeking care from the hospital or activities that result in the provision of health care services that do not meet accepted standards of care).</p> <p>HHS also would establish safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate, or subjective hospital data.</p> <p>A Hospital Quality Advisory Committee with specified membership would be created to advise the Centers for Medicare and Medicaid Services (CMS) for no more than five years on the reporting of quality measures data by Medicare-participating hospitals.</p>

Bill name	VA Hospital Quality Report Card Act of 2006	Hospital Quality Report Card Act of 2006
Privacy and confidentiality protections	The VA would be required to ensure that no patient-identifiable data are made public.	HHS would be required to ensure that no patient-identifiable data are made public.
Technical assistance, grants, and demonstration programs	None provided.	HHS would award grants to national or state organizations to assist with hospital quality improvement.
Financing	None provided.	The bill would authorize appropriations of the funds necessary for fiscal years 2007 through 2016 to carry out the bill's provisions.
Key implementation dates	The new initiative would begin no later than 18 months after the date of enactment.	The new initiative would begin no later than 18 months after the date of enactment.
Evaluation of health system improvements	The VA would be required to periodically submit reports to Congress regarding the effectiveness of this initiative.	AHRQ would be required to periodically evaluate the hospital-reported information and submit reports to Congress regarding the effectiveness of the initiative.
Other key elements of the bill	Not applicable.	HHS would be required to provide at least a 60-day window for public comment and review of the quality measures to be reported by hospitals.

Table A-5. Side-by-Side Analysis of the
Medicare Payment Rate Disclosure Act of 2006
and the Hospital Price Reporting and Disclosure Act of 2005

Bill name	Medicare Payment Rate Disclosure Act of 2006	Hospital Price Reporting and Disclosure Act of 2005
Bill number(s)	S. 2606	S. 1827
Bill sponsor(s)	S. 2606 is sponsored by Senator Brownback and has two cosponsors.	S. 1827 is sponsored by Senator DeMint and has two cosponsors.
Latest Congressional action	S. 2606 was referred to the Senate Finance Committee on April 7, 2006.	S. 1827 was referred to the Senate Committee on Health, Education, Labor, and Pensions on October 6, 2005.
Basic structure of health system improvement	Medicare payment rate information would be made publicly available for frequently used hospital inpatient, hospital outpatient, and physician services.	Information would be made publicly available on the amount hospitals charge for frequently used hospital services and hospital-administered drugs.
Health system improvement requirements	<p>The secretary of Health and Human Services (HHS) would post on the department Web site Medicare payment rates for certain hospital inpatient, hospital outpatient, and physician services.</p> <p>Medicare payment rates would be posted in two phases:</p> <ul style="list-style-type: none"> • In the first phase, which would last 120 days, HHS would post payment rates for at least 30 of the most frequently provided services in each of the health care settings (i.e., hospital inpatient services and drugs, hospital outpatient services, and physician services); • In the second phase, which would begin after the 120-day initial phase and would continue indefinitely, HHS would post payment rates for at least 100 of the most frequently provided services in each of the specified health care settings. <p>HHS would periodically update the list of reported services and drugs to ensure its accuracy.</p> <p>In addition to the 100 most frequently provided services, HHS would post payment rate information for procedures or services deemed useful for other individuals not enrolled in the Medicare program.</p>	<p>The secretary of Health and Human Services (HHS) would post on the department Web site hospital-reported data on the amounts charged for certain hospital inpatient services, hospital outpatient services, and hospital-administered drugs. The data would be organized in a manner permitting comparisons among hospitals.</p> <p>Hospitals would be required to report to HHS on a semiannual basis information on:</p> <ul style="list-style-type: none"> • The 25 most frequently performed hospital inpatient services; • The 50 most frequently administered drugs in the hospital inpatient setting; and • The 25 most frequently performed hospital outpatient services. <p>HHS would determine the most frequently provided services and drugs in each of these three reporting categories based on national data and would periodically update the items to be included in each reporting category.</p> <p>For each service and drug included in the reporting categories, hospitals would be required to provide data on the:</p> <ul style="list-style-type: none"> • Frequency of the service; • Frequency of the hospital's administering of the drug in the inpatient setting; and • Average and median amount charged for the service and drug.
Federal incentives and penalties	None provided.	HHS would be authorized to impose civil monetary penalties on hospitals that fail to report the required information of up to \$10,000 per each knowing violation.

Bill name	Medicare Payment Rate Disclosure Act of 2006	Hospital Price Reporting and Disclosure Act of 2005
Administration and oversight of the health system improvements	None provided.	Identification and classification of services and drugs into the three reporting categories and the methodology for computing average and median charges would be established by HHS through formal rulemaking.
Privacy and confidentiality protections	None provided.	None provided.
Technical assistance, grants and demonstration programs	None provided.	None provided.
Financing	None provided.	None provided.
Key implementation dates	The initiative would begin no later than 120 days after date of enactment.	The initiative would begin at least one year after the date of enactment.
Evaluation of health system improvements	None provided.	None provided.
Other key elements of the bill	Not applicable.	Hospitals would be required to provide reports to HHS no later than 80 days after the end of each semiannual period. Semiannual periods would begin January 1st and July 1st of each year.

Table A-6. Side-by-Side Analysis of the
Wired for Health Care Quality Act and the
Health Information Technology Promotion Act of 2006

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
Bill number(s)	S. 1418	H.R. 4157
Bill sponsor(s)	S. 1418 is sponsored by Senator Enzi and has 38 cosponsors.	H.R. 4157 is sponsored by Senator Nancy Johnson and has 58 cosponsors.
Latest Congressional action	S. 1418 passed the Senate by voice vote and was referred to the House Committee on Energy and Commerce, Subcommittee on Health, on November 18, 2005.	H.R. 4157 passed the House, as amended, on July 27, 2006, and was placed on the Senate Legislative Calendar on September 5, 2006.
Principal elements of proposed change	<p>Promotes the adoption of a nationwide health information technology (HIT) infrastructure by establishing:</p> <ul style="list-style-type: none"> • An Office of the National Coordinator of Health Information Technology (Office); and • A public-private American Health Information Collaborative to provide recommendations to the Office for the development of the HIT infrastructure and standards for the electronic exchange of health information. <p>Requires the secretary of Health and Human Services (HHS) to develop quality measures.</p> <p>Establishes a Health Information Technology Resource Center and a series of grants to assist in the adoption and use of HIT. Grants would be available for:</p> <ul style="list-style-type: none"> • Not-for-profit hospitals and other providers to purchase and use HIT systems; • States to provide loans to providers for the purchase and use of HIT; and • Entities to implement regional or local networks to improve patient care through the electronic exchange of information. <p>Provides for demonstration project grants to academic institutions to develop educational curricula for health professionals that include the use of HIT systems.</p>	<p>Promotes the adoption of a nationwide health information technology (HIT) infrastructure by establishing:</p> <ul style="list-style-type: none"> • An Office of the National Coordinator for Health Information Technology (Office); and • A process for expediting updates to standards for electronic transactions. Also replaces certain standards for the electronic exchange of information and replaces the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) with the 10th revision. <p>Creates safe harbors in the existing anti-kickback law and physician referral prohibitions related to certain HIT and training services.</p> <p>Requires the secretary of Health and Human Services (HHS) to study and report on a variety of issues related to HIT adoption, health information exchanges, the digitizing of electronic health records, health care classification methodologies and codes, and telehealth services.</p> <p>Provides for a series of grants for integrated health systems and small physician practices to use HIT to improve care for medically underserved populations.</p>

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
Nationwide HIT infrastructure	<p data-bbox="391 260 911 527">Establishes within HHS an Office of the National Coordinator of Health Information Technology (Office). The Office would be headed by a National Coordinator of Health Information Technology (National Coordinator).¹ The Office would coordinate with federal agencies and private entities to develop a nationwide interoperable HIT infrastructure to:</p> <ul data-bbox="391 562 911 1192" style="list-style-type: none"> • Ensure the protection of patients' private health information; • Improve quality of care, reduce medical errors, and promote patient-centered care; • Reduce health care costs due to inefficiency, errors, inappropriate care, and incomplete information; • Ensure that medical decision-making information is available at the time of care; • Improve coordination of care among various providers; • Promote a more effective marketplace, greater competition, and increased choice by making available health care cost, quality, and outcome information; • Improve public health reporting and facilitate the early identification of public health threats and emergencies; • Facilitate health research; and • Promote prevention of chronic diseases. <p data-bbox="391 1220 911 1310">The National Coordinator could request personnel from other agencies to assist in carrying out these duties.</p> <p data-bbox="391 1339 911 1402">The National Coordinator overseeing the Office would fulfill the following duties:</p> <ul data-bbox="391 1436 911 1740" style="list-style-type: none"> • Serve as the key adviser to HHS for the development, application, and use of HIT; • Coordinate and oversee HHS' HIT programs; • Facilitate the adoption of a nationwide, interoperable system for the electronic exchange of health information; • Ensure the adoption and implementation of standards for the exchange of information to reduce costs and improve quality; 	<p data-bbox="932 260 1463 527">Establishes within HHS an Office of the National Coordinator for Health Information Technology (Office). The Office would be headed by a National Coordinator of Health Information Technology (National Coordinator).² Under the direction of the National Coordinator, the Office would work to develop a nationwide interoperable HIT infrastructure to:</p> <ul data-bbox="932 562 1463 1499" style="list-style-type: none"> • Provide for the protection of individually identifiable health information; • Improve health care quality, reduce medical errors, and increase the efficiency of care; • Reduce health care costs resulting from inefficiency, medical errors, inappropriate care, and incomplete information; • Promote the availability of medical decision-making information at the time of care and advance the delivery of appropriate, evidence-based health care; • Promote data accuracy; • Promote a more effective marketplace, greater competition, increased choice, enhanced quality, and improved outcomes; • Advance the portability of health information through an infrastructure for the secure exchange of health information; • Promote the creation and maintenance of Internet-based personal health records; • Promote a patient's access to his/her own electronic health records and improve the availability of information for persons with low or limited literacy or language skills; • Promote the development, submission, and maintenance of electronic health care clinical trial data; and • Promote wellness, disease prevention, and management of chronic illnesses. <p data-bbox="932 1528 1463 1591">The National Coordinator overseeing the Office would fulfill the following duties:</p> <ul data-bbox="932 1625 1463 1740" style="list-style-type: none"> • Serve as principal adviser to HHS on the development and use of HIT, including coordinating HHS policies for promoting the use of HIT;

¹ Note that the Office of the National Coordinator of Health Information Technology already exists by virtue of Executive Order 13335 (April 27, 2004). S. 1418 would statutorily create the Office of the National Coordinator of Health Information Technology and codify its responsibilities as well as those of the national coordinator.

