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Regulatory Reform Provisions of S. 1, as Passed by the Senate, and H.R. 1, as Passed by the House

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Summary

On June 27, 2003, the Senate passed the Prescription Drug and Medicare Improvement Act of 2003 by a vote of 76-21. Later that same evening, the House passed the Medicare modernization and Prescription Drug Act of 2003 by a recorded vote of 216-215 with one voting present.

Each of the bills contain numerous provisions regarding the Medicare prescription drug benefit, the new MedicareAdvantage program, Medicare payment and benefit changes, Medicare program administration, and regulatory reform, appeals and contracting reform. This report provides a detailed side-by-side comparison of the regulatory reform, appeals, and contracting reform provisions of both S. 1 and H.R. 1.

Title V of S. 1 and Title IX of H.R. 1 would modify how Medicare regulations and guidance are communicated; would modify the procedures used to resolve payment disputes; and would establish various provider appeal processes, particularly for those who face termination of Medicare participation or denial of their application to participate in the program. As well as attempting to minimize Medicare's administrative burden, the bills address appeals issues; change Medicare's authority to contract for claims processing services; establish that these contracts be competitively bid at least every 5 years in H.R. 1 and every 6 years in S. 1; and place new requirements on the Medicare claims processing contractors, including an increased emphasis on provider education. Other program changes, demonstration projects, and mandated studies are also included in these titles. Many of the provisions of these titles codify initiatives underway within the Centers for Medicare and Medicaid Services (CMS), the agency that administers Medicare, under its current authority. The proposed legislation authorizes increased funding but action by the appropriations committees would be required for CMS to receive additional money.

The Congressional Budget Office (CBO) has estimated that the added administrative costs to the government in implementing the regulatory reform provisions of S. 1 and H.R. 1 would be $4 billion over the FY2004 through FY2013 period. However, these are administrative costs that are subject to the appropriations process rather than mandatory benefit spending. As a result, the appropriations committees have discretion to determine the actual level at which any of the new requirements would actually be funded. CBO also estimates that mandatory benefit spending would be increased in S. 1 by almost $1 billion over the FY2004 through FY2013 period (due to the change in procedures for appealing local coverage determinations and the inclusion of additional funding in the mandatory Medicare Integrity Program funding for provider education). Those provisions are not in H.R. 1 and CBO estimated that there was no increase in direct funding in that bill.

This report will be updated as events warrant.

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Regulatory Reform Provisions of S. 1, as Passed by the Senate, and H.R. 1, as Passed by the House

Introduction

Overview

For some time, observers have expressed concern over the way in which Medicare has been administered. Some believe that the Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration or HCFA) has not been provided with sufficient resources, both staff and funding, or management flexibility to enable it to carry out its ever increasing responsibilities. Others believe that organizational shortcomings are exacerbated by a bureaucratic approach emphasizing regulatory controls that adversely affect program administration. The General Accounting Office (GAO) describes the agency as a lightning rod attracting the criticism from those discontented with program policies because of the number and diverse interests of its stakeholders (which run the gamut from providers, including general and specialty physicians; hospitals; practitioners; and medical suppliers, to beneficiaries and taxpayers), its responsibility to ensure fiscal prudence, Medicare's market dominance, and its very nature as a public program. Moreover, Medicare, because of its sheer size and fragmented, decentralized operations, is seen as highly vulnerable to fraud, waste, and abuse.[1]

One of the central issues driving the debate over the effectiveness of Medicare's administration is the perception that the enforcement of Medicare's payment rules imposes too great a burden on health care providers and confuses Medicare beneficiaries. Essentially, complaints about unreasonable demands for claims documentation, contradictory billing instructions, excessive paperwork, and the sense that providers and physicians are being unfairly investigated, if not prosecuted, over purportedly innocent billing errors have prompted efforts to provide regulatory relief.

Title V of S. 1 and Title IX H.R. 1 would modify how Medicare regulations and guidance are communicated; would modify the procedures used to resolve payment disputes; and would establish various provider appeal processes, particularly for those who face termination of Medicare participation or denial of their application to participate in the program. As well as attempting to minimize Medicare's administrative burden, the bill would address appeals issues and would provide for

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[1] U.S. General Accounting Office, *Medicare: Successful Reform Requires Meeting Key Management Challenges*, GAO-01-1006, July 25, 2001 and *Regulatory Issues for Medicare Providers*, GAO-01-802R, June 11, 2001 for additional information.

more competition in the way Medicare claims processing contractors are chosen. Many of the provisions of the bill codify initiatives underway within the Centers for Medicare and Medicaid Services (CMS), the agency that administers Medicare, under its current authority.

