

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

* * * * *

PART A—GENERAL PROVISIONS

SEC. 1108. ADDITIONAL GRANTS TO PUERTO RICO, THE VIRGIN ISLANDS, GUAM, AND AMERICAN SAMOA; LIMITATION ON TOTAL PAYMENTS.

(a) * * *

* * * * *

(f) Subject to subsection (g) and section 1935(e)(1)(B), the total amount certified by the Secretary under title XIX with respect to a fiscal year for payment to—

(1) * * *

* * * * *

APPOINTMENT OF ADVISORY COUNCIL AND OTHER ADVISORY GROUPS

SEC. 1114. (a) * * *

* * * * *

[(i)(1) Any advisory committee appointed under subsection (f) to advise the Secretary on matters relating to the interpretation, application, or implementation of section 1862(a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

[(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

[(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

[(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.]

* * * * *



EXCLUSION OF CERTAIN INDIVIDUALS AND ENTITIES FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS

SEC. 1128. (a) * * *

* * * * *

(c) NOTICE, EFFECTIVE DATE, AND PERIOD OF EXCLUSION.— (1) * * *

* * * * *

(3)(A) * * *

(B) [Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of a State, the Secretary may waive the exclusion under subsection (a)(1) in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.] Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. The Secretary's decision whether to waive the exclusion shall not be reviewable.

* * * * *

CRIMINAL PENALTIES FOR ACTS INVOLVING FEDERAL HEALTH CARE PROGRAMS

SEC. 1128B. (a) * * *

(b)(1) * * *

* * * * *

(3) Paragraphs (1) and (2) shall not apply to—

(A) * * *

* * * * *

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987; [and]

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide[.];

(G) the waiver or reduction of any cost-sharing imposed under part D of title XVIII; and



(H) any remuneration between a public or nonprofit private health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations or loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.

* * * * *

PART B—PEER REVIEW OF THE UTILIZATION AND QUALITY OF HEALTH CARE SERVICES

FUNCTIONS OF PEER REVIEW ORGANIZATIONS

SEC. 1154. (a) * * *

* * * * *

(e)(1) * * *

[(5) In any review conducted under paragraph (2) or (3), the organization shall solicit the views of the patient involved (or the patient's representative).]

* * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

NOTICE OF MEDICARE BENEFITS; MEDICARE AND MEDIGAP INFORMATION

SEC. 1804. (a) * * *

(b) The Secretary shall provide information via a toll-free telephone number on the programs under this title. The Secretary shall provide, through the toll-free number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.

* * * * *

MEDICARE PAYMENT ADVISORY COMMISSION

SEC. 1805. (a) * * *

(b) DUTIES.—

(1) * * *

(2) SPECIFIC TOPICS TO BE REVIEWED.—

(A) * * *

(B) ORIGINAL MEDICARE FEE-FOR-SERVICE SYSTEM.—

Specifically, the Commission shall review payment policies under parts A and B, including—



(i) the factors affecting expenditures for the efficient provision of services in different sectors, including the process for updating hospital, skilled nursing facility, physician, and other fees,

* * * * *
(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.
* * * * *

MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM

SEC. 1807. (a) IN GENERAL.—The Secretary (or the Medicare Benefits Administrator pursuant to section 1808(c)(3)(C)) shall establish a program—

(1) to endorse prescription drug discount card programs that meet the requirements of this section; and

(2) to make available to medicare beneficiaries information regarding such endorsed programs.

(b) REQUIREMENTS FOR ENDORSEMENT.—The Secretary may not endorse a prescription drug discount card program under this section unless the program meets the following requirements:

(1) SAVINGS TO MEDICARE BENEFICIARIES.—The program passes on to medicare beneficiaries who enroll in the program discounts on prescription drugs, including discounts negotiated with manufacturers.

(2) PROHIBITION ON APPLICATION ONLY TO MAIL ORDER.—The program applies to drugs that are available other than solely through mail order.

(3) BENEFICIARY SERVICES.—The program provides pharmaceutical support services, such as education and counseling, and services to prevent adverse drug interactions.

(4) INFORMATION.—The program makes available to medicare beneficiaries through the Internet and otherwise information, including information on enrollment fees, prices charged to beneficiaries, and services offered under the program, that the Secretary identifies as being necessary to provide for informed choice by beneficiaries among endorsed programs.

(5) DEMONSTRATED EXPERIENCE.—The entity operating the program has demonstrated experience and expertise in operating such a program or a similar program.

(6) QUALITY ASSURANCE.—The entity has in place adequate procedures for assuring quality service under the program.

(7) ADDITIONAL BENEFICIARY PROTECTIONS.—The program meets such additional requirements as the Secretary identifies to protect and promote the interest of medicare beneficiaries, including requirements that ensure that beneficiaries are not charged more than the lower of the negotiated retail price or the usual and customary price.

(c) PROGRAM OPERATION.—The Secretary shall operate the program under this section consistent with the following:



(1) *PROMOTION OF INFORMED CHOICE.*—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which compares the costs and benefits of such programs in a manner coordinated with the dissemination of educational information on Medicare+Choice plans under part C.

(2) *OVERSIGHT.*—The Secretary shall provide appropriate oversight to ensure compliance of endorsed programs with the requirements of this section, including verification of the discounts and services provided.

(3) *USE OF MEDICARE TOLL-FREE NUMBER.*—The Secretary shall provide through the 1-800-medicare toll free telephone number for the receipt and response to inquiries and complaints concerning the program and programs endorsed under this section.

(4) *DISQUALIFICATION FOR ABUSIVE PRACTICES.*—The Secretary shall revoke the endorsement of a program that the Secretary determines no longer meets the requirements of this section or that has engaged in false or misleading marketing practices.

(5) *ENROLLMENT PRACTICES.*—A medicare beneficiary may not be enrolled in more than one endorsed program at any time.

(d) *TRANSITION.*—The Secretary shall provide for an appropriate transition and discontinuation of the program under this section at the time prescription drug benefits first become available under part D.

(e) *AUTHORIZATION OF APPROPRIATIONS.*—There are authorized to be appropriated such sums as may be necessary to carry out the program under this section.

MEDICARE BENEFITS ADMINISTRATION

SEC. 1808. (a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

(b) *ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF ACTUARY.*—

(1) *ADMINISTRATOR.*—

(A) *IN GENERAL.*—The Medicare Benefits Administration shall be headed by an administrator to be known as the “Medicare Benefits Administrator” (in this section referred to as the “Administrator”) who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

(B) *COMPENSATION.*—The Administrator shall be paid at the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5, United States Code.

(C) *TERM OF OFFICE.*—The Administrator shall be appointed for a term of 5 years. In any case in which a successor does not take office at the end of an Administrator's term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator appointed to a term of office after the commencement



of such term may serve under such appointment only for the remainder of such term.

(D) GENERAL AUTHORITY.—The Administrator shall be responsible for the exercise of all powers and the discharge of all duties of the Administration, and shall have authority and control over all personnel and activities thereof.

(E) RULEMAKING AUTHORITY.—The Administrator may prescribe such rules and regulations as the Administrator determines necessary or appropriate to carry out the functions of the Administration. The regulations prescribed by the Administrator shall be subject to the rulemaking procedures established under section 553 of title 5, United States Code.

(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL UNITS.—The Administrator may establish, alter, consolidate, or discontinue such organizational units or components within the Administration as the Administrator considers necessary or appropriate, except as specified in this section.

(G) AUTHORITY TO DELEGATE.—The Administrator may assign duties, and delegate, or authorize successive redelegations of, authority to act and to render decisions, to such officers and employees of the Administration as the Administrator may find necessary. Within the limitations of such delegations, redelegations, or assignments, all official acts and decisions of such officers and employees shall have the same force and effect as though performed or rendered by the Administrator.

(2) DEPUTY ADMINISTRATOR.—

(A) IN GENERAL.—There shall be a Deputy Administrator of the Medicare Benefits Administration who shall be appointed by the President, by and with the advice and consent of the Senate.

(B) COMPENSATION.—The Deputy Administrator shall be paid at the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(C) TERM OF OFFICE.—The Deputy Administrator shall be appointed for a term of 5 years. In any case in which a successor does not take office at the end of a Deputy Administrator's term of office, such Deputy Administrator may continue in office until the entry upon office of such a successor. A Deputy Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

(D) DUTIES.—The Deputy Administrator shall perform such duties and exercise such powers as the Administrator shall from time to time assign or delegate. The Deputy Administrator shall be Acting Administrator of the Administration during the absence or disability of the Administrator and, unless the President designates another officer of the Government as Acting Administrator, in the event of a vacancy in the office of the Administrator.

(3) CHIEF ACTUARY.—



(A) *IN GENERAL.*—There is established in the Administration the position of Chief Actuary. The Chief Actuary shall be appointed by, and in direct line of authority to, the Administrator of such Administration. The Chief Actuary shall be appointed from among individuals who have demonstrated, by their education and experience, superior expertise in the actuarial sciences. The Chief Actuary may be removed only for cause.

(B) *COMPENSATION.*—The Chief Actuary shall be compensated at the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

(C) *DUTIES.*—The Chief Actuary shall exercise such duties as are appropriate for the office of the Chief Actuary and in accordance with professional standards of actuarial independence.

(4) *SECRETARIAL COORDINATION OF PROGRAM ADMINISTRATION.*—The Secretary shall ensure appropriate coordination between the Administrator and the Administrator of the Centers for Medicare & Medicaid Services in carrying out the programs under this title.

(c) *DUTIES; ADMINISTRATIVE PROVISIONS.*—

(1) *DUTIES.*—

(A) *GENERAL DUTIES.*—The Administrator shall carry out parts C and D, including—

(i) negotiating, entering into, and enforcing, contracts with plans for the offering of Medicare+Choice plans under part C, including the offering of qualified prescription drug coverage under such plans; and

(ii) negotiating, entering into, and enforcing, contracts with PDP sponsors for the offering of prescription drug plans under part D.

(B) *OTHER DUTIES.*—The Administrator shall carry out any duty provided for under part C or part D, including demonstration projects carried out in part or in whole under such parts, the programs of all-inclusive care for the elderly (PACE program) under section 1894, the social health maintenance organization (SHMO) demonstration projects (referred to in section 4104(c) of the Balanced Budget Act of 1997), and through a Medicare+Choice project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of a interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved).

(C) *PRESCRIPTION DRUG CARD.*—The Administrator shall carry out section 1807 (relating to the medicare prescription drug discount card endorsement program).

(D) *NONINTERFERENCE.*—In carrying out its duties with respect to the provision of qualified prescription drug coverage to beneficiaries under this title, the Administrator may not—



(i) require a particular formulary or institute a price structure for the reimbursement of covered outpatient drugs;

(ii) interfere in any way with negotiations between PDP sponsors and Medicare+Choice organizations and drug manufacturers, wholesalers, or other suppliers of covered outpatient drugs; and

(iii) otherwise interfere with the competitive nature of providing such coverage through such sponsors and organizations.

(E) ANNUAL REPORTS.—Not later March 31 of each year, the Administrator shall submit to Congress and the President a report on the administration of parts C and D during the previous fiscal year.

(2) STAFF.—

(A) IN GENERAL.—The Administrator, with the approval of the Secretary, may employ, without regard to chapter 31 of title 5, United States Code, other than sections 3110 and 3112, such officers and employees as are necessary to administer the activities to be carried out through the Medicare Benefits Administration. The Administrator shall employ staff with appropriate and necessary expertise in negotiating contracts in the private sector.

(B) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

(i) IN GENERAL.—The staff of the Medicare Benefits Administration shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 (other than section 5101) and chapter 53 (other than section 5301) of such title (relating to classification and schedule pay rates).

(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(C) LIMITATION ON FULL-TIME EQUIVALENT STAFFING FOR CURRENT CMS FUNCTIONS BEING TRANSFERRED.—The Administrator may not employ under this paragraph a number of full-time equivalent employees, to carry out functions that were previously conducted by the Centers for Medicare & Medicaid Services and that are conducted by the Administrator by reason of this section, that exceeds the number of such full-time equivalent employees authorized to be employed by the Centers for Medicare & Medicaid Services to conduct such functions as of the date of the enactment of this Act.

(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

(A) IN GENERAL.—The Secretary, the Administrator, and the Administrator of the Centers for Medicare & Medicaid Services shall establish an appropriate transition of responsibility in order to redelegate the administration of part C from the Secretary and the Administrator of the Centers for Medicare & Medicaid Services to the Adminis-



trator as is appropriate to carry out the purposes of this section.

(B) *TRANSFER OF DATA AND INFORMATION.*—The Secretary shall ensure that the Administrator of the Centers for Medicare & Medicaid Services transfers to the Administrator of the Medicare Benefits Administration such information and data in the possession of the Administrator of the Centers for Medicare & Medicaid Services as the Administrator of the Medicare Benefits Administration requires to carry out the duties described in paragraph (1).

(C) *CONSTRUCTION.*—Insofar as a responsibility of the Secretary or the Administrator of the Centers for Medicare & Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare & Medicaid Services in this title or title XI with respect to such responsibility is deemed to be a reference to the Administrator.

(d) *OFFICE OF BENEFICIARY ASSISTANCE.*—

(1) *ESTABLISHMENT.*—The Secretary shall establish within the Medicare Benefits Administration an Office of Beneficiary Assistance to coordinate functions relating to outreach and education of medicare beneficiaries under this title, including the functions described in paragraph (2). The Office shall be separate operating division within the Administration.

(2) *DISSEMINATION OF INFORMATION ON BENEFITS AND APPEALS RIGHTS.*—

(A) *DISSEMINATION OF BENEFITS INFORMATION.*—The Office of Beneficiary Assistance shall disseminate, directly or through contract, to medicare beneficiaries, by mail, by posting on the Internet site of the Medicare Benefits Administration and through a toll-free telephone number, information with respect to the following:

(i) Benefits, and limitations on payment (including cost-sharing, stop-loss provisions, and formulary restrictions) under parts C and D.

(ii) Benefits, and limitations on payment under parts A and B, including information on medicare supplemental policies under section 1882.

Such information shall be presented in a manner so that medicare beneficiaries may compare benefits under parts A, B, D, and medicare supplemental policies with benefits under Medicare+Choice plans under part C.

(B) *DISSEMINATION OF APPEALS RIGHTS INFORMATION.*—The Office of Beneficiary Assistance shall disseminate to medicare beneficiaries in the manner provided under subparagraph (A) a description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program under parts A and B, the Medicare+Choice program under part C, and the Voluntary Prescription Drug Benefit Program under part D.

(e) *MEDICARE POLICY ADVISORY BOARD.*—

(1) *ESTABLISHMENT.*—There is established within the Medicare Benefits Administration the Medicare Policy Advisory



Board (in this section referred to the "Board"). The Board shall advise, consult with, and make recommendations to the Administrator of the Medicare Benefits Administration with respect to the administration of parts C and D, including the review of payment policies under such parts.

(2) REPORTS.—

(A) IN GENERAL.—With respect to matters of the administration of parts C and D, the Board shall submit to Congress and to the Administrator of the Medicare Benefits Administration such reports as the Board determines appropriate. Each such report may contain such recommendations as the Board determines appropriate for legislative or administrative changes to improve the administration of such parts, including the topics described in subparagraph (B). Each such report shall be published in the Federal Register.

(B) TOPICS DESCRIBED.—Reports required under subparagraph (A) may include the following topics:

(i) FOSTERING COMPETITION.—Recommendations or proposals to increase competition under parts C and D for services furnished to medicare beneficiaries.

(ii) EDUCATION AND ENROLLMENT.—Recommendations for the improvement to efforts to provide medicare beneficiaries information and education on the program under this title, and specifically parts C and D, and the program for enrollment under the title.

(iii) IMPLEMENTATION OF RISK-ADJUSTMENT.—Evaluation of the implementation under section 1853(a)(3)(C) of the risk adjustment methodology to payment rates under that section to Medicare+Choice organizations offering Medicare+Choice plans that accounts for variations in per capita costs based on health status and other demographic factors.

(iv) DISEASE MANAGEMENT PROGRAMS.—Recommendations on the incorporation of disease management programs under parts C and D.

(v) RURAL ACCESS.—Recommendations to improve competition and access to plans under parts C and D in rural areas.

(C) MAINTAINING INDEPENDENCE OF BOARD.—The Board shall directly submit to Congress reports required under subparagraph (A). No officer or agency of the United States may require the Board to submit to any officer or agency of the United States for approval, comments, or review, prior to the submission to Congress of such reports.

(3) DUTY OF ADMINISTRATOR OF MEDICARE BENEFITS ADMINISTRATION.—With respect to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report is submitted, the Administrator of the Medicare Benefits Administration shall submit to Congress and the President an analysis of recommendations made by the Board in such report. Each such analysis shall be published in the Federal Register.

(4) MEMBERSHIP.—



(A) *APPOINTMENT.*—Subject to the succeeding provisions of this paragraph, the Board shall consist of seven members to be appointed as follows:

(i) Three members shall be appointed by the President.

(ii) Two members shall be appointed by the Speaker of the House of Representatives, with the advice of the chairmen and the ranking minority members of the Committees on Ways and Means and on Energy and Commerce of the House of Representatives.

(iii) Two members shall be appointed by the President pro tempore of the Senate with the advice of the chairman and the ranking minority member of the Senate Committee on Finance.

(B) *QUALIFICATIONS.*—The members shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education and experience in health care benefits management, exceptionally qualified to perform the duties of members of the Board.

(C) *PROHIBITION ON INCLUSION OF FEDERAL EMPLOYEES.*—No officer or employee of the United States may serve as a member of the Board.