² Note that the Office of the National Coordinator of Health Information Technology already exists by virtue of Executive Order 13335 (April 27, 2004). H.R. 4157 would statutorily create the Office of the National Coordinator of Health Information Technology and would render Executive Order 13335 null and void.

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
	<ul style="list-style-type: none"> • Ensure that HHS’s HIT policy and programs are coordinated with those of executive branch agencies to avoid duplication of efforts; • Coordinate outreach and consultation by the relevant executive branch agencies with public and private parties (e.g., consumers, payers, employers, hospitals, physicians, community health centers, laboratories, and vendors); • Advise the President on federal HIT programs; and • Prepare annual reports as required by this Act. <p>Also establishes a public–private American Health Information Collaborative (Collaborative) to serve as a forum for a wide range of stakeholders to provide input on HIT interoperability and recommend uniform national policies.</p> <p>The Collaborative would make recommendations on uniform national policies to support the widespread adoption of HIT within a year of the Act’s implementation and annually thereafter. Recommendations could include policies related to:</p> <ul style="list-style-type: none"> • Protecting private health information; • Notifying patients in the event of wrongful disclosure of information; • Facilitating patient access to information; • Fostering public understanding of HIT; • Harmonizing industrywide HIT standards; and • Identifying instances in which HIT is valuable, beneficial, and feasible. <p>HHS would appoint members for two-year terms to the Collaborative. Collaborative members would include representatives from consumer or patient organizations, organizations with expertise in privacy and security, providers, insurance plans, information technology vendors, and employers or other purchasers of health coverage.</p>	<ul style="list-style-type: none"> • Provide a strategic plan for the nationwide implementation of interoperable HIT in the public and private health care sectors; • Ensure that HHS policies relating to HIT are coordinated with those of relevant executive branch departments and agencies to avoid duplication of effort; • Advise the director of the Office of Management and Budget (OMB) regarding federal HIT programs; and • Promote HIT in medically underserved communities by identifying sources of funds and collaborating with the Agency for Healthcare Research and Quality (AHRQ) and the Health Services Resource Administration (HRSA) to support communities seeking to adopt HIT and establish electronic health information networks. <p>The national coordinator would publish by December 31, 2006, a strategic plan for the assessment and endorsement of core, voluntary interoperability guidelines for “significant use cases” (e.g., designation by the National Coordinator to identify a significant use for HIT interoperability, such as drug prescriptions).</p> <p>The strategic plan and all endorsements would be developed in consultation with the American Health Information Community (AHIC) and other entities as appropriate. (AHIC is a federally chartered commission established in 2005 to provide input on how to make electronic health records digital and interoperable.)</p> <p>Following publication of the strategic plan, the National Coordinator would:</p> <ul style="list-style-type: none"> • Endorse a subset of core (e.g., essential and necessary) interoperability guidelines within a year of the plan’s publication; • Endorse additional subsets annually, with endorsement of all guidelines completed by August 31, 2009. <p>Additionally, the President would be directed to take action to ensure that federal collection and submission of health information is consistent with endorsed core interoperability guidelines within three years of the endorsement.</p>

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
Standards for the electronic exchange of health information	<p>The Collaborative also would recommend standards for interoperability by:</p> <ul style="list-style-type: none"> Reviewing existing standards for the electronic exchange of health information; Identifying deficiencies, omissions, duplication, and overlap in existing standards; and Recommending new standards as necessary.³ <p>HHS, the secretary of Veterans Affairs and the secretary of Defense would jointly review the Collaborative’s recommendations (during the first year, the initial recommendations would be reviewed within 90 days). Where appropriate, HHS would adopt the recommendations.</p> <ul style="list-style-type: none"> Within a year of their adoption, federal agencies could not purchase new HIT systems inconsistent with any adopted standards. This prohibition would not apply to the purchase of minor hardware or software; Within three years of their adoption, all federal agencies collecting health data would be required to comply with the adopted standards; and Private entities would not have to comply with adopted standards except for activities provided under contract with the federal government. <p>For private entities voluntarily adopting standards, HHS would develop criteria:</p> <ul style="list-style-type: none"> For the uniform and consistent implementation of the standards; and To certify that hardware and software comply with relevant standards. HHS could use a private entity to assist with the certification and in developing criteria. 	<p>Establishes an expedited administrative process for adding and making modifications to standards for the electronic exchange of information.</p> <p>Under this process, organizations proposing to add or modify existing standards would:</p> <ul style="list-style-type: none"> Submit to HHS a request for publication of a notice in the Federal Register pertaining to the proposed change; Provide a process for: (1) receiving and responding to public comments; (2) making publicly available a written explanation for responses to timely comments; and (3) making public comments received available to HHS; and Submit the proposed change to the National Committee on Vital and Health Statistics for review and consideration. <p>HHS would be required to:</p> <ul style="list-style-type: none"> Within 30 days of receiving a request for publication from an organization proposing a change to existing standards, publish a notice in the Federal Register that: (1) identifies the subject matter; (2) describes the number of persons that may participate in the process; and (3) invites public participation in the process; and Within 30 days of being notified that the proposed change has been drafted or is ready for review, publish another notice in the Federal Register that: (1) identifies the subject matter; (2) specifies the procedure for obtaining the draft; (3) describes the number of persons that may submit comments (in writing and at a hearing); and (4) invites submission of comments. <p>As part of the review process, the National Committee on Vital and Health Statistics (Committee) would provide opportunity for public testimony at a hearing concerning the proposed change. HHS could participate in the hearing.</p> <p>The Committee would submit to HHS its recommendations (to adopt or not) within 120 days of receiving the proposal. HHS would make a final determination within 90 days of receiving the Committee’s recommendation.</p>

³ Under this Act, the standards adopted by the Consolidated Health Informatics Initiative (an eGov initiative of the Office of Management and Budget focused on the adoption of information interoperability standards) would be deemed to be recommended by the Collaborative.

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
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HHS's final determination on the proposed change would be published in the Federal Register within 30 days of the decision. If HHS adopts the proposed change, HHS would promulgate the modified standard in the form of a final rule. If HHS rejects the proposed change, HHS would include in the notice its reasons for the rejection. The Paperwork Reduction Act would not apply to a final rule promulgated in this way, nor would the final rule be subject to judicial review. The Administrative Procedures Act's notice and comment requirements would be treated as having been satisfied by this process as well.

In addition, HHS would consult with relevant public and private entities within 180 days of the Act's implementation regarding the development of a strategic plan for coordinating the replacement of: (1) certain transaction standards required by the SSA, including modifications to such standards; and (2) the current version of the ICD.

The replacement of transaction standards required by the SSA would not be subject to judicial review. HHS would publish notices in the Federal Register for the following replacements, which would apply to transactions on or after April 1, 2009:

- The Accredited Standards Committee X12 (i.e., a committee created in the 1970s to develop uniform standards for inter-industry electronic interchange of business transactions)—version 4010 would be replaced with version 5010, as reviewed by the Committee; and
- The National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard (i.e., a standard developed for the processing of retail pharmacy transactions by all health plans)—version 5.1 would be replaced with the latest version approved by the NCPDP and reviewed by the Committee as of April 1, 2007.

For the ICD replacement, HHS would publish a notice in the Federal Register of the change from the ICD-9-CM to the ICD-10-CM and the ICD, 10th revision, Procedure Coding System (ICD-10-PCS).

The replacement would apply to services furnished on or after October 1, 2010, and

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
Other health system changes	<p>HHS would develop risk-adjusted quality measures of patient care. Measures would:</p> <ul style="list-style-type: none"> • Be evidence-based, reliable, and valid; • Be consistent with the development of a nationwide interoperable HIT infrastructure; • Include measures of clinical processes and outcomes, patient experience, efficiency, and equity; and • Include measures of underuse and overuse of care. <p>In developing the measures, priority would be given to measures that may: (1) have the greatest potential to improve quality and efficiency of care; (2) be rapidly implemented; and (3) inform consumer and patient health care decisions.</p> <p>In developing and updating quality measures, HHS would ensure that the measures complement those developed under programs administered by the Social Security Act (SSA) (e.g., Medicaid, Medicare, and SCHIP) and do not conflict with the needs and priorities of these programs. HHS also could consider:</p> <ul style="list-style-type: none"> • HHS quality- or efficiency-of-care demonstrations, pilot programs, or other activities; • Quality or efficiency activities by private entities (e.g., health insurance plans); • The Institute of Medicine’s (IOM’s) report evaluating health care measures; and • Issues of data collection and reporting. <p>Quality measures would be updated no more than once a year. In developing, updating, and implementing the measures, HHS would consult with the following entities and individuals:</p> <ul style="list-style-type: none"> • Health insurance plans and providers, including those with experience in the care of the frail elderly and individuals with multiple complex chronic conditions; • Patient and consumer groups; • Employers and health care purchasers; • Quality improvement organizations; • Provider certification and licensing organizations; 	<p>regulations implementing the new ICD-10 would not require providers to code to a level of specificity information for non-medical causes of a given injury.</p> <p>Creates safe harbors in the existing anti-kickback law and an exception to physician referral prohibitions related to certain HIT and training services. The safe harbors would be effective 120 days after the Act’s implementation. As part of the safe harbors, the creation of a consortium composed of providers, payers, employers and other interested entities to collectively purchase and donate HIT—or to offer a choice of HIT products to providers— would not be prohibited.</p> <p>For anti-kickback civil penalties, a safe harbor from the prohibition on payments to physicians to induce reduction or limitation of services would be provided for practical or other advantages resulting from HIT (e.g., hardware, software, license, right, intellectual property, or equipment provided primarily for the electronic creation, maintenance, or exchange of health information) or related installation, maintenance, support, or training services.</p> <p>For anti-kickback criminal penalties, a safe harbor would be provided for nonmonetary remuneration in the form of HIT or related installation, maintenance, support, or training services made to a person by a specified entity (e.g., a hospital, group practice, prescription drug plan sponsor, or Medicare Advantage organization) if the following conditions are satisfied:</p> <ul style="list-style-type: none"> • The remuneration does not include an agreement or legal condition that: (1) limits or restricts the use of HIT to services provided by the physician to individuals receiving services at the specified entity; (2) limits or restricts the use of HIT in conjunction with other HIT; or (3) conditions the provision of remuneration on the referral of patients or business; • The remuneration is arranged for in a written agreement, signed by all involved parties, indicating that the purpose of such remuneration is better coordination of care or improvement of health quality, efficiency, or research; and • The entity providing the remuneration has not disabled any feature of the technology that would permit interoperability.