The regulatory reform titles in these bills came from S. 3018 introduced at the close of the 107th Congress and H.R. 810 which was reported out of the House Committee on Ways and Means and the Committee on Energy and Commerce. The provisions of both those bills comprise Title V in S. 1 and Title IX of H.R. 1. A number of bills were developed in the 107th Congress. The precursor of all the legislation was the Medicare Education and Regulatory Fairness Act (MERFA or H.R. 868). MERFA was criticized by the Office of the Inspector General (OIG) in HHS as potentially encouraging fraud, in part, because it would have granted physicians immunity if they voluntarily returned overpayments when potentially facing investigation. That provision was dropped in later legislation that passed the House December 4, 2001, the Medicare Regulatory and Contracting Reform Act of 2001(H.R. 3391), which also incorporated changes suggested by the OIG, GAO and the Department of Justice to ensure that the government's ability to address Medicare fraud, waste, and abuse would not be significantly weakened. Selected provisions of H.R. 3391 were also incorporated into the Medicare Modernization and Prescription Drug Act of 2002 (H.R. 4954) which passed the House on June 28, 2002. Similar legislation was introduced in the Senate: S. 452, the Medicare Education and Regulatory Fairness Act of 2001 which was very similar to the original House bill; S. 1738, the Medicare Appeals, Regulatory, and Contracting Improvement Act of 2001 which incorporated similar concerns regarding the government's ability to address Medicare program integrity issues; and S. 3018, the Beneficiary Access to Care and Medicare Equity Act of 2002 which contained selected provisions from S. 1738. None of these bills came to a vote by the Senate. H.R. 810 was introduced during the beginning of the 108th Congress and was based on H.R. 4954. The House Energy and Commerce Committee and the House Ways and Means Committee reported out slightly different versions of Medicare regulatory relief legislation on March 26, 2003 and on April 11, 2003, respectively.

A major feature of both S. 1 and H.R. 1 (and one ardently supported by the Secretary of HHS) is contracting reform. The contracting reform provisions would change Medicare's authority to contract for claims processing services, another central issue seen to complicate effective program administration. Presently there are statutory limits on which entities may process Medicare claims. Generally, fiscal intermediaries process claims from institutional providers and carriers process Part B claims, including those submitted by physicians, durable medical equipment suppliers, laboratories and other practitioners. The Medicare statute's provider nomination provision allows professional associations of hospitals and certain other providers to choose claims processing intermediaries on behalf of their members; the statute requires that CMS choose only health insurance companies as carriers. Medicare regulations coupled with long-standing agency practices have limited the way that contracts for claims administration services can be established. For example, the contracts are cost-based and lack incentives for quality performance. Both bills would generally allow for greater flexibility in contracting for Medicare claims processing functions by permitting the Secretary to enter into contracts with

any qualified entity for any or all functions of a Medicare claims processing contractor.[2]

The Congressional Budget Office (CBO) has estimated that the added administrative costs to the government in implementing the regulatory reform provisions of S. 1 and H.R. 1 would be $4 billion over the FY2004 through FY2013 period. However, these are administrative costs that are subject to the appropriations process rather than mandatory benefit spending. As a result, the appropriations committees have discretion to determine the actual level at which any of the new requirements would actually be funded. CBO also estimates that mandatory benefit spending would be increased in S. 1 by almost $1 billion over the FY2004 through FY2013 period (due to the change in procedures for appealing local coverage determinations and the inclusion of additional funding in the mandatory Medicare Integrity Program funding for provider education). Those provisions are not in H.R. 1 and CBO estimated that there was no increase in direct funding in that bill.

This report provides a detailed side-by-side comparison of the regulatory reform, appeals, education, and contracting reform provisions of both bills. It will be updated as events warrant.

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[2] For additional information, see U.S. General Accounting Office, *Medicare Contracting Reform: Opportunities and Challenges in Contracting for Claims Administration Services*, GAO-01-918, June 28, 2001 and *Medicare: Comments on HHS' Claims Administration Contracting Reform Proposal*, GAO-01-1046, Aug. 17, 2001. OIG testimony on the need for contractor reform can be found at [http://oig.hhs.gov/testimony/2001/062801mm.pdf].

Side-by-Side Comparison of S. 1 and H.R. 1 Regulatory Reform Provisions

Subtitle A. Regulatory Reform

Provisions	Current Law	S. 1	H.R. 1
Construction; definition of supplier	Section 1861 of the Social Security Act contains definitions of services, institutions, and so forth under Medicare. Supplier is not explicitly defined.	No provision.	**Section 901.** Would clarify that "supplier" means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare.
Publication of a final regulation based on the previous publication of an interim final regulation	The Secretary is required to prescribe regulations that are necessary to administer the Medicare program. The Secretary must publish proposed regulations in the *Federal Register*, with at least 30 days to solicit public comment before issuing the final regulation except in the following circumstances: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementing a provision is less than 150 days after the date of enactment of the statute containing the provision; (3) under the good cause exception contained in the rule-making provision of Title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary or contrary to the public interest.	**Section 501.** The Secretary would be required to publish a final regulation within 12 months of the publication of the interim final regulation or the interim final regulation would no longer be effective. Subject to appropriate notice, the Secretary could extend this deadline for up to 12 additional months. Within 6 months of enactment, the Secretary would be required to publish a notice in the *Federal Register* that provides the status of each interim final regulation published before enactment for which no final regulation has been issued as well as the date by which the Secretary plans to publish the final regulation.	**Section 902.** Would require the Secretary to establish and publish a timeline for the publication of final regulations based on the publication of a proposed or interim final regulation. The timeline for publishing the final regulation would be allowed to vary but could not exceed 3 years except for exceptional circumstances. Any variation of the timeline would have to be explained by the Secretary in the *Federal Register*. Has similar requirement to S. 1 regarding publishing a final regulation after an interim final regulation. Also would require that the Secretary report to Congress annually describing instances in which a final regulation was not published within the applicable regular time line and the reasons the time frame was not met. Any provision in a final regulation that was not a logical outgrowth of a previously published notice of proposed rule making or interim final rule would be required to be treated as a proposed regulation and would

