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Summary of the Medicare Regulatory and Contracting Reform Act of 2001 (H.R. 3391)

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Summary

For some time, observers have expressed concern over the way in which Medicare has been administered, particularly with respect to its complexity and regulatory demands that burden providers and confuse beneficiaries. One of the central issues driving the debate 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. Other core issues seen to confound effective program administration are the statutory limits on which entities may process Medicare claims and the terms of such contracts.

The Medicare Regulatory and Contracting Reform Act of 2001 (H.R. 2768) would modify how Medicare regulations and guidance are communicated and enforced; 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 provide for the transfer of the administrative law judge function (ALJ) from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS); change Medicare's authority to contract for claims administration services, establish that these contracts be competitively bid at least every 5 years, and place new requirements on the Medicare administrative contractors, including an increased emphasis on provider education. Other program changes, demonstration projects, and mandated studies are also included in the legislation.

The House Ways and Means Committee and the House Energy and Commerce Committee reported out different versions of Medicare regulatory relief legislation (H.R. 2768 on October 11, 2001 and H. R. 3046 on October 31, 2001 respectively). H.R. 3391, a combination of those bills, is expected to go the House floor the week of December 3rd. The provisions of H.R. 3391 are described in this report. The cost of the combined bill has not yet been estimated by the Congressional Budget Office (CBO). However, H.R. 2768 reported out by the House Ways and Means Committee was estimated to cost $41 million in 2001 and $548 million over the 2002-2006 period. CBO acknowledged that many of those provisions would codify or standardize existing practices but estimated that others would increase or decrease spending for covered services. CBO attributed a significant portion of the bill's cost to contracting reform ($336 million over 2002-2006) and reform of appeals and claims payment procedures ($46 million over 2002-2006).

The Senate Finance Committee has not yet taken action on regulatory reform, but a bipartisan bill, S. 1728, containing elements of the different House bills was introduced on November 28, 2001.

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Introduction

For some time, observers have expressed concern over the way in which Medicare has been administered. Some feel that the Centers for Medicare and Medicaid (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 feel 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 lightening 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.

The Medicare Regulatory and Contracting Reform Act of 2001 (H.R. 3391) would modify how Medicare regulations and guidance are communicated and enforced; 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 provide for the transfer of the administrative law judge functions (ALJ) from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS). The precursor of this legislation, the Medicare Education and Regulatory Fairness Act (MERFA or H.R. 868), was criticized by Office of the

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[1] See *Medicare: Successful Reform Requires Meeting Key Management Challenges*, (7/25/2001, GAO-01-1006) and *Regulatory Issues for Medicare Providers* (6/11/2001, GAO-01-802R) for additional information.

Inspector General (OIG) in HHS as potentially encouraging fraud, in part, because it would have granted physicians immunity if they voluntarily returned overpayments under certain circumstances. That provision has been dropped from H.R. 3391, which also incorporates 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 will not be significantly weakened.

H.R. 3391 combines regulatory relief with provisions to change Medicare's authority to contract for claims processing services, another central issue seen to confound effective program administration. Presently there are statutory limits on which entities may process Medicare claims and the terms of such contracts. 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 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. Specifically, the contracts are awarded without full and open competition; generally must cover the range of claims processing and related activities; cannot be terminated without cause and without the opportunity for a public hearing; and incorporate cost-based, not performance-based, reimbursement methods with no incentive bonuses. H.R. 3391 would generally allow for greater flexibility in contracting for Medicare claims processing functions by permitting the Secretary to enter into contracts with any entity for any or all functions of a Medicare claims processing contractor.[2]

The House Ways and Means Committee and the House Energy and Commerce Committee reported out different versions of Medicare regulatory relief legislation (H.R. 2768 on October 11, 2001 and H. R. 3046 on October 31, 2001 respectively). A combined version of these bills, H.R. 3391, is expected to go the House floor the week of December 3rd. The cost of the combined bill has not yet been estimated by the Congressional Budget Office (CBO). However, H.R. 2768 reported out by the House Ways and Means Committee was estimated to cost $41 million in 2001 and $548 million over the 2002-2006 period. CBO acknowledged that many of those provisions would codify or standardize existing practices but estimated that others would increase or decrease spending for covered services. CBO attributed a significant portion of the bill's cost to contracting reform ($14 million in 2002 and $336 million over 2002-2006) and reform of appeals and claims payment procedures ($9 million in 2002 and $46 million over 2002-2006).[3]

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[2]For additional information, see *Medicare Contracting Reform: Opportunities and Challenges in Contracting for Claims Administration Services*, (6/28/2001, GAO-01-918T) and *Medicare: Comments on HHS' Claims Administration Contracting Reform Proposal* (8/17/2001 GAO-01-1046R). OIG testimony on the need for contractor reform can be found at [http://oig.hhs.gov/testimony/2001/062801mm.pdf].

[3]See [http://www.cbo.gov/showdoc.cfm?index=3102&sequence=0&from=6] for CBO's cost estimate of H.R. 2768 reported out by the Committee of Ways and Means on 10/11/2001.

The Senate Finance Committee has not yet taken action on regulatory reform, but a bipartisan bill, the Medicare Appeals, Regulatory, and Contracting Improvement Act (S. 1728), containing elements of the different House bills was introduced on November 28, 2001.

The remainder of this report addresses the specific provisions contained in H.R. 3391, the combined regulatory relief legislation. Current law descriptions are included where they exist.

Sections 1, 2, and 3

Explanation of Provisions. Except as otherwise specified, the provisions would amend or repeal a section or other provisions of the Social Security Act (the Act).

None of the provisions would be construed to (1) compromise existing remedies for addressing Medicare fraud or abuse with respect to criminal prosecution, civil enforcement, or administrative remedies, including those established by the False Claims Act or (2) prevent HHS from its ongoing efforts to eliminate waste, fraud, and abuse in Medicare. Also, consolidation of Medicare's administrative contracting provided for in this bill would not consolidate the Federal Hospital Insurance Trust Fund which pays for Part A services and the Federal Supplementary Medical Insurance Trust Fund which pays for Part B services. The bill notes that this administrative consolidation does not reflect any position on that issue.

The bill defines a "supplier" as a physician, practitioner, facility or other nonprovider entity that furnishes Medicare items or services unless otherwise indicated, and "Secretary" as the Secretary of Health and Human Services (the Secretary).

Title I – Regulatory Reform

Section 101. Issuance of Regulations.

(a) Consolidation of Promulgation to Once a Month.

Current Law. The Secretary is required to prescribe regulations that are necessary to administer Parts A and B of the Medicare program. No rule, requirement or policy statement (other than a national coverage determination) that establishes or changes a substantive legal standard that determines Medicare's scope of benefits, level of payment, or eligibility of individuals, entities or organizations to receive benefits or furnish services can take effect unless it is promulgated by regulation. The Secretary must publish a proposed regulation in the *Federal Register*, with at least 60 days to solicit public comment, before issuing the final regulation with the following exceptions: (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 implementation of 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. The Secretary must publish in the *Federal Register* no less frequently than every 3 months a list of all manual instructions, interpretative rules, statements of policy, and guidelines which are promulgated to carry out Medicare's law.