(5) *COMPENSATION.*—Members of the Board shall receive, for each day (including travel time) they are engaged in the performance of the functions of the board, compensation at rates not to exceed the daily equivalent to the annual rate in effect for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(6) *TERMS OF OFFICE.*—

(A) *IN GENERAL.*—The term of office of members of the Board shall be 3 years.

(B) *TERMS OF INITIAL APPOINTEES.*—As designated by the President at the time of appointment, of the members first appointed—

(i) one shall be appointed for a term of 1 year;

(ii) three shall be appointed for terms of 2 years;

and

(iii) three shall be appointed for terms of 3 years.

(C) *REAPPOINTMENTS.*—Any person appointed as a member of the Board may not serve for more than 8 years.

(D) *VACANCY.*—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Board shall be filled in the manner in which the original appointment was made.

(7) *CHAIR.*—The Chair of the Board shall be elected by the members. The term of office of the Chair shall be 3 years.

(8) *MEETINGS.*—The Board shall meet at the call of the Chair, but in no event less than three times during each fiscal year.

(9) *DIRECTOR AND STAFF.*—



(A) *APPOINTMENT OF DIRECTOR.*—The Board shall have a Director who shall be appointed by the Chair.

(B) *IN GENERAL.*—With the approval of the Board, the Director may appoint, without regard to chapter 31 of title 5, United States Code, such additional personnel as the Director considers appropriate.

(C) *FLEXIBILITY WITH RESPECT TO COMPENSATION.*—

(i) *IN GENERAL.*—The Director and staff of the Board shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 and chapter 53 of such title (relating to classification and schedule pay rates).

(ii) *MAXIMUM RATE.*—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(D) *ASSISTANCE FROM THE ADMINISTRATOR OF THE MEDICARE BENEFITS ADMINISTRATION.*—The Administrator of the Medicare Benefits Administration shall make available to the Board such information and other assistance as it may require to carry out its functions.

(10) *CONTRACT AUTHORITY.*—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(f) *FUNDING.*—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account), such sums as are necessary to carry out this section.

MEDICARE BENEFICIARY OMBUDSMAN

SEC. 1809. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

(b) *DUTIES.*—The Medicare Beneficiary Ombudsman shall—

(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

(A) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary; and

(B) assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such



recommendations for improvement in the administration of this title as the Ombudsman determines appropriate. The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs.

PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

SCOPE OF BENEFITS

SEC. 1812. (a) The benefits provided to an individual by the insurance program under this part shall consist of entitlement to have payment made on his behalf or, in the case of payments referred to in section 1814(d)(2) to him (subject to the provisions of this part) for—

(1) * * *

* * * * *
(3) for individuals not enrolled in part B, home health services, and for individuals so enrolled, post-institutional home health services furnished during a home health spell of illness for up to 100 visits during such spell of illness; [and]

(4) in lieu of certain other benefits, hospice care with respect to the individual during up to two periods of 90 days each and an unlimited number of subsequent periods of 60 days each with respect to which the individual makes an election under subsection (d)(1)[.]; and

(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician who is either the medical director or an employee of a hospice program and that consist of—

(A) an evaluation of the individual's need for pain and symptom management;

(B) counseling the individual with respect to end-of-life issues and care options; and

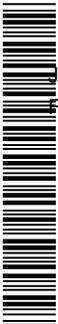
(C) advising the individual regarding advanced care planning.

* * * * *

DEDUCTIBLES AND COINSURANCE

SEC. 1813. (a)(1) * * *

* * * * *



(5)(A)(i) Subject to clause (ii), the amount payable for home health services furnished to the individual under this title for each episode of care beginning in a year (beginning with 2003) shall be reduced by a copayment equal to the copayment amount specified in subparagraph (B)(ii) such year.

(ii) The copayment under clause (i) shall not apply—

(I) in the case of an individual who has been determined to be a qualified medicare beneficiary (as defined in section 1905(p)(1)) or otherwise to be entitled to medical assistance under section 1902(a)(10)(A) or 1902(a)(10)(C); and

(II) in the case of an episode of care which consists of 4 or fewer visits.

(B)(i) The Secretary shall estimate, before the beginning of each year (beginning with 2003), the national average payment under this title per episode for home health services projected for the year involved.

(ii) For each year the copayment amount under this clause is equal to 1.5 percent of the national average payment estimated for the year involved under clause (i). Any amount determined under the preceding sentence which is not a multiple of \$5 shall be rounded to the nearest multiple of \$5.

(iii) There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the estimation of average payment under clause (i).

* * * * *

CONDITIONS OF AND LIMITATIONS ON PAYMENT FOR SERVICES

Requirement of Requests and Certifications

SEC. 1814. (a) * * *

* * * * *

Payment for Hospice Care

(i)(1)(A) * * *

* * * * *

(D) With respect to hospice care furnished in a frontier area on or after January 1, 2003, and before January 1, 2008, the payment rates otherwise established for such care shall be increased by 10 percent. For purposes of this subparagraph, the term 'frontier area' means a county in which the population density is less than 7 persons per square mile.

* * * * *

(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount equivalent to the amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.



(5) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.

* * * * *

PAYMENT TO PROVIDERS OF SERVICES

SEC. 1815. (a) * * *

* * * * *

(e)(1) * * *

(2) The Secretary shall provide (or continue to provide) for payment on a periodic interim payment basis (under the standards established under section 405.454(j) of title 42, Code of Federal Regulations, as in effect on October 1, 1986) with respect to—

(A) * * *

* * * * *

(C) extended care services; [and]

(D) hospice care; and

(E) inpatient critical access hospital services;

if the provider of such services elects to receive, and qualifies for, such payments.

【USE OF PUBLIC AGENCIES OR PRIVATE ORGANIZATIONS TO FACILITATE PAYMENT TO PROVIDERS OF SERVICES】

PROVISIONS RELATING TO THE ADMINISTRATION OF PART A

SEC. 1816. 【(a) If any group or association of providers of services wishes to have payments under this part to such providers made through a national, State, or other public or private agency or organization and nominates such agency or organization for this purpose, the Secretary is authorized to enter into an agreement with such agency or organization providing for the determination by such agency or organization (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the agreement) of the amount of the payments required pursuant to this part to be made to such providers (and to providers assigned to such agency or organization under subsection (e)), and for the making of such payments by such agency or organization to such providers (and to providers assigned to such agency or organization under subsection (e)). Such agreement may also include provision for the agency or organization to do all or any part of the following: (1) to provide consultative services to institutions or agencies to enable them to establish and maintain fiscal records necessary for purposes of this part and otherwise to qualify as hospitals, extended care facilities, or home health agencies, and (2) with respect to the providers of services which are to receive payments through it (A) to serve as a center for, and communicate to providers, any information or instructions furnished to it by the Secretary, and serve as a channel of communication from providers to the Secretary; (B) to make such audits of the records of providers as may be necessary to insure that proper payments are made under this part; and (C) to perform such other functions as



are necessary to carry out this subsection. As used in this title and part B of title XI, the term "fiscal intermediary" means an agency or organization with a contract under this section.

[(b) The Secretary shall not enter into or renew an agreement with any agency or organization under this section unless—

[(1) he finds—

[(A) after applying the standards, criteria, and procedures developed under subsection (f), that to do so is consistent with the effective and efficient administration of this part, and

[(B) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 226, and the agreement provides for such assistance; and

[(2) such agency or organization agrees—

[(A) to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section, and

[(B) to provide the Secretary with access to all such data, information, and claims processing operations, as the Secretary may find necessary in performing his functions under this part.]

(a) *The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.*

(c) [(1) An agreement with any agency or organization under this section may contain such terms and conditions as the Secretary finds necessary or appropriate, may provide for advances of funds to the agency or organization for the making of payments by it under subsection (a), and shall provide for payment of so much of the cost of administration of the agency or organization as is determined by the Secretary to be necessary and proper for carrying out the functions covered by the agreement. The Secretary shall provide that in determining the necessary and proper cost of administration, the Secretary shall, with respect to each agreement, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated agency or organization in carrying out the terms of its agreement. The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for fiscal intermediaries under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used. The Secretary may not require, as a condition of entering into or renewing an agreement under this section or under section 1871, that a fiscal intermediary match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which the provisions of section 1862(b) may apply.]



(2)(A) Each [agreement under this section] contract under section 1874A that provides for making payments under this part shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this title—

(i) * * *

* * * * *

(3)(A) Each [agreement under this section] contract under section 1874A that provides for making payments under this part shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this title within the applicable number of calendar days after the date on which the claim is received.

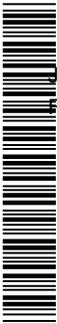
* * * * *

[(d) If the nomination of an agency or organization as provided in this section is made by a group or association of providers of services, it shall not be binding on members of the group or association which notify the Secretary of their election to that effect. Any provider may, upon such notice as may be specified in the agreement under this section with an agency or organization, withdraw its nomination to receive payments through such agency or organization. Any provider which has withdrawn its nomination, and any provider which has not made a nomination, may elect to receive payments from any agency or organization which has entered into an agreement with the Secretary under this section if the Secretary and such agency or organization agree to it.

[(e)(1) Notwithstanding subsections (a) and (d), the Secretary, after taking into consideration any preferences of providers of services, may assign or reassign any provider of services to any agency or organization which has entered into an agreement with him under this section, if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such assignment or reassignment would result in the more effective and efficient administration of this part.

[(2) Notwithstanding subsections (a) and (d), the Secretary may (subject to the provisions of paragraph (4)) designate a national or regional agency or organization which has entered into an agreement with him under this section to perform functions under the agreement with respect to a class of providers of services in the Nation or region (as the case may be), if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such designation would result in more effective and efficient administration of this part.

[(3)(A) Before the Secretary makes an assignment or reassignment under paragraph (1) of a provider of services to other than the agency or organization nominated by the provider, he shall furnish (i) the provider and such agency or organization with a full explanation of the reasons for his determination as to the efficiency and effectiveness of the agency or organization to perform the functions required under this part with respect to the provider, and (ii) such agency or organization with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.



[(B) Before the Secretary makes a designation under paragraph (2) with respect to a class of providers of services, he shall furnish (i) such providers and the agencies and organizations adversely affected by such designation with a full explanation of the reasons for his determination as to the efficiency and effectiveness of such agencies and organizations to perform the functions required under this part with respect to such providers, and (ii) the agencies and organizations adversely affected by such designation with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

[(4) Notwithstanding subsections (a) and (d) and paragraphs (1), (2), and (3) of this subsection, the Secretary shall designate regional agencies or organizations which have entered into an agreement with him under this section to perform functions under such agreement with respect to home health agencies (as defined in section 1861(o)) in the region, except that in assigning such agencies to such designated regional agencies or organizations the Secretary shall assign a home health agency which is a subdivision of a hospital (and such agency and hospital are affiliated or under common control) only if, after applying such criteria relating to administrative efficiency and effectiveness as he shall promulgate, he determines that such assignment would result in the more effective and efficient administration of this title. By not later than July 1, 1987, the Secretary shall limit the number of such regional agencies or organizations to not more than ten.

[(5) Notwithstanding any other provision of this title, the Secretary shall designate the agency or organization which has entered into an agreement under this section to perform functions under such an agreement with respect to each hospice program, except that with respect to a hospice program which is a subdivision of a provider of services (and such hospice program and provider of services are under common control) due regard shall be given to the agency or organization which performs the functions under this section for the provider of services.

[(f)(1) In order to determine whether the Secretary should enter into, renew, or terminate an agreement under this section with an agency or organization, whether the Secretary should assign or reassign a provider of services to an agency or organization, and whether the Secretary should designate an agency or organization to perform services with respect to a class of providers of services, the Secretary shall develop standards, criteria, and procedures to evaluate such agency's or organization's (A) overall performance of claims processing (including the agency's or organization's success in recovering payments made under this title for services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A))) and other related functions required to be performed by such an agency or organization under an agreement entered into under this section, and (B) performance of such functions with respect to specific providers of services, and the Secretary shall establish standards and criteria with respect to the efficient and effective administration of this part. No agency or organization shall be found under such standards and criteria not to be efficient or effective or to be less efficient or effective solely on



the ground that the agency or organization serves only providers located in a single State.

[(2) The standards and criteria established under paragraph (1) shall include—

[(A) with respect to claims for services furnished under this part by any provider of services other than a hospital—

[(i) whether such agency or organization is able to process 75 percent of reconsiderations within 60 days (except in the case of fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days, and

[(ii) the extent to which such agency's or organization's determinations are reversed on appeal; and

[(B) with respect to applications for an exemption from or exception or adjustment to the target amount applicable under section 1886(b) to a hospital that is not a subsection (d) hospital (as defined in section 1886(d)(1)(B))—

[(i) if such agency or organization receives a completed application, whether such agency or organization is able to process such application not later than 75 days after the application is filed, and

[(ii) if such agency or organization receives an incomplete application, whether such agency or organization is able to return the application with instructions on how to complete the application not later than 60 days after the application is filed.

[(g) An agreement with the Secretary under this section may be terminated—

[(1) by the agency or organization which entered into such agreement at such time and upon such notice to the Secretary, to the public, and to the providers as may be provided in regulations, or

[(2) by the Secretary at such time and upon such notice to the agency or organization, to the providers which have nominated it for purposes of this section, and to the public, as may be provided in regulations, but only if he finds, after applying the standards, criteria, and procedures developed under subsection (f) and after reasonable notice and opportunity for hearing to the agency or organization, that (A) the agency or organization has failed substantially to carry out the agreement, or (B) the continuation of some or all of the functions provided for in the agreement with the agency or organization is disadvantageous or is inconsistent with the efficient administration of this part.

[(h) An agreement with an agency or organization under this section may require any of its officers or employees certifying payments or disbursing funds pursuant to the agreement, or otherwise participating in carrying out the agreement, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

[(i)(1) No individual designated pursuant to an agreement under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.



[(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

[(3) No such agency or organization shall be liable to the United States for any payments referred to in paragraph (1) or (2).]

(j) [An agreement with an agency or organization under this section] *A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part* shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to [such agency or organization] *such medicare administrative contractor* that is denied, [such agency or organization] *such medicare administrative contractor—*

(1) * * *

* * * * *

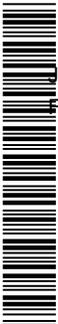
(k) [An agreement with an agency or organization under this section] *A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part* shall require that [such agency or organization] *such medicare administrative contractor* submit an annual report to the Secretary describing the steps taken to recover payments made for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)).

[(l) No agency or organization may carry out (or receive payment for carrying out) any activity pursuant to an agreement under this section to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893.]

FEDERAL HOSPITAL INSURANCE TRUST FUND

SEC. 1817. (a) * * *

(b) With respect to the Trust Fund, there is hereby created a body to be known as the Board of Trustees of the Trust Fund (hereinafter in this section referred to as the "Board of Trustees") composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, [and the Secretary of Health and Human Services, all ex officio,] *the Secretary of Health and Human Services, and the Administrator of the Medicare Benefits Administration, all ex officio*, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by the Senate. A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term. The Secretary of the



Treasury shall be the Managing Trustee of the Board of Trustees (hereinafter in this section referred to as the "Managing Trustee"). The Administrator of the Health Care Financing Administration shall serve as the Secretary of the Board of Trustees. The Board of Trustees shall meet not less frequently than once each calendar year. It shall be the duty of the Board of Trustees to—

(1) * * *

* * * * *

MEDICARE RURAL HOSPITAL FLEXIBILITY PROGRAM

SEC. 1820. (a) * * *

* * * * *

(c) MEDICARE RURAL HOSPITAL FLEXIBILITY PROGRAM DESCRIBED.—

(1) * * *

(2) STATE DESIGNATION OF FACILITIES.—

(A) * * *

(B) CRITERIA FOR DESIGNATION AS CRITICAL ACCESS HOSPITAL.—A State may designate a facility as a critical access hospital if the facility—

(i) * * *

* * * * *

(iii) provides *subject to paragraph (3)* not more than 15 (or, in the case of a facility under an agreement described in subsection (f), 25) acute care inpatient beds (meeting such standards as the Secretary may establish) for providing inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient;

* * * * *

(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—

(A) IN GENERAL.—*In the case of a hospital that demonstrates that it meets the standards established under subparagraph (B), the bed limitations otherwise applicable under paragraph (2)(B)(iii) and subsection (f) shall be increased by 5 beds.*

(B) STANDARDS.—*The Secretary shall specify standards for determining whether a critical access hospital has sufficiently strong seasonal variations in patient admissions to justify the increase in bed limitation provided under subparagraph (A).*

* * * * *

(f) PERMITTING MAINTENANCE OF SWING BEDS.—Nothing in this section shall be construed to prohibit a State from designating or the Secretary from certifying a facility as a critical access hospital solely because, at the time the facility applies to the State for designation as a critical access hospital, there is in effect an agreement between the facility and the Secretary under section 1883 under which the facility's inpatient hospital facilities are used for the provision of extended care services, so long as the total number



of beds that may be used at any time for the furnishing of either such services or acute care inpatient services does not exceed 25 beds and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. For purposes of the previous sentence, any bed of a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time the facility applies to the State for designation as a critical access hospital shall not be counted. *The limitations in numbers of beds under the first sentence are subject to adjustment under subsection (c)(3).*

* * * * *
(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated from the Federal Hospital Insurance Trust Fund for making grants to all States under subsection (g), \$25,000,000 in each of the fiscal years 1998 through [2002] 2007.
* * * * *

PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * *

PAYMENT OF BENEFITS

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1832(a)(1)—
80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1861(s)(10)(A), the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule under subsection (h)(1) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case



of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881, (F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L), (H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (I), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and (J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent of the fee schedule amount provided under section 1848 for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)), the amounts paid shall be 80 percent (*or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww)*) of the payment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the



amounts paid shall be equal to 80 percent (or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww)) of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S) with respect to drugs and biologicals not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, and (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section;

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881)—

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1861(kk)), the amount determined under the prospective payment system under section 1895 less the copayment amount applicable under section 1813(a)(5);

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of \$75 for calendar years before 1991 and \$100 for 1991 and subsequent years; except that (1) such total amount shall not include expenses incurred for items and services described in section 1861(s)(10)(A), (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk))), (3) such



deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866, or (B) on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj)), [and] (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn)), and (7) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) to blood or blood cells furnished the individual in the year.