Provisions	Current Law	S. 1	H.R. 1
			not take effect until there is opportunity for public comment and the provision is published again as a final rule.
Compliance with changes in regulations and policies	No explicit statutory instruction. As a result of case law, there is a strong presumption against retroactive rulemaking. In *Bowen v. Georgetown University Hospital*, the Supreme Court ruled that there must be explicit statutory authority to engage in retroactive rulemaking.	**Section 502.** Would bar retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest. Any substantive changes would not be able to take effect until 30 days after the issuance of the substantive change unless needed to comply with statutory requirements or the 30-day period is contrary to the public interest.	**Section 903.** Same provisions.
Report on legal and regulatory inconsistencies	No provision.	**Section 503.** The Secretary would be required to report to Congress every 2 years on the administration of Title XVIII and areas of inconsistency or conflict among various provisions under law and regulation and recommendations for legislation or administrative action that the Secretary determined appropriate to further reduce such inconsistency or conflicts.	**Section 904.** Same provision but additionally would require the Comptroller General to determine the feasibility and appropriateness of giving the Secretary the authority to provide legally binding advisory opinions on interpretation and application of Medicare regulations.
Streamlining and simplification of Medicare regulations	No provision.	**Section 504.** The Secretary would be required to analyze Medicare regulations for the purposes of determining how to streamline the regulations and reduce the number of words in the regulations by two-thirds by October 1, 2004. If the Secretary determines that the two-thirds reduction is infeasible, he would be required to inform Congress in writing by July 1, 2004 of the reasons and then establish a feasible reduction to be achieved by January 1, 2005.	No provision.

Subtitle B. Appeals Process Reform

Provisions	Current Law	S. 1	H.R. 1
Transfer of responsibility for Medicare appeals	Denials of claims for Medicare payment may be appealed by beneficiaries (or providers who are representing the beneficiary) or in certain circumstances, providers or suppliers directly. The third level of appeal is to an administrative law judge (ALJ). The ALJs that hear Medicare cases are employed by the Social Security Administration — a legacy from the inception of the Medicare program when Medicare was part of Social Security.	**Section 511.** The Secretary and Commissioner of Social Security would be required to develop and transmit to Congress a plan for transferring the functions of administrative law judges (ALJs) responsible for hearing cases under Title XVIII from the Social Security Administration to HHS no later than April 1, 2004. The plan would include information on: workload, cost projections and financing, transition timetable, regulations, development of a case tracking system, feasibility of precedential authority, feasibility of electronic appeals filings and teleconference, steps needed to ensure the independence of ALJs (including ensuring the ALJs are in an office functionally and operationally separate from the Centers for Medicare & Medicaid Services and the Center for Medicare Choices), geographic distribution of ALJs, hiring of ALJs, performance standards of ALJs, sharing resources with Social Security regarding ALJs, training and recommendations for further Congressional action. The GAO would be required to evaluate the Secretary's and Commissioner's plan. Further, the Secretary and Commissioner could not implement the plan to transfer the ALJ function until at least 6 months after the GAO report	**Section 931.** Similar provision regarding plan submission, but also would transfer the ALJ function from SSA to HHS within a prescribed timeframe. The Commissioner of SSA and the Secretary would be required to develop a plan to transfer the functions of the ALJs who are responsible for hearing Medicare cases from SSA to HHS. This plan would be due to Congress not later than October 1, 2004. A GAO evaluation of the plan would be due within 6 months of the plan's submission. ALJ functions would be transferred no earlier than July 1, 2005 and no later than October 1, 2005. The Secretary would be required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services. Would further require that the ALJs report to, and be supervised by, the Secretary or Deputy Secretary and no other official within the Department. Would authorize to be appropriated such sums as are necessary for FY2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs and to increase the staff of the Departmental Appeals Board (the final level of appeal).