Explanation of Provisions. The Secretary would be required to issue proposed or final regulations (including interim final regulations) on only one business day of every month, unless the Secretary finds that publication on other dates is required to comply with Medicare law or that this restriction is contrary to the public interest. In such instances, the Secretary would be required to include an explanation of such a finding when the regulations are issued. For the issuance of new regulations relating to a category of provider or supplier, the Secretary would be required to undertake an analysis of the collective impact of the regulatory changes on such category. No later than 3 years after enactment, GAO would be required to report to Congress on the feasibility of issuing regulations only on one day in each calendar quarter. The provisions would apply to regulations issued 30 days after enactment.

(b) Regular Timeline for Publication of Final Rules.

Current Law. See above. The Secretary must publish in the *Federal Register* no less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines which are promulgated to carry out Medicare's law.

Explanation of Provisions. The Secretary, in consultation with the Director of the Office of Management and Budget, would establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. The timeline may vary by regulation due to complexity, number and scope of comments received and other factors, but would not be longer than 3 years unless there are exceptional circumstances. If the Secretary intends to vary a regulation's timeline, a notice of the different timeline would be required to be published in the *Federal Register*. This notice would include a brief explanation of the justification for such variation. If the timeline established for an interim final regulation expires without promulgation of a final regulation (including the public comment period), the interim final regulation would not remain in effect unless the Secretary publishes a notice of continuation that includes an explanation for not complying with the deadlines. This provision applies to the regular timelines and any subsequent 1-year extension to the timeline. If a notice of continuation is published, the regular timeline or the timeline as previously extended would be extended for 1 additional year. The Secretary would be required to submit a report to Congress that describes and explains the instances where the final regulation was not published within the applicable timeline. The Secretary would be required to provide for a transition period for previously published interim final regulations.

(c) Limitation on New Matter in Final Regulations.

Explanation of Provisions. A provision in a final regulation that is not a logical outgrowth of the proposed regulation (including an interim final regulation) would be treated as a proposed regulation and would not take effect without a separate public comment period followed by its publication as a final regulation. This provision would apply to final regulations published on or after enactment.

Section 102. Compliance with Changes in Regulations and Policies.

(a) No Retroactive Application of Substantive Changes.

Explanation of Provisions. A substantive change in a regulatory or a subregulatory issuance would not be applied retroactively to items or services, unless the Secretary determines that retroactive application (1) would be necessary to comply with statutory requirements; or (2) would be beneficial to the public interest. This provision would apply to substantive changes issued on or after enactment.

(b) Timeline for Compliance with Substantive Changes After Notice.

Explanation of Provisions. A substantive change would not become effective before 30 days after the date the change is issued or published. The Secretary would be able to waive the 30-day period to comply with statutory requirements or if such waiver is in the public interest. If an earlier date is established, the Secretary would be required to include a brief explanation of such finding in the issuance or publication of the substantive change. No compliance action against a provider or supplier for goods and services furnished before the effective date of the substantive change would be permitted. This provision would apply to compliance actions undertaken on or after enactment.

(c) Reliance on Guidance.

Explanation of Provisions. If (1) a provider or supplier follows written guidance (which may be transmitted electronically) provided by the Secretary or a Medicare contractor when furnishing an item or service and submitting a claim; (2) the Secretary finds that the circumstances relating to the furnished items and services have been accurately presented in writing to the contractor and (3) the guidance is inaccurate, then the provider or supplier who reasonably relied on the guidance would not be subject to any sanction or penalty, including repayment. This provision would not be construed to prevent recoupment or repayment (without additional penalty) if the overpayment was solely the result of a clerical or technical operational error. This provision would be effective upon enactment, but would not apply to sanctions where notice was provided on or before enactment.

Section 103. Reports and Studies Relating to Regulatory Reform.

Explanation of Provisions. GAO would be required to conduct a study to determine the appropriateness and feasibility of providing the authority to the

Secretary to issue legally binding advisory opinions on the interpretation and application of Medicare regulations. The study would examine the appropriate time frame for issuing the opinions as well as the need for additional staff and funding. GAO would submit the study to Congress by January 1, 2003.

The Secretary would be required to report to Congress on the administration of the Medicare program and inconsistencies among existing Medicare statutory or regulatory provisions. The report would include (1) information from beneficiaries, providers, suppliers, Medicare Beneficiary and Provider Ombudsmen (established in Section 303 of this legislation), and Medicare contractors; (2) descriptions of efforts to reduce inconsistencies; and (3) recommendations from the Secretary for appropriate legislation or administrative actions. The report would be due no later than 2 years after enactment and every 2 years thereafter.

Title II – Contracting Reform

Section 201. Increased Flexibility in Medicare Administration.

(a) Consolidation and Flexibility in Medicare Administration.

Current Law. Section 1816 of the Act authorizes the Secretary to establish agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. Section 1842 of the Act authorizes the Secretary to enter into contracts with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. Section 1893 authorizes the Secretary to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries 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. Specifically, the contracts are awarded without full and open competition; generally must cover the range of claims processing and related activities; cannot be terminated without cause and without the opportunity for a public hearing; and incorporate cost-based, not performance-based, reimbursement methods with no incentive bonuses.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments to give surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

Explanation of Provisions. The legislation would add Section 1874A to the Act which would permit the Secretary to enter into contracts with any eligible entity to serve as a Medicare administrative contractor. These contractors would perform or secure the performance (through subcontracting) of some or all of the following tasks: determine payment amounts; make payments; educate and assist beneficiaries; provide consultative services; communicate with providers and suppliers; educate and offer technical assistance to providers; and perform additional functions as necessary. An entity eligible to enter into a contract with respect to the performance of a particular function would (1) have demonstrated capability to carry out such function; (2) comply with conflict of interest standards that are generally applicable to Federal acquisition and procurement; (3) have sufficient assets to financially support the performance of such functions; and (4) meet other requirements imposed by the Secretary. The claims processing jurisdiction of Medicare administrative contractor would be determined by the scope of the contract awarded to the entity. Specifically, the Medicare administrative contractor that would perform a particular function is the entity that has the contract to perform that function for any given beneficiary, any given provider or supplier, or class of same.

The Federal Acquisition Regulations (FAR) would apply to Medicare administration contracts except to the extent inconsistent with a specific Medicare requirement. The Secretary would be required to use competitive procedures when entering into a Medicare administrative contract and would take into account performance quality, price, and other factors. The Secretary would be able to renew a contract for up to 5 years without regard to statutory requirements concerning competitive contracting if the entity has met or exceeded specified performance standards. The Secretary would be able to transfer functions among contractors consistent with these provisions. The Secretary would be required to (1) ensure that performance quality is considered in such transfers and (2) provide notice of such transfer (in the *Federal Register* or otherwise) that describes the transferred functions and the affected providers and suppliers and also includes contractor contact information.

The Secretary would be required to (1) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; and (2) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors. In developing the performance standards, the Secretary would be able to consult with providers and suppliers, organizations representing Medicare beneficiaries, and Medicare contractors. The Secretary would be required to contract only with those entities that (1) perform efficiently and effectively; (2) meet standards for financial responsibility,

legal authority and service quality among other pertinent matters; (3) agree to furnish timely and necessary data; and (4) maintain and provide access to necessary records.

The performance requirements would be (1) set forth in the contract between the Secretary and the appropriate Medicare contractor; (2) used to evaluate contractor performance; and (3) consistent with the contract's written statement of work. A Medicare administrative contract would contain provisions deemed necessary by the Secretary and may provide for advances of Medicare funds for the purposes of making payments to providers and suppliers. In developing contract performance requirements for Medicare administrative contractors, the Secretary would be required to consider the existing timeliness standards for reconsiderations, applications for exemption, initial determinations and fair hearing decisions.