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
	<ul style="list-style-type: none"> • State public health programs; • Biomedical, health services, and health economics research experts; • Entities involved in developing standards for HIT systems and clinical data; and • Entities with experience in urban, safety net, and rural health care issues. <p>HHS would establish procedures for the electronic submission of quality measurement data and for reporting measures used to make value-based payments under the SSA. HHS also could establish collaborative agreements with private entities to encourage the use of these measures and foster uniformity among the measures used.</p> <p>Where practicable, HHS would use quality measures for activities and programs conducted under the Act. HHS would provide for the dissemination, aggregation, and analysis of quality measures collected from the three competitive grant programs (see below) as well as recommendations and best practices beginning on January 1, 2008.</p>	<p>For prohibitions on physician referrals, the Stark Law (limiting physician referrals) would be amended to provide for an exception with respect to the provision of any nonmonetary remuneration (in the form of HIT or related installation, maintenance, support, or training services) made by a specified entity to a physician so long as the remuneration complies with those requirements applicable to the safe harbor for criminal penalties under the anti-kickback statute (described above).</p>
<p>Technical assistance, grants, and demonstration programs</p>	<p>In conjunction with the director of the Agency for Healthcare Research and Quality (AHRQ), HHS would establish a Health Information Technology Resource Center (Center) to provide technical assistance and develop best practices regarding the adoption, implementation, and use of interoperable HIT.⁴ The Center would:</p> <ul style="list-style-type: none"> • Provide a forum for the exchange of knowledge and experience; • Accelerate the transfer of lessons learned from existing initiatives; • Assemble, analyze, and disseminate evidence on the adoption, implementation, and use of interoperable HIT; • Establish regional and local health information networks to facilitate interoperability; • Develop solutions to obstacles to the electronic exchange of health information; and • Conduct other activities for developing and sharing best practices. <p>Technical assistance also would be provided by HHS to public and private entities to enable them</p>	<p>HHS could establish three types of demonstration programs to improve care for vulnerable populations through HIT.</p> <p>One type of demonstration program would provide grants to integrated health care systems to better coordinate the provision of care through the adoption of HIT (or improvement to existing HIT) in order to improve care to uninsured, underinsured, and medically underserved individuals. Grants could not be used for HIT used exclusively for financial record-keeping, billing, or other nonclinical applications.</p> <p>Integrated health care systems include systems of providers organized to provide care in a coordinated fashion and with a commitment to underserved individuals. To be eligible to receive a grant, an integrated health care system would have to:</p> <ul style="list-style-type: none"> • Describe how the project will advance the goals of improved care and address the needs of the populations to be served; • Provide matching funds in an amount equal to \$1 for every \$5 of federal funds provided; and

⁴ Note that the similarly named National Resource Center for Health Information Technology (National Resource Center) already exists by virtue of AHRQ's HIT initiative. S. 1418 would statutorily create the Health Information Technology Resource Center and codify its responsibilities.

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
	<p>to implement and use evidence-based guidelines and establish mechanisms for the rapid dissemination of information regarding these guidelines. A toll-free number or Web site would be established to offer providers and patients with a single point of contact to learn about federal grants related to interoperable HIT, criteria and quality measures developed under the Act, regional and local health information networks, and additional information, as necessary.</p> <p>In addition, HHS could award three types of competitive grants to providers and states to assist in the purchase of HIT and for entities establishing regional health information networks. Each grantee could receive only one nonrenewable grant under each of the three competitive grant award programs.</p> <p>In addition to the requirements outlined below, each grant recipient would have to:</p> <ul style="list-style-type: none"> • Demonstrate financial need; • Ensure that the Collaborative's standards and the quality measures developed under this Act are adopted by participating entities; and • Ensure that patients are notified if individually identifiable health information is wrongfully disclosed. <p>One type of competitive grant would be available for providers for the purchase and use of qualified HIT systems and to train personnel in the use of such technology.</p> <p>Eligible providers include not-for-profit hospitals, federally qualified health centers (FQHCs), individual or group practices, and other health care providers.</p> <p>Eligible entities would be required to:</p> <ul style="list-style-type: none"> • Submit a strategic plan for the implementation of data sharing and interoperability measures; and • Provide matching funds of \$1 for every \$3 of federal funds provided. <p>Preference would be given to entities: (1) located in underserved areas; (2) who will link with local or regional health information networks; and (3) who are nonprofit health care providers other than a hospital, individual, or group practice.</p>	<ul style="list-style-type: none"> • At HHS's discretion, submit a report on the impact the HIT adopted for the project has on quality of care. <p>Preference could be given to:</p> <ul style="list-style-type: none"> • Integrated health care systems with past successful community-wide efforts to improve quality and coordination of care for the relevant populations; • Projects that will demonstrate savings for state or federal health care benefits programs by reducing duplicative services, administrative costs, and medical errors; and • Projects that will emphasize improved access to care for medically underserved populations located in geographically isolated or underserved urban areas. <p>A second type of demonstration program would provide grants to small physician practices located in rural or medically underserved urban areas to assist in the purchase and support of HIT.</p> <p>Physician practices receiving a grant would have to submit to HHS an evaluation of the funded HIT, including information on barriers to HIT adoption, issues in the use of HIT, effect HIT will have on quality of care, and effect of medical liability rules on the physician practice.</p> <p>A third type of demonstration program would be a two-year project with states to determine the impact of HIT on disease management for Medicaid-eligible individuals. The project would create a Web-based virtual case management tool providing access to best practices for the management of chronic disease. Chronic disease patients and caregivers also would be provided with access to their own medical records.</p> <p>HHS would seek proposals from states to carry out the project within 90 days of the Act's implementation. At least four state proposals would be selected, one or more of which would include a regional approach that provides access to an integrated hospital information system in at least two adjoining states and that permits the measurement of health outcomes.</p>

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
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A second type of competitive grant would be available for states to establish loan programs to assist providers in the purchase and use of qualified HIT and the training of personnel in using such technology.

States would be required to:

- Establish a qualified HIT loan fund;
- Submit an annual strategic plan identifying the intended uses of the funds;
- Provide matching funds equal to the federal funds provided (e.g., a \$1 to \$1 match); and
- Establish requirements for providers receiving loans, including requirements that providers (1) link to a local or regional health information network and (2) consult with the Health Information Technology Resource Center.

Preference would be given to states adopting value-based purchasing programs. The grant could only be used by the state to:

- Award loans for which: (1) the interest rate would be less than or equal to the market interest rate; (2) the principal and interest payments would commence no later than one year after the award date, with each loan fully amortized (e.g., extinguished) within 10 years; and (3) the state loan fund would be credited with all payments of principal and interest;
- Guarantee a local obligation (the proceeds of which would finance an eligible project) if doing so would improve credit market access or reduce the applicable interest rate;
- Provide a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the state if the proceeds of selling such bonds would be deposited into the state loan fund; and
- Earn interest on amounts deposited into the state loan fund.

States could receive the grant and still accept contributions from private sector entities so long as the private entities do not specify the recipient of any loans issued. States would have to make publicly available the identity of private contributors and the amount contributed by these entities.

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
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A third type of competitive grant would be available for entities to develop regional or local health information networks designed to improve quality and efficiency of care through the electronic exchange of health information.

Eligible entities would have to meet specified requirements, including:

- Demonstrating that the governance structure and decision-making processes allow for participation of multiple stakeholders, or else providing justification for the nonparticipation of multiple stakeholders;
- Demonstrating the participation of stakeholders in the electronic exchange of health information within the local or regional plan;
- Adopting nondiscrimination and conflict of interest policies;
- Providing matching funds (in cash or in kind) of \$1 for each \$2 of federal funds; and
- Submitting detailed plans, including plans for:
 - (1) encouraging provider participation;
 - (2) ensuring privacy and security of personal health information;
 - (3) allowing stakeholders to make policy and operational decisions; and
 - (4) financing.

In addition, HHS could award demonstration projects grants to academic institutions to develop HIT curricula integrating qualified HIT systems in the clinical education of health professionals. Eligible entities would include health professional schools, schools of nursing, or institutions with a graduate medical education program.

The projects would seek to improve patient safety and the efficiency of care as well as increase the likelihood that graduates will incorporate HIT in the delivery of health care. The grant could not be used to purchase hardware, software, or services and the demonstration program would sunset on September 30, 2010.

Eligible entities would have to comply with specified requirements, including:

- Submitting a strategic plan for integrating HIT and decision support software in the clinical education of health professionals;

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
Administration and oversight of the proposed changes	<ul style="list-style-type: none"> • Collecting data regarding the effectiveness of the demonstration project; • Providing matching funds (in cash or in kind) of \$1 for each \$2 of federal funds; • Collaborating with two or more disciplines; • Using the funds to integrate qualified HIT into community-based clinical education. <p>The Office of the National Coordinator would be responsible for promoting a nationwide interoperable HIT infrastructure.</p> <p>HHS would be responsible for appointing members to the Collaborative, adopting the Collaborative’s recommendations, and developing quality measures.</p> <p>In conjunction with AHRQ, HHS would be responsible for establishing the Health Information Technology Resource Center.</p> <p>HHS also would promulgate regulations and oversee the competitive grants and demonstration projects.</p>	<p>The Office of the National Coordinator would be responsible for promoting a nationwide interoperable HIT infrastructure.</p> <p>Along with the National Committee on Vital and Health Statistics, HHS would be responsible for the expedited administrative process for updating standards for the electronic exchange of information. HHS also would be responsible for replacing existing standards for certain electronic transactions.</p> <p>HHS would oversee the demonstration projects.</p>
Financing	<p>For the Office of the National Coordinator of HIT, \$5,000,000 would be appropriated for fiscal year (FY) 2006, \$5,000,000 for FY 2007, and sums as necessary for FYs 2008 through 2010.</p> <p>For the American Health Information Collaborative, \$4,000,000 would be appropriated for each of FY 2006 and 2007, and sums as necessary for FYs 2008 through 2010.</p> <p>For the Health Information Technology Resource Center, sums as necessary would be appropriated for FYs 2006 and 2007.</p> <p>For the three competitive grant programs, \$116,000,000 would be appropriated for FY 2006, \$141,000,000 for FY 2007, and sums as necessary for FYs 2008 through 2010. Appropriated amounts would remain available through FY 2010.</p> <p>For the demonstration projects for academic institutions, \$5,000,000 would be appropriated for FY 2007, and sums as necessary for FYs 2008 through 2010.</p>	<p>For the grants to integrated health systems, \$15,000,000 would be appropriated for each of fiscal year (FY) 2007 and 2008.</p> <p>For the grants to small physician practices awarded under the demonstration program, \$5,000,000 would be appropriated for each of FY 2007 and 2009.</p>