Provisions	Current Law	S. 1	H.R. 1
Expedited access to judicial review	In general, administrative appeals must be exhausted prior to judicial review.	**Section 512.** The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain access to judicial review when a review entity (of up to three qualified reviewers drawn from appeals levels other than the redetermination level) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and would be awarded by the reviewing court in favor of the prevailing party. This expedited access to judicial review would be permitted for cases where the Secretary did not enter into or renew provider agreements. GAO would be required to report to Congress on the access of Medicare beneficiaries and health care providers to judicial review of actions of the Secretary and HHS after February 29, 2000 (the date of the decision of *Shalala v. Illinois Council on Long Term Care, Inc.* (529 U.S. 1 (2000)).	**Section 932.** Same provision except review entity would be defined as a 3-member panel consisting of ALJs, members of the Departmental Appeals Board (DAB), or qualified individuals associated with a qualified independent contractor. No provision regarding Illinois Council case.
Expedited review of certain provider agreement determinations	No provision.	**Section 513.** The Secretary would be required to develop and implement a process to expedite review for certain remedies imposed against skilled nursing facilities (SNFs) including termination of participation, immediate denial of payments, immediate imposition of temporary management, and suspension of nurse aide training programs.	**Section 932(d).** Substantially similar provision although drafted differently; however, this provision would not include suspension of nurse aide training programs.

Provisions	Current Law	S. 1	H.R. 1
		The appropriation of such sums as needed for FY2005 and subsequent years to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues would be authorized.	
Process for reinstatement of approval of nurse aide training programs	The statute prohibits approval of nurse aide training programs in skilled nursing facilities that have been subject to extended survey (that is, found to provide substandard care), have had serious sanctions imposed such as large civil money penalties, or have waivers for required licensed nurse staffing. The statute mandates a 2-year loss of nurse aide training program in the case of any of the above violations.	No provision.	**Section 932(e).** The Secretary would be required to develop a process for reinstating approval of nurse aide training programs that have been terminated (before the end of the mandatory 2-year disapproval period) if the facility has come into compliance with the applicable requirements. This provision would apply only if the basis for the loss of training was the assessment of a civil money penalty of $5,000 or more.
Revisions to Medicare appeals process: *— completing the record*		**Section 514(a).** A 90-day timeframe for completing the record in a hearing before an ALJ or the DAB (with extensions for good cause) would be established.	No provision.

Provisions	Current Law	S. 1	H.R. 1
— use of medical records		**Section 514(b).** Beneficiaries' medical records would be able to be used in qualified independent contractors (QIC) reconsiderations.	**Section 933(b).** Same provision.
— notice requirements for Medicare appeals		**Section 514(c).** Notice of and decisions from determinations, redeterminations, reconsiderations, ALJ appeals, and DAB appeals would be required to be written in a manner understandable to a beneficiary and that includes, as appropriate, reasons for the determination or decision, for a redetermination an explanation of the medical or scientific rationale for the decision, and the process for further appeal.	**Section 933(c).** Substantially the same provision, with minor differences in process and requirements, although there are drafting differences.
— eligibility requirements of QICs		**Section 514(d).** Eligibility requirements would be clarified for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, prohibition on compensation being linked to decisions rendered. Peer review organizations would be explicitly permitted to be QICs. Would reduce the required number of QICs from 12 to four.	**Section 933(d).** Substantially the same provision, although there are drafting differences. The provision would not change the eligibility requirements of QICs to explicitly permit peer review organizations to serve.
— implementation of certain Benefits Improvement and Protection Act of 2000 (BIPA) reforms		**Section 514(e).** The effective date of certain appeals provisions would be delayed until December 1, 2004. Expedited determinations would be delayed until October 1, 2003. Peer review organizations (now called quality improvement organizations by the Secretary) would, on a transitional basis, conduct expedited determinations until the QICs are operational.	No provision.
— requiring full and early presentation of evidence	New evidence can be presented at any stage of the appeals process.	No provision.	**Section 933(a).** A provider or supplier would be prohibited from presenting any evidence in appeals that was not presented at the qualified independent contractor level, unless there was good cause for not presenting the evidence.

Provisions	Current Law	S. 1	H.R. 1
— effective dates		**Section 514(g).** Section 514 provisions are effective as if enacted in BIPA.	**Section 933(d)(4).** QIC eligibility requirements and reviewer eligibility requirements would be effective as if enacted in BIPA
Hearing rights related to decisions by the Secretary to deny or not renew a Medicare enrollment agreement; consultation before changing provider enrollment agreement	Under administrative authorities, CMS has established provider enrollment processes in instructions to the contractors. A provider denied a provider agreement is entitled to a hearing by the Secretary.	**Section 515.** The Secretary would be required to develop a timeline for action on Medicare enrollment applications and a process for providers to appeal denials or non-renewals of enrollment applications. The Secretary would be required to consult with providers and suppliers before changing the provider enrollment forms.	**Section 936.** Same provision, although there are drafting differences.
Appeals by providers when there is no other party available	No provision.	**Section 516.** Would require the Secretary to permit a provider or supplier to appeal in the case where a beneficiary dies before assigning appeal rights.	No provision.
Provider access to review of local coverage determinations	Only beneficiaries have standing to appeal local coverage decisions by Medicare contractors.	**Section 517.** The parties that have standing to appeal local coverage decisions would be expanded to include providers or suppliers adversely affected by the determination. The Secretary would be required to establish a process whereby a provider or supplier may request a local coverage determination under certain circumstances. The provision would authorize to be appropriated such sums as necessary to carry out the provisions above. Also the Secretary would be required to study and report to Congress on the feasibility and advisability of requiring Medicare contractors to track the subject and status of claims denials that are appealed and final determinations.	No provision.