(g)(1) * * *

* * * * *

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, [and 2002] 2002, 2003, and 2004.

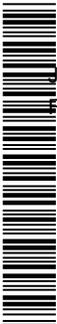
(h)(1) * * *

* * * * *

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2004 (in this paragraph referred to as 'new tests').

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;



(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

* * * * *

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) * * *



(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term “covered OPD services”—

(i) * * *

* * * * *

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) *and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography.*

* * * * *

(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) * * *

(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy [or temperature monitored cryoablation], if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

* * * * *

(8) COPAYMENT AMOUNT.—

(A) * * *

* * * * *

(C) LIMITATION ON COPAYMENT AMOUNT.—

(i) * * *

(ii) TO SPECIFIED PERCENTAGE.—The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) * * *

* * * * *

[(III) For procedures performed in 2004, 50 percent.

[(IV) For procedures performed in 2005, 45 percent.

[(V) For procedures performed in 2006 and thereafter, 40 percent.]



- (III) For procedures performed in 2004, 45 percent.
- (IV) For procedures performed in 2005, 40 percent.
- (V) For procedures performed in 2006, 2007, 2008 and 2009, 35 percent.
- (VI) For procedures performed in 2010, 30 percent.
- (VII) For procedures performed in 2011, 25 percent.
- (VIII) For procedures performed in 2012 and thereafter, 20 percent.

* * * * *

SPECIAL PAYMENT RULES FOR PARTICULAR ITEMS AND SERVICES

SEC. 1834. (a) * * *

* * * * *

(g) PAYMENT FOR OUTPATIENT CRITICAL ACCESS HOSPITAL SERVICES.—

(1) * * *

(2) ELECTION OF COST-BASED HOSPITAL OUTPATIENT SERVICE PAYMENT PLUS FEE SCHEDULE FOR PROFESSIONAL SERVICES.—A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1866(a)(2)(A):

(A) * * *

(B) FEE SCHEDULE FOR PROFESSIONAL SERVICES.—With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians who have not assigned such billing rights.

* * * * *

(l) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES.—

(1) * * *

(2) CONSIDERATIONS.—In establishing such fee schedule, the Secretary shall—

(A) * * *

* * * * *

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (10), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid



by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

* * * * *

[(8)] (9) TRANSITIONAL ASSISTANCE FOR RURAL PROVIDERS.—In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than 1/2 of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year before January 1, 2007, the portion of the payment amount that is based on the fee schedule shall not be less than the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2003, the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2004, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2005, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2006, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the 9 Census divisions using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after January 1, 2003, and before January 1, 2008, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile



rate otherwise established shall be increased by 1/4 of the payment per mile otherwise applicable to such miles.

* * * * *

AMOUNTS OF PREMIUMS

SEC. 1839. (a)(1) * * *

(2) The monthly premium of each individual enrolled under this part for each month after December 1983 shall be the amount determined under paragraph (3), adjusted as required in accordance with subsections (b), (c), and (f) [, and to reflect 80 percent of any reduction elected under section 1854(f)(1)(E).] .

* * * * *

(b) In the case of an individual whose coverage period began pursuant to an enrollment after his initial enrollment period (determined pursuant to subsection (c) or (d) of section 1837) and not pursuant to a special enrollment period under section 1837(i)(4), the monthly premium determined under subsection (a) shall be increased by 10 percent of the monthly premium so determined for each full 12 months (in the same continuous period of eligibility) in which he could have been but was not enrolled. For purposes of the preceding sentence, there shall be taken into account (1) the months which elapsed between the close of his initial enrollment period and the close of the enrollment period in which he enrolled, plus (in the case of an individual who reenrolls) (2) the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which he reenrolled, but there shall not be taken into account months for which the individual can demonstrate that the individual was enrolled in a group health plan described in section 1862(b)(1)(A)(v) by reason of the individual's (or the individual's spouse's) current employment or months during which the individual has not attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a large group health plan as an active individual (as those terms are defined in section 1862(b)(1)(B)(iii)). Any increase in an individual's monthly premium under the first sentence of this subsection with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which such individual may have. *No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, who enrolls under this part during 2001, 2002, or 2003, and who demonstrates to the Secretary before December 31, 2003, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.*

* * * * *

(h)(1) In the case of an individual who resides in a competitive-demonstration area designated under section 1851(k)(1) and who is not enrolled in a Medicare+Choice plan under part C, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this sub-



section) shall be adjusted as follows: If the fee-for-service area-specific non-drug bid (as defined in section 1853(k)(6)) for the Medicare+Choice area in which the individual resides for a month—

(A) does not exceed the choice non-drug benchmark (as determined under section 1853(k)(2)) for such area, the amount of the premium for the individual for the month shall be reduced by an amount equal to 75 percent of the amount by which such benchmark exceeds such fee-for-service bid; or

(B) exceeds such choice non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure that—

(i) the sum of the amount of the adjusted premium and the choice non-drug benchmark for the area, is equal to

(ii) the sum of the unadjusted premium plus amount of the fee-for-service area-specific non-drug bid for the area.

(2) Nothing in this subsection shall be construed as preventing a reduction under paragraph (1)(A) in the premium otherwise applicable under this part to zero or from requiring the provision of a rebate to the extent such premium would otherwise be required to be less than zero.

(3) The adjustment in the premium under this subsection shall be effected in such manner as the Medicare Benefits Administrator determines appropriate.

(4) In order to carry out this subsection (insofar as it is effected through the manner of collection of premiums under 1840(a)), the Medicare Benefits Administrator shall transmit to the Commissioner of Social Security—

(A) at the beginning of each year, the name, social security account number, and the amount of the adjustment (if any) under this subsection for each individual enrolled under this part for each month during the year; and

(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

* * * * *

FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

SEC. 1841. (a) * * *

(b) With respect to the Trust Fund, there is hereby created a body to be known as the Board of Trustees of the Trust Fund (hereinafter in this section referred to as the "Board of Trustees") composed of the Commissioner of Social Security, Secretary of the Treasury, the Secretary of Labor, [and the Secretary of Health and Human Services, all ex officio,] the Secretary of Health and Human Services, and the Administrator of the Medicare Benefits Administration, all ex officio, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by the Senate. A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nomi-



nated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term. The Secretary of the Treasury shall be the Managing Trustee of the Board of Trustees (hereinafter in this section referred to as the "Managing Trustee"). The Administrator of the Health Care Financing Administration shall serve as the Secretary of the Board of Trustees. The Board of Trustees shall meet not less frequently than once each calendar year. It shall be the duty of the Board of Trustees to—

(1) * * *

* * * * *

【USE OF CARRIERS FOR ADMINISTRATION OF BENEFITS】

PROVISIONS RELATING TO THE ADMINISTRATION OF PART B

SEC. 1842. **【(a) In order to provide for the administration of the benefits under this part with maximum efficiency and convenience for individuals entitled to benefits under this part and for providers of services and other persons furnishing services to such individuals, and with a view to furthering coordination of the administration of the benefits under part A and under this part, the Secretary is authorized to enter into contracts with carriers, including carriers with which agreements under section 1816 are in effect, which will perform some or all of the following functions (or, to the extent provided in such contracts, will secure performance thereof by other organizations); and, with respect to any of the following functions which involve payments for physicians' services on a reasonable charge basis, the Secretary shall to the extent possible enter into such contracts:**

【(1)(A) make determinations of the rates and amounts of payments required pursuant to this part to be made to providers of services and other persons on a reasonable cost or reasonable charge basis (as may be applicable);

【(B) receive, disburse, and account for funds in making such payments; and

【(C) make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part;

【(2)(A) determine compliance with the requirements of section 1861(k) as to utilization review; and

【(B) assist providers of services and other persons who furnish services for which payment may be made under this part in the development of procedures relating to utilization practices, make studies of the effectiveness of such procedures and methods for their improvement, assist in the application of safeguards against unnecessary utilization of services furnished by providers of services and other persons to individuals entitled to benefits under this part, and provide procedures for and assist in arranging, where necessary, the establishment of groups outside hospitals (meeting the requirements of section 1861(k)(2)) to make reviews of utilization;



[(3) serve as a channel of communication of information relating to the administration of this part; and

[(4) otherwise assist, in such manner as the contract may provide, in discharging administrative duties necessary to carry out the purposes of this part.]

(a) *The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.*

(b) [(1) Contracts with carriers under subsection (a) may be entered into without regard to section 3709 of the Revised Statutes or any other provision of law requiring competitive bidding.]

(2) [(A) No such contract shall be entered into with any carrier unless the Secretary finds that such carrier will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as he finds pertinent. The Secretary shall publish in the Federal Register standards and criteria for the efficient and effective performance of contract obligations under this section, and opportunity shall be provided for public comment prior to implementation. In establishing such standards and criteria, the Secretary shall provide a system to measure a carrier's performance of responsibilities described in paragraph (3)(H), subsection (h), and section 1845(e)(2). The Secretary may not require, as a condition of entering into or renewing a contract under this section or under section 1871, that a carrier match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which section 1862(b) may apply.

[(B) The Secretary shall establish standards for evaluating carriers' performance of reviews of initial carrier determinations and of fair hearings under paragraph (3)(C), under which a carrier is expected—

[(i) to complete such reviews, within 45 days after the date of a request by an individual enrolled under this part for such a review, in 95 percent of such requests, and

[(ii) to make a final determination, within 120 days after the date of receipt of a request by an individual enrolled under this part for a fair hearing under paragraph (3)(C), in 90 percent of such cases.]

(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1861(s)(2)(K) performed by a member of a team, the Secretary shall instruct [carriers] *medicare administrative contractors* to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

[(D) In addition to any other standards and criteria established by the Secretary for evaluating carrier performance under this paragraph relating to avoiding erroneous payments, the carrier shall be subject to standards and criteria relating to the carrier's success in recovering payments made under this part for items or



services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)).

[(E) With respect to the payment of claims for home health services under this part that, but for the amendments made by section 4611 of the Balanced Budget Act of 1997, would be payable under part A instead of under this part, the Secretary shall continue administration of such claims through fiscal intermediaries under section 1816.]

(3) [Each such contract shall provide that the carrier] *The Secretary*—

(A) [will] *shall* take such action as may be necessary to assure that, where payment under this part for a service is on a cost basis, the cost is reasonable cost (as determined under section 1861(v));

(B) [will] *shall* take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, [to the policyholders and subscribers of the carrier] *to the policyholders and subscribers of the medicare administrative contractor*, and such payment will (except as otherwise provided in section 1870(f)) be made—

(i) * * *

* * * * *

[(C) will establish and maintain procedures pursuant to which an individual enrolled under this part will be granted an opportunity for a fair hearing by the carrier, in any case where the amount in controversy is at least \$100, but less than \$500, when requests for payment under this part with respect to services furnished him are denied or are not acted upon with reasonable promptness or when the amount of such payment is in controversy;

[(D) will furnish to the Secretary such timely information and reports as he may find necessary in performing his functions under this part;

[(E) will maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (D) and otherwise to carry out the purposes of this part;]

(F) [will] *shall* take such action as may be necessary to assure that where payment under this part for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) [will] *shall*, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1848(g)—



(i) * * *

* * * * *

(H) [if it makes determinations or payments with respect to physicians' services, will] shall implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the [carrier] medicare administrative contractor, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

* * * * *

[(I) will submit annual reports to the Secretary describing the steps taken to recover payments made under this part for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)); and]

(L) [will] shall monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality;]. [and shall contain such other terms and conditions not inconsistent with this section as the Secretary may find necessary or appropriate.] In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part on December 31, 1970, or (ii) the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the 12-month period ending on the June 30 last preceding the start of the calendar year in which the service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level) for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1861(s)(6), charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (in-



cluding equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, *medicare administrative contractor*, or agent of the Department of Health and Human Services performing functions under this title and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. Notwithstanding the provisions of the third and fourth sentences preceding this sentence, the prevailing charge level in the case of a physician service in a particular locality determined pursuant to such third and fourth sentences for any calendar year after 1974 shall, if lower than the prevailing charge level for the fiscal year ending June 30, 1975, in the case of a similar physician service in the same locality by reason of the application of economic index data, be raised to such prevailing charge level for the fiscal year ending June 30, 1975, and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1861(v)(1)(K), and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility.

* * * * *

[(5) Each contract under this section shall be for a term of at least one year, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that the Secretary may terminate any such contract at any time (after such reasonable notice and opportunity for hearing to the carrier involved as he may provide in regulations) if he finds that the carrier has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the insurance program established by this part.]

(6) No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment



may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service, (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part, (C) in the case of services described in clause (i) of section 1861(s)(2)(K), payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1861(aa)(2)) for a continuous period beginning prior to the date of the enactment of the Balanced Budget Act of 1997 and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1861(aa)(2), payment may be made directly to the physician assistant, (D) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days; and (iv) the claim form submitted to the [carrier] *medicare administrative contractor* for such services includes the second physician's unique identifier (provided under the system established under subsection (r)) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician, (E) in the case of an item or service (other than services described in section 1888(e)(2)(A)(ii)) furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise), and (G) in the case of services in a hospital or clinic to which section 1880(e) applies, payment shall be made to such hospital or clinic. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant



to an assignment described in subparagraph (B)(ii) of paragraph (3) shall be made to anyone else under a reassignment or power of attorney (except to an employer or facility as described in clause (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed.

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), [the carrier] *the Secretary* shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) * * *

* * * * *

(B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:

(i) In the case of a physician who is not a teaching physician (as defined by the Secretary), [the carrier] *the Secretary* shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.

(ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, [the carrier] *the Secretary* shall base payment under this title on the greatest of—

(I) * * *

* * * * *

(C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects payment to be determined under this subparagraph, [the carrier] *the Secretary* shall provide for payment for such services under this part



on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).

* * * * *

(c) [(1) Any contract entered into with a carrier under this section shall provide for advances of funds to the carrier for the making of payments by it under this part, and shall provide for payment of the cost of administration of the carrier, as determined by the Secretary to be necessary and proper for carrying out the functions covered by the contract. The Secretary shall provide that in determining a carrier's necessary and proper cost of administration, the Secretary shall, with respect to each contract, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated carrier in carrying out the terms of its contract. The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for carriers under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used.]

(2)(A) Each [contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B),] *contract under section 1874A that provides for making payments under this part* shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part—

(i) * * *

* * * * *

(3)(A) Each contract under this section which provides for the disbursement of funds, as described in [subsection (a)(1)(B)] *section 1874A(a)(3)(B)*, shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this title within the applicable number of calendar days after the date on which the claim is received.

(4) Neither a [carrier] *medicare administrative contractor* nor the Secretary may impose a fee under this title—

(A) * * *

* * * * *

[(5) Each contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B), shall require the carrier to meet criteria developed by the Secretary to measure the timeliness of carrier responses to requests for payment of items described in section 1834(a)(15)(C).

[(6) No carrier may carry out (or receive payment for carrying out) any activity pursuant to a contract under this subsection to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).



[(d) Any contract with a carrier under this section may require such carrier or any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

[(e)(1) No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.

[(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

[(3) No such carrier shall be liable to the United States for any payments referred to in paragraph (1) or (2).

[(f) For purposes of this part, the term "carrier" means—

[(1) with respect to providers of services and other persons, a voluntary association, corporation, partnership, or other nongovernmental organization which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee organization; and

[(2) with respect to providers of services only, any agency or organization (not described in paragraph (1)) with which an agreement is in effect under section 1816.]

(g) The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a [carrier or carriers] *medicare administrative contractor or contractors* to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 226(a) of this Act and section 7(d) of the Railroad Retirement Act of 1974.

(h)(1) * * *

(2) [Each carrier having an agreement with the Secretary under subsection (a)] *The Secretary* shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part may obtain the names, addresses, specialty, and telephone numbers of participating physicians and suppliers and may request a copy of an appropriate directory published under paragraph (4). [Each such carrier] *The Secretary* shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which [a carrier having an agreement with the Secretary under subsection (a)] *medicare administrative contractor having a contract under section 1874A that provides for making payments under this part* is able to develop a system for the electronic transmission to [such carrier] *such contractor* of bills for services, such carrier shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.



(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (described in section 1882(g)(1)) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by [a carrier] *a medicare administrative contractor* with a contract under this section, [the carrier] *the contractor* shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by [a carrier] *a medicare administrative contractor*, whether electronically or otherwise, and such user fees shall be collected and retained by [the carrier] *the contractor*.

* * * * *

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make the appropriate area directory or directories available in each district and branch office of the Social Security Administration, in the offices of [carriers] *medicare administrative contractors*, and to senior citizen organizations.