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
Reports and studies	<p>Providers, states, or entities establishing local or regional networks and receiving a grant under this Act would be required to submit annual reports to HHS that include:</p> <ul style="list-style-type: none"> • A description of the financial costs and benefits of the project and the entities to which such costs and benefits accrue; • An analysis of the impact of the project on quality and safety of care; • A description of any reduction in duplicative care as a result of the project; • A description of recipients' efforts to facilitate secure patient access to information; and • Other information as required by HHS. <p>HHS would submit to Congress three reports:</p> <ul style="list-style-type: none"> • One annual report would describe actions taken to facilitate the adoption of an interoperable nationwide system for the electronic exchange of health information, describe barriers to adoption of the system, make recommendations to achieve full implementation, and provide a plan for the establishment of an entity to ensure the continuation of the functions of the Collaborative; • A second annual report would summarize reports from states receiving grants for the development of state loan programs to facilitate HIT adoption; and • A third annual report would describe demonstration projects for the development of academic curricula integrating HIT in the education of health professionals. <p>HHS would be responsible for conducting or contracting with a private entity to conduct two studies:</p> <ul style="list-style-type: none"> • One study would examine the variation among state laws relating to the licensure, registration, and certification of medical professionals and examine how the variation impacts the secure exchange of health information among states and between states and the federal government. This study would be published within one year of the Act's implementation and would include recommendations to the states on how to harmonize state laws; and • A second study would examine ways of creating efficient reimbursement incentives for improving quality of care in FQHCs, rural health clinics, and free clinics. 	<p>HHS would submit two reports to Congress pertaining to the demonstration projects established under this Act:</p> <ul style="list-style-type: none"> • A report on the results of the small physician practices demonstration program by January 1, 2009; and • A report on the state disease management demonstration program for the Medicaid population. This report would be completed within 90 days of the project's conclusion and include the amount of any resulting cost-savings as well as recommendations for legislation or administrative action. <p>HHS and the National Coordinator would submit to Congress three reports.</p> <p>One report would focus on the work of AHIC and include information on AHIC's:</p> <ul style="list-style-type: none"> • Accomplishments regarding the promotion of national guidelines, development of a nationwide health information network, and adoption of HIT; • Use of model privacy and security policies to protect information confidentiality; and • Progress in establishing industrywide HIT standards, achieving an Internet-based nationwide health information network, achieving interoperable electronic health record adoption, and creating technological innovations to promote the confidentiality of private health information. <p>In this report, recommendations would be provided for the transition of AHIC to a longer-term or permanent entity and for the inclusion of emergency contact or next-of-kin information in electronic health records.</p> <p>A second evaluative report, which would be submitted to Congress within 180 days of the Act's implementation, would focus on health care classification methodologies and include information on:</p> <ul style="list-style-type: none"> • The applicability of methodologies and codes for purposes beyond the coding of services for diagnostic documentation and/or billing purposes; • The usefulness, accuracy, and completeness of methodologies and codes; and • The capacity of methodologies and codes to produce erroneous or misleading information.

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
	<p>The Comptroller General of the Government Accountability Office (GAO) would submit within six months of the Act's implementation a report to Congress on the necessity and feasibility of requiring health plans, health care clearinghouses, and health care providers transmitting health information electronically to notify patients if individually identifiable health information is wrongfully disclosed.</p>	<p>A third evaluative report would be submitted by the National Coordinator to the President and Congress annually for five years following the Act's implementation. This report would review the health information collected by and submitted to the federal government as well as the government's purchases of HIT.</p> <p>The report would include recommendations on methods to eliminate redundancy and improve efficiency in the information collection and submission processes, increase the ability to assess quality of care, and reduce health care costs.</p> <p>HHS also would conduct five studies.</p> <p>One study would focus on issues related to the development, operation, and implementation of state, regional, and community health information exchanges. The report along with recommendations would be submitted to Congress within one year of the Act's implementation and would include information on:</p> <ul style="list-style-type: none"> • The current stages of health information exchanges; • The impact of exchanges on health care quality, safety, and efficiency; • Best-practice models for financing, "incentivizing," and sustaining exchanges; • Common principles, policies, tools, and standards used in the public and private sectors in support of exchanges; and • Areas in which federal government leadership is needed to support growth and sustainability of exchanges. <p>A second study would examine the variation among existing state laws and current federal standards on security and confidentiality of health information as they relate to the availability of the information necessary to make medical decisions at the time care is provided.</p> <p>The study would be submitted to Congress within 18 months of the Act's implementation and include information on:</p> <ul style="list-style-type: none"> • The degree of variation and commonality among the requirements of state laws, and variation between state laws and current federal standards; • The strengths and weaknesses of different legal requirements and the extent to which variation

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
	<p>may adversely impact exchanges of health information among the states, federal government, and public and private entities; and</p> <ul style="list-style-type: none"> • A determination by HHS on the need for greater commonality of the requirements of state laws and federal standards on security and confidentiality. <p>This study of variation in state and federal privacy laws would include recommendations on changes for federal standards to provide greater commonality (if needed) and recommendations and legislative language regarding which and how federal standards should supersede state laws to provide greater commonality.</p> <p>At the same time at which this report is submitted to Congress, a bill would be introduced in the House and the Senate. This bill would be entitled “A Bill to provide the commonality needed to better protect, strengthen, or otherwise improve the secure, confidential, and timely exchange of health information.” The bill’s text would include the report submitted to Congress. Following its introduction, the bill would be referred to the appropriate committee(s).</p> <p>A third study would focus on the impact of the safe harbors pertaining to anti-kickback penalties and the exception to the prohibition on physician referrals created by the Act.</p> <p>This study would be submitted to Congress within three years of the implementation of the safe harbors and would examine:</p> <ul style="list-style-type: none"> • The effectiveness of these changes in increasing HIT adoption; • The types of HIT provided; • The extent to which financial or other business relationships between providers changed in a way that adversely affects or benefits the health care system or consumer choice; and • The impact of the adoption of HIT on health care quality, cost, and access. <p>A fourth study would focus on the feasibility, advisability, and costs of expanding telehealth, including:</p> <ul style="list-style-type: none"> • The inclusion of coverage and payment for home health–related telehealth services as part of Medicare home health services; and 	

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
		<ul style="list-style-type: none"> • The expansion of existing sites (under the SSA) for telehealth services to include county or other publicly funded mental health facilities. <p>In determining whether telehealth services should be expanded, the study would describe effects on health outcomes, communication among providers, monitoring of patients, reductions in expenditures, and improved access to care. The report, along with any recommendations for legislation or administrative action, would be submitted to Congress within 18 months of the Act's implementation.</p> <p>HHS would, acting through the director of the Office for the Advancement of Telehealth, conduct a study on the use of "store and forward" technologies (e.g., technologies providing for the asynchronous transmission of health care information in single or multimedia formats) in the provision of telehealth services. The study would include an assessment of the feasibility, advisability, and costs of using such technologies in the diagnosis and treatment of certain conditions. Within 18 months of the Act's implementation, HHS would submit to Congress a report on the study, including recommendations for legislation or administrative action.</p> <p>The National Coordinator would conduct one study of the development and implementation of HIT in medically underserved areas. This study would be submitted to Congress within 18 months of the Act's implementation along with any recommendations for action, and would include information on:</p> <ul style="list-style-type: none"> • Barriers to implementation of HIT; • The impact of HIT on quality of care and reduction of cost; • The impact of HIT on primary health providers; and • The feasibility of HIT in these medically underserved areas. <p>The National Coordinator also would conduct surveys to measure the capability of entities (e.g., federal and state agencies, private sector entities) to exchange electronic health information. These surveys would be conducted by August 31, 2008, and the results would be disseminated to inform the public about the capabilities of entities to exchange electronic health</p>

Bill name	Wired for Health Care Quality Act	Health Information Technology Promotion Act of 2006
Other key elements of the bill	<p>The Act reauthorizes existing incentive grants (under the Public Health Service Act) to state professional licensing boards to carry out programs (under which boards develop policies to reduce barriers to telemedicine) through 2010—currently the grants are only authorized through 2006.</p> <p>Up to 4 percent of the funds provided to the state could be used to pay the reasonable costs associated with fund administration.</p>	<p>information, assist in establishing more interoperable information architecture, and identify the status of such health information systems in federal agencies.</p> <p>Executive Order No. 13335 would be rendered null and void. This order required the National Coordinator to report regarding the development and implementation of a strategic plan to guide the nationwide implementation of HIT. All functions, personnel, assets, liabilities, administrative actions, and statutory reporting requirements applicable to the old (that is, existing) National Coordinator would be transferred to the new (that is, created by this Act) National Coordinator and Office.</p> <p>HHS would coordinate with stakeholders (e.g., physicians, health care practitioners, patient advocates) to encourage and facilitate the adoption of state reciprocity agreements for practitioner licensure to expedite the provision of telehealth services across state lines. HHS would submit to Congress a report on these actions within 18 months of the Act’s implementation.</p> <p>Health care providers participating in a program receiving federal funds under this Act, the federal Maternal and Child Health Block Grant, SCHIP, Medicare, or Medicaid would be deemed as meeting any requirement for the maintenance of data in paper form if the data are maintained in electronic form. This provision:</p> <ul style="list-style-type: none"> • Supersedes any contrary state law provision within one year of the Act’s implementation; and • Does not require providers to maintain data in electronic form, prevent a state from permitting providers to maintain data in paper form, or prevent a state from requiring providers to maintain data in electronic form. <p>The President would consult with HHS and appropriate federal agencies to permit timely access by researchers to nonidentifiable health information maintained by the federal government in order to advance health care quality and research objectives. Voluntary private and public sector efforts would be encouraged to access these data.</p>

Table A-7. Side-by-Side Analysis of the
Safe Health Care Reporting Act of 2005
and the National Medical Error Disclosure and Compensation (MEDiC) Act