Provisions	Current Law	S. 1	H.R. 1
Revisions to appeals time frames	BIPA revised the time frames for Medicare appeals. For the first level of appeal, the "redetermination" level, the time frame for decisions was reduced from 90 days for a part A appeal and 45 days for a part B appeal to 30 days; for the second level, the "reconsideration" level, the time frame was reduced from 120 days for a part B appeal to 30 days (this is a new level of appeal for part A appeals); for the third level, appeals before administrative law judges, the time frame was reduced from no time limit to 90 days; and the fourth level, appeals before the Department Appeals Board, the time frame was reduced from no time limit to 90 days. BIPA also provided that a beneficiary could "escalate" his or her appeal to the next level if the appeal was not decided in a timely fashion.	**Section 518.** This provision would add 30 days to the time frame for deciding an appeal at each of the four levels of appeal.	No provision.
Elimination of requirement to use Social Security Administration administrative law judges	BIPA Section 522 requires that appeals of local coverage determinations be heard by ALJs of the Social Security Administration (SSA). As a result, if the ALJ function were moved from SSA to HHS, these local coverage determination appeals would still need to be heard by SSA ALJs.	**Section 519.** The statutory language that requires SSA ALJs be used to hear appeals of local coverage determinations would be eliminated. The requirement that these appeals be heard by ALJs would be retained.	No provision.
Elimination of requirement for de novo review by the Departmental Appeals Board	BIPA Section 521 requires that the Departmental Appeals Board, the fourth level of appeal, review appeals cases *de novo*. Prior to BIPA, the DAB reviewed appeals based on the record established during the previous three levels of appeal.	**Section 520.** The DAB would be required to conduct a review of the decision and make a decision or remand the appeal to the ALJ within the 90-day period.	No provision.

Subtitle C. Contracting Reform

Provisions	Current Law	S. 1	H.R. 1
Increased flexibility in Medicare administration	The Secretary is required to contract with health insurance companies to process and pay Medicare Part B claims and may accept the nomination of hospitals for entities to process and pay their Medicare claims.	**Section 521.** Adds Section 1874A to the Social Security Act permitting the Secretary to competitively contract with any eligible entity to serve as a Medicare contractor (called "Medicare Administrative Contractors" (MACs)) and eliminates the distinction between Part A contractors and Part B contractors. The Secretary may renew these contracts annually for up to 6 years. All contracts must be recompeted at least every 6 years. Federal Acquisition Regulations (FAR) would apply to these contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. Competitive bidding for the MACs must begin for annual contract periods that begin on or after October 1, 2011.	**Section 911.** Same provisions, except contracts must be recompeted at least once every 5 years. Competitive bidding for the MACs must begin for annual contract periods that begin on or after October 1, 2010.
	Certain terms and conditions of the contracting agreements for fiscal intermediaries (FIs) and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established. The certifying and disbursing officers of contractors and the contractors, as entities, are protected from liability for payments, except in the case of gross negligence or intent to defraud the United States.	Liability of certifying and disbursing officers and the Medicare Administrative Contractors would be limited except in cases of reckless disregard or the intent to defraud the United States. This limitation on liability does not limit liability under the False Claims Act. Circumstances where contractors and their employees would be indemnified would be established, both in the contract and as the Secretary determines appropriate.	
Information security requirements for Medicare administrative contractors.	No provision.	No provision.	**Section 912.** Medicare contractors would be required to implement an information security program that meets the same requirements as those imposed on federal agencies.

Subtitle D. Education and Outreach

Provisions	Current Law	S. 1	H.R. 1
Provider education and technical assistance *— coordination of education funding*	Medicare's provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). The statute requires toll-free lines that beneficiaries can call with questions or to report suspicious bills. Under administrative authority, CMS requires the contractors to have internet sites and to respond to written inquiries.	**Section 531(a)**. The Secretary would be required to coordinate the educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers.	**Section 921 (a)**. Same provision except it also would require the Secretary to submit a report to Congress by October 1, 2004 describing and evaluating the steps taken to coordinate the funding of provider education.
— incentives to improve contractor performance		**Section 531(b)**. The Secretary would be required to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers. The GAO would study the adequacy of the methodology and make recommendations to the Secretary. The Secretary would be required to report to the Congress on how he intends to use the methodology in improving education and outreach and whether the methodology is a basis for performance bonuses.	**Section 921(b).** Same provision.
improved provider education and training		**Section 531(c).** Increased funding would be provided for the Medicare Integrity Program of $35 million beginning with FY2004 for increased provider and supplier education. Also would require Medicare contractors to take into consideration the special needs of small providers or suppliers when conducting education and training activities and permits provision of technical assistance.	**Section 921(d).** Would authorize to be appropriated $25 million for fiscal years 2005 and 2006 and such sums as necessary for succeeding fiscal years to increase education and training of providers and suppliers. Funds would also be able to be used to improve the accuracy, consistency, and timeliness of contractor responses. Medicare contractors would be required to tailor education and training activities to meet the needs of small providers or suppliers.