The existing MSP provision would apply: the Secretary would not be able to require contractors to match their data with Medicare data for the purposes of identifying beneficiaries with other insurance coverage. The Secretary would assure that the activities of the Medicare administrative contractors do not duplicate the Medicare Integrity Program (MIP) functions except with respect to the prior authorization of durable medical equipment. An entity with a MIP contract would not be treated as a Medicare administrative contractor, solely by reason of the MIP contract.

A Medicare administrative contractor and any of its employees certifying or disbursing payments may be required to give surety bond to the United States in an amount established by the Secretary. The contractor's employee who certifies payments will be liable for erroneous payments in the absence of of gross negligence or intent to defraud the United States. The contractor's employee who disburses payments would not be liable for erroneous payments in the absence, if such payments are based upon an authorization from the certifying employee and the authorization meets the internal control standards established by GAO. The contractor would not be liable for payments made by certifying or disbursing officers unless grossly negligent when supervising or selecting these officers.

The Secretary would be able to indemnify a Medicare administrative contractor, subcontractor, or employee who is made a party to any judicial or administrative proceeding arising from the claims administration process to an appropriate extent as determined by the Secretary and specified in the contract. Indemnification in this case may include payment of judgments, certain settlements, awards and costs (including reasonable legal expenses). Settlement proposals would not be negotiated or compromised without prior written approval by the Secretary. The Secretary would not be able to provide any indemnification if the liability arises directly from conduct that is determined in the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent; if such indemnification is provided before this determination, the contractor would reimburse the Secretary for the costs. The provisions would not change common law immunity available to the Medicare contractor or other party or permit the payment of costs not otherwise allowable, reasonable or allocable under FAR.

(b) Conforming Amendments to Section 1816 (Relating to Fiscal Intermediaries).

Current Law. Section 1816 of the Act establishes the provider nomination process, the contracting specifications, and performance standards for fiscal intermediaries that currently contract with Medicare to process claims and perform other related administrative activities for institutional providers.

Explanation of Provisions. The provisions would establish that the existing administrative activities of fiscal intermediaries would be conducted through contracts with Medicare administrative contractors set forth previously. The provider nomination process and contracting specifications would be repealed. Certain performance standards with respect to the processing of clean claims would be retained. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

(c) Conforming Amendments to Section 1842 (Relating to Carriers).

Current Law. Section 1842 of the Act establishes that carriers will be used to administer certain Medicare benefits as well as the contracting requirements and certain performance standards for those activities.

Explanation of Provisions. The provisions would establish that the existing administrative activities of carriers would be conducted through contracts with Medicare administrative contractors set forth previously. Certain instructions including those pertaining to nursing facilities payments, claims assignment, physician participation, overpayment recoveries and billing by suppliers would be retained. Certain performance standards with respect to the processing of clean claims would be retained. Contracting specifications and other conforming changes would be established. The Secretary, not the contractor, would be responsible for taking necessary actions to assure that reasonable payments are made, for those made on both a cost and charge basis. The Secretary, not the contractor, would be responsible for maintaining a toll-free telephone number for beneficiaries to obtain information on participating suppliers. The requirements for carrier fair hearings would be eliminated to conform with existing law. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

(d) Effective Date; Transition Rule.

Explanation of Provisions. Except as otherwise provided in this subsection, the provisions in this section would be effective October 1, 2003. The Secretary would be authorized to take necessary actions prior to that date in order to implement these amendments on a timely basis, to transition from the contracts established under sections 1816 and 1842 of the Act to those established under the new section 1874A created by this legislation. The transition would be consistent with the requirement that the administrative contracts be competitively bid by October 1, 2008. The MIP contracts be awarded on a competitive basis would continue to apply and would not be affected by the provisions in this section. Any reference to a contract in the existing MIP contracting exceptions would be deemed to include a contract under the new 1874A that continues such MIP activities.

(e) References.

Explanation of Provisions. After this section becomes effective, any reference to fiscal intermediary or carrier would be considered a reference to the appropriate Medicare administrative contractor.

(f) Reports on Implementation.

Explanation of Provisions. The Secretary would submit an implementation plan to Congress and GAO no later than October 1, 2002. GAO would evaluate the plan and include appropriate recommendations no later than 6 months after the plan is received. No later than October 1, 2006, the Secretary would be required to submit a status report to Congress including (1) the number of contracts that have been competitively bid; (2) the distribution of functions among contracts and contractors; (3) a timeline for complete transition to full competition; and (4) a detailed description of changes to contractor oversight and management.

Section 202. Requirements for Information Security.

Explanation of Provisions. Medicare administrative contractors that determine and make payments would be required to implement a contractor-wide information security program that meets the requirements imposed on Federal agencies to ensure the security, integrity, confidentiality, authenticity, and availability of operational data and systems supporting operations. An annual audit of the information security at each Medicare administrative contractor: (1) would be performed by an independent entity that meets the independence requirements specified by the OIG in HHS; and (2) would test the effectiveness of the information security techniques for an appropriate subset of the contractor's systems. An audit of new contractors (those that have not been fiscal intermediaries or carriers) would be required prior to the start of their performing Medicare payment functions. An audit of existing contractors (those that are now fiscal intermediaries and carriers) would be required to be completed within 1 year from enactment. The results of the audits would be reported promptly to the OIG which will submit a report annually to Congress. These provisions would be equally applicable to fiscal intermediaries and carriers as to Medicare administrative contractors.

Title III – Education and Outreach Improvements

Section 301. Provider Education and Technical Assistance.

(a) Coordination of Education Funding.

Current Law. Medicare's provider education activities are funded through the program management appropriation and through the Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

Explanation of Provisions. The provision would add Section 1889 to the Act which would require the Secretary (1) to coordinate the educational activities provided through the Medicare administrative and MIP contractors; and (2) to submit an evaluation to Congress, no later than October 1, 2002, on actions taken to coordinate the funding of provider education.

(b) Incentives to Improve Contractor Performance.

Current Law. No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an estimate of improper payments in Medicare fee-for-service has been made annually. As a recent initiative, CMS is implementing a comprehensive error rate testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

Explanation of Provisions. The Secretary would be required to develop and implement a methodology to measure the specific claims payment error rates at each Medicare administrative contractor. This methodology would apply to existing fiscal intermediaries and carriers in the same manner as it applies to Medicare administrative contractors. No later than October 1, 2002, GAO would submit to Congress and to the Secretary a report on the adequacy of the methodology, including recommendations as appropriate. No later than October 1, 2002, the Secretary would be required to report to Congress on (1) the use of the claims error rate methodology in assessing the effectiveness of contractors' provider education and outreach programs; and (2) whether such methodology should be used as a basis of contractors' performance bonuses.

(c) Provision of Access to and Prompt Responses from Medicare Administrative Contractors.

Current Law. No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment; and (2) serve as a center for any information as well as a channel for communication with providers.