Bill name	Safe Health Care Reporting Act of 2005	National Medical Error Disclosure and Compensation Act (National MEDiC Act)
Bill number(s)	S. 948 / H.R. 2006	S. 1784
Bill sponsor(s)	S. 948 is sponsored by former Senator Corzine and has one cosponsor. H.R. 2006 is sponsored by Representative Pallone and has no cosponsors.	S. 1784 is sponsored by Senator Clinton and has one cosponsor.
Latest Congressional action	S. 948 was referred to the Senate Committee on Health, Education, Labor, and Pensions on April 28, 2005. H.R. 2006 was referred to the House Committee on Energy and Commerce, Subcommittee on Health, on May 13, 2005.	S. 1784 was referred to the Committee on Health, Education, Labor, and Pensions on September 28, 2006.
Basic structure of health system improvement	<p>Expands the requirements for reporting and obtaining information from the National Practitioner Data Bank (Data Bank) by amending the Health Care Quality Improvement Act of 1986.</p> <ul style="list-style-type: none"> • State licensing boards would be required to submit information on sanctions against both physicians and other health care practitioners. Currently, states only have to report sanctions against physicians. • Health care entities, including skilled nursing facilities, would be required to report actions against all licensed health care practitioners (physicians and other licensed practitioners) and request information on actions or sanctions against these individuals. <p>Creates civil penalties for health care entities that do not comply with the requirements of this bill. Creates protections for health care entities and practitioners reporting required data.</p> <p>Requires that states establish a system of reporting criminal background information on licensed health care practitioners to the secretary of Health and Human Services (HHS) or the agency's designee.</p>	<p>Creates the Office of Patient Safety and Health Care Quality to improve patient safety and reduce medical errors across the health care system by:</p> <ul style="list-style-type: none"> • Establishing a National Medical Error Disclosure and Compensation (MEDiC) program. The MEDiC program would require the reporting, investigation, and communication of medical errors and other patient safety events to a national database and to the affected patients. Patients injured due to a reported event could elect to enter into negotiations for compensation through the MEDiC program; and • Establishing a National Patient Safety Database (Database). The Database would be used for the collection and study of non-identifiable data on medical errors and patient safety events, as well as information on the outcome of negotiations undertaken through the MEDiC program. <p>Creates grants for health care entities, providers, and medical liability insurers to develop the capacity to meet the MEDiC program reporting requirements.</p> <p>Grants also would be available for patient safety organizations and researchers to analyze the Database and develop training and education materials for providers on reducing medical errors and improving patient safety.</p>

Bill name	Safe Health Care Reporting Act of 2005	National Medical Error Disclosure and Compensation Act (National MEDiC Act)
Description of affected entities	<p>State licensing boards, health care entities, physicians, and nonphysician health care practitioners would be affected by the expansions to the Data Bank.</p> <p>Health care entities affected by the Act would include hospitals, skilled nursing facilities, health maintenance organizations, and group medical practices that provide health care services, and professional societies.</p>	<p>Health care entities, health care providers, medical liability insurers, and patients could be affected by this bill.</p> <p>Health care entities would include hospitals, health plans, community clinic, nursing facilities, comprehensive rehabilitation facilities, home health agencies, hospice programs, renal dialysis facilities, ambulatory surgical centers, pharmacies, doctors' or health care practitioners' offices, long-term care facilities, behavior health residential treatment facilities, clinical laboratories, and health centers.</p> <p>Health care providers would include doctors, nurses, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse midwives, psychologists, certified social workers, registered dietitians or nutrition professionals, physical or occupational therapists, pharmacists, and other individual health care practitioners.</p> <p>Medical malpractice insurers for doctors or other health care providers would include mutual insurance companies; privately held or publicly traded liability insurance companies; self-insured hospitals; captive insurance companies (insurers that cover limited risk or groups) or providers covered by captive insurance companies; risk-retention groups and any other alternative malpractice insurance mechanisms; and all or a subset of a medical liability insurer.</p>
Health system improvement requirements	<p>State licensing boards would have to report to the Data Bank sanctions taken against physicians or other health care practitioners. Currently, states are required only to report sanctions against physicians. Sanctions include the revocation or suspension of a health care practitioner's license and censures or other reprimands for reasons relating to professional competence or conduct.</p> <p>Health care entities would have to report to the state licensing board (rather than the board of medical examiners) professional review actions taken against physicians and other licensed health care practitioners. Currently, the reporting of actions against nonphysician practitioners is voluntary. Professional review actions include:</p> <ul style="list-style-type: none"> • Actions affecting the clinical privileges of a physician for longer than 30 days for reasons relating to possible incompetence or improper professional conduct; and 	<p>The Office of Patient Safety and Health Care Quality (Office) would be established within the Agency for Healthcare Research and Quality (AHRQ) to improve patient safety and reduce medical errors across the health care system.</p> <p>The Office would establish a National Medical Error Disclosure and Compensation (MEDiC) program. The goal of the MEDiC program would be to:</p> <ul style="list-style-type: none"> • Improve the quality of health care by encouraging open communication between patients and providers about medical errors and other patient safety events; • Reduce rates of preventable medical errors; • Ensure that patients have access to fair compensation for medical injury due to medical error, negligence, or malpractice; and • Reduce the cost of medical liability insurance for doctors, hospitals, health systems, and other health care providers.

Bill name	Safe Health Care Reporting Act of 2005	National Medical Error Disclosure and Compensation Act (National MEDiC Act)
	<ul style="list-style-type: none"> Dismissals and adverse actions against a health care practitioner for conduct violating any federal or state law, including laws governing professional practice standards. <p>In reporting professional actions, health care entities must include information on any dismissal or review actions as well as information on practitioners who voluntarily resign during or as a result of a pending dismissal or review action. These reports would be made in accordance with existing standards for professional review actions.</p> <p>Hospitals and health care entities or agencies that employ health care practitioners (physicians or other licensed health care practitioners) would be required to request information on these practitioners. These entities would have to request information from the Data Bank and state licensing boards at the time the individual applies to practice with the entity and once every two years thereafter. Currently, hospitals (but not other health care entities) are required to obtain this information from the Data Bank for physicians only.</p> <p>States would be required to establish a system for reporting criminal background information on licensed health care practitioners to HHS or its designee.</p>	<p>Health care entities, health care providers, and medical malpractice insurers could participate in the MEDiC program.</p> <p>Health care providers, including providers covered by a health care entity or insurer in the MEDiC program, would be required to report to patient safety officers (e.g., persons responsible for ensuring the MEDiC program requirements are met) the following information:</p> <ul style="list-style-type: none"> Any incident involving a patient thought to be a medical error or patient safety event; and Any legal action related to the medical liability of a health care provider. <p>As appropriate, an investigation of reported events would be conducted to determine what caused the event and whether the medical error was preventable or the result of a failure to provide standard care. This investigation would occur within 90 days of the filing of the report.</p> <p>If the investigation determined a patient was harmed as a result of a medical error or failure to provide standard care, the patient would have to be informed of this finding within five business days of the investigation's completion.</p> <p>Patients informed of a medical error or patient safety event could, upon request of the patient safety officer, obtain information contained in the report on the event.</p> <p>When disclosing an event to a patient, the MEDiC program participant would offer to:</p> <ul style="list-style-type: none"> Negotiate compensation with the patient; Provide (at the discretion of the health care provider) an apology or expression of remorse; and Share with the patient the efforts being made by the provider, health care entity, or insurer to prevent recurrences of a similar event. <p>Patients electing to enter into negotiations for compensation under the MEDiC program would be provided with written notification of their right to legal counsel. This notice also would affirm that no inappropriate action was taken to dissuade the patient from utilizing counsel for the negotiations.</p> <p>A neutral third-party mediator could be used to facilitated the negotiations. The proceedings of</p>

Bill name	Safe Health Care Reporting Act of 2005	National Medical Error Disclosure and Compensation Act (National MEDiC Act)
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the negotiation and any agreement or apologies expressed during the negotiations would be confidential. If the negotiations did not resolve the issue, agreements and apologies expressed during the negotiations could not be used in subsequent legal proceedings.

If an agreement could not be reached within six months, both parties could agree to extend the negotiations for three months. Alternatively, the patient could proceed directly to the judicial system for resolution of the issue.

If an agreement were reached, the MEDiC program participant would have to compensate the patient as agreed and the patient could not engage in further litigation related to this event in federal or state court.

The new Office within AHRQ also would establish a National Patient Safety Database (Database) for the collection and study of non-identifiable data on medical errors and patient safety events.

MEDiC program participants would be required to report to this Database:

- Nonidentifiable information on medical errors and patient safety events (Non-identifiable information would not contain information identifying the health care provider, the patient affected by the event, or the individual reporting the event. The information must be submitted in the required, standardized electronic format. Single events must be assigned a common identifier to link entries of related data.);
- The findings of investigations of reported events within five business days of the completion of the study;
- Terms of agreement reached through negotiations undertaken through the MEDiC program;
- Compensation provided to patients obtained through the MEDiC program negotiations; and
- Any disciplinary actions taken against a health care provider as a result of the event.

In addition, as part of their application to enter the MEDiC program, participants would have to submit:

- A comprehensive plan to reduce the incidence of medical errors and improve patient safety; and

Bill name	Safe Health Care Reporting Act of 2005	National Medical Error Disclosure and Compensation Act (National MEDiC Act)
		<ul style="list-style-type: none"> • Cost analysis statements outlining real and projected costs and savings related to the liability coverage and legal defense costs of doctors and other health care providers for the two fiscal years prior to entry into the program. <p>As part of the terms of participating in the program, cost analysis statements also would have to be submitted at the end of every year.</p> <p>A portion of the savings that medical liability insurers gain from participating in the MEDiC program would have to be used to reduce premiums for health care providers. Similarly, health care entities and providers would have to use a portion of these savings for activities to reduce medical errors or improve patient safety. The portion of savings required to be used for reducing premiums or improving patient care would be as follows:</p> <ul style="list-style-type: none"> • In the first year of participation, at least 50 percent of projected savings; • In the second year, at least 40 percent of actual savings; and • In the third and each subsequent year, at least 30 percent of savings. <p>In addition, the Office would (directly or through a contract with a patient safety organization):</p> <ul style="list-style-type: none"> • Quarterly, analyze the Database and report on trends with regard to medical errors and other findings; and • Yearly, develop recommendations for health care providers for reducing the incidence of medical errors, improving patient safety, and increasing quality. <p>The Office also would maintain information concerning the MEDiC program and the Database on its publicly available Web site.</p>