Provisions	Current Law	S. 1	H.R. 1
additional provider education provisions		**Section 531(d).** Medicare contractors would be prohibited from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review.	**Section 921(f).** Same provision.
Access to and prompt responses from Medicare contractors	No specific statutory provision. The Medicare statute generally requires that the Medicare contractors communicate information about Medicare administration.	**Section 532.** The Secretary would be required to develop a process for Medicare contractors to communicate with beneficiaries and with providers and suppliers. Also requires a clear, concise written response to inquiries within 45 business days. The Secretary would ensure that Medicare contractors provide a toll-free number where beneficiaries, providers and suppliers can obtain billing, coding, claims, coverage and other information. The Medicare contractors would be required to maintain a system for identifying the staff person who provided information and monitoring the accuracy, consistency and timeliness of information provided. The Secretary would establish standards regarding accuracy, consistency, and timeliness and would evaluate the Medicare contractors on these standards. Would authorize to be appropriated such sums as necessary.	**Section 921(c)**. Same provision.
Reliance on guidance	As a general principle of law, that has been sustained by the Supreme Court, a Federal government agent cannot undo Federal government statutory or regulatory law.	**Section 533.** If a provider or supplier follows written guidance provided by the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance was inaccurate, the provider or supplier would not be required to repay the overpayment (unless the inaccurate information was due to a clerical or technical operational error).	**Section 903(c).** Same provision.

Provisions	Current Law	S. 1	H.R. 1
Medicare provider ombudsman	No provision.	**Section 534.** The Secretary would be directed to create a Medicare Provider Ombudsman within the Department of Health and Human Services and to provide staff to the Ombudsman. The Ombudsman would provide assistance to providers on a confidential basis. Authorizes such sums as necessary be appropriated for FY2004 and subsequent years.	**Section 923.** Substantially similar provision, although would not require staff to be provided. Also would establish a Beneficiary Ombudsman to provide confidential assistance to Medicare beneficiaries. Section 1 would establish a Beneficiary Ombudsman in **Section 301**.
Beneficiary outreach demonstration program	No explicit statutory instruction for demonstration. Assistance is currently available to beneficiaries through 1-800-Medicare and through the State Health Insurance Counseling Programs which are mandated by the statute.	**Section 535.** The Secretary would be required to establish a demonstration program where Medicare specialists provided assistance to beneficiaries in at least six local Social Security offices (two of which would be located in rural areas).	**Section 924.** Same provision.
Prior determination of coverage	Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for noncovered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.	**Section 535 (b).** A demonstration project would be established by the Secretary to test the administrative feasibility of providing a process for beneficiaries and providers to request and receive a determination as to whether the item or service is covered under Medicare by reasons of medical necessity, before the item or service involved is furnished to the beneficiary.	**Section 938.** The Secretary would be required to establish a process where physicians and beneficiaries can establish if Medicare covers certain items and services before the services are provided. A GAO report would be required within 18 months of program implementation.

Provisions	Current Law	S. 1	H.R. 1
Small provider technical assistance demonstration program	No provision.	No provision.	**Section 922.** A demonstration program would be established for the contractors to provide technical assistance to small providers and suppliers, when requested, to improve compliance with Medicare requirements. If errors were found, the contractors would be barred from recovering any overpayments if certain requirements are met and barring evidence of fraud. A GAO study would be required not later than 2 years after the demonstration program begins. Would authorize $1 million in FY2005 and $6 million in FY2006 to conduct the demonstration.

Subtitle E. Review, Recovery, and Enforcement Review

Provisions	Current Law	S. 1	H.R. 1
Prepayment review	No explicit statutory instruction. Under administrative authorities, CMS has instructed the contractors to use random prepayment reviews to develop contractor-wide and program-wide error rates. Non-random payment reviews are permitted in certain circumstances laid out in instructions to the contractors.	**Section 541.** The conduct of random prepayment review would be limited to only those done in accordance with standard protocol developed by the Secretary. Non-random reviews would be prohibited unless there is a likelihood of sustained or high level of payment error (as defined by the Secretary) and would require the Secretary to establish protocols for terminating the non-random reviews.	**Section 934.** The use of random prepayment reviews by Medicare contractors would be limited to only developing a contractor-wide or program-wide error rate or under such additional circumstances provided under regulation and in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews would be permitted only under certain circumstances.
Recovery of overpayments — extended repayment plans	No explicit statutory instruction. Under administrative authorities, CMS negotiates extended repayment plans with providers that need additional time to repay Medicare overpayments.	**Section 542.** Would add new subsection to 1874A that: **(h)(1)** Would require establishment of at least a 1-year repayment plan — but not longer than 3 years — when a provider requests a repayment plan, unless the Secretary believes the provider may declare bankruptcy. If a provider or supplier fails to make a scheduled payment, the Secretary may immediately offset or recover the outstanding	**Section 935.** Would add new subsection to 1893 that: **(f)(1)** Similar provision. Would require that, in cases of hardship, extended repayment plans be given ranging from 6 months and up to 5 years. In cases of extreme hardship, 6-year repayment plans would be permitted. If the provider or supplier had previous repayment plans, those