Explanation of Provisions. By October 1, 2002, the Secretary would be required to develop a communication strategy with beneficiaries, providers and suppliers. Each Medicare administrative contractor would be required to (1) provide general written responses (which may be through electronic transmission) in a clear, concise and accurate manner to written inquiries from beneficiaries, providers and suppliers within 45 business days; (2) provide a toll-free telephone number where these interested parties may obtain billing, coding, claims, coverage and other appropriate Medicare information; (3) maintain a system for identifying which employee provided both the written and oral information; and (4) monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public the standards used to monitor the

accuracy, consistency, and timeliness of information provided in response to written and telephone inquiries. The standards would be developed in consultation with provider, supplier, and beneficiary organizations and would be consistent with the contractors' performance requirements. The Secretary would be able to directly monitor the quality of the information so provided. These provisions would also apply to existing fiscal intermediaries and carriers.

(d) Improved Provider Education and Training.

Current Law. In FY2000, $54.8 million was spent on provider education and training activities: about $43 million came from the program management appropriation and about $12 million came from the Provider Education and Training component of MIP. In FY2001, about $57.3 million was budgeted for these activities.

Explanation of Provisions. The provisions would authorize $25 million in Medicare appropriations in FY2003 and FY2004 and such funds as necessary in subsequent years to increase provider education and training and to improve the accuracy and quality of contractor responses. Starting on October 1, 2002, the contractors' training activities would be tailored to the special needs of small providers and suppliers. The provisions defines a small provider as an institution with fewer than 25 full-time equivalents employees (FTEs) and a small supplier as one with fewer than 10 FTEs.

(e) Requirement to Maintain Internet Sites.

Explanation of Provisions. By October 1, 2002, the Secretary and each contractor would be required to maintain an Internet site that provides answers to frequently asked questions in an easily accessible format as well as other materials published by the contractor.

(f) Additional Provider Education Provisions.

Explanation of Provisions. A Medicare contractor would not be able to use attendance records at educational programs or information gathered during these programs to select or track candidates for audit or prepayment review. Nothing in the proposed legislation would require Medicare administrative contractors to disclose information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

Section 302. Small Provider Technical Assistance Demonstration Program.

Explanation of Provision. The Secretary would be required to establish a demonstration program and contract with qualified entities to offer technical assistance, when requested and on a voluntary basis, to small providers or suppliers. Small providers and suppliers would be those institutional providers with less than 25 FTEs or suppliers with less than 10 FTEs. Technical assistance would include direct, in-person examination of billing systems and internal controls by qualified entities such

as peer review organizations or other entities. In awarding these contracts, the Secretary would be required to consider any prior investigations of the entity's work by the OIG in HHS or GAO. Participating providers and suppliers would be required to pay an amount estimated and disclosed in advance that would equal 25% of the cost of the technical assistance they received. Absent indications of fraud, errors found in the review would not be subject to recovery if the problem is corrected within 30 days of the on-site visit and remains corrected for an appropriate period. However, this protection would only apply to claims filed as part of the demonstration project, would last only for the duration of the project and only as long as the provider or supplier was participating in the project. GAO, in consultation with the OIG, would be required to evaluate and recommend continuation of the demonstration project no later than 2 years after its implementation. The evaluation would include a determination of whether claims error rates were reduced for providers and suppliers who participated in the program. The demonstration project would be authorized at $1 million in FY2003 and $6 million in FY2004 of appropriations from the Medicare Trust Funds.

Section 303. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.

(a) Medicare Provider Ombudsman.

Explanation of Provision. One year after enactment, the Secretary would be required to appoint a Medicare Provider Ombudsman within HHS to (1) to resolve unclear guidance and provide confidential assistance to providers and suppliers regarding complaints or questions about the Medicare program including peer review and administrative requirements; and (2) recommend changes to improve program administration. The ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies.

(b) Medicare Beneficiary Ombudsman.

Explanation of Provisions. One year after enactment, the Secretary would be required to appoint a Medicare Beneficiary Ombudsman within HHS from individuals with health care expertise, advocacy, and education of Medicare beneficiaries. The ombudsman would (1) receive complaints, grievances, and requests for information from Medicare beneficiaries; (2) provide assistance with respect to those complaints, grievances and requests, including assistance to beneficiaries who appeal claims determinations or those affected by the decisions of Medicare+Choice (M+C) organizations to leave Medicare; and (3) submit an annual report to Congress and the Secretary describing activities and recommending changes to improve program administration. The ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies.. To the extent possible, the Beneficiary Ombudsman would work with the Health Insurance Counseling Programs, authorized under Section 4360 of Omnibus Reconciliation Act of 1990, to facilitate the provision of information to Medicare beneficiaries regarding M+C plans and any changes related to those plans.

Nothing in this subsection would preclude further collaboration between the Medicare Beneficiary Ombudsman and these programs.

(c) Deadline for Appointment.

Explanation of Provisions. The Secretary would be required to appoint the Medicare Provider Ombudsman and the Medicare Beneficiary Ombudsman by no later than 1 year after enactment.

(d) Funding.

Explanation of Provisions. The provision would authorize appropriations of necessary sums in FY2002 and subsequently from the appropriate Medicare Trust Funds for the ombudsman programs.

(e) Use of Central Toll Free Number (1-800 MEDICARE).

Current Law. The Secretary is required to prepare and distribute an annual notice explaining Medicare benefits and limitations to coverage to Medicare beneficiaries. The Secretary is also required to provide information via a toll-free telephone number.

Explanation of Provisions. The Secretary would be required to establish a toll-free number (1-800-MEDICARE) which will transfer individuals with questions or seeking help to the appropriate entities. The transfer would occur with no charge. This toll-free number would be the general information and assistance number listed on the annual notice provided to beneficiaries. GAO would be required to (1) monitor the adequacy, accuracy, and consistency of the information provided to Medicare beneficiaries through the toll-free 1-800 MEDICARE number; and (2) examine the education and training of those providing the information through the toll-free number. GAO would be required to submit a report to Congress no later than 1 year from enactment.

Section 304. Beneficiary Outreach Demonstration Program.

Explanation of Provision. The Secretary would be required to establish a 3-year demonstration project where Medicare specialists who are HHS employees are placed in at least six SSA offices to advise and assist Medicare beneficiaries. The SSA offices would be those with a high-volume of visits by Medicare beneficiaries; at least two of which would be in rural areas. In the rural SSA offices, the Secretary would provide for the Medicare specialists to travel among local offices on a scheduled basis. The Secretary would be required to (1) evaluate the project with respect to beneficiary utilization, beneficiary satisfaction, and cost-effectiveness; and (2) recommend whether the demonstration should be established on a permanent basis.

Title IV – Appeals and Recovery

Section 401. Transfer of Responsibility for Medicare Appeals.

Current Law. Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal claims that are denied or payments that are reduced. Section 1869 of the Act, which covers the Medicare claims appeals process, was amended by the Medicare Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) in its entirety, but the BIPA provisions are not yet effective. Generally, parties who have been denied coverage of an item or service have the right to appeal that decision through a series of administrative appeals and then to a federal district court if the amounts of disputed claims in question meet certain thresholds at each step of the appeals process. A hearing by an ALJ in the SSA and a review by the Department Appeals Board (DAB) are components of the administrative appeals process.