		National Medical Error Disclosure and Compensation Act (National MEDiC Act)
Bill name	Safe Health Care Reporting Act of 2005	
Federal incentives and penalties	<p>Civil penalties would be permitted for health care entities that fail to comply with the requirements for reporting professional actions and for requesting information on health care practitioners:</p> <ul style="list-style-type: none"> • Health care entities failing to report or obtain information on health care practitioners as required under the Act could be fined up to \$50,000 per violation; • HHS could levy additional fines against entities with patterns of repeated violations. <p>Health care entities and practitioners would be protected from adverse consequences of reporting conduct requiring professional action against a practitioner:</p> <ul style="list-style-type: none"> • Health care entities disclosing required information to state licensing boards would be immune to civil liability for the disclosure of this information and any resulting consequences. Entities knowingly providing false information or violating any right of the employee protected under federal or state laws would not be afforded this immunity. • Employers could not adversely affect (e.g., penalize, discriminate against, or retaliate against) health care practitioners who, in good faith, report conduct that results in a professional action against an individual. 	Not discussed.
Administration and oversight of the health system improvements	HHS would create regulations for implementing this Act and be responsible for administering and overseeing its provisions.	<p>The Office would be responsible for establishing and administering the MEDiC program, including:</p> <ul style="list-style-type: none"> • Determining eligibility requirements for the program; • Overseeing the application process for interested individuals, including the development of a standardized application; and • Providing technical assistance to applicants and participants. <p>The Office would be responsible for establishing and maintaining the Database. In developing standards for the collection and reporting of data to the Database, the Office would:</p> <ul style="list-style-type: none"> • Consider federal, state, and local patient safety reporting requirements and attempt to reduce duplications of efforts; • Consult with the Joint Commission on Accreditation of the Healthcare Organizations and other experts in adopting standardized patient safety taxonomy;

		National Medical Error Disclosure and Compensation Act (National MEDiC Act)
Bill name	Safe Health Care Reporting Act of 2005	
		<ul style="list-style-type: none"> • Include necessary elements, common and consistent definitions, and a standardized electronic interface for the entry and processing of the data; • Allow for comprehensive collection of the patient safety data; and • Include patient safety data required to be submitted by participants in the MEDiC program. <p>The Office would permit, upon approval of an application, researchers and other qualified individuals and institutions access to the Database. The Office also would maintain on its Web site information concerning the MEDiC program and the Database.</p>
Privacy and confidentiality protections	Not discussed.	Information submitted to the Database would be confidential and protected from disclosure in accordance with the regulations for the privacy of individually identified health information related to the standards in the Health Insurance Portability and Accountability Act of 1996 to enable electronic exchange.
Technical assistance, grants and demonstration programs	Not applicable.	<p>The Office would award grants to MEDiC participants for:</p> <ul style="list-style-type: none"> • Development and implementation of communication programs to help providers disclose to patients medical errors and other patient safety events; and • Procurement of information technology products (e.g., hardware, software, and support services) to facilitate the reporting, collection, and analysis of patient safety data required. <p>MEDiC grants also would be awarded to patient safety organizations and other qualified institutions or individuals for:</p> <ul style="list-style-type: none"> • Tracking and analyzing local and regional patient safety trends; and • Developing and disseminating training guidelines and other recommendations for health care providers to reduce medical errors and improve patient safety and quality. <p>Twenty percent of the funds appropriated for the grants would be reserved and could be distributed by the Office to participants incurring higher costs for the year under the MEDiC program than they would have incurred otherwise (e.g., their costs would have been lower if the cases had not been negotiated through the MEDiC program).</p>

		National Medical Error Disclosure and Compensation Act (National MEDiC Act)
Bill name	Safe Health Care Reporting Act of 2005	
Financing	Not discussed.	The Act would authorize the appropriation of the funds necessary to carry out its provisions.
Key implementation dates	HHS would create regulations for the implementation of the Act within one year of its enactment.	Not discussed.
Evaluation of health system improvements	Not discussed.	<p>Every two years, the Office would contract with an independent entity to evaluate the MEDiC program. This evaluation would be provided to program participants, Congress, and the public.</p> <p>The Office also would conduct (directly or through a contract with a patient safety organization) and make public several studies:</p> <ul style="list-style-type: none"> • Within two years of the Act’s implementation, a study would be conducted to analyze the Database and other data to determine standards, tools, and best practices (including peer review) for health care providers for preventing medical errors, improving patient safety, and increasing accountability within the health care system. This report also would consider the value of including provider-identifiable data in the Database and would provide recommendations for improvements to the peer review process. • Within two years of the Act’s implementation, a study would be conducted of the medical liability insurance market. This study would look at: (1) the historic and current legal costs related to medical liability according to type of insurance carrier; (2) factors leading to increased medical liability legal costs; and (3) which, if any, state medical liability insurance reforms have led to stabilization or reduction in medical liability premiums. • Within five years of the Act’s implementation, an examination would be conducted of: (1) events in the Database that were not successfully negotiated through the MEDiC program; and (2) events for which the provider or patient chose not to participate in the MEDiC negotiations program. The report would include the reasons, trends, and impact of these events on program participants and would make recommendations to Congress based on its findings. Prior to completing this report, Congress would be provided with interim reports on the study’s progress and findings.
Other key elements	Not applicable.	Not applicable.

Table A-8. Analysis of the Fair and Reliable Medical Justice Act

Bill name	Fair and Reliable Medical Justice Act
Bill number(s)	S. 1337
Bill sponsor(s)	S. 1337 is sponsored by Senator Enzi and cosponsored by Senator Baucus.
Latest Congressional action	S. 1337 was referred to the Committee on Health, Education, Labor, and Pensions (HELP Committee) on June 29, 2005. The HELP Committee held hearings on the bill on June 22, 2006.
Basic structure of health system improvement	Authorizes the secretary of the Department of Health and Human Services (HHS) to award up to 10 demonstration grants to states to develop, implement, and evaluate alternatives to current medical tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.
Description of affected entities	States, health care providers, health care organizations, and patients would be affected by the demonstration programs. Relevant state licensing boards, patient advocacy groups, attorneys, and judges also could be affected by the demonstration programs.
Health system improvement requirements	<p>To receive a demonstration grant, states would be required to:</p> <ul style="list-style-type: none"> • Develop an alternative to tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations; • Effect a reduction in health care errors by allowing the collection and analysis of patient safety data related to the disputes resolved by the alternative processes; • Demonstrate how the proposed alternatives to tort litigation would make the medical liability system more reliable through prompt and fair resolution of disputes, encouraging early disclosure of health care errors, enhancing patient safety, and maintaining access to liability insurance; and • Identify compensation sources and methods for claims resolved under the proposed alternative to tort litigation, which could include both public and private funding sources and, if practicable, financial incentives for activities that improve patient safety.
Federal incentives and penalties	Not applicable.
Privacy and confidentiality protections	Not applicable.
Technical assistance	<p>HHS would provide technical assistance to states awarded demonstration grants, including:</p> <ul style="list-style-type: none"> • The development of a defined payment schedule for noneconomic damages, including guidance on considering individual facts and circumstances when determining appropriate payment; • Guidance on early disclosure to patients of adverse events; and • In consultation with states, the development of common definitions, formats, and data collection infrastructure reporting data. States that do not receive grants would also be able to use the material developed.
Grants and demonstration programs	<p>HHS would award up to 10 demonstration grants, each of which may not be longer than five years in duration. The scope of the demonstration programs may specify a scope of jurisdiction (e.g., designated geographic region, designated area of health care practice, or designated types of health care providers or health care organizations).</p> <p>When reviewing state applications for demonstration programs, HHS would consult with a review panel chaired by the Comptroller General or a designee from within the Government Accountability Office (GAO) composed of 11 to 15 relevant experts, including, but not limited to, patient advocates, health care providers and organizations, attorneys with experience representing patients and health care providers, insurers, and state officials.</p> <p>Although states would be able to create their own reform packages, HHS also would provide three standard models that states could use to “automatically” meet HHS standards for approval:</p>

(1) Under the “Early Disclosure and Compensation Model”:

- The state would require health care providers/organizations to notify patients of any “adverse events” that occur that could result in serious injury to the patient;
- Health care providers/organizations would be granted immunity from tort liability (except in cases of fraud or criminal or intentional harm) for any good faith offers to compensate patients for injuries. Time limits for such compensation offers would be created, accounting for circumstances where injuries may not be promptly recognized;
- Compensation would include payments for the net economic loss⁵ to the patient, the noneconomic damages⁶ to the patient, if appropriate, and reasonable attorneys’ fees;
- The right of an injured patient to seek redress through the state tort system would not be restricted if the health care provider/organization did not enter into a compensation agreement, if the compensation offered did not meet statutory requirements, or if the compensation was not offered in good faith;
- Health care providers/organizations that offered to pay compensation to injured patients would be permitted to join in other liable health care providers/organizations.

(2) Under the “Administrative Determination of Compensation Model”:

- The state would designate an administrative board (consisting of representatives from relevant state licensing boards, patient advocacy groups, health care providers, health care organizations, and attorneys in relevant practice areas) to conduct reviews of health care liability claims pertaining specifically to “avoidable injuries.”⁷ State tort liability would be modified to bar negligence claims for avoidable injuries, except when the claims arise in the context of fraud or crime or intentional harm;
- The board would determine compensation for the claims and would develop a schedule of compensation;
- Compensation would include payments for the net economic loss⁸ of the patient, payments for non-economic damages,⁹ if appropriate, and reasonable attorneys’ fees;
- Notice of the new system would be given prior to the provision of care;
- The state must establish an appeals process, but would have flexibility in determining how much deference to give to the board’s initial findings.

(3) Under the “Special Health Care Court Model:”

- The state would establish a special court for the timely adjudication of disputes over patients’ injuries allegedly caused by a health care provider/organization during the provision of health care services;

⁵ Net economic loss includes: reasonable expenses from products, services, and accommodations needed for health care, training, and other treatment for an injured patient; reasonable and appropriate expenses for rehabilitation treatment and occupational training; 100 percent of the loss of income from work that an injured patient would have performed if they were not injured, reduced by any income from substitute work actually performed; and reasonable expenses for obtaining ordinary and necessary services to replace any activities that injured individuals would have performed themselves if they had not been injured.

⁶ Noneconomic damages would include losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), injury to reputation, and all other nonpecuniary losses of any kind to the extent permitted under state law.

⁷ HHS would provide states with technical assistance in identifying types of injuries that qualify as “avoidable.”

⁸ “Net economic loss” would be defined the same as under option 1, the Early Disclosure and Compensation Model.

⁹ “Noneconomic damages” would be defined the same as under option 1, the Early Disclosure and Compensation Model.