Provisions	Current Law	S. 1	H.R. 1
		balance. The Secretary would be required to develop standards for the recovery of overpayments.	could not to be considered in determining hardship.
— limitation on recoupment		**(h)(2)** The Secretary would be prohibited from recouping any overpayments until a reconsideration-level appeal is decided (if one was requested). Interest would be paid to the provider if the appeal is successful (beginning from the time the overpayment is recouped) or that interest shall be paid to the Secretary if the appeal is unsuccessful (and if the overpayment is not paid to the Secretary).	**(f)(2)** Similar provision. Would provide for redetermination by a Medicare contractor in the event that qualified independent contractors have not been established.
— payment audits		**(h)(3)** If post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.	**(f)(7)** Similar provision. Also would require the Medicare contractor to consider the information provided by the provider or supplier.
— notice of over-utilization of codes		**(h)(4)** The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes are over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.	**(f)(6)** Same provision.

Provisions	Current Law	S. 1	H.R. 1
— standard methodology for probe sampling		**(h)(5)** The Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.	**(f)(8)** Same provision.
— consent settlement reforms		**(h)(6)** Would permit the Secretary to use a consent settlement process to settle projected overpayments under certain specified conditions.	**(f)(5)** Substantially similar provision (minor differences).
— extrapolation		No provision.	**(f)(3)** The use of extrapolation would be limited unless there was a high level of payment error or documented educational intervention had failed to correct the payment error.
Process for correction of minor errors and omissions	No explicit statutory instruction. Administratively, the Medicare contractors send a claims denial when a claim has been submitted lacking required information. Amendments to cost reports are not allowed once a cost report is settled.	**Section 543.** The Secretary would be required to establish a process so providers and suppliers can correct minor errors in claims that have been submitted for payment.	**Section 937.** Same provision relating to correcting minor errors. Contains additional provision that would require the Secretary to permit hospitals to correct wage data errors that affect geographic reclassification even if the cost report has been settled. For FY2004 alone, the resubmittal of the application for geographic reclassification would be permitted.
Authority to waive program exclusion	The Secretary has the authority to waive exclusion from participation in any federal health program when the provider is the sole source of care in a community, at the request of a state.	**Section 544.** The Secretary would be permitted to waive a program exclusion at the request of an administrator of a federal health care program (which includes state health care programs).	**Section 949.** Same provision.

Subtitle F. Other Improvements

Provisions	Current Law	S. 1	H.R. 1
Inclusion of additional information in notices to beneficiaries about skilled nursing facility (SNF) and hospital benefits	Although the statute requires that beneficiaries receive a statement listing the items and services for which payment has been made, there is no explicit statutory instruction that requires the notice to include information about the number of days of coverage remaining in either the hospital or SNF benefit.	**Section 551.** Beneficiary notices for those beneficiaries in SNFs and hospital would be required to include information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved.	**Section 925.** Similar provision. Would require information for beneficiaries in a SNF stay only.
Information on Medicare-certified SNF in hospital discharge plans	The hospital discharge planning process requires evaluation of a patient's likely need for post-hospital services including hospice and home care.	**Section 552.** The Secretary would be required to make information publicly available regarding whether SNFs were participating in the Medicare program. Hospital discharge planning would be required to include evaluating a patient's need for SNF care.	**Section 926.** Same provision.
Physician evaluation and management (E&M) documentation guidelines	Initial E&M guidelines were issued in 1995 with revisions issued in 1997 and both remain in force today. Approximately 40% of Medicare payments for physician services are for services which are classified as evaluation and management services (i.e., physician visits). The Secretary announced that HHS was stopping work on the current re-draft of E and M codes in order to reassess the entire effort.	**Section 553.** The Secretary would be required to ensure, before making changes in documentation guidelines for, or clinical examples of, or codes to report E and M physician services, that the process used in developing the guidelines, examples, or codes was widely consultative among physicians, reflects a broad consensus among specialties, and would allow verification of reported and furnished services.	**Section 941.** Would bar the Secretary from implementing new E and M documentation guidelines unless the Secretary followed the criteria laid out in the provision.
Improvement in oversight of technology and coverage	(a) No explicit statutory provision on the Council. Under administrative authorities, CMS announced in March 2003 the establishment of a technology council charged with improving Medicare coverage, coding and payment for emerging technologies. Council membership includes senior CMS staff. The Health Care Procedure Coding System (HCPCS) is the procedure coding system used for Part B items and services. No statutory provision regarding the GAO study. The Secretary is required to rely on recommendations of the National Committee on Vital and Health Statistics (NCVHS) in adopting standards under HIPAA.	**Section 554.** Would require the Secretary to establish a Council for Technology and Innovation composed of senior CMS staff and clinicians to coordinate coverage, coding, and payment processes under Title XVIII and the exchange of information on new technologies between CMS and other entities that make similar decisions.	**Section 942.** Same provision on the Council. Also would require the Secretary to establish procedures for determining the basis for and amount of payment for a new clinical diagnostic laboratory test that has been assigned a new (or substantially revised) Health Care Procedure Coding System (HCPCS) code after January 1, 2005. Would require a GAO study analyzing which external data could be collected in a shorter time frame than that currently used in computing inpatient hospital payments. Would permit the Secretary to adopt the International Classification of