(B) The annual notice provided under subparagraph (A) shall include—

(i) * * *

(iii) an explanation of the assistance offered by [carriers] *medicare administrative contractors* in obtaining the names of participating physicians and suppliers, and

* * * * *

(l)(1)(A) Subject to subparagraph (C), if—

(i) * * *

(iii)(I) a [carrier] *medicare administrative contractor* determines under this part or a peer review organization determines under part B of title XI that payment may not be made by reason of section 1862(a)(1) because a service otherwise covered under this title is not reasonable and necessary under the standards described in that section or (II) payment under this title for such services is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B), and

* * * * *

(2) Each [carrier] *medicare administrative contractor* with a contract in effect under this section with respect to physicians and each peer review organization with a contract under part B of title XI shall send any notice of denial of payment for physicians' services based on section 1862(a)(1) and for which payment is not re-



quested on an assignment-related basis to the physician and the individual involved.

(p)(1) * * *
* * * * *

(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)—

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a [carrier] medicare administrative contractor, the physician may be subject to a civil money penalty in an amount not to exceed \$2,000, and

(q)(1)(A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all [carrier] localities in making payment for physician anesthesia services furnished under this part. Such guide shall be designed so as to result in expenditures under this title for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.

APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS AND CONTINGENCY RESERVE

SEC. 1844. (a) * * *

(c) The Secretary shall determine the Government contribution under subparagraphs (A) and (B) of subsection (a)(1) without regard to any premium reduction resulting from an election under section 1854(f)(1)(E) and without regard to any premium adjustment effected under section 1839(h).

[SEC. 1847. DEMONSTRATION PROJECTS FOR COMPETITIVE ACQUISITION OF ITEMS AND SERVICES.

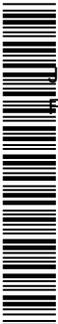
[(a) ESTABLISHMENT OF DEMONSTRATION PROJECT BIDDING AREAS.—

[(1) IN GENERAL.—The Secretary shall implement not more than 5 demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing under this part of the items and services described in subsection (d).

[(2) PROJECT REQUIREMENTS.—Each demonstration project under paragraph (1)—

[(A) shall include such group of items and services as the Secretary may prescribe,

[(B) shall be conducted in not more than 3 competitive acquisition areas, and



[(C) shall be operated over a 3-year period.

[(3) CRITERIA FOR ESTABLISHMENT OF COMPETITIVE ACQUISITION AREAS.—Each competitive acquisition area established under a demonstration project implemented under paragraph (1)—

[(A) shall be, or shall be within, a metropolitan statistical area (as defined by the Secretary of Commerce), and

[(B) shall be chosen based on the availability and accessibility of entities able to furnish items and services, and the probable savings to be realized by the use of competitive bidding in the furnishing of items and services in such area.

[(b) AWARDING OF CONTRACTS IN AREAS.—

[(1) IN GENERAL.—The Secretary shall conduct a competition among individuals and entities supplying items and services described in subsection (c) for each competitive acquisition area established under a demonstration project implemented under subsection (a).

[(2) CONDITIONS FOR AWARDING CONTRACT.—The Secretary may not award a contract to any entity under the competition conducted pursuant to paragraph (1) to furnish an item or service unless the Secretary finds that the entity meets quality standards specified by the Secretary and that the total amounts to be paid under the contract are expected to be less than the total amounts that would otherwise be paid.

[(3) CONTENTS OF CONTRACT.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

[(4) LIMIT ON NUMBER OF CONTRACTORS.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts.

[(c) EXPANSION OF PROJECTS.—

[(1) EVALUATIONS.—The Secretary shall evaluate the impact of the implementation of the demonstration projects on medicare program payments, access, diversity of product selection, and quality. The Secretary shall make annual reports to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate on the results of the evaluation described in the preceding sentence and a final report not later than 6 months after the termination date specified in subsection (e).

[(2) EXPANSION.—If the Secretary determines from the evaluations under paragraph (1) that there is clear evidence that any demonstration project—

[(A) results in a decrease in Federal expenditures under this title, and

[(B) does not reduce program access, diversity of product selection, and quality under this title,
the Secretary may expand the project to additional competitive acquisition areas.

[(d) SERVICES DESCRIBED.—The items and services to which this section applies are all items and services covered under this



part (except for physicians' services as defined in section 1861(s)(1)) that the Secretary may specify. At least one demonstration project shall include oxygen and oxygen equipment.

[(e) TERMINATION.—Notwithstanding any other provision of this section, all projects under this section shall terminate not later than December 31, 2002.]

COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

(1) IMPLEMENTATION OF PROGRAMS.—

(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

(i) at least 1/3 of such areas in 2004; and

(ii) at least 2/3 of such areas in 2005.

(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

(A) DURABLE MEDICAL EQUIPMENT AND INHALATION DRUGS USED IN CONNECTION WITH DURABLE MEDICAL EQUIPMENT.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), other than items used in infusion, and inhalation drugs used in conjunction with durable medical equipment.

(B) OFF-THE-SHELF ORTHOTICS.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(h) which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the patient.

(3) EXEMPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

(A) areas that are not competitive due to low population density; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(b) PROGRAM REQUIREMENTS.—



(1) *IN GENERAL.*—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

(2) *CONDITIONS FOR AWARDING CONTRACT.*—

(A) *IN GENERAL.*—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets quality and financial standards specified by the Secretary or developed by accreditation entities or organizations recognized by the Secretary.

(ii) The total amounts to be paid under the contract (including costs associated with the administration of the contract) are expected to be less than the total amounts that would otherwise be paid.

(iii) Beneficiary access to a choice of multiple suppliers in the area is maintained.

(iv) Beneficiary liability is limited to the applicable percentage of contract award price.

(B) *QUALITY STANDARDS.*—The quality standards specified under subparagraph (A)(i) shall not be less than the quality standards that would otherwise apply if this section did not apply and shall include consumer services standards. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of physicians, practitioners, and suppliers to review (and advise the Secretary concerning) such quality standards.

(3) *CONTENTS OF CONTRACT.*—

(A) *IN GENERAL.*—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) *TERM OF CONTRACTS.*—The Secretary shall rebid contracts under this section not less often than once every 3 years.

(4) *LIMIT ON NUMBER OF CONTRACTORS.*—

(A) *IN GENERAL.*—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of beneficiaries for such items or services in the geographic area covered under the contract on a timely basis.

(B) *MULTIPLE WINNERS.*—The Secretary shall award contracts to more than one entity submitting a bid in each area for an item or service.



(5) *PARTICIPATING CONTRACTORS.*—Payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

(A) the contractor has submitted a bid for such items and services under this section; and

(B) the Secretary has awarded a contract to the contractor for such items and services under this section.

(6) *AUTHORITY TO CONTRACT FOR EDUCATION, OUTREACH AND COMPLAINT SERVICES.*—The Secretary may enter into a contract with an appropriate entity to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such beneficiaries with respect to the program.

(c) *ANNUAL REPORTS.*—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction.

(d) *DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.*—

(1) *IN GENERAL.*—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

(A) for which payment is otherwise made under section 1833(h) or 1834(d)(1) (relating to colorectal cancer screening tests); and

(B) which are furnished without a face-to-face encounter between the individual and the hospital or physician ordering the tests.

(2) *TERMS AND CONDITIONS.*—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

(3) *REPORT.*—The Secretary shall submit to Congress—

(A) an initial report on the project not later than December 31, 2004; and

(B) such progress and final reports on the project after such date as the Secretary determines appropriate.

* * * * *

PAYMENT FOR PHYSICIANS' SERVICES

SEC. 1848. (a) * * *

* * * * *

(d) *CONVERSION FACTORS.*—

(1) * * *

* * * * *

(4) *UPDATE FOR YEARS BEGINNING WITH 2001.*—

(A) * * *

(B) *UPDATE ADJUSTMENT FACTOR.*—For purposes of subparagraph (A)(ii), subject to subparagraph (D) and paragraph (6), the “update adjustment factor” for a year is



equal (as estimated by the Secretary) to the sum of the following:

(i) * * *

* * * * *

(F) TRANSITIONAL ADJUSTMENT DESIGNED TO PROVIDE FOR BUDGET NEUTRALITY.—Under this subparagraph the Secretary shall provide for an adjustment to the update under [subparagraph (A)—

[(i) for each of 2001, 2002, 2003, and 2004, of -0.2 percent; and

[(ii) for 2005 of +0.8 percent.] subparagraph (A), for each of 2001 and 2002, of -0.2 percent.

(5) UPDATE FOR 2003.—The update to the single conversion factor established in paragraph (1)(C) for 2003 is 2 percent.

(6) SPECIAL RULES FOR UPDATE FOR 2004 AND 2005.—The following rules apply in determining the update adjustment factors under paragraph (4)(B) for 2004 and 2005:

(A) USE OF 2002 DATA IN DETERMINING ALLOWABLE COSTS.—

(i) The reference in clause (ii)(I) of such paragraph to April 1, 1996, is deemed to be a reference to January 1, 2002.

(ii) The allowed expenditures for 2002 is deemed to be equal to the actual expenditures for physicians' services furnished during 2002, as estimated by the Secretary.

(B) 1 PERCENTAGE POINT INCREASE IN GDP UNDER SGR.—The annual average percentage growth in real gross domestic product per capita under subsection (f)(2)(C) for each of 2003, 2004, and 2005 is deemed to be increased by 1 percentage point.

* * * * *

(f) SUSTAINABLE GROWTH RATE.—

(1) * * *

(2) SPECIFICATION OF GROWTH RATE.—The sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000 shall be equal to the product of—

(A) * * *

* * * * *

(C) 1 plus the Secretary's estimate of the [projected] annual average percentage growth in real gross domestic product per capita (divided by 100) [from the previous applicable period to the applicable period involved] during the 10-year period ending with the applicable period involved, and

* * * * *

(j) DEFINITIONS.—In this section:

(1) * * *

* * * * *



(3) PHYSICIANS' SERVICES.—The term "physicians' services" includes items and services described in paragraphs (1), (2)(A), (2)(D), (2)(G), (2)(P) (with respect to services described in subparagraphs (A) and (C) of section 1861(oo)(2)), (2)(R) (with respect to services described in subparagraphs (B), (C), and (D) of section 1861(pp)(1)), (2)(S), (2)(W), (3), (4), (13), (14) (with respect to services described in section 1861(nn)(2)), and (15) of section 1861(s) (other than clinical diagnostic laboratory tests and, except for purposes of subsection (a)(3), (g), and (h) such other items and services as the Secretary may specify).

* * * * *

PART C—MEDICARE+CHOICE PROGRAM

ELIGIBILITY, ELECTION, AND ENROLLMENT

SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS THROUGH MEDICARE+CHOICE PLANS.—

(1) IN GENERAL.—Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this title—

- (A) through the original medicare fee-for-service program under parts A and B, or
(B) through enrollment in a Medicare+Choice plan under this part [1], and may elect qualified prescription drug coverage in accordance with section 1860A.

(2) TYPES OF MEDICARE+CHOICE PLANS THAT MAY BE AVAILABLE.—A Medicare+Choice plan may be any of the following types of plans of health insurance:

- (A) COORDINATED CARE PLANS.—Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by provider-sponsored organizations (as defined in section 1855(d)), and preferred provider organization plans. Specialized Medicare+Choice plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.

* * * * *

(b) SPECIAL RULES.—

(1) * * *

* * * * *

(4) COVERAGE UNDER MSA PLANS [ON A DEMONSTRATION BASIS].—

(A) IN GENERAL.—[An individual is not eligible to enroll in an MSA plan under this part—

- [(i) on or after January 1, 2003, unless the enrollment is the continuation of such an enrollment in effect as of such date; or

- [(ii) as of any date if the number of such individuals so enrolled as of such date has reached 390,000.]



Under rules established by the Secretary, an individual is not eligible to enroll (or continue enrollment) in an MSA plan for a year unless the individual provides assurances satisfactory to the Secretary that the individual will reside in the United States for at least 183 days during the year.

* * * * *

(C) REPORTS.—The Secretary shall submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted under subparagraph (B). [The Secretary shall submit such a report, by not later than March 1, 2002, on whether the time limitation under subparagraph (A)(i) should be extended or removed and whether to change the numerical limitation under subparagraph (A)(ii).]

* * * * *

(d) PROVIDING INFORMATION TO PROMOTE INFORMED CHOICE.—

(1) * * *

(2) PROVISION OF NOTICE.—

(A) OPEN SEASON NOTIFICATION.—At least 15 days before the beginning of each annual, coordinated election period (as defined in subsection (e)(3)(B)), the Secretary shall mail to each Medicare+Choice eligible individual residing in an area the following:

(i) GENERAL INFORMATION.—The general information described in paragraph (3).

(ii) LIST OF PLANS AND COMPARISON OF PLAN OPTIONS.—A list identifying the Medicare+Choice plans that are (or will be) available to residents of the area and information described in paragraph (4) concerning such plans *to the extent such information is available at the time of preparation of materials for the mailing*. Such information shall be presented in a comparative form.

* * * * *

(e) COVERAGE ELECTION PERIODS.—

(1) * * *

* * * * *

(3) ANNUAL, COORDINATED ELECTION PERIOD.—

(A) * * *

(B) ANNUAL, COORDINATED ELECTION PERIOD.—For purposes of this section, the term “annual, coordinated election period” means, with respect to a year before 2003 [and after 2005, the month of November before such year and with respect to 2003, 2004, and 2005], *the month of November before such year and with respect to 2003 and any subsequent year, the period beginning on November 15 and ending on December 31 of the year before such year.*

* * * * *

(5) SPECIAL RULES FOR MSA PLANS.—Notwithstanding the preceding provisions of this subsection, an individual—

(A) may elect an MSA plan only during—



- (i) an initial open enrollment period described in paragraph (1), or
- (ii) an annual, coordinated election period described in paragraph (3)(B)[, or];
- [(iii) the month of November 1998;]

* * * * *

(g) GUARANTEED ISSUE AND RENEWAL.—

(1) IN GENERAL.—Except as provided in this subsection and section 1860A(c)(2)(B), a Medicare+Choice organization shall provide that at any time during which elections are accepted under this section with respect to a Medicare+Choice plan offered by the organization, the organization will accept without restrictions individuals who are eligible to make such election.

* * * * *

(h) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—

(1) * * *

* * * * *

(4) PROHIBITION OF CERTAIN MARKETING PRACTICES.—Each Medicare+Choice organization shall conform to fair marketing standards, in relation to Medicare+Choice plans offered under this part, included in the standards established under section 1856. Such standards—

(A) shall not permit a Medicare+Choice organization to provide for cash or other monetary rebates as an inducement for enrollment or otherwise *except as provided under section 1854(b)(1)(C)*, and

* * * * *

(j) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS.—

(1) OFFER OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

(A) IN GENERAL.—A Medicare+Choice organization may not offer prescription drug coverage (other than that required under parts A and B) to an enrollee under a Medicare+Choice plan unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

(B) CONSTRUCTION.—Nothing in this subsection shall be construed as—

- (i) requiring a Medicare+Choice plan to include coverage of qualified prescription drug coverage; or
- (ii) permitting a Medicare+Choice organization from providing such coverage to an individual who has not elected such coverage under section 1860A(b).

For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860A(b) shall be treated as being ineligible to enroll in a Medicare+Choice plan under this part that offers such coverage.

(2) COMPLIANCE WITH ADDITIONAL BENEFICIARY PROTECTIONS.—With respect to the offering of qualified prescription



drug coverage by a Medicare+Choice organization under a Medicare+Choice plan, the organization and plan shall meet the requirements of section 1860C, including requirements relating to information dissemination and grievance and appeals, in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860F(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

(3) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME ENROLLEES AND DIRECT AND REINSURANCE SUBSIDY PAYMENTS FOR ORGANIZATIONS.—For provisions—

(A) providing premium and cost-sharing subsidies to low-income individuals receiving qualified prescription drug coverage through a Medicare+Choice plan, see section 1860G; and

(B) providing a Medicare+Choice organization with direct and insurance subsidy payments for providing qualified prescription drug coverage under this part, see section 1860H.

(4) TRANSITION IN INITIAL ENROLLMENT PERIOD.—Notwithstanding any other provision of this part, the annual, coordinated election period under subsection (e)(3)(B) for 2005 shall be the 6-month period beginning with November 2004.

(5) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms “qualified prescription drug coverage” and “standard coverage” have the meanings given such terms in section 1860B.

BENEFITS AND BENEFICIARY PROTECTIONS

SEC. 1852. (a) BASIC BENEFITS.—

(1) * * *

(2) SATISFACTION OF REQUIREMENT.—

(A) * * *

* * * * *

(C) ELECTION OF UNIFORM COVERAGE [POLICY] DETERMINATION.—In the case of a Medicare+Choice organization that offers a Medicare+Choice plan in an area in which more than one local coverage [policy] determination is applied with respect to different parts of the area, the organization may elect to have the local coverage [policy] determination for the part of the area that is most beneficial to Medicare+Choice enrollees (as identified by the Secretary) apply with respect to all Medicare+Choice enrollees enrolled in the plan.

* * * * *

[(5) NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—If there is a national coverage determination or legislative change in benefits required to be provided under this part made in the period beginning on the date of an announcement under section 1853(b) and ending on the



date of the next announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a Medicare+Choice organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the annual Medicare+Choice capitation rate under section 1853 included in the announcement made at the beginning of such period, then, unless otherwise required by law—

[(A) such determination or legislative change in benefits shall not apply to contracts under this part until the first contract year that begins after the end of such period, and

[(B) if such coverage determination or legislative change provides for coverage of additional benefits or coverage under additional circumstances, section 1851(i)(1) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

The projection under the previous sentence shall be based on an analysis by the Chief Actuary of the Health Care Financing Administration of the actuarial costs associated with the coverage determination or legislative change in benefits.]