Bill name	Fair and Reliable Medical Justice Act
	<ul style="list-style-type: none"> • The judges presiding over the court would be required to serve voluntarily and have health care expertise; • The judges would have the authority to make binding decisions on causation, compensation, standard of care, and related issues. Independent expert witnesses commissioned by the court would also be permitted; • A process to appeal the judges' decisions would be established; and • The state would have the option of establishing an administrative entity to provide advice and guidance to the court.
Financing	<p>The bill would authorize the appropriation of funds necessary to carry out the Act. Once appropriated, the funds would remain available until expended.</p> <p>HHS would be authorized to use a portion of the funds appropriated for the bill, not to exceed \$500,000 per state, to provide planning grants to states for the development of demonstration project applications that meet the statutory criteria. When selecting the states to receive planning grants, HHS would give preference to states where the state law at the time of the application does not prohibit the adoption of an alternative to current tort litigation.</p>
Key implementation dates	Not applicable.
Evaluation and oversight of health system improvements	<p>States that receive demonstration grants would be required to submit a report to HHS evaluating the effectiveness of activities funded with the award funds.</p> <p>HHS would consult with the review panel established to evaluate applications and would contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of the demonstration grants awarded. The evaluation process would begin no later than 18 months after the first program funded by a demonstration grant is implemented, and would include an analysis of the effect of the grants on health care liability claims, a comparison of the claim and cost information of each state that receives a grant, and a comparison between states that received grants and states that did not receive grants. The research organization would prepare and submit annual reports to Congress.</p>
Other key elements of the bill	Not applicable.

Table A-9. Analysis of the Faircare Act

Bill name	Faircare Act
Bill number(s)	S. 1929
Bill sponsor(s)	S. 1929 is sponsored by Senator Lieberman and has two cosponsors.
Latest Congressional action	S. 1929 was referred to the Senate Committee on Finance on October 27, 2005.
Basic structure of health system improvement	<p>Requires federal agencies to collect demographic data on participants in health-related programs funded by the Department of Health and Human Services (HHS). HHS could provide grants to assist hospitals and federally qualified health centers (FQHCs) in collecting the required data.</p> <p>Requires the development of new quality measures by the Agency for Healthcare Research and Quality (AHRQ). AHRQ would develop quality measures for each of the most common treatment settings, including quality measures that are hospital-specific and outpatient facility-specific.</p> <p>Financial incentives would be provided to hospitals and FQHCs that demonstrate decreases in disparities in care among patients. In addition, AHRQ and HHS could provide grants to help these health care facilities improve the quality of care provided to populations experiencing disparities in care compared with the general population.</p> <p>Requires the Centers for Disease Control and Prevention (CDC) to expand the Racial and Ethnic Approaches to Community Health Programs (REACH 2010) to all 50 states. REACH 2010 is an initiative currently funding coalitions in 21 states to eliminate disparities in the health status of ethnic minorities in six key health areas.</p>
Description of affected entities	<p>All entities receiving federal funds for health-related programs or financial assistance (e.g., funding for health care, biomedical research, and health services research) from HHS would be required to report demographic data according to the categories and standards developed under this Act.</p> <p>Hospitals participating in the Medicare program and reporting on quality measures as part of the Medicare program would be required to report on the newly developed hospital-specific quality measures.</p> <p>FQHCs could voluntarily report the newly developed outpatient-specific quality measures.</p>
Health system improvement requirements	<p>Agencies responsible for federally supported health-related assistance or programs would collect demographic data from participating health care entities.</p> <p>Required demographic data would include the race, ethnicity, highest education level attained, and primary language of the individual who is provided services.</p> <ul style="list-style-type: none"> • Racial and ethnicity data would be collected according to the Office of Management and Budget’s (OMB’s) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. • Primary language data would be collected according to standards developed by the Office of Minority Health. <p>When practicable, data would be collected on additional subpopulations related to OMB’s racial and ethnic categories. Additionally, data would be obtained through individual self-reporting when feasible.</p> <p>Data for minors and individuals legally incapacitated would be obtained from the parent or legal guardian. In these instances, information on the preferred language of the parent or guardian also would be collected.</p> <p>In addition, AHRQ would develop a new set of quality measures for each of the most common treatment settings, including hospitals, pediatric centers, outpatient facilities, FQHCs, long-term care facilities, and other health care facilities.</p>

AHRQ's new quality measures would reflect:

- The health care priority areas determined by the Institute of Medicine (IOM), the National Quality Forum, the Quality Initiative, and other health care quality and disparity organizations;
- The IOM's goals of inclusiveness, improvability, and impact by addressing problems that: (1) produce a high level of morbidity and mortality; (2) have the potential for improvement with the application of proven medical interventions; and (3) disproportionately affect health disparity populations. Health disparity populations include groups of individuals identified by the National Center on Minority Health and Health Disparities as experiencing significant disparities in the overall rates of disease incidence and prevalence, mortality, or survival rates compared with the general population; and
- Process measures, as practical.

AHRQ would develop hospital-specific measures in conjunction with the Centers for Medicare and Medicaid Services (CMS). CMS would use these measures as part of its quality initiatives for hospitals. Hospitals would submit these new measures according to existing requirements for Medicare payment adjustments related to quality.

ARHQ would develop outpatient-specific measures in conjunction with the Bureau of Primary Health Care (BPHC) for FQHCs. These measures could be collected as a supplement to existing reports and would include quality measures for pediatric diseases. FQHCs would not be required to report on the quality measures. However, CMS could use these measures for quality improvement initiatives.

To the extent possible, hospitals and FQHCs would report these quality measures according to the demographic data categories outlined in this Act.

AHRQ would rank the quality measures according to each particular measure's potential to remedy health care disparities. Rankings would be done overall for all of the quality measures and within specific categories. The measures applicable to the following categories would be ranked together:

- Quality measures for care provided in the hospital setting;
- Quality measures for care provided in the outpatient setting;
- Quality measures for care provided to adults; and
- Quality measures for care provided to pediatric patients.

AHRQ would establish an Advisory Committee on Quality (Advisory Committee) to provide recommendations for the quality data sets to be developed.

The Advisory Committee could be an existing entity as long as it meets the specific membership requirements contained in the Act (e.g., a minimum of 10 members from select federal agencies, nongovernmental quality organizations, and other stakeholders).

Every three years, beginning with fiscal year 2006, the Advisory Committee would provide AHRQ with its recommendations for quality measures. As part of these recommendations, the Advisory Committee would indicate how best to integrate the findings of other quality or disparity organizations into the hospital- and outpatient-specific measures and how best to address issues of continuity of care between inpatient and outpatient settings.

At least once every three years, beginning in fiscal year 2009, AHRQ would update the quality measures based on recommendations from the Advisory Committee and in consultation with CMS and the Health Resources and Services Administration

Bill name	Faircare Act
	<p>(HRSA, within which is the BPHC). These updates would include the addition of quality measures for at least four conditions identified by the IOM National Roundtable on Healthcare Quality, or other quality or disparity organizations as necessary, until all of the IOM priority areas have been addressed.</p> <p>The Act also would establish an Office of National Healthcare Disparities and Quality within AHRQ. This Office would produce the annual <i>National Healthcare Disparities Report</i> and <i>National Healthcare Quality Report</i>.</p> <p>These disparity and quality reports would not identify individual hospitals or health care providers but would include regional and state-level data. To the extent possible, these reports would indicate regional and state variation in health care quality and report these data according to the demographic data categories outlined in this Act.</p> <p>In addition, the Office would annually publish a report describing the activities of Faircare Level I hospitals and FQHCs identified as having the greatest decrease in disparities in care or improvement in quality of care (described below). This report would include recommendations for implementing successful activities at other health care facilities.</p> <p>The new Office also would hold an annual conference at which individuals from Faircare Level I facilities could share information with personnel from other health care facilities.</p>
Federal incentives and penalties	<p>CMS and the BPHC would provide financial incentives to hospitals and FQHCs based on the extent to which these facilities reduced disparities in care and improved health care quality during the preceding 24 months.</p> <p>CMS would increase Medicare payments for eligible hospitals reporting the hospital-specific quality measures developed in accordance with this Act.</p> <ul style="list-style-type: none"> • Increased Medicare reimbursement would be available to inpatient hospitals but not to specialty hospitals (e.g., psychiatric or rehabilitation hospitals) or long-stay hospitals (e.g., hospitals with an average length of stay greater than 25 days). • The measures must be reported to CMS according to Medicare’s quality initiative reporting requirements and using the demographic data categories outlined in this Act. • CMS would verify the accuracy of the data provided and designate hospitals with improvements as Level I – Level III Faircare hospitals each year, during 2007 through 2015. <p>BPHC would provide bonuses to eligible FQHCs reporting the outpatient-specific quality measures developed in accordance with this Act.</p> <ul style="list-style-type: none"> • The measures could be reported to BPHC as a supplement to existing reports according to the standards established by BPHC and using the demographic data categories outlined in this Act. • BPHC would verify the accuracy of the data and designate FQHCs with improvements as Level I – Level III Faircare FQHCs each year, during 2007 through 2015. <p>Level I Faircare hospitals and FQHCs would be required to demonstrate that:</p> <ul style="list-style-type: none"> • The frequency of appropriate care has improved for the majority of applicable measures by at least 5 percentage points within each measure; or • the frequency of appropriate care provided for each applicable measure is at least 10 percentage points greater than the national average; and

Bill name	Faircare Act
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- No significant disparity exists in the treatment of health disparity populations relative to other patients for measures ranked in the top three quartiles by AHRQ.

Financial incentives provided in the year following a Level I designation would be:

- Medicare reimbursement rates increased by 2 percentage points for hospitals (hospitals serving a disproportionate share—more than 25 percent—of low-income patients could have reimbursement rates increased by 4 percentage points);
- A bonus of at least \$500,000 for FQHCs.

Level II Faircare hospitals and FQHCs would be required to demonstrate significant reductions in the disparities of care for health disparity populations relative to other patients for:

- The majority of applicable quality measures; or
- All of the applicable measures ranked in the top 25 percent, as ranked by AHRQ according to importance.

Financial incentives provided the year following a Level II designation would be:

- Medicare reimbursement rates increased by 1 percentage point for hospitals (hospitals serving a disproportionate share—(more than 25 percent—of low-income patients could have reimbursement rates increased by 2 percentage points);
- A bonus of at least \$300,000 for FQHCs.

Level III Faircare hospitals would be required to have increased the frequency of appropriate care for the majority of applicable measures by at least 5 percentage points within each measure for the last 24 months.

Financial incentives provided the year following a Level III designation would be:

- Medicare reimbursement rates increased by 0.5 percentage points for hospitals. Hospitals serving a disproportionate share (more than 25 percent) of low-income patients could have reimbursement rates increased by 1 percentage point.
- A bonus of at least \$200,000 for FQHCs.

The percentage increase in Medicare payment rates provided to Faircare hospitals would be reduced proportionately as necessary to avoid exceeding the funding appropriated for these payments. Additionally, increased payments provided under this Act would not be taken into account when computing the applicable increase in Medicare payments for future years.