Provisions	Current Law	S. 1	H.R. 1
	The current standard for diagnosis codes is the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). ICD-9-CM is the basis of the Medicare inpatient hospital PPS payment system.) The NCVHS has not made a recommendation to the Secretary about ICD-10-PCS (the 10th revision, procedure coding system) or ICD-10-CM.		Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) and the ICD-10-Clinical Modification (CM) without receiving a recommendation from the National Committee on Vital and Health Statistics (NCVHS).
Dental claims	The statute does not authorize dental benefits in Medicare. Apparently, some insurers may require a claim denial from Medicare before accepting the claim for payment review, even if the service is not covered by Medicare.	**Section 555.** Starting 60 days after enactment, a group health plan providing supplemental or secondary coverage to Medicare beneficiaries would not be able to require dentists to obtain a claim denial from Medicare for noncovered dental services prior to paying the claim.	**Section 950.** Same provision.
Medicare secondary payor	In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. An entity furnishing a Part B service is required to obtain information from the beneficiary on whether other insurance coverage is available.	No provision.	**Section 943.** The Secretary would not be able to require that a hospital obtain information on other insurance coverage for reference laboratory services, if the Secretary does not impose such requirements in the case of services furnished by independent laboratories.
Emergency Medical Treatment and Active Labor Act (EMTALA) improvements	Medicare participating hospitals that operate an emergency room are required to provide necessary screening and stabilization services to any patient who comes to an emergency department requesting examination or treatment for a medical condition, in order to determine whether an emergency medical situation exists. Hospitals found in violation of EMTALA may face civil money penalties and termination of their provider agreement.	No provision.	**Section 944.** For EMTALA-required services provided to a Medicare beneficiary, determinations about medical necessity would be required to be made on the basis of the information available to the treating physician or practitioner at the time the item or service was ordered or furnished and not on the patient's principal diagnosis. The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Provisions	Current Law	S. 1	H.R. 1
			Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violation. The period of 5 business days would apply to such a PRO review. The Secretary would be required to provide a copy of the report to the hospital or physician, consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment. The requirement for a hospital to conduct an appropriate medical screening examination for a patient presenting in the emergency department would not include cases where an individual comes to an emergency department and the individual (or another person on the individual's behalf) does not specifically request an examination or treatment for an emergency medical condition.
EMTALA technical advisory group	No explicit statutory instruction.	No provision.	**Section 945.** The Secretary would be required to establish a technical advisory group comprised of the CMS Administrator, the Inspector General of HHS, hospital, physician and patient representatives, CMS staff investigating EMTALA cases and a state survey office representative to review issues related to EMTALA.

Provisions	Current Law	S. 1	H.R. 1
Core hospice services	A hospice must ensure that substantially all its core services are routinely provided directly by hospice employees (including volunteers) or, during peak patient loads or under extraordinary circumstances, by contract staff. Certain hospices in non-urbanized areas can receive waivers to this requirement.	**Section 406.** A hospice would be permitted to enter into arrangements with another hospice program to provide core service in extraordinary circumstances, such as unanticipated high patient loads, staffing shortages due to illness or temporary travel by a patient outside the hospice's service area; and bill and be paid for the hospice care provided under these arrangements.	**Section 946**. Same provision.
OSHA bloodborne pathogens standards	Section 1866 establishes certain conditions of participation that hospitals must meet in order to participate in Medicare.	No provision.	**Section 947.** As of July 1, 2004, public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under Section 1910.1030 of Title 29 of the *Code of Federal Regulations*. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.
BIPA-related technical amendments and corrections	BIPA Section 522 contained several technical errors.	No provision.	**Section 948.** Technical corrections would be made to BIPA Section 522.
Revisions to Reassignment Provisions	Under certain circumstances, a person or entity other than the individual providing the service may receive Medicare payments.	**Section 434.** Entities, as defined by the Secretary, could receive Medicare payments for services provided by a physician or other person if the service was provided under a contractual arrangement and if the arrangement includes joint and "several liability" (liability for several parties) for overpayment and the entities' meet program integrity specifications determined by the Secretary.	**Section 952.** Same provision.