Explanation of Provisions. By October 1, 2002, the Commissioner of SSA and the Secretary would develop a plan to transfer the functions of the ALJs who are responsible for hearing Medicare and Medicare related cases from SSA to HHS. The plan would be transmitted to Congress and GAO no later than October 1, 2002. GAO would evaluate the plan and submit a report to Congress by April 1, 2003. The Secretary and the Commissioner of SSA would implement the transition plan and transfer the ALJ functions no earlier than July 1, 2003 and no later than October 1, 2003. The Secretary would (1) assure the independence of the ALJs performing the ALJ function from the Centers of Medicare and Medicaid Services (CMS) and its contractors; and (2) locate the ALJs with an appropriate geographic distribution to ensure access. Subject to appropriations, the Secretary would be permitted to hire ALJs and support staff with priority given to ALJs with experience in handling Medicare appeals. Amounts previously paid to SSA for the ALJs performing the ALJ functions would be payable to the Secretary for the transferred functions. The Secretary would be permitted to enter into arrangements with SSA to share office space, support staff, and other resources with appropriate reimbursement from the Medicare trust funds. Increased appropriations would be permitted to increase the number of ALJs and support staff; improve education and training for ALJs and their staff; and increase DAB staff.

Section 402. Process for Expedited Access to Review.

(a) Expedited Access to Judicial Review.

Current Law. Section 521 of BIPA (which is not yet implemented) amends Section 1869 to establish deadlines for filing appeals and for making decisions in the Medicare appeals process. Generally, an initial determination is to be completed no later than 45 days from the date a claim for benefits is received; an individual dissatisfied with an initial determination is entitled to a redetermination by a carrier or fiscal intermediary if requested within 120 days of the determination date. The redetermination is to be completed no later than 30 days from the request date. The Secretary may reopen or revise any initial determination or reconsidered determination under guidelines established by regulation.

An individual dissatisfied with the redetermination is entitled to a reconsideration by a qualified independent contractor (QIC) if the request is initiated within 180 days of the notice of the adverse redetermination. With certain exceptions, a QIC reconsideration decision is to be completed within 30 days from the date a timely request has been filed. After a QIC's reconsideration, if the remaining contested amount is greater than $100, an individual is entitled to a hearing by an administrative law judge and then a review by the DAB. Both the ALJ hearing and the DAB review are to be completed within 90 days of a timely filed request for such an action.

If the dispute is not satisfactorily resolved and the contested amounts are greater than $1,000, the individual is entitled to judicial review of the decision. Under certain circumstances, a beneficiary is entitled to an expedited determination with accelerated deadlines. BIPA also provides for an expedited hearing under Section 1869, where the moving party alleges that no material issues of fact are in dispute; the Secretary makes an expedited determination as to whether any such facts are in dispute and, if not, renders a decision expeditiously.

Explanation of Provisions. The Secretary would establish an appeals process for a provider, supplier, or beneficiary which permits access to judicial review when a review panel determines that no entity in the administrative appeals process has authority to decide the question of law or regulation in controversy and where material facts are not in dispute. The appellant would be able to make such request only once with respect to a question of law or regulation for a specific dispute. If the appellant requests this determination and submits appropriate supporting documentation, the review panel would make this determination in writing no later than 60 days after the receiving the request. A review panel would consist of a panel of three members who are ALJs, members of the DAB, or qualified individuals associated with a QIC or other independent entity designated by the Secretary to make these determinations. The determination by the review panel would be considered a final decision and not subject to review by the Secretary. Given such a determination or a failure to make the determination within the 60-day deadline, the appellant would be able to request judicial review before a civil court. The filing deadline for this civil action would be within 60 days of the determination or within 60 days of the end of the deadline to make such determination. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants are located, or in the district court for the District of Columbia. The amount in controversy would be subject to annual interest beginning on the first day of the first month beginning after the 60-day deadline for filing. Interest would be equal to the rate of interest on obligations issued for purchase by the Medicare trust funds effective for the month that the civil action is authorized to commence. The interest payments would not be deemed to be Medicare reimbursement.

(b) Application to Provider Agreement Determinations.

Current Law. Section 1866(h) of the Act provides for a hearing and for judicial review for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider).

Explanation of Provisions. An agency or institution's appeal concerning program participation under Section 1866 would have access to expedited judicial review under Section 1869 provisions. This provision would not be construed to affect remedies applied to assure quality of care in skilled nursing facilities (under Section 1819) while such appeals are pending.

(c) Effective Date.

Explanation of Provision. Amendments in the section would apply to appeals filed on or after October 1, 2002.

(d) Expedited Review of Certain Provider Agreement Determinations.

Explanation of Provisions. The Secretary would develop and implement a process under 1866(h) to expedite provider agreement determinations including those instances where participation is terminated or other sanctions (including denials of new admissions or the immediate appointment of temporary management) against skilled nursing facilities have been imposed. Priority would be given to termination of provider agreements. Increased appropriations from the Medicare trust funds in FY2003 and subsequently would be authorized in order to (1) reduce the average time for administrative determinations on provider participation appeals by 50%; (2) increase the number of ALJs and their staff as well as appellate level staff at the DAB; and (3) educate such judges and their staff on long-term care issues.

Section 403. Revisions to Medicare Appeals Process.

(a) Requiring Full and Early Presentation of Evidence.

Explanation of Provision. Starting no later than October 1, 2002, a provider or supplier would not be able to introduce evidence that was not presented at reconsideration conducted by the QIC unless a good cause precluded its introduction at or before that reconsideration.

(b) Use of Patients' Medical Records.

Current Law. BIPA established QIC reconsiderations as part of the Medicare's administrative review process. To reconsider whether a service is reasonable and necessary, a QIC will employ panel of physicians or other appropriate health care professionals to review the facts and the circumstances of the initial determination. The QIC reconsideration is to be based on applicable information, including clinical experience, and medical, technical, and scientific evidence.

Explanation of Provisions. Medical records of the individual involved in the appeal would be included as part of the applicable information used by QICs in their reconsideration process.

(c) Notice Requirements for Medicare Appeals.

Current Law. Section 521 of BIPA (which is not yet implemented) amends Section 1869 appeals process in its entirety, but did not establish specific notice requirements for each part of the Medicare appeals process.

Explanation of Provisions. The provisions would establish that a written notice of an initial determination associated with a claims denial be provided. The notice would include: (1) the reason for the denial and, upon request, the policy, manual or regulation used to make the decision; (2) the procedures for obtaining additional information concerning the determination; and (3) the notification of appeal rights and associated instructions.

The provisions would amend the existing requirement that a reconsideration decision be written and would establish that the decision be provided in printed form and written in a manner that could be understood by the beneficiary; the notice would include: as appropriate, a summary of the clinical or scientific evidence used to make the decision; upon request, the policy manual or regulation used to make the decision; and a detailed explanation of the decision to the extent appropriate. The requirement that the reconsideration decision include a notice of appeal rights and relevant instructions would also be established.

Comparable requirements would be extended to ALJ decisions. These decisions would have to be written in an understandable manner and include the specific reasons for the decision, an appropriate summary of the evidence, the procedures for obtaining additional information about the decision, and a notification of appeal rights and instructions.

The current requirements that a QIC prepare documentation and an explanation of the issues for an appeal to an ALJ would be modified: a QIC would be required to submit the information required in an appeal of a Medicare contractor's decision to the ALJ.

(d) Qualified Independent Contractors.

Current Law. BIPA established QIC reconsiderations as part of Medicare's administrative review process. A QIC is an entity or organization that is independent of any organization under contract with the Secretary, that makes initial determinations and that meets the established requirements for sufficient training and expertise in medical science and legal matters to make such reconsiderations. QIC reviews include consideration of the facts and circumstances by a panel of physicians or appropriate health professionals. No physician or health care professional employed by a QIC may review determinations regarding services provided to a patient, if directly responsible for furnishing the services to that patient. Review of home health care services is also prohibited by physicians and other professionals who have a significant direct or indirect financial interest in the agency or institution providing the care. This prohibition extends to physicians and professionals who have family members with such significant financial interests.