(5) PROSPECTIVE IMPLEMENTATION OF NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall only implement a national coverage determination that will result in a significant change in the costs to a Medicare+Choice organization in a prospective manner that applies to announcements made under section 1853(b) after the date of the implementation of the determination.

(b) ANTIDISCRIMINATION.—

(1) BENEFICIARIES.—

(A) IN GENERAL.—A Medicare+Choice organization may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act. The Administrator shall not approve a plan of an organization if the Administrator determines that the benefits are designed to substantially discourage enrollment by certain Medicare+Choice eligible individuals with the organization.

* * * * *

(c) DISCLOSURE REQUIREMENTS.—

(1) DETAILED DESCRIPTION OF PLAN PROVISIONS.—A Medicare+Choice organization shall disclose, in clear, accurate, and standardized form to each enrollee with a Medicare+Choice plan offered by the organization under this part at the time of enrollment and at least annually thereafter, the following information regarding such plan:

(A) * * *

* * * * *



(I) QUALITY ASSURANCE PROGRAM.—A description of the organization's quality assurance program under subsection (e) if required under such section.

* * * * *

(e) QUALITY ASSURANCE PROGRAM.—

(1) IN GENERAL.—Each Medicare+Choice organization must have arrangements, consistent with any regulation, for an ongoing quality assurance program for health care services it provides to individuals enrolled with Medicare+Choice plans (other than MSA plans) of the organization.

* * * * *

(k) TREATMENT OF SERVICES FURNISHED BY CERTAIN PROVIDERS.—

(1) IN GENERAL.—Except as provided in paragraph (2), a physician or other entity (other than a provider of services) that does not have a contract establishing payment amounts for services furnished to an individual enrolled under this part with a Medicare+Choice organization described in section 1851(a)(2)(A) or with an organization offering a MSA plan shall accept as payment in full for covered services under this title that are furnished to such an individual the amounts that the physician or other entity could collect if the individual were not so enrolled. Any penalty or other provision of law that applies to such a payment with respect to an individual entitled to benefits under this title (but not enrolled with a Medicare+Choice organization under this part) also applies with respect to an individual so enrolled.

* * * * *

PAYMENTS TO MEDICARE+CHOICE ORGANIZATIONS

SEC. 1853. (a) PAYMENTS TO ORGANIZATIONS.—

(1) MONTHLY PAYMENTS.—

(A) IN GENERAL.—Under a contract under section 1857 and subject to subsections (e), (g), and (i) and section 1859(e)(4), the Secretary shall make monthly payments under this section in advance to each Medicare+Choice organization, with respect to coverage of an individual under this part in a Medicare+Choice payment area for a month, [in an amount equal to 1/12 of the annual Medicare+Choice capitation rate (as calculated under subsection (c)) with respect to that individual for that area, reduced by the amount of any reduction elected under section 1854(f)(1)(E) and adjusted for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such factors, if such changes will improve the determination of actuarial equivalence.] in an amount determined as follows:

(i) PAYMENT BEFORE 2005.—For years before 2005, the payment amount shall be equal to 1/12 of the annual Medicare+Choice capitation rate (as calculated



under subsection (c) with respect to that individual for that area, reduced by the amount of any reduction elected under section 1854(f)(1)(E) and adjusted under clause (iii).

(ii) PAYMENT FOR STATUTORY NON-DRUG BENEFITS BEGINNING WITH 2005.—For years beginning with 2005—

(I) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C) (or, in the case of a competitive-demonstration area, described in section 1854(b)(4)), the payment under this subsection is equal to the unadjusted non-drug monthly bid amount (or, in the case of a competitive-demonstration area, the choice non-drug benchmark amount), adjusted under clause (ii), plus the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year.

(II) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C) (or, in the case of a competitive-demonstration area, described in section 1854(b)(4)), the payment amount under this subsection is equal to the fee-for-service area-specific non-drug benchmark amount, adjusted under clause (ii).

(iii) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust the payment amount under clause (i), the unadjusted non-drug monthly bid amount under clause (ii)(I), and the fee-for-service area-specific non-drug benchmark amount under clause (ii)(II) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

(iv) REFERENCE TO SUBSIDY PAYMENT FOR STATUTORY DRUG BENEFITS.—In the case in which an enrollee is enrolled under part D, the Medicare+Choice organization also is entitled to a subsidy payment amount under section 1860H.

* * * * *

(b) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—

(1) ANNUAL ANNOUNCEMENT.—The Secretary shall annually determine, and shall announce (in a manner intended to provide notice to interested parties) for years before 2004 [and after 2005 not later than March 1 before the calendar year concerned and for 2004 and 2005] not later than March 1 before



the calendar year concerned and for 2004 and each subsequent year not later than the second Monday in May before [the respective calendar year—

[(A) the annual Medicare+Choice capitation rate for each Medicare+Choice payment area for the year, and

[(B) the risk and other factors to be used in adjusting such rates under subsection (a)(1)(A) for payments for months in that year.] the calendar year concerned with respect to each Medicare+Choice payment area, the following:

(A) PRE-COMPETITION INFORMATION.—For years before 2005, the following:

(i) MEDICARE+CHOICE CAPITATION RATES.—The annual Medicare+Choice capitation rate for each Medicare+Choice payment area for the year.

(ii) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(A) for payments for months in that year.

(B) COMPETITION INFORMATION.—For years beginning with 2005, the following:

(i) BENCHMARKS.—The fee-for-service area-specific non-drug benchmark under section 1853(j) and, if applicable, the choice non-drug benchmark under section 1853(k)(2), for the year involved and, if applicable, the national fee-for-service market share percentage.

(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iii) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment).

(iii) PROJECTED FEE-FOR-SERVICE BID.—In the case of a competitive area, the projected fee-for-service area-specific non-drug bid (as determined under subsection (k)(6)) for the area.

(iv) INDIVIDUALS.—The number of individuals counted under subsection (k)(4)(B) and enrolled in each Medicare+Choice plan in the area.

* * * * *

(3) EXPLANATION OF ASSUMPTIONS.—In each announcement made under paragraph (1), the Secretary shall include an explanation of the assumptions and changes in methodology used in the announcement [in sufficient detail so that Medicare+Choice organizations can compute monthly adjusted Medicare+Choice capitation rates for individuals in each Medicare+Choice payment area which is in whole or in part within the service area of such an organization].

(c) CALCULATION OF ANNUAL MEDICARE+CHOICE CAPITATION RATES.—

(1) IN GENERAL.—For purposes of this part, subject to paragraphs (6)(C) and (7), each annual Medicare+Choice capitation rate, for a Medicare+Choice payment area for a contract year consisting of a calendar year, is equal to the largest of the amounts specified in the following subparagraph (A), (B), [(C)] (C), or (D):

(A) BLENDED CAPITATION RATE.—The sum of—



(i) * * *

* * * * *
multiplied (for a year before 2003) by the budget neutrality
adjustment factor determined under paragraph (5).

* * * * *

(C) MINIMUM PERCENTAGE INCREASE.—

(i) * * *

* * * * *

[(iv) For 2002 and each succeeding year, 102 per-
cent of the annual Medicare+Choice capitation rate
under this paragraph for the area for the previous
year.]

(iv) For 2002, 102 percent of the annual
Medicare+Choice capitation rate under this paragraph
for the area for 2001.

(v) For 2003 and 2004, 103 percent of the annual
Medicare+Choice capitation rate under this paragraph
for the area for the previous year.

(vi) For 2005 and each succeeding year, 102 per-
cent of the annual Medicare+Choice capitation rate
under this paragraph for the area for the previous
year.

(D) BASED ON 100 PERCENT OF FEE-FOR-SERVICE
COSTS.—

(i) IN GENERAL.—For 2003 and 2004, the adjusted
average per capita cost for the year involved, deter-
mined under section 1876(a)(4) for the
Medicare+Choice payment area for services covered
under parts A and B for individuals entitled to benefits
under part A and enrolled under part B who are not
enrolled in a Medicare+Choice plan under this part for
the year, but adjusted to exclude costs attributable to
payments under section 1886(h).

(ii) INCLUSION OF COSTS OF VA AND DOD MILITARY
FACILITY SERVICES TO MEDICARE-ELIGIBLE BENE-
FICIARIES.—In determining the adjusted average per
capita cost under clause (i) for a year, such cost shall
be adjusted to include the Secretary's estimate, on a per
capita basis, of the amount of additional payments
that would have been made in the area involved under
this title if individuals entitled to benefits under this
title had not received services from facilities of the De-
partment of Veterans Affairs or the Department of De-
fense.

* * * * *

(3) ANNUAL AREA-SPECIFIC MEDICARE+CHOICE CAPITATION
RATE.—

(A) IN GENERAL.—For purposes of paragraph (1)(A),
subject to [subparagraph (B)] subparagraphs (B) and (E),
the annual area-specific Medicare+Choice capitation rate
for a Medicare+Choice payment area—



(i) * * *

* * * * *

(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2003), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

(4) INPUT-PRICE-ADJUSTED ANNUAL NATIONAL MEDICARE+CHOICE CAPITATION RATE.—

(A) * * *

(B) NATIONAL STANDARDIZED ANNUAL MEDICARE+CHOICE CAPITATION RATE.—

In subparagraph (A)(i), the "national standardized annual Medicare+Choice capitation rate" for a year is equal to—

(i) the sum (for all Medicare+Choice payment areas) of the product of—

(I) the annual area-specific Medicare+Choice capitation rate for that year for the area under paragraph (3), and

(II) the average number of medicare beneficiaries who (with respect to determinations for 2003 and for 2004) are enrolled in a Medicare+Choice plan residing in that area in the year, multiplied by the average of the risk factor weights used to adjust payments under subsection (a)(1)(A) for such beneficiaries in such area; divided by

* * * * *

(5) PAYMENT ADJUSTMENT BUDGET NEUTRALITY FACTOR.—For purposes of paragraph (1)(A), for each year (before 2003), the Secretary shall determine a budget neutrality adjustment factor so that the aggregate of the payments under this part (other than those attributable to subsections (a)(3)(C)(iii) and (i)) shall equal the aggregate payments that would have been made under this part if payment were based entirely on area-specific capitation rates.

(d) MEDICARE+CHOICE PAYMENT AREA DEFINED.—

(1) * * *

* * * * *

(3) GEOGRAPHIC ADJUSTMENT.—

(A) IN GENERAL.—Upon written request of the chief executive officer of a State for a contract year (beginning after 1998) made by not later than February 1 of the previous year, the Secretary shall make a geographic adjust-



ment to a Medicare+Choice payment area in the State otherwise determined under paragraph (1)—

[(i) to a single statewide Medicare+Choice payment area,]

(i) to a single statewide Medicare+Choice payment area,

* * * * *

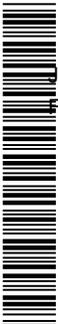
[(B) BUDGET NEUTRALITY ADJUSTMENT.—In the case of a State requesting an adjustment under this paragraph, the Secretary shall initially (and annually thereafter) adjust the payment rates otherwise established under this section for Medicare+Choice payment areas in the State in a manner so that the aggregate of the payments under this section in the State shall not exceed the aggregate payments that would have been made under this section for Medicare+Choice payment areas in the State in the absence of the adjustment under this paragraph.]

(B) BUDGET NEUTRALITY ADJUSTMENT.—In the case of a State requesting an adjustment under this paragraph, the Medicare Benefits Administrator shall initially (and annually thereafter) adjust the payment rates otherwise established under this section for Medicare+Choice payment areas in the State in a manner so that the aggregate of the payments under this section in the State shall not exceed the aggregate payments that would have been made under this section for Medicare+Choice payment areas in the State in the absence of the adjustment under this paragraph.

* * * * *

(j) COMPUTATION OF FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG BENCHMARK AMOUNT.—For purposes of this part, the term “fee-for-service area-specific non-drug benchmark amount” means, with respect to a Medicare+Choice payment area for a month in a year, an amount equal to the greater of the following (but in no case less than 1/12 of the rate computed under subsection (c)(1), without regard to subparagraph (A), for the year):

(1) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS IN THE AREA.—An amount equal to 1/12 of 100 percent (for 2005 through 2007, or 95 percent for 2008 and years thereafter) of the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare+Choice payment area, for the area and the year involved, for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in a Medicare+Choice plan under this part for the year, and adjusted to exclude from such cost the amount the Medicare Benefits Administrator estimates is payable for costs described in subclauses (I) and (II) of subsection (c)(3)(C)(i) for the year involved and also adjusted in the manner described in subsection (c)(1)(D)(ii) (relating to inclusion of costs of VA and DOD military facility services to medicare-eligible beneficiaries).



(2) *MINIMUM MONTHLY AMOUNT.*—The minimum amount specified in this paragraph is the amount specified in subsection (c)(1)(B)(iv) for the year involved.

(k) *ESTABLISHMENT OF COMPETITIVE DEMONSTRATION PROGRAM.*—

(1) *DESIGNATION OF COMPETITIVE-DEMONSTRATION AREAS AS PART OF PROGRAM.*—

(A) *IN GENERAL.*—For purposes of this part, the Administrator shall establish a demonstration program under which the Administrator designates Medicare+Choice areas as competitive-demonstration areas consistent with the following limitations:

(i) *LIMITATION ON NUMBER OF AREAS THAT MAY BE DESIGNATED.*—The Administrator may not designate more than 4 areas as competitive-demonstration areas.

(ii) *LIMITATION ON PERIOD OF DESIGNATION OF ANY AREA.*—The Administrator may not designate any area as a competitive-demonstration area for a period of more than 2 years.

The Administrator has the discretion to decide whether or not to designate as a competitive-demonstration area an area that qualifies for such designation.

(B) *QUALIFICATIONS FOR DESIGNATION.*—For purposes of this title, a Medicare+Choice area (which is a metropolitan statistical area or other area with a substantial number of Medicare+Choice enrollees) may not be designated as a “competitive-demonstration area” for a 2-year period beginning with a year unless the Administrator determines, by such date before the beginning of the year as the Administrator determines appropriate, that—

(i) there will be offered during the open enrollment period under this part before the beginning of the year at least 2 Medicare+Choice plans (in addition to the fee-for-service program under parts A and B), each offered by a different Medicare+Choice organization; and

(ii) during March of the previous year at least 50 percent of the number of Medicare+Choice eligible individuals who reside in the area were enrolled in a Medicare+Choice plan.

(2) *CHOICE NON-DRUG BENCHMARK AMOUNT.*—For purposes of this part, the term “choice non-drug benchmark amount” means, with respect to a Medicare+Choice payment area for a month in a year, the sum of the 2 components described in paragraph (3) for the area and year. The Administrator shall compute such benchmark amount for each competitive-demonstration area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2005) in which it is designated as such an area.

(3) *2 COMPONENTS.*—For purposes of paragraph (2), the 2 components described in this paragraph for an area and a year are the following:

(A) *FEE-FOR-SERVICE COMPONENT WEIGHTED BY NATIONAL FEE-FOR-SERVICE MARKET SHARE.*—The product of the following:

(i) *NATIONAL FEE-FOR-SERVICE MARKET SHARE.*—The national fee-for-service market share percentage (determined under paragraph (5)) for the year.

(ii) *FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG BID.*—The fee-for-service area-specific non-drug bid (as defined in paragraph (6)) for the area and year.

(B) *M+C COMPONENT WEIGHTED BY NATIONAL MEDICARE+CHOICE MARKET SHARE.*—The product of the following:

(i) *NATIONAL MEDICARE+CHOICE MARKET SHARE.*—1 minus the national fee-for-service market share percentage for the year.

(ii) *WEIGHTED AVERAGE OF PLAN BIDS IN AREA.*—The weighted average of the plan bids for the area and year (as determined under paragraph (4)(A)).

(4) *DETERMINATION OF WEIGHTED AVERAGE BIDS FOR AN AREA.*—

(A) *IN GENERAL.*—For purposes of paragraph (3)(B)(ii), the weighted average of plan bids for an area and a year is the sum of the following products for Medicare+Choice plans described in subparagraph (C) in the area and year:

(i) *PROPORTION OF EACH PLAN'S ENROLLEES IN THE AREA.*—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all Medicare+Choice plans described in subparagraph (C) for that area and year.

(ii) *MONTHLY NON-DRUG BID AMOUNT.*—The unadjusted non-drug monthly bid amount.

(B) *COUNTING OF INDIVIDUALS.*—The Administrator shall count, for each Medicare+Choice plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part during March of the previous year.

(C) *EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.*—For an area and year, the Medicare+Choice plans described in this subparagraph are plans that are offered in the area and year and were offered in the area in March of the previous year.

(5) *COMPUTATION OF NATIONAL FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.*—The Administrator shall determine, for a year, the proportion (in this subsection referred to as the “national fee-for-service market share percentage”) of Medicare+Choice eligible individuals who during March of the previous year were not enrolled in a Medicare+Choice plan.

(6) *FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG BID.*—For purposes of this part, the term “fee-for-service area-specific non-drug bid” means, for an area and year, the amount described in section 1853(j)(1) for the area and year, except that any reference to a percent of less than 100 percent shall be deemed a reference to 100 percent.



PREMIUMS AND BID AMOUNTS.