The bonuses provided to Faircare FQHCs also would be reduced proportionately as necessary to avoid exceeding the funding appropriated for these payments.

Privacy and confidentiality protections

The demographic and quality measures data would be:

- Afforded the same privacy protections provided under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) related to the privacy of individually identifiable health information; and
 - Protected from inappropriate internal use by any entity, including the use of these data for determining an individual's eligibility (or continued eligibility) in a health plan.
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Bill name	Faircare Act
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Technical assistance, grants and demonstration programs

HHS would provide affected health care entities with assistance on the revised HIPAA administrative simplification regulations for the new demographic data.

HHS could provide grants for demonstration programs (50 grants to FQHCs and 50 grants to hospitals) to enhance the ability of these facilities to collect, analyze, and report the required demographic data. These grants could be used to:

- Enhance or upgrade information technology that would facilitate the collection and analysis of the required data;
- Improve methods for collecting and analyzing data on additional subpopulations related to the OMB population groups;
- Develop mechanisms for submitting data that comply with privacy and confidentiality regulations;
- Develop educational programs to inform health care entities (e.g., insurers, health plans, providers, and health-related agencies) and the general public about the need to collect these data for eliminating health and health care disparities; and
- Develop quality assurance systems to track disparities and quality improvement systems to eliminate disparities in care.

The Office of Minority Health could award research grants to study the effectiveness of the quality measures and programs, recommend ways to improve the measures and programs, and implement the findings of the IOM evaluation study of these quality measures (described below).

The newly created Office of National Healthcare Disparities and Quality would offer technical assistance to help facilities reduce health care disparities. This assistance would be disseminated through the Office's Web site, an electronic e-mail list of best practices, and the maintenance of a database and clearinghouse of best practices.

HHS would provide technical assistance to eligible hospitals conducting demonstration projects to improve health care quality and reduce disparities in care. The assistance could include competitively awarded grants and would be available to hospitals that:

- Provide patients with access to services regardless of their ability to pay;
- Provide care for a substantial number of patients who are uninsured, Medicaid patients, or members of a health disparity population; and
- Have a patient population that predominantly (at least 50 percent) comprises racial or ethnic minorities or individuals with limited English language proficiency.

The BPHC could provide technical assistance to FQHCs reporting outpatient-specific quality data. Priority would be given to FQHCs showing no improvement or showing a decrease in quality on at least 30 percent of all quality measures for three or more years.

In addition, BPHC would provide funding to expand an existing initiative to improve quality of care, the health disparity collaboratives. The funding would be expanded with the goal of adding 50 FQHCs to these collaboratives each year.

Health disparity collaboratives seek to document and improve health outcomes for patients in FQHCs. The collaboratives focus on select health areas (e.g., diabetes, cardiovascular disease, asthma, cancer, and depression). As part of this funding, areas of focus of the collaboratives could be expanded to include priority areas designated by AHRQ.

Bill name	Faircare Act
	<p>The CDC would award grants to expand the Racial and Ethnic Approaches to Community Health Programs (REACH 2010) to support coalitions in all 50 states and territories. Currently, CDC provides grants to 42 coalitions in 21 states. REACH 2010 grants could be awarded to coalitions comprising at least one community-based organization and three other organizations, one of which is either a state or local health department or a university or research organization.</p> <p>REACH 2010 grants could be used to support coalitions in designing, implementing, and evaluating community-driven strategies to eliminate health disparities, with an emphasis on African Americans, American Indians, Alaska Natives, Asian Americans, Hispanic Americans, and Pacific Islanders.</p> <p>Priority areas for the reduction of health disparities through the awarding of REACH 2010 grants would include:</p> <ul style="list-style-type: none"> • Cardiovascular disease; • Immunizations; • Breast and cervical cancer screening and management; • Diabetes; • HIV/AIDS; • Infant mortality; • Asthma; and • Obesity.
Administration and oversight of the health system improvements	<p>HHS would oversee the collection, reporting, and privacy of the required demographic data. HHS also would revise regulations related to HIPAA's administrative simplification requirements to apply to the new demographic data, including establishing new data code sets for the collection of these data.</p> <p>AHRQ would oversee the development of new quality measures. The newly created Office of National Healthcare Disparities and Quality would be responsible for annual health care quality and disparity reports and facilitating the sharing of information from Faircare Level I health care facilities with other facilities.</p> <p>HHS would oversee grants to hospitals and FQHCs to enhance the collection and use of the required demographic data. HHS also would oversee the technical assistance provided to hospitals conducting projects to improve health care quality and reduce disparities in care.</p> <p>The Office of Minority Health would oversee grants to study the effectiveness of the quality measures and programs.</p> <p>CMS would oversee the financial incentives provided to Faircare hospitals, and BPHC would oversee the bonuses and technical assistance provided to Faircare FQHCs.</p> <p>BPHC would oversee grants for the expansion of health disparity collaboratives.</p> <p>CDC would oversee grants to coalitions to expand the REACH 2010 program and reduce disparities in care for select health areas.</p>
Financing	<p>The Act would authorize the appropriation of funds to the following entities in the following amounts:</p> <ul style="list-style-type: none"> • For HHS activities related to the collection and reporting of required demographic data, \$50 million for fiscal year 2006, and funds as needed in each year 2007 through 2016; • For AHRQ to develop the quality measures, \$5 million for each of fiscal years 2006 through 2008, and funds as needed in each year 2009 through 2016;

Bill name	Faircare Act
	<ul style="list-style-type: none"> • For establishment and operation of the Office of National Healthcare Disparities and Quality, \$10 million for each of fiscal years 2006 through 2008, and funds as needed each year 2009 through 2016; • For the Office of National Healthcare Disparities and Quality to provide health care facilities with technical assistance, \$5 million for each of fiscal years 2006 through 2008, and funds as needed in each year 2009 through 2016; and • For CDC to provide the REACH 2010 grants, \$200 million for each of fiscal years 2006 through 2008, and funds as needed each year 2009 through 2016. <p>The Act also would authorize the appropriation of funds necessary for:</p> <ul style="list-style-type: none"> • HHS to modify HIPAA’s administrative simplicity requirements relating to the collection and reporting of the demographic data and to provide technical assistance to affected health care entities; • CMS to provide increased Medicare payments to Faircare hospitals in each of fiscal years 2008 through 2016; • BPHC to provide bonuses to Faircare FQHCs in each of fiscal years 2007 through 2016; • HHS to provide technical assistance to eligible hospitals for improving quality or reducing disparities of care in each of fiscal years 2006 through 2016; • BPHC to provide technical assistance to eligible FQHCs for improving quality or reducing disparities of care in each of fiscal years 2008 through 2016; and • BPHC to provide technical assistance to Health Disparity Collaboratives in each of fiscal years 2006 through 2016.
Key implementation dates	<p>The director of the Office of Minority Health, in consultation with the Office for Civil Rights of HHS, would develop standards for classifying the federal data on preferred written and spoken language within one year of the Act’s implementation.</p> <p>Within one year of the Act’s implementation, HHS would revise its regulations related to the HIPAA administrative simplification requirements to include provisions for the collecting and reporting of demographic data.</p> <p>Within two years of the Act’s implementation, demographic data would be collected from health care entities providing services to Medicare beneficiaries, including as part of data collected for:</p> <ul style="list-style-type: none"> • The Medicare Hospital Quality Initiative; • The CMS Abstraction or Reporting Tools (CART); • All CART-equivalent private databases used to submit data for the Medicare Hospital Quality Initiative or Medicare billing; and • All Medicare billing communications. <p>Within four years of the Act’s implementation, the demographic data would be collected from entities providing services to Medicaid and State Children’s Health Insurance Program enrollees.</p> <p>Demographic data would be collected from entities conducting federally funded biomedical and health services research or receiving federal funds for programs not otherwise specified within six years of the Act’s implementation.</p> <p>Within a year of the Act’s implementation, the Office of National Healthcare Disparities and Quality within AHRQ would release a report on the disparities in health care using the new quality measures.</p> <p>Within a year of the Act’s implementation, BPHC would determine the outpatient-specific data requirements and criteria for bonuses for FQHCs.</p>

Bill name	Faircare Act
Evaluation of health system improvements	Within five years of the Act's implementation, IOM would be required to report on the effectiveness of the quality measures developed by AHRQ to accurately assess the quality of health care and disparities present in hospitals, community FQHCs, and other health care settings.
Other key elements of the bill	The collection and reporting of the demographic data and quality measures would be prohibited from adversely affecting the services provided to individuals reporting this information. For example, individuals who refuse to provide demographic data cannot be denied assistance.

NOTES

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⁴ S. C. Schoenbaum, A. J. Audet, and K. Davis, “[Obtaining Greater Value from Health Care: The Roles of the U.S. Government](#),” *Health Affairs*, Nov./Dec. 2003 22(6):183–90.

⁵ G. F. Anderson, U. E. Reinhardt, P. Hussey et al., “It’s the Prices, Stupid: Why the United States Is So Different from Other Countries,” *Health Affairs*, May/June 2003 22(3):89–105. They note that the supplies of doctors, nurses, and hospital beds are not greater in the United States than in other countries nor are basic use rates. In fact, U.S. patients are admitted to the hospital less frequently and typically have shorter stays for each diagnosis than their counterparts in other countries, resulting in U.S. hospital days per capita that are well below the OECD median. U.S. average doctors’ visits per year are similar to other countries overall. U.S. patients, however, use more specialized physicians and receive more intensive specialized services (e.g., MRIs, CT scans, and coronary angioplasties) than patients in other countries.

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⁹ D. Marron, Letter to Hon. John D. Dingell, January 10, 2007, available at <http://www.cbo.gov/ftpdocs/77xx/doc7722/hr4.pdf> (accessed Feb. 26, 2007).

¹⁰ Collins, Davis, and Kriss, *Congressional Health Care Bills, 2007*. Estimates are for 2007 by Lewin Group using the Health Benefits Simulation Model (HBSM). See [Table A-1](#) for more details on the Medicare for All and AmeriCare Health Acts.

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¹² I. B. Wilson, C. Schoen, P. Neuman et al., “[Physician–Patient Communication About Prescription Medication Nonadherence: A 50-State Study of America’s Seniors](#),” *Journal of General Internal Medicine*, Jan. 2007 22(1):6–12; D. G. Safran, T. Neuman, C. Schoen et al., “[Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey](#),” *Health Affairs* Web Exclusive (Apr. 19, 2005):w5-152–w5-166.

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