Explanation of Provisions. To qualify as a QIC, an entity would be required to have sufficient medical, legal and other expertise, including knowledge of the Medicare program as well as sufficient professional qualifications, independence and staffing to make reconsideration decisions. A QIC would be required to assure that reviewers meet qualification and compensation requirements. If a reconsideration request indicates that the treatment was furnished or the item or service was provided by a physician, each reviewing professional should be a physician.

Entities and their professional reviewers would have to meet independence requirements and may not (1) be a related party; (2) have a material familial, financial, or professional relationship with a related party; or (3) have a conflict of interest with respect to a related party. QIC's compensation would not be contingent on any decision by the QIC or by any reviewing professional. A reviewer's compensation would not be contingent on any decision rendered by the reviewer. In this context, a related party to a Medicare case involving an individual beneficiary would be (1) the Secretary, the Medicare administrative contractor involved, any fiduciary, officer, director or employee of HHS or such Medicare contractor; (2) the individual or authorized representative; (3) the health professional, institution or entity that provides or manufactures the item or service involved in the case; and (4) any other party with substantial interest in the case, as defined by regulation. An individual affiliated with a fiscal intermediary, carrier or other contractor would be able to act as a QIC reviewer if (1) the individual is not involved with the provision of the item or service of the case; (2) the individual is not an employee of the Medicare contractor and does not provide services exclusively or primarily to or on behalf of the contractor; and (3) the fact of the relationship is disclosed to the Secretary and the Medicare beneficiary or authorized representative who do not object. An individual with staff privileges at the institution where treatment occurs would be able to serve as a reviewer if the affiliation is disclosed without objection.

Each reviewing professional would be required to be (1) an allopathic or osteopathic physician or health care professional who is appropriately credentialed or licensed in one or more states to deliver health care services and has medical expertise in the field of practice appropriate for the case; or (2) a health care professional who is legally authorized in one or more states (in accordance with state law or according to the appropriate state regulatory mechanism) to furnish the health care items or service and has medical expertise in the field of practice appropriate for the case

Section 404. Prepayment Review.

Explanation of Provisions. Medicare administrative contractors would be able to conduct random prepayment reviews in order to develop contractor-wide or program-wide claims payment error rates or under additional circumstances as established by regulations that are developed in consultation with providers and suppliers. Medicare administrative contractors would be permitted to conduct random prepayment reviews in accordance with a standard protocol developed by the Secretary. The Secretary would not be able to initiate a non-random prepayment review based on the initial identification by a provider or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations relating to the termination of such non-random prepayment reviews which could incorporate differences in the circumstances that triggered such a review that may affect its duration. No provision

would prevent the denial of payment for claims actually reviewed under random prepayment review. These provisions would be applied to fiscal intermediaries and carriers. The provisions would be effective no later than 1 year from enactment. The Secretary would be required to issue regulations before that deadline; the random prepayment review protocols would apply to reviews after a date specified by the Secretary (but no later than 1 year from enactment.)

Section 405. Recovery of Overpayments.

Current Law. No provision with respect to repayment plans. Section 1833(j) of the Act provides that interest accrues on underpayments or overpayments starting within 30 days of the date of the final determination of the accurate payment amount.

Explanation of Provisions. Subject to certain qualifications, in circumstances where refund of an overpayment within 30 days would constitute a hardship, providers and suppliers on request would be allowed to repay the overpayment amount (by offset or otherwise) over a period of at least 6 months and up to 3 years when their obligation exceeds a 10% threshold of their annual payments from Medicare. The Secretary would be able to establish a repayment period of up to 5 years in cases of extreme hardship. Interest would accrue on the balance through the repayment period. The Secretary would be required to establish a process under which newly-participating providers and suppliers could qualify for a repayment plan under this hardship provision. Previous overpayment amounts already included in an ongoing repayment plan would not be included in the calculation of the hardship threshold. The Secretary would be allowed to seek immediate collection if payments are not made as scheduled. Exceptions to this provision would be permitted in cases where bankruptcy may be declared, where Medicare participation may be discontinued, or where fraud or abuse against Medicare is indicated. This provision would not affect the application of existing no-fault provisions which preclude recovery under circumstances where incorrect payment has been made to an individual who is without fault or where the recovery would decrease payments to another person who is without fault.

Upon enactment, the Secretary would not be able to initiate any recovery action if the provider or supplier has sought a reconsideration of the Medicare overpayment by a QIC until the date of the reconsideration decision. If QIC's are not yet in place, the recovery would not be initiated until the date of a redetermination decision by a fiscal intermediary or a carrier. If monies have been offset or repaid, the Secretary would return those amounts plus applicable interest if the original overpayment determination is reversed. If such an overpayment determination is upheld, interest would accrue beginning on the date of the original overpayment notice; the interest amount would be the rate otherwise applicable for Medicare overpayments.

Not later than 1 year after enactment, a Medicare contractor would not be able to use extrapolation to determine overpayment amounts for statistically valid random samples initiated after the date of enactment, unless, as determined by the Secretary, a sustained or high level of payment error exists or a documented educational intervention did not correct the payment error. Where providers and suppliers have previously been overpaid, Medicare contractors would be able to require periodic

production of records or supporting documentation for a limited sample of submitted claims to ensure that a previous practice has been discontinued.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. Before entering into any consent settlements after the date of enactment, the Secretary would be required to communicate to a provider or supplier that based on a preliminary evaluation of a medical records review, an overpayment may exist; the nature of the identified problems; and the necessary steps to address the problem.. The Secretary would provide 45 days where additional information may be submitted concerning the claims for which the medical records have been reviewed. After considering the additional information, the Secretary would provide notice and explanation of any remaining overpayment determination and would offer the opportunity for a statistically valid random sample (which would not waive appeal rights) or a consent settlement (based on a smaller sample with a waiver of appeal rights) to resolve the overpayment amounts.

Not later than 1 year after enactment, the Secretary would be required to establish, in consultation with health care associations, a process where classes of providers and suppliers are notified that their Medicare contractor has identified specific billing codes that may be over-utilized.

For audits initiated after enactment, Medicare contractors would be required to provide a written notice (which may be in electronic form) of the intent to conduct a post-payment audit to those selected as audit candidates. Medicare contractors would be required to provide those who have been audited a full review and understandable explanation of the findings that: (1) permits the development of an appropriate corrective action plan; (2) provides information on appeal rights as well as consent settlements (which are at the discretion of the Secretary); and (3) provides for an opportunity to supply additional information to the contractor. Medicare contractors would be required to take into account the information provided, on a timely basis. The provisions requiring notice of audit and findings would not apply if pending law enforcement activities would be compromised or findings of law enforcement-related audits would be revealed.

Not later than 1 year after enactment, the Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a claims sample for a review of abnormal billing patterns. These provisions would apply to Medicare administrative contractors including fiscal intermediaries and carriers as well as those eligible entities with MIP contracts.

Section 406. Provider Enrollment Process; Right of Appeal.