SEC. 1854. (a) SUBMISSION OF PROPOSED PREMIUMS AND BID AMOUNTS AND RELATED INFORMATION.—

(1) IN GENERAL.—Not later than the second Monday in September of 2002, 2003, and 2004 (or July 1 of each other year), each Medicare+Choice organization shall submit to the Secretary, in a form and manner specified by the Secretary and for each Medicare+Choice plan for the service area (or segment of such an area if permitted under subsection (h)) in which it intends to be offered in the following year—

[(A)] (A)(i) if the following year is before 2005, the information described in paragraph (2), (3), or (4) for the type of plan involved or (ii) if the following year is 2005 or later, the information described in paragraph (6)(A); and

* * * * *

(5) REVIEW.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall review the adjusted community rates, the amounts of the basic and supplemental premiums, and values filed under paragraphs (2), (3), and (4) of this subsection and shall approve or disapprove such rates, amounts, and values so submitted. The Chief Actuary of the Health Care Financing Administration shall review the actuarial assumptions and data used by the Medicare+Choice organization with respect to such rates, amounts, and values so submitted to determine the appropriateness of such assumptions and data.

* * * * *

(6) SUBMISSION OF BID AMOUNTS BY MEDICARE+CHOICE ORGANIZATIONS.—

(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

(i) The monthly aggregate bid amount for provision of all items and services under this part and the actuarial basis for determining such amount.

(ii) The proportions of such bid amount that are attributable to—

(I) the provision of statutory non-drug benefits (such portion referred to in this part as the “unadjusted non-drug monthly bid amount”);

(II) the provision of statutory prescription drug benefits; and

(III) the provision of non-statutory benefits; and the actuarial basis for determining such proportions.

(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

(i) The term “statutory non-drug benefits” means benefits under parts A and B.



(ii) The term "statutory prescription drug benefits" means benefits under part D.

(iii) The term "statutory benefits" means statutory prescription drug benefits and statutory non-drug benefits.

(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—The Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)). The Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

(b) MONTHLY PREMIUM CHARGED.—

(1) IN GENERAL.—

(A) * * *

* * * * *

(C) BENEFICIARY REBATE RULE.—

(i) REQUIREMENT FOR NON-COMPETITIVE-DEMONSTRATION AREAS.—In the case of a Medicare+Choice payment area that is not a competitive-demonstration area designated under section 1853(k)(1), the Medicare+Choice plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3) applicable to the plan and year involved.

(ii) REQUIREMENT FOR COMPETITIVE-DEMONSTRATION AREAS.—In the case of a Medicare+Choice payment area that is designated as a competitive-demonstration area under section 1853(k)(1), if there are average per capita monthly savings described in paragraph (4) for a Medicare+Choice plan and year, the Medicare+Choice plan shall provide to the enrollee a monthly rebate equal to 75 percent of such savings.

(iii) FORM OF REBATE.—A rebate required under this subparagraph shall be provided—

(I) through the crediting of the amount of the rebate towards the Medicare+Choice monthly supplementary beneficiary premium or the premium imposed for prescription drug coverage under part D;

(II) through a direct monthly payment (through electronic funds transfer or otherwise); or

(III) through other means approved by the Medicare Benefits Administrator, or any combination thereof.

(2) PREMIUM TERMINOLOGY DEFINED.—For purposes of this part:

[(A) THE MEDICARE+CHOICE MONTHLY BASIC BENEFICIARY PREMIUM.—The term "Medicare+Choice monthly basic beneficiary premium" means, with respect to a Medicare+Choice plan, the amount authorized to be charged under subsection (e)(1) for the plan, or, in the case



of a Medicare+Choice private fee-for-service plan, the amount filed under subsection (a)(4)(A)(ii).

[(B) MEDICARE+CHOICE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term “Medicare+Choice monthly supplemental beneficiary premium” means, with respect to a Medicare+Choice plan, the amount authorized to be charged under subsection (e)(2) for the plan or, in the case of a MSA plan or Medicare+Choice private fee-for-service plan, the amount filed under paragraph (3)(B) or (4)(B) of subsection (a).**]**

*(A) MEDICARE+CHOICE MONTHLY BASIC BENEFICIARY PREMIUM.—*The term “Medicare+Choice monthly basic beneficiary premium” means, with respect to a Medicare+Choice plan—

(i) described in section 1853(a)(1)(A)(ii)(I) (relating to plans providing rebates), zero; or

(ii) described in section 1853(a)(1)(A)(ii)(II), the amount (if any) by which the unadjusted non-drug monthly bid amount exceeds the fee-for-service area-specific non-drug benchmark amount.

*(B) MEDICARE+CHOICE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—*The term “Medicare+Choice monthly supplemental beneficiary premium” means, with respect to a Medicare+Choice plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.

*(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—*For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for a Medicare+Choice plan and year is computed as follows:

(A) DETERMINATION OF STATE-WIDE AVERAGE RISK ADJUSTMENT.—

*(i) IN GENERAL.—*The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2005), for each State the average of the risk adjustment factors to be applied to enrollees under section 1853(a)(1)(A) in that State. In the case of a State in which a Medicare+Choice plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied in that State in a previous year.

*(ii) TREATMENT OF NEW STATES.—*In the case of a State in which no Medicare+Choice plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable States or applied on a national basis.

*(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—*For each Medicare+Choice plan offered in a State, the Administrator shall—



(i) adjust the fee-for-service area-specific non-drug benchmark amount by the applicable average risk adjustment factor computed under subparagraph (A); and

(ii) adjust the unadjusted non-drug monthly bid amount by such applicable average risk adjustment factor.

(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

(D) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Administrator may provide for the determination and application of risk adjustment factors under this paragraph on the basis of areas other than States.

(4) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR COMPETITIVE-DEMONSTRATION AREAS.—For purposes of paragraph (1)(C)(ii), the average per capita monthly savings referred to in such paragraph for a Medicare+Choice plan and year shall be computed in the same manner as the average per capita monthly savings is computed under paragraph (3) except that the reference to the fee-for-service area-specific non-drug benchmark amount in paragraph (3)(B)(i) (or to the benchmark amount as adjusted under paragraph (3)(C)(i)) is deemed to be a reference to the choice non-drug benchmark amount (or such amount as adjusted in the manner described in paragraph (3)(B)(i)).

[(c) UNIFORM PREMIUM.—The Medicare+Choice monthly basic and supplemental beneficiary premium, the Medicare+Choice monthly MSA premium charged under subsection (b) of a Medicare+Choice organization under this part may not vary among individuals enrolled in the plan.]

(c) UNIFORM BID AMOUNTS.—The Medicare+Choice monthly bid amount submitted under subsection (a)(6) of a Medicare+Choice organization under this part may not vary among individuals enrolled in the plan.

(d) TERMS AND CONDITIONS OF IMPOSING PREMIUMS.—Each Medicare+Choice organization shall permit the payment of Medicare+Choice monthly basic and supplemental beneficiary premiums on a monthly basis, may terminate election of individuals for a Medicare+Choice plan for failure to make premium payments only in accordance with section 1851(g)(3)(B)(i), and may not provide, except as provided under subsection (b)(1)(C) and subsection (b)(1)(D), for cash or other monetary rebates as an inducement for enrollment or otherwise.

[(e) LIMITATION ON ENROLLEE LIABILITY.—

[(1) FOR BASIC AND ADDITIONAL BENEFITS.—In no event may—

[(A) the Medicare+Choice monthly basic beneficiary premium (multiplied by 12) and the actuarial value of the



deductibles, coinsurance, and copayments applicable on average to individuals enrolled under this part with a Medicare+Choice plan described in section 1851(a)(2)(A) of an organization with respect to required benefits described in section 1852(a)(1)(A) and additional benefits (if any) required under subsection (f)(1)(A) for a year, exceed

[(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals entitled to benefits under part A and enrolled under part B if they were not members of a Medicare+Choice organization for the year.

[(2) FOR SUPPLEMENTAL BENEFITS.—If the Medicare+Choice organization provides to its members enrolled under this part in a Medicare+Choice plan described in section 1851(a)(2)(A) with respect to supplemental benefits described in section 1852(a)(3), the sum of the Medicare+Choice monthly supplemental beneficiary premium (multiplied by 12) charged and the actuarial value of its deductibles, coinsurance, and copayments charged with respect to such benefits may not exceed the adjusted community rate for such benefits (as defined in subsection (f)(3)).

[(3) DETERMINATION ON OTHER BASIS.—If the Secretary determines that adequate data are not available to determine the actuarial value under paragraph (1)(A) or (2), the Secretary may determine such amount with respect to all individuals in same geographic area, the State, or in the United States, eligible to enroll in the Medicare+Choice plan involved under this part or on the basis of other appropriate data.

[(4) SPECIAL RULE FOR PRIVATE FEE-FOR-SERVICE PLANS.—With respect to a Medicare+Choice private fee-for-service plan (other than a plan that is an MSA plan), in no event may—

[(A) the actuarial value of the deductibles, coinsurance, and copayments applicable on average to individuals enrolled under this part with such a plan of an organization with respect to required benefits described in section 1852(a)(1), exceed

[(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals entitled to benefits under part A and enrolled under part B if they were not members of a Medicare+Choice organization for the year.

[(f) REQUIREMENT FOR ADDITIONAL BENEFITS.—

[(1) REQUIREMENT.—

[(A) IN GENERAL.—Each Medicare+Choice organization (in relation to a Medicare+Choice plan, other than an MSA plan, it offers) shall provide that if there is an excess amount (as defined in subparagraph (B)) for the plan for a contract year, subject to the succeeding provisions of this subsection, the organization shall provide to individuals such additional benefits (as the organization may specify) in a value which the Secretary determines is at least equal to the adjusted excess amount (as defined in subparagraph (C)).



[(B) EXCESS AMOUNT.—For purposes of this paragraph, the “excess amount”, for an organization for a plan, is the amount (if any) by which—

[(i) the average of the capitation payments made to the organization under section 1853 for the plan at the beginning of contract year, exceeds

[(ii) the actuarial value of the required benefits described in section 1852(a)(1)(A) under the plan for individuals under this part, as determined based upon an adjusted community rate described in paragraph (3) (as reduced for the actuarial value of the coinsurance, copayments, and deductibles under parts A and B).

[(C) ADJUSTED EXCESS AMOUNT.—For purposes of this paragraph, the “adjusted excess amount”, for an organization for a plan, is the excess amount reduced to reflect any amount withheld and reserved for the organization for the year under paragraph (2).

[(D) UNIFORM APPLICATION.—This paragraph shall be applied uniformly for all enrollees for a plan.

[(E) PREMIUM REDUCTIONS.—

[(i) IN GENERAL.—Subject to clause (ii), as part of providing any additional benefits required under subparagraph (A), a Medicare+Choice organization may elect a reduction in its payments under section 1853(a)(1)(A) with respect to a Medicare+Choice plan and the Secretary shall apply such reduction to reduce the premium under section 1839 of each enrollee in such plan as provided in section 1840(i).

[(ii) AMOUNT OF REDUCTION.—The amount of the reduction under clause (i) with respect to any enrollee in a Medicare+Choice plan—

[(I) may not exceed 125 percent of the premium described under section 1839(a)(3); and

[(II) shall apply uniformly to each enrollee of the Medicare+Choice plan to which such reduction applies.

[(F) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing a Medicare+Choice organization from providing supplemental benefits (described in section 1852(a)(3)) that are in addition to the health care benefits otherwise required to be provided under this paragraph and from imposing a premium for such supplemental benefits.

[(2) STABILIZATION FUND.—A Medicare+Choice organization may provide that a part of the value of an excess amount described in paragraph (1) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to stabilize and prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with such paragraph. Any of such



value of the amount reserved which is not provided as additional benefits described in paragraph (1)(A) to individuals electing the Medicare+Choice plan of the organization in accordance with such paragraph prior to the end of such periods, shall revert for the use of such trust funds.

[(3) ADJUSTED COMMUNITY RATE.—For purposes of this subsection, subject to paragraph (4), the term “adjusted community rate” for a service or services means, at the election of a Medicare+Choice organization, either—

[(A) the rate of payment for that service or services which the Secretary annually determines would apply to an individual electing a Medicare+Choice plan under this part if the rate of payment were determined under a “community rating system” (as defined in section 1302(8) of the Public Health Service Act, other than subparagraph (C)), or

[(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to such an individual, as the Secretary annually estimates is attributable to that service or services,

but adjusted for differences between the utilization characteristics of the individuals electing coverage under this part and the utilization characteristics of the other enrollees with the plan (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of individuals selecting other Medicare+Choice coverage, or Medicare+Choice eligible individuals in the area, in the State, or in the United States, eligible to elect Medicare+Choice coverage under this part and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

[(4) DETERMINATION BASED ON INSUFFICIENT DATA.—For purposes of this subsection, if the Secretary finds that there is insufficient enrollment experience to determine an average of the capitation payments to be made under this part at the beginning of a contract period or to determine (in the case of a newly operated provider-sponsored organization or other new organization) the adjusted community rate for the organization, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this part and may determine such a rate using data in the general commercial marketplace.]

* * * * *

ESTABLISHMENT OF STANDARDS

SEC. 1856. (a) * * *

(b) ESTABLISHMENT OF OTHER STANDARDS.—

(1) * * *

* * * * *

[(3) RELATION TO STATE LAWS.—

[(A) IN GENERAL.—The standards established under this subsection shall supersede any State law or regulation (including standards described in subparagraph (B)) with



respect to Medicare+Choice plans which are offered by Medicare+Choice organizations under this part to the extent such law or regulation is inconsistent with such standards.

[(B) STANDARDS SPECIFICALLY SUPERSEDED.—State standards relating to the following are superseded under this paragraph:

[(i) Benefit requirements (including cost-sharing requirements).

[(ii) Requirements relating to inclusion or treatment of providers.

[(iii) Coverage determinations (including related appeals and grievance processes).

[(iv) Requirements relating to marketing materials and summaries and schedules of benefits regarding a Medicare+Choice plan.]

(3) RELATION TO STATE LAWS.—The standards established under this subsection shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to Medicare+Choice plans which are offered by Medicare+Choice organizations under this part.

* * * * *

DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 1859. (a) * * *

(b) DEFINITIONS RELATING TO MEDICARE+CHOICE PLANS.—

(1) * * *

* * * * *

(4) SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

(A) IN GENERAL.—The term “specialized Medicare+Choice plan for special needs beneficiaries” means a Medicare+Choice plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

(B) SPECIAL NEEDS BENEFICIARY.—The term “special needs beneficiary” means a Medicare+Choice eligible individual who—

(i) is institutionalized (as defined by the Secretary);

(ii) is entitled to medical assistance under a State plan under title XIX; or

(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare+Choice plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.

* * * * *

(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2007, the plan may restrict the enrollment of indi-



viduals under the plan to individuals who are within one or more classes of special needs beneficiaries.

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

SEC. 1860A. BENEFITS; ELIGIBILITY; ENROLLMENT; AND COVERAGE PERIOD.

(a) *PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.*—Subject to the succeeding provisions of this part, each individual who is entitled to benefits under part A or is enrolled under part B is entitled to obtain qualified prescription drug coverage (described in section 1860B(a)) as follows:

(1) *MEDICARE+CHOICE PLAN.*—If the individual is eligible to enroll in a Medicare+Choice plan that provides qualified prescription drug coverage under section 1851(j), the individual may enroll in the plan and obtain coverage through such plan.

(2) *PRESCRIPTION DRUG PLAN.*—If the individual is not enrolled in a Medicare+Choice plan that provides qualified prescription drug coverage, the individual may enroll under this part in a prescription drug plan (as defined in section 1860J(a)(5)).

Such individuals shall have a choice of such plans under section 1860E(d).

(b) *GENERAL ELECTION PROCEDURES.*—

(1) *IN GENERAL.*—An individual eligible to make an election under subsection (a) may elect to enroll in a prescription drug plan under this part, or elect the option of qualified prescription drug coverage under a Medicare+Choice plan under part C, and to change such election only in such manner and form as may be prescribed by regulations of the Administrator of the Medicare Benefits Administration (appointed under section 1808(b)) (in this part referred to as the “Medicare Benefits Administrator”) and only during an election period prescribed in or under this subsection.

(2) *ELECTION PERIODS.*—

(A) *IN GENERAL.*—Except as provided in this paragraph, the election periods under this subsection shall be the same as the coverage election periods under the Medicare+Choice program under section 1851(e), including—

- (i) annual coordinated election periods; and
- (ii) special election periods.

In applying the last sentence of section 1851(e)(4) (relating to discontinuance of a Medicare+Choice election during the first year of eligibility) under this subparagraph, in the case of an election described in such section in which the individual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug plan under this part at the time of the election of coverage under the original fee-for-service plan.

(B) *INITIAL ELECTION PERIODS.*—

(i) *INDIVIDUALS CURRENTLY COVERED.*—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of November 1, 2004,



there shall be an initial election period of 6 months beginning on that date.

(ii) *INDIVIDUAL COVERED IN FUTURE.*—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

(C) *ADDITIONAL SPECIAL ELECTION PERIODS.*—The Administrator shall establish special election periods—

(i) in cases of individuals who have and involuntarily lose prescription drug coverage described in subsection (c)(2)(C);

(ii) in cases described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B;

(iii) in the case of an individual who meets such exceptional conditions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

(c) *GUARANTEED ISSUE; COMMUNITY RATING; AND NON-DISCRIMINATION.*—

(1) *GUARANTEED ISSUE.*—

(A) *IN GENERAL.*—An eligible individual who is eligible to elect qualified prescription drug coverage under a prescription drug plan or Medicare+Choice plan at a time during which elections are accepted under this part with respect to the plan shall not be denied enrollment based on any health status-related factor (described in section 2702(a)(1) of the Public Health Service Act) or any other factor.

(B) *MEDICARE+CHOICE LIMITATIONS PERMITTED.*—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to PDP sponsors under this subsection.

(2) *COMMUNITY-RATED PREMIUM.*—

(A) *IN GENERAL.*—In the case of an individual who maintains (as determined under subparagraph (C)) continuous prescription drug coverage since the date the individual first qualifies to elect prescription drug coverage under this part, a PDP sponsor or Medicare+Choice organization offering a prescription drug plan or Medicare+Choice plan that provides qualified prescription drug coverage and in which the individual is enrolled may not deny, limit, or condition the coverage or provision of covered prescription drug benefits or increase the premium under the plan based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act or any other factor.



(B) LATE ENROLLMENT PENALTY.—In the case of an individual who does not maintain such continuous prescription drug coverage (as described in subparagraph (C)), a PDP sponsor or Medicare+Choice organization may (notwithstanding any provision in this title) adjust the premium otherwise applicable or impose a pre-existing condition exclusion with respect to qualified prescription drug coverage in a manner that reflects additional actuarial risk involved. Such a risk shall be established through an appropriate actuarial opinion of the type described in subparagraphs (A) through (C) of section 2103(c)(4).

(C) CONTINUOUS PRESCRIPTION DRUG COVERAGE.—An individual is considered for purposes of this part to be maintaining continuous prescription drug coverage on and after the date the individual first qualifies to elect prescription drug coverage under this part if the individual establishes that as of such date the individual is covered under any of the following prescription drug coverage and before the date that is the last day of the 63-day period that begins on the date of termination of the particular prescription drug coverage involved (regardless of whether the individual subsequently obtains any of the following prescription drug coverage):

(i) COVERAGE UNDER PRESCRIPTION DRUG PLAN OR MEDICARE+CHOICE PLAN.—Qualified prescription drug coverage under a prescription drug plan or under a Medicare+Choice plan.

(ii) MEDICAID PRESCRIPTION DRUG COVERAGE.—Prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for the Elderly (PACE) under section 1934, through a social health maintenance organization (referred to in section 4104(c) of the Balanced Budget Act of 1997), or through a Medicare+Choice project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of a interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved.

(iii) PRESCRIPTION DRUG COVERAGE UNDER GROUP HEALTH PLAN.—Any outpatient prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan as defined in section 1860H(f)(1), but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

(iv) PRESCRIPTION DRUG COVERAGE UNDER CERTAIN MEDIGAP POLICIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such



coverage conforms to the standards for packages of benefits under section 1882(p)(1)), but only if the policy was in effect on January 1, 2005, and if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

(v) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

(vi) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans under chapter 17 of title 38, United States Code, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

(D) CERTIFICATION.—For purposes of carrying out this paragraph, the certifications of the type described in sections 2701(e) of the Public Health Service Act and in section 9801(e) of the Internal Revenue Code shall also include a statement for the period of coverage of whether the individual involved had prescription drug coverage described in subparagraph (C).

(E) DISCLOSURE.—

(i) IN GENERAL.—Each entity that offers coverage of the type described in clause (iii), (iv), (v), or (vi) of subparagraph (C) shall provide for disclosure, consistent with standards established by the Administrator, of whether such coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

(ii) WAIVER OF LIMITATIONS.—An individual may apply to the Administrator to waive the requirement that coverage of such type provide benefits at least equivalent to the benefits under a qualified prescription drug plan, if the individual establishes that the individual was not adequately informed that such coverage did not provide such level of benefits.

(F) CONSTRUCTION.—Nothing in this section shall be construed as preventing the disenrollment of an individual from a prescription drug plan or a Medicare+Choice plan based on the termination of an election described in section 1851(g)(3), including for non-payment of premiums or for other reasons specified in subsection (d)(3), which takes into account a grace period described in section 1851(g)(3)(B)(i).

(3) NONDISCRIMINATION.—A PDP sponsor offering a prescription drug plan shall not establish a service area in a manner that would discriminate based on health or economic status of potential enrollees.

(d) EFFECTIVE DATE OF ELECTIONS.—



(1) *IN GENERAL.*—Except as provided in this section, the Administrator shall provide that elections under subsection (b) take effect at the same time as the Administrator provides that similar elections under section 1851(e) take effect under section 1851(f).

(2) *NO ELECTION EFFECTIVE BEFORE 2005.*—In no case shall any election take effect before January 1, 2005.

(3) *TERMINATION.*—The Administrator shall provide for the termination of an election in the case of—

(A) termination of coverage under both part A and part B; and

(B) termination of elections described in section 1851(g)(3) (including failure to pay required premiums).

SEC. 1860B. REQUIREMENTS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

(a) *REQUIREMENTS.*—

(1) *IN GENERAL.*—For purposes of this part and part C, the term “qualified prescription drug coverage” means either of the following:

(A) *STANDARD COVERAGE WITH ACCESS TO NEGOTIATED PRICES.*—Standard coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

(B) *ACTUARIALLY EQUIVALENT COVERAGE WITH ACCESS TO NEGOTIATED PRICES.*—Coverage of covered outpatient drugs which meets the alternative coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if it is approved by the Administrator, as provided under subsection (c).

(2) *PERMITTING ADDITIONAL OUTPATIENT PRESCRIPTION DRUG COVERAGE.*—

(A) *IN GENERAL.*—Subject to subparagraph (B), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered outpatient drugs that exceeds the coverage required under paragraph (1), but any such additional coverage shall be limited to coverage of covered outpatient drugs.

(B) *DISAPPROVAL AUTHORITY.*—The Administrator shall review the offering of qualified prescription drug coverage under this part or part C. If the Administrator finds that, in the case of a qualified prescription drug coverage under a prescription drug plan or a Medicare+Choice plan, that the organization or sponsor offering the coverage is engaged in activities intended to discourage enrollment of classes of eligible medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage, the Administrator may terminate the contract with the sponsor or organization under this part or part C.

(3) *APPLICATION OF SECONDARY PAYOR PROVISIONS.*—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under part C.

(b) *STANDARD COVERAGE.*—For purposes of this part, the “standard coverage” is coverage of covered outpatient drugs (as defined in subsection (f)) that meets the following requirements:



(1) *DEDUCTIBLE.*—The coverage has an annual deductible—
 (A) for 2005, that is equal to \$250; or
 (B) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

(2) *LIMITS ON COST-SHARING.*—

(A) *IN GENERAL.*—The coverage has cost-sharing (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) as follows:

(i) *FIRST COPAYMENT RANGE.*—For costs above the annual deductible specified in paragraph (1) and up to amount specified in subparagraph (C), the cost-sharing—

(I) is equal to 20 percent; or
 (II) is actuarially equivalent (using processes established under subsection (e)) to an average expected payment of 20 percent of such costs.

(ii) *SECONDARY COPAYMENT RANGE.*—For costs above the amount specified in subparagraph (C) and up to the initial coverage limit, the cost-sharing—

(I) is equal to 50 percent; or
 (II) is actuarially consistent (using processes established under subsection (e)) with an average expected payment of 50 percent of such costs.

(B) *USE OF TIERED COPAYMENTS.*—Nothing in this part shall be construed as preventing a PDP sponsor from applying tiered copayments, so long as such tiered copayments are consistent with subparagraph (A).

(C) *INITIAL COPAYMENT THRESHOLD.*—The amount specified in this subparagraph—

(i) for 2005, is equal to \$1,000; or
 (ii) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

Any amount determined under clause (ii) that is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

(3) *INITIAL COVERAGE LIMIT.*—Subject to paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes—

(A) for 2005, that is equal to \$2,000; or
 (B) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of \$25 shall be rounded to the nearest multiple of \$25.

(4) *CATASTROPHIC PROTECTION.*—

(A) *IN GENERAL.*—Notwithstanding paragraph (3), the coverage provides benefits with no cost-sharing after the in-



dividual has incurred costs (as described in subparagraph (C)) for covered outpatient drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B).

(B) ANNUAL OUT-OF-POCKET THRESHOLD.—For purposes of this part, the “annual out-of-pocket threshold” specified in this subparagraph—

(i) for 2005, is equal to \$3,800; or

(ii) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

Any amount determined under clause (ii) that is not a multiple of \$100 shall be rounded to the nearest multiple of \$100.

(C) APPLICATION.—In applying subparagraph (A)—

(i) incurred costs shall only include costs incurred for the annual deductible (described in paragraph (1)), cost-sharing (described in paragraph (2)), and amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3); and

(ii) such costs shall be treated as incurred only if they are paid by the individual, under section 1860G, or under title XIX and the individual is not reimbursed (through insurance or otherwise) by another person for such costs.

(5) ANNUAL PERCENTAGE INCREASE.—For purposes of this part, the annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as determined by the Administrator for the 12-month period ending in July of the previous year.

(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A prescription drug plan or Medicare+Choice plan may provide a different prescription drug benefit design from the standard coverage described in subsection (b) so long as the Administrator determines (based on an actuarial analysis by the Administrator) that the following requirements are met and the plan applies for, and receives, the approval of the Administrator for such benefit design:

(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage (as determined under subsection (e)) is at least equal to the actuarial value (as so determined) of standard coverage.

(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (e)) exceeds the actuarial value of the subsidy payments under section 1860H with respect to such coverage.

- (C) *ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.*—The coverage is designed, based upon an actuarially representative pattern of utilization (as determined under subsection (e)), to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3), of an amount equal to at least the sum of the following products:
- (i) *FIRST COPAYMENT RANGE.*—The product of—
 - (I) the amount by which the initial copayment threshold described in subsection (b)(2)(C) exceeds the deductible described in subsection (b)(1); and
 - (II) 100 percent minus the cost-sharing percentage specified in subsection (b)(2)(A)(i)(I).
 - (ii) *SECONDARY COPAYMENT RANGE.*—The product of—
 - (I) the amount by which the initial coverage limit described in subsection (b)(3) exceeds the initial copayment threshold described in subsection (b)(2)(C); and
 - (II) 100 percent minus the cost-sharing percentage specified in subsection (b)(2)(A)(ii)(I).
- (2) *CATASTROPHIC PROTECTION.*—The coverage provides for beneficiaries the catastrophic protection described in subsection (b)(4).
- (d) *ACCESS TO NEGOTIATED PRICES.*—
- (1) *IN GENERAL.*—Under qualified prescription drug coverage offered by a PDP sponsor or a Medicare+Choice organization, the sponsor or organization shall provide beneficiaries with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of cost-sharing or an initial coverage limit (described in subsection (b)(3)). Insofar as a State elects to provide medical assistance under title XIX for a drug based on the prices negotiated by a prescription drug plan under this part, the requirements of section 1927 shall not apply to such drugs. The prices negotiated by a prescription drug plan under this part, by a Medicare+Choice plan with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860H(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).
 - (2) *DISCLOSURE.*—The PDP sponsor or Medicare+Choice organization shall disclose to the Administrator (in a manner specified by the Administrator) the extent to which discounts or rebates made available to the sponsor or organization by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Administrator under this paragraph in the same manner as



such provisions apply to information disclosed under such section.

(e) *ACTUARIAL VALUATION; DETERMINATION OF ANNUAL PERCENTAGE INCREASES.*—

(1) *PROCESSES.*—For purposes of this section, the Administrator shall establish processes and methods—

(A) for determining the actuarial valuation of prescription drug coverage, including—

(i) an actuarial valuation of standard coverage and of the reinsurance subsidy payments under section 1860H;

(ii) the use of generally accepted actuarial principles and methodologies; and

(iii) applying the same methodology for determinations of alternative coverage under subsection (c) as is used with respect to determinations of standard coverage under subsection (b); and

(B) for determining annual percentage increases described in subsection (b)(5).

(2) *USE OF OUTSIDE ACTUARIES.*—Under the processes under paragraph (1)(A), PDP sponsors and Medicare+Choice organizations may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values, but the Administrator shall determine whether such actuarial values meet the requirements under subsection (c)(1).

(f) *COVERED OUTPATIENT DRUGS DEFINED.*—

(1) *IN GENERAL.*—Except as provided in this subsection, for purposes of this part, the term “covered outpatient drug” means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section,

and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

(2) *EXCLUSIONS.*—

(A) *IN GENERAL.*—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

(B) *AVOIDANCE OF DUPLICATE COVERAGE.*—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

(3) *APPLICATION OF FORMULARY RESTRICTIONS.*—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered



under a plan if the plan excludes the drug under a formulary and such exclusion is not successfully appealed under section 1860C(f)(2).

(4) *APPLICATION OF GENERAL EXCLUSION PROVISIONS.*—A prescription drug plan or Medicare+Choice plan may exclude from qualified prescription drug coverage any covered outpatient drug—

(A) for which payment would not be made if section 1862(a) applied to part D; or

(B) which are not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860C(f).

SEC. 1860C. BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

(a) *GUARANTEED ISSUE, COMMUNITY-RATED PREMIUMS, ACCESS TO NEGOTIATED PRICES, AND NONDISCRIMINATION.*—For provisions requiring guaranteed issue, community-rated premiums, access to negotiated prices, and nondiscrimination, see sections 1860A(c)(1), 1860A(c)(2), 1860B(d), and 1860F(b), respectively.

(b) *DISSEMINATION OF INFORMATION.*—

(1) *GENERAL INFORMATION.*—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

(A) Access to covered outpatient drugs, including access through pharmacy networks.

(B) How any formulary used by the sponsor functions.

(C) Co-payments and deductible requirements, including the identification of the tiered or other co-payment level applicable to each drug (or class of drugs).

(D) Grievance and appeals procedures.

(2) *DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.*—Upon request of an individual eligible to enroll under a prescription drug plan, the PDP sponsor shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such individual.

(3) *RESPONSE TO BENEFICIARY QUESTIONS.*—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information to enrollees upon request. The sponsor shall make available on a timely basis, through an Internet website and in writing upon request, information on specific changes in its formulary.

(4) *CLAIMS INFORMATION.*—Each PDP sponsor offering a prescription drug plan must furnish to enrolled individuals in a form easily understandable to such individuals an explanation of benefits (in accordance with section 1806(a) or in a comparable manner) and a notice of the benefits in relation to initial coverage limit and annual out-of-pocket threshold for the current year, whenever prescription drug benefits are provided



under this part (except that such notice need not be provided more often than monthly).

(c) ACCESS TO COVERED BENEFITS.—

(1) ASSURING PHARMACY ACCESS.—

(A) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (as determined by the Administrator and including adequate emergency access) for enrolled beneficiaries, in accordance with standards established under section 1860D(e) that ensure such convenient access.

(B) USE OF POINT-OF-SERVICE SYSTEM.—A PDP sponsor shall establish an optional point-of-service method of operation under which—

(i) the plan provides access to any or all pharmacies that are not participating pharmacies in its network; and

(ii) the plan may charge beneficiaries through adjustments in premiums and copayments any additional costs associated with the point-of-service option.

The additional copayments so charged shall not count toward the application of section 1860B(b).

(2) USE OF STANDARDIZED TECHNOLOGY.—

(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrolled beneficiary to assure access to negotiated prices under section 1860B(d) for the purchase of prescription drugs for which coverage is not otherwise provided under the prescription drug plan.

(B) STANDARDS.—

(i) DEVELOPMENT.—The Administrator shall provide for the development of national standards relating to a standardized format for the card or other technology referred to in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

(ii) APPLICATION OF ADVISORY TASK FORCE.—The advisory task force established under subsection (d)(3)(B)(ii) shall provide recommendations to the Administrator under such subsection regarding the standards developed under clause (i).

(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan uses a formulary, the following requirements must be met:

(A) PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

The sponsor must establish a pharmacy and therapeutic committee that develops and reviews the formulary. Such committee shall include at least one physician and at least one pharmacist both with expertise in the care of elderly or disabled persons and a majority of its members shall consist of individuals who are a physician or a pharmacist (or both).



(B) *FORMULARY DEVELOPMENT.*—In developing and reviewing the formulary, the committee shall base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determines to be appropriate.

(C) *INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES.*—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (although not necessarily for all drugs within such categories and classes).

(D) *PROVIDER EDUCATION.*—The committee shall establish policies and procedures to educate and inform health care providers concerning the formulary.

(E) *NOTICE BEFORE REMOVING DRUGS FROM FORMULARY.*—Any removal of a drug from a formulary shall take effect only after appropriate notice is made available to beneficiaries and physicians.

(F) *GRIEVANCES AND APPEALS RELATING TO APPLICATION OF FORMULARIES.*—For provisions relating to grievances and appeals of coverage, see subsections (e) and (f).

(d) *COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.*—

(1) *IN GENERAL.*—The PDP sponsor shall have in place with respect to covered outpatient drugs—

(A) an effective cost and drug utilization management program, including medically appropriate incentives to use generic drugs and therapeutic interchange, when appropriate;

(B) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including a medication therapy management program described in paragraph (2) and for years beginning with 2006, an electronic prescription program described in paragraph (3); and

(C) a program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor from applying cost management tools (including differential payments) under all methods of operation.

(2) *MEDICATION THERAPY MANAGEMENT PROGRAM.*—

(A) *IN GENERAL.*—A medication therapy management program described in this paragraph is a program of drug therapy management and medication administration that is designed to assure, with respect to beneficiaries with chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that covered outpatient drugs under the prescription drug plan are appropriately used to achieve therapeutic goals and reduce the risk of adverse events, including adverse drug interactions.