Current Law. Providers and, to some extent suppliers, have access to certain appeal mechanisms if their application to participate in Medicare is denied or terminated. Section 1866(h) of the Act provides for a hearing and for judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider). There is no statutory provision extending such judicial appeal rights to suppliers. Sections 1128(a) and (b) of the Act provide for the exclusion of certain individuals or entities because of the conviction of crimes related to their participation in Medicare; Section 1128(f)

provides for hearing and judicial review for exclusions. In 1999, HCFA– now CMS – published a proposed regulation that would revise existing Medicare Part B administrative appeals procedures and extend them to all suppliers not currently covered.

Explanation of Provision. The Secretary would be required to (1) establish by regulation an enrollment process for providers and suppliers which would include deadlines for actions on enrollment applications within 6 months of enactment; (2) monitor the performance of Medicare administrative contractors in meeting the deadlines; and (3) consult with providers and suppliers in making changes to the enrollment forms made on or after January 1, 2002.

Providers and suppliers whose application to enroll or reenroll has been denied and who are dissatisfied with the determination would be entitled to a hearing and judicial review of the determination under the procedures that currently apply to providers. This provision would apply to denials after a date specified by the Secretary which could not be later than 1 year from enactment.

Section 407. Process for Correction of Minor Errors and Omissions on Claims Without Pursuing Appeals Process.

Explanation of Provision. The Secretary would be required to develop, in consultation with appropriate Medicare contractors and health care associations, a process where minor claims errors and omissions can be corrected and resubmitted without appealing the claims denial.

Section 408. Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices.

Current Law. 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.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, the provider may limit his liability by providing an acceptable advance notice of Medicare's possible denial of payment to the patient The notice must be given in writing, in advance of providing the service; include the patient's name, date and description of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced.

Explanation of Provisions. The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain items and services before such services are provided. An

eligible requestor would be either a physician, but only with respect to eligible items and services for which the physician may be paid directly or a Medicare beneficiary who receives an advance beneficiary notice (ABN) from the physician who may be paid directly for the service in question.

The Secretary would establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination may be requested. The Secretary would be able to require that the request be accompanied by a description of the item or service and other supporting documentation including a copy of the ABN if the beneficiary is requesting the prior determination.

The contractor would be required to provide the eligible requester with a written notice stating whether the item or service is covered or not covered or whether the information is not sufficient to make a decision. This notice would be subject to existing deadlines applying to initial determinations and would include a brief explanation of the basis for the decision and the right to redetermination. If a physician's request for a prior determination was unsuccessful, the beneficiary would be informed of that decision. These prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts. If unsuccessful, the requestor would have the right to request a redetermination. Contractors' prior determinations (and redeterminations) would not be subject to further administrative or judicial review. However, an individual would retain existing rights to administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. No prior determinations would be rendered after services are rendered or items are provided.

The Secretary would be required to (1) establish the process to allow for the processing of such requests beginning 18 months after enactment; (2) collect data on the advance determinations; and (3) establish a beneficiary and provider outreach and education program. GAO would be required to report on the use of the advance beneficiary notice and prior determination process no later than 18 months of its implementation.

Title V – Miscellaneous Provisions

Section 501. Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines.

Explanation of Provision. The Secretary would not be permitted to implement any new documentation guidelines on or after enactment for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians (both generalists and specialists) after assessment by the physician community; (2) based on a plan with deadlines for improving use of E&M codes; (3) are developed after completion of the pilot projects to test modifications to the codes; (4) are found to meet the desired objectives; and (5) are preceded by establishment of appropriate outreach and education of the physician community. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The Secretary would be required to modify E&M guidelines to (1) identify clinically relevant documentation:

(2) decrease non-clinically pertinent documentation; (3) increase the reviewers' accuracy; and (4) educate the physicians and the reviewers.

The provisions would establish different pilot projects in specified settings that would be (1) conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists); (2) be of sufficient length to educate physicians and contractors on E&M guidelines and (3) allow for an assessment of E&M guidelines and their use. A range of different projects would be established and include at least one project that (1) uses a physician peer review method; (2) uses an alternative method based on face-to-face encounter time with the patient; (3) is in a rural area; (4) is outside a rural area; and (5) involves physicians billing in a teaching setting and nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project, and would last for as long as the provider participated in the project. The Secretary, in consultation with practicing physicians including those in groups practices as well as generalists and specialists, would be required to evaluate the development of alternative E&M documentation systems with respect to administrative simplification requirements and report results of the study to Congress by October 1, 2003. The Medicare Payment Advisory Commission would conduct an analysis of the results of this study and submit a report to Congress.

The Secretary would be required to conduct a study of the appropriate coding of extended office visits where no diagnosis is made and submit a report with recommendations to Congress no later than October 1, 2003.

Section 503. Improvement in Oversight of Technology and Coverage.

(a) Improved Coordination Between FDA and CMS on Coverage of Breakthrough Medical Devices.

Explanation of Provision. Upon request and to the extent feasible, the Secretary would be required to ensure that appropriate information from the review for application for premarket approval of class III medical devices conducted by the Federal Drug Administration (FDA) is shared for the purposes of making Medicare coverage decisions. Within 6 months of enactment, the Secretary would be required to submit a report to the appropriate congressional committees on the implementation plan to shorten the delay between FDA's premarket approval and Medicare's coding and coverage decisions. This provision would not change Medicare's coverage nor FDA's premarket approval criteria. Nothing in this subsection would be construed to increase the premarket approval application requirements under the Federal Food, Drug, and Cosmetic Act.

(b) Council for Technology and Innovation.

Explanation of Provision. The Secretary is required to establish a Council for Technology and Innovation within CMS. The council would be composed of senior CMS staff with an executive coordinator, who is designated or appointed by the Secretary and reports to the CMS administrator. The chairperson would serve as a single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System.

Explanation of Provision. GAO would be required to conduct a study analyzing which external data can be collected by CMS for use in computing Medicare's inpatient hospital payments. The study may include an evaluation of the feasibility and appropriateness of using quarterly samples or special surveys among other methods. The study would include an analysis of whether other agencies, such as the Bureau of Labor Statistics in the Department of Commerce (sic), are best suited to collect this information. The report would be submitted to Congress no later than October 1, 2002

(d) IOM Study on Local Coverage Determinations.

Explanation of Provision. The Secretary would be required to arrange for a study by the Institute of Medicine (IOM) that would examine Medicare's local coverage determinations. The study would examine (1) the consistency of definitions used in the determinations; (2) the types of evidence that are the basis of the determinations; (3) the advantages and disadvantages of local coverage decisionmaking and of maintaining local Medicare contractor advisory committees; and (4) the manner in which local coverage decisions are used to develop data to support national coverage determinations. The IOM study would be due to the Secretary no later than 3 years after enactment when it would be promptly transmitted to Congress.

(e) Methods for Determining Payment Basis for New Lab Tests.

Current Law. Outpatient clinical diagnostic laboratory tests are paid on the basis of areawide fee schedules. The law establishes a cap on the payment amounts which is currently set at 74% of the median for all fee schedules for that test. The cap is set at 100% of the median for tests performed after January 1,2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

Explanation of Provisions. The Secretary would be required to establish procedures (by regulation) for determining the basis and amount of payments for new or substantially revised clinical diagnostic laboratory tests assigned a Health Care Procedure Coding System (HCPCS) code on or after January 1, 2003. A code would

be considered as substantially revised if there is a substantive change to the definition of a test or procedure to which the HCPCS code applies.

The Secretary, as part of this procedure, would be required to (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the *Federal Register* on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations; (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary.

Section 503. Treatment of Hospitals for Certain Services Under the Medicare Secondary Payor (MSP) Provisions.

Current Law. In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payor is the Medicare program's coordination of benefits with other insurers. Section 1862(b)(6) of the Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

Explanation of Provision. The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payor provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Section 504. EMTALA Improvements.

Current Law. Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exists before asking about insurance status of the patient. Hospitals that are found to be in violation of the Emergency Medical Treatment and Labor Act (EMTALA) requirements may face civil monetary penalties and termination of their provider agreement. After a state investigation of an EMTALA complaint, the CMS Regional Office may ask its local peer review organization (PRO) to perform a 5-day review to obtain additional medical expertise. However, prior to imposing a civil monetary penalty, the Secretary is required to request that a PRO assess whether the involved beneficiary had an emergency condition which had not been stabilized and provide a report on its findings. Except in the case where a delay would jeopardize the health or safety of individuals, the Secretary provides 60-day period for the requested PRO review.

Explanation of Provisions. Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2002, would be evaluated as reasonable and necessary on the basis of the patient's presenting symptoms or

complaint available to the treating physician or practitioner at the time the services were ordered and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit. The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

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.

Section 505. Emergency Medical Treatment and Active Labor (EMTALA) Task Force.

Explanation of Provision. The Secretary would be required to establish a 19-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS administrator; the OIG; four hospital representatives who have EMTALA experience (including one person from a public hospital and at least two of whom have not experienced EMTALA violations), seven practicing physicians with EMTALA experience; two patient representatives; two regional CMS staff involved in EMTALA investigations; one representative from a state survey organization and one representative from a PRO. The Secretary would (1) consider qualified individuals who are nominated by organizations representing providers and patients in selecting the task force; and (2) establish the advisory group without regard to any limits on the number of such group that may be established (within HHS or otherwise).

The advisory group would be required to (1) elect a member as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; and (3) terminate 30 months after the date of its first meeting. The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations.

Section 506. Authorizing Use of Arrangements with Other Hospice Programs to Provide the Core Hospice Services in Certain Circumstances.

Current Law. A hospice is a public agency or private organization which is primarily engaged in providing and making available certain care to a terminally ill Medicare beneficiary under a written plan. 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 nonurbanized areas can receive waivers to this

requirement. Other non-core services may be provided under arrangement, subject to certain conditions.

Explanation of Provision. Hospice programs may enter into arrangements with another certified hospice program to provide services. The services that could be provided under these arrangements would be limited to extraordinary or non-routine circumstances, such as unanticipated periods of staffing shortages. The originating hospice program would continue to be responsible for billing and maintaining quality of care.

Section 507. Application of OSHA Bloodborne Pathogens Standard to Certain Hospitals.

Current Law. Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

Explanation of Provision. As of July 1, 2002, 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.

Section 508. One-Year Delay in Lock-in Procedures for Medicare+Choice Plans; Change in Medicare+Choice Reporting Deadlines and Annual, Coordinated Election Period for 2002.

(a) One-Year Delay in Lock-in Procedures for Medicare+Choice Plans.

Current Law. Under the provisions in the Balanced Budget Act of 1997, Medicare beneficiaries are able to enroll in a M+C plan, change plans, or return to traditional fee-for-service Medicare at any point in the calendar year through 2001. After a transition period, a beneficiary will be permitted to make and change health plan elections only during an annual coordinated election period. Beneficiaries are also provided a 3-month period after making an election when they can change their election. Additional election periods called "special election periods" will apply for newly eligible Medicare beneficiaries and beneficiaries who experience certain events. Limited exceptions are provided. The lock-in provision (which limits beneficiaries' ability to enroll and disenroll in Medicare managed care plans) will be fully implemented in FY2002.

Explanation of Provisions. The full implementation of the M+C lock-in provision would be delayed from FY2002 to FY2003.

(b) Change in Medicare+Choice Reporting Deadlines and Annual, Coordinated Election Period for 2002.

Current Law. M+C plans are required to include all Medicare covered services (except hospice services) and may offer additional benefits. The adjusted community rate (ACR) mechanism is the procedure that determines the minimum amount of additional benefits health plans are required to provide and the related cost-sharing amounts, if any. No later than July 1 of each year, each M+C organization is required to submit its ACR to HHS.

Explanation of Provisions. This provision would move the filing date for the ACR for 2002 from July 1, 2002 to the third Monday in September, 2002 and change the current open enrollment period in 2003 to a period beginning on November 15, 2002 ending on December 31, 2002. GAO would be required to study the enrollment process that occurred in 2001 and submit a report to Congress by May 31, 2002. The report would include an examination of the impact of moving the ACR date on (1) M+C participation and benefits offered, and (2) timeliness and adequacy of the plan-specific information provided to beneficiaries. The report would also include results from surveying beneficiaries and M+C organizations as well as any appropriate recommendations.

Section 509. BIPA-Related Technical Amendments and Corrections.

Current Law. BIPA established an advisory committee structure, the Medicare Coverage Advisory Committee, to assist the Secretary in making national coverage determinations by citing Section 1114 of the Act.

Explanation of Provision. The provisions would incorporate Section 1114 of the Act which relates to the appointment of advisory councils and other advisory groups into Section 1862 of the Act which relates to exclusions from Medicare coverage. Other terms established by BIPA would be changed–from "policy" to "determinations."

Section 510. Conforming Authority to Waive a Program Exclusion.

Current Law. The Secretary is required to exclude individuals and entities from participation in federal health programs who are (1) convicted of a criminal offense related to health care delivery under Medicare or under state health programs; (2) convicted of a criminal offense related to patient abuse or neglect under federal or state law; (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care program financed or operated by the federal, state or local government; or (4) convicted of a felony related to a controlled substance. At the request of a state, the Secretary is permitted to waive a program exclusion with respect to Medicare or Medicaid, but only for exclusions described in (1) above.

Explanation of Provisions. The Administrator of a federal health program would be permitted to request a waiver of a program exclusion if the exclusion of a

sole community physician or source of specialized services in a community would impose a hardship. This conforming change would extend the same waiver authority currently in Medicare and Medicaid to federal health programs. In addition, waivers could be requested for Medicare, Medicaid, and federal health programs with respect to all exclusions except those related to patient abuse or neglect.

Section 511. Treatment of Certain Dental Claims.

Explanation of Provisions. 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 documentation from Medicare that categorically excluded dental services are not covered prior to paying the claim.

Section 512. Miscellaneous Reports, Studies and Publication Requirements.

(a) GAO Reports on Physician Compensation.

Explanation of Provisions. No later than 6 months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequent years. The report would examine the stability and predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review alternative physician payment structures, and provide recommendations to make the current system more stable and less complex.

(b) Submission of Overdue Reports on Payment and Utilization of Outpatient Therapy Services.

Current Law. Congress required the Secretary to submit a report by January 1, 2001 on the establishment of a mechanism for assuring appropriate utilization of outpatient therapy services. The Secretary was also required to conduct a study on the utilization of therapy services by June 30, 2001. The imposition of annual outpatient therapy caps by the Balanced Budget Act of 1997 has been delayed until October 1, 2002.

Explanation of Provision. The Secretary is urged to submit the mandated reports to Congress immediately.

(c) Annual Publication of List on National Coverage Determinations.

Explanation of Provisions. The Secretary would be required to provide, in an annual report that will be publicly available, a list of Medicare's national coverage determinations made in the previous year and include information on how to learn more about such determinations.