(B) *ELEMENTS.*—Such program may include—



(i) enhanced beneficiary understanding of such appropriate use through beneficiary education, counseling, and other appropriate means;

(ii) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other appropriate means; and

(iii) detection of patterns of overuse and underuse of prescription drugs.

(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed pharmacists and physicians.

(D) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug program shall take into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program.

(3) ELECTRONIC PRESCRIPTION PROGRAM.—

(A) IN GENERAL.—An electronic prescription drug program described in this paragraph is a program that includes at least the following components, consistent with national standards established under subparagraph (B):

(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions are only received electronically, except in emergency cases and other exceptional circumstances recognized by the Administrator.

(ii) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL.—The program provides, upon transmittal of a prescription by a prescribing health care professional, for transmittal by the pharmacist to the professional of information that includes—

(I) information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

(B) STANDARDS.—

(i) DEVELOPMENT.—The Administrator shall provide for the development of national standards relating to the electronic prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.



(ii) *ADVISORY TASK FORCE.*—In developing such standards and the standards described in subsection (c)(2)(B)(i) the Administrator shall establish a task force that includes representatives of physicians, hospitals, pharmacists, and technology experts and representatives of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Administrator on such standards, including recommendations relating to the following:

(I) The range of available computerized prescribing software and hardware and their costs to develop and implement.

(II) The extent to which such systems reduce medication errors and can be readily implemented by physicians and hospitals.

(III) Efforts to develop a common software platform for computerized prescribing.

(IV) The cost of implementing such systems in the range of hospital and physician office settings, including hardware, software, and training costs.

(V) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

(iii) *DEADLINES.*—

(I) The Administrator shall constitute the task force under clause (ii) by not later than April 1, 2003.

(II) Such task force shall submit recommendations to Administrator by not later than January 1, 2004.

(III) The Administrator shall develop and promulgate the national standards referred to in clause (ii) by not later than January 1, 2005.

(C) *REFERENCE TO AVAILABILITY OF GRANT FUNDS.*—Grant funds are authorized under section 3990 of the Public Health Service Act to provide assistance to health care providers in implementing electronic prescription drug programs.

(4) *TREATMENT OF ACCREDITATION.*—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to prescription drug plans under this part with respect to the following requirements, in the same manner as they apply to Medicare+Choice plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

(A) Paragraph (1) (including quality assurance), including medication therapy management program under paragraph (2).

(B) Subsection (c)(1) (relating to access to covered benefits).

(C) Subsection (g) (relating to confidentiality and accuracy of enrollee records).



(5) *PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.*—Each PDP sponsor shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug shall inform the beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost generic drug covered under the plan that is therapeutically equivalent and bioequivalent.

(e) *GRIEVANCE MECHANISM, COVERAGE DETERMINATIONS, AND RECONSIDERATIONS.*—

(1) *IN GENERAL.*—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

(2) *APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.*—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to a Medicare+Choice organization with respect to benefits it offers under a Medicare+Choice plan under part C.

(3) *REQUEST FOR REVIEW OF TIERED FORMULARY DETERMINATIONS.*—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, an individual who is enrolled in the plan may request coverage of a nonpreferred drug under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition is not as effective for the individual or has adverse effects for the individual.

(f) *APPEALS.*—

(1) *IN GENERAL.*—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to drugs not included on any formulary in the same manner as such requirements apply to a Medicare+Choice organization with respect to benefits it offers under a Medicare+Choice plan under part C.

(2) *FORMULARY DETERMINATIONS.*—An individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal to obtain coverage for a covered outpatient drug that is not on a formulary of the sponsor if the prescribing physician determines that the formulary drug for treatment of the same condition is not as effective for the individual or has adverse effects for the individual.

(g) *CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.*—A PDP sponsor shall meet the requirements of section 1852(h) with respect to enrollees under this part in the same manner as such requirements apply to a Medicare+Choice organization with respect to enrollees under part C.



SEC. 1860D. REQUIREMENTS FOR PRESCRIPTION DRUG PLAN (PDP) SPONSORS; CONTRACTS; ESTABLISHMENT OF STANDARDS.

(a) *GENERAL REQUIREMENTS.*—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) *LICENSURE.*—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) *ASSUMPTION OF FINANCIAL RISK.*—

(A) *IN GENERAL.*—Subject to subparagraph (B) and section 1860E(d)(2), the entity assumes full financial risk on a prospective basis for qualified prescription drug coverage that it offers under a prescription drug plan and that is not covered under section 1860H.

(B) *REINSURANCE PERMITTED.*—The entity may obtain insurance or make other arrangements for the cost of coverage provided to any enrolled member under this part.

(3) *SOLVENCY FOR UNLICENSED SPONSORS.*—In the case of a sponsor that is not described in paragraph (1), the sponsor shall meet solvency standards established by the Administrator under subsection (d).

(b) *CONTRACT REQUIREMENTS.*—

(1) *IN GENERAL.*—The Administrator shall not permit the election under section 1860A of a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860G or 1860H, unless the Administrator has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) *NEGOTIATION REGARDING TERMS AND CONDITIONS.*—The Administrator shall have the same authority to negotiate the terms and conditions of prescription drug plans under this part as the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. In negotiating the terms and conditions regarding premiums for which information is submitted under section 1860F(a)(2), the Administrator shall take into account the subsidy payments under section 1860H and the adjusted community rate (as defined in section 1854(f)(3)) for the benefits covered.

(3) *INCORPORATION OF CERTAIN MEDICARE+CHOICE CONTRACT REQUIREMENTS.*—The following provisions of section 1857 shall apply, subject to subsection (c)(5), to contracts under this section in the same manner as they apply to contracts under section 1857(a):

(A) *MINIMUM ENROLLMENT.*—Paragraphs (1) and (3) of section 1857(b).

(B) *CONTRACT PERIOD AND EFFECTIVENESS.*—Paragraphs (1) through (3) and (5) of section 1857(c).



- (C) *PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).*
- (D) *ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that in applying section 1857(e)(2) under this part—*
- (i) *such section shall be applied separately to costs relating to this part (from costs under part C);*
- (ii) *in no case shall the amount of the fee established under this subparagraph for a plan exceed 20 percent of the maximum amount of the fee that may be established under subparagraph (B) of such section; and*
- (iii) *no fees shall be applied under this subparagraph with respect to Medicare+Choice plans.*
- (E) *INTERMEDIATE SANCTIONS.—Section 1857(g).*
- (F) *PROCEDURES FOR TERMINATION.—Section 1857(h).*
- (4) *RULES OF APPLICATION FOR INTERMEDIATE SANCTIONS.—In applying paragraph (3)(E)—*
- (A) *the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part; and*
- (B) *the reference in section 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall not be applied.*
- (c) *WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—*
- (1) *IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Administrator shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Administrator determines, based on the application and other evidence presented to the Administrator, that any of the grounds for approval of the application described in paragraph (2) has been met.*
- (2) *GROUND FOR APPROVAL.—The grounds for approval under this paragraph are the grounds for approval described in subparagraph (B), (C), and (D) of section 1855(a)(2), and also include the application by a State of any grounds other than those required under Federal law.*
- (3) *APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply.*
- (4) *LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that an entity is licensed in accordance with subsection (a)(1) does not deem the entity to meet other requirements imposed under this part for a PDP sponsor.*
- (5) *REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying provisions of section 1855(a)(2) under this subsection to prescription drug plans and PDP sponsors—*
- (A) *any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1); and*
- (B) *any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d).*
- (d) *SOLVENCY STANDARDS FOR NON-LICENSED SPONSORS.—*



(1) *ESTABLISHMENT.*—The Administrator shall establish, by not later than October 1, 2003, financial solvency and capital adequacy standards that an entity that does not meet the requirements of subsection (a)(1) must meet to qualify as a PDP sponsor under this part.

(2) *COMPLIANCE WITH STANDARDS.*—Each PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Administrator shall establish certification procedures for such PDP sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

(e) *OTHER STANDARDS.*—The Administrator shall establish by regulation other standards (not described in subsection (d)) for PDP sponsors and plans consistent with, and to carry out, this part. The Administrator shall publish such regulations by October 1, 2003.

(f) *RELATION TO STATE LAWS.*—

(1) *IN GENERAL.*—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency, except as provided in subsection (d)) with respect to prescription drug plans which are offered by PDP sponsors under this part.

(2) *PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.*—No State may impose a premium tax or similar tax with respect to premiums paid to PDP sponsors for prescription drug plans under this part, or with respect to any payments made to such a sponsor by the Administrator under this part.

SEC. 1860E. PROCESS FOR BENEFICIARIES TO SELECT QUALIFIED PRESCRIPTION DRUG COVERAGE.

(a) *IN GENERAL.*—The Administrator shall establish a process for the selection of the prescription drug plan or Medicare+Choice plan which offer qualified prescription drug coverage through which eligible individuals elect qualified prescription drug coverage under this part.

(b) *ELEMENTS.*—Such process shall include the following:

(1) Annual, coordinated election periods, in which such individuals can change the qualifying plans through which they obtain coverage, in accordance with section 1860A(b)(2).

(2) Active dissemination of information to promote an informed selection among qualifying plans based upon price, quality, and other features, in the manner described in (and in coordination with) section 1851(d), including the provision of annual comparative information, maintenance of a toll-free hotline, and the use of non-Federal entities.

(3) Coordination of elections through filing with a Medicare+Choice organization or a PDP sponsor, in the manner described in (and in coordination with) section 1851(c)(2).

(c) *MEDICARE+CHOICE ENROLLEE IN PLAN OFFERING PRESCRIPTION DRUG COVERAGE MAY ONLY OBTAIN BENEFITS THROUGH THE PLAN.*—An individual who is enrolled under a Medicare+Choice plan that offers qualified prescription drug coverage may only elect to receive qualified prescription drug coverage under this part through such plan.



(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—

(A) IN GENERAL.—The Administrator shall assure that each individual who is entitled to benefits under part A or enrolled under part B and who is residing in an area in the United States has available, consistent with subparagraph (B), a choice of enrollment in at least two qualifying plans (as defined in paragraph (5)) in the area in which the individual resides, at least one of which is a prescription drug plan.

(B) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—

The requirement in subparagraph (A) is not satisfied with respect to an area if only one PDP sponsor or Medicare+Choice organization offers all the qualifying plans in the area.

(2) GUARANTEEING ACCESS TO COVERAGE.—In order to assure access under paragraph (1) and consistent with paragraph (3), the Administrator may provide financial incentives (including partial underwriting of risk) for a PDP sponsor to expand the service area under an existing prescription drug plan to adjoining or additional areas or to establish such a plan (including offering such a plan on a regional or nationwide basis), but only so long as (and to the extent) necessary to assure the access guaranteed under paragraph (1).

(3) LIMITATION ON AUTHORITY.—In exercising authority under this subsection, the Administrator—

(A) shall not provide for the full underwriting of financial risk for any PDP sponsor;

(B) shall not provide for any underwriting of financial risk for a public PDP sponsor with respect to the offering of a nationwide prescription drug plan; and

(C) shall seek to maximize the assumption of financial risk by PDP sponsors or Medicare+Choice organizations.

(4) REPORTS.—The Administrator shall, in each annual report to Congress under section 1808(f), include information on the exercise of authority under this subsection. The Administrator also shall include such recommendations as may be appropriate to minimize the exercise of such authority, including minimizing the assumption of financial risk.

(5) QUALIFYING PLAN DEFINED.—For purposes of this subsection, the term “qualifying plan” means a prescription drug plan or a Medicare+Choice plan that includes qualified prescription drug coverage.

SEC. 1860F. SUBMISSION OF BIDS.

(a) SUBMISSION OF BIDS AND RELATED INFORMATION.—

(1) IN GENERAL.—Each PDP sponsor shall submit to the Administrator information of the type described in paragraph (2) in the same manner as information is submitted by a Medicare+Choice organization under section 1854(a)(1).

(2) TYPE OF INFORMATION.—The information described in this paragraph is the following:

(A) Information on the qualified prescription drug coverage to be provided.



(B) Information on the actuarial value of the coverage.

(C) Information on the bid for the coverage, including an actuarial certification of—

(i) the actuarial basis for such bid;

(ii) the portion of such bid attributable to benefits in excess of standard coverage; and

(iii) the reduction in such bid resulting from the subsidy payments provided under section 1860H.

(D) Such other information as the Administrator may require to carry out this part.

(3) REVIEW.—The Administrator shall review the information filed under paragraph (2) for the purpose of conducting negotiations under section 1860D(b)(2).

(b) UNIFORM BID.—

(1) IN GENERAL.—The bid for a prescription drug plan under this section may not vary among individuals enrolled in the plan in the same service area.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing the imposition of a late enrollment penalty under section 1860A(c)(2)(B).

(c) COLLECTION.—

(1) USE AT BENEFICIARY'S OPTION OF WITHHOLDING FROM SOCIAL SECURITY PAYMENT AND USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a PDP sponsor shall permit each enrollee, at the enrollee's option, to make payment of premiums through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839. In the case in which an enrollee does not elect such option, a PDP sponsor may, in accordance with regulations, encourage enrollees to make payment of the premium established by the plan under this part through an electronic funds transfer mechanism, such as automatic charges of an account at a financial institution or a credit or debit card account. All such amounts shall be credited to the Medicare Prescription Drug Trust Fund.

(2) OFFSETTING.—Reductions in premiums for coverage under parts A and B as a result of a selection of a Medicare+Choice plan may be used to reduce the premium otherwise imposed under paragraph (1).

(3) PAYMENT OF PLANS.—PDP plans shall receive payment based on bid amounts in the same manner as Medicare+Choice organizations receive payment based on bid amounts under section 1853(a)(1)(A)(ii) except that such payment shall be made from the Medicare Prescription Drug Trust Fund.

(d) ACCEPTANCE OF BENCHMARK AMOUNT AS FULL PREMIUM FOR SUBSIDIZED LOW-INCOME INDIVIDUALS IF NO STANDARD (OR EQUIVALENT) COVERAGE IN AN AREA.—

(1) IN GENERAL.—If there is no standard prescription drug coverage (as defined in paragraph (2)) offered in an area, in the case of an individual who is eligible for a premium subsidy under section 1860G and resides in the area, the PDP sponsor of any prescription drug plan offered in the area (and any Medicare+Choice organization that offers qualified prescription drug coverage in the area) shall accept the benchmark bid



amount (under section 1860G(b)(2)) as payment in full for the premium charge for qualified prescription drug coverage.

(2) *STANDARD PRESCRIPTION DRUG COVERAGE DEFINED.*—For purposes of this subsection, the term “standard prescription drug coverage” means qualified prescription drug coverage that is standard coverage or that has an actuarial value equivalent to the actuarial value for standard coverage.

SEC. 1860G. PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS.

(a) *INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME BELOW 175 PERCENT OF FEDERAL POVERTY LEVEL.*—

(1) *FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY LEVEL.*—In the case of a subsidy eligible individual (as defined in paragraph (4)) who is determined to have income that does not exceed 150 percent of the Federal poverty level, the individual is entitled under this section—

(A) to an income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1); and

(B) subject to subsection (c), to the substitution for the beneficiary cost-sharing described in paragraphs (1) and (2) of section 1860B(b) (up to the initial coverage limit specified in paragraph (3) of such section) of amounts that do not exceed \$2 for a multiple source or generic drug (as described in section 1927(k)(7)(A)) and \$5 for a non-preferred drug.

(2) *SLIDING SCALE PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR INDIVIDUALS WITH INCOME ABOVE 150, BUT BELOW 175 PERCENT, OF FEDERAL POVERTY LEVEL.*—In the case of a subsidy eligible individual who is determined to have income that exceeds 150 percent, but does not exceed 175 percent, of the Federal poverty level, the individual is entitled under this section to—

(A) an income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in subsection (b)(1) for individuals with incomes at 150 percent of such level to 0 percent of such amount for individuals with incomes at 175 percent of such level; and

(B) subject to subsection (c), to the substitution for the beneficiary cost-sharing described in paragraphs (1) and (2) of section 1860B(b) (up to the initial coverage limit specified in paragraph (3) of such section) of amounts that do not exceed \$2 for a multiple source or generic drug (as described in section 1927(k)(7)(A)) and \$5 for a non-preferred drug.

(3) *CONSTRUCTION.*—Nothing in this section shall be construed as preventing a PDP sponsor from reducing to 0 the cost-sharing otherwise applicable to generic drugs.

(4) *DETERMINATION OF ELIGIBILITY.*—

(A) *SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.*—For purposes of this section, subject to subparagraph (D), the term “subsidy eligible individual” means an individual who—



(i) is eligible to elect, and has elected, to obtain qualified prescription drug coverage under this part;

(ii) has income below 175 percent of the Federal poverty line; and

(iii) meets the resources requirement described in section 1905(p)(1)(C).

(B) DETERMINATIONS.—The determination of whether an individual residing in a State is a subsidy eligible individual and the amount of such individual's income shall be determined under the State medicaid plan for the State under section 1935(a) or by the Social Security Administration. In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

(C) INCOME DETERMINATIONS.—For purposes of applying this section—

(i) income shall be determined in the manner described in section 1905(p)(1)(B); and

(ii) the term "Federal poverty line" means the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(D) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of an individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual but may be eligible for financial assistance with prescription drug expenses under section 1935(e).

(E) TREATMENT OF CONFORMING MEDIGAP POLICIES.—For purposes of this section, the term "qualified prescription drug coverage" includes a medicare supplemental policy described in section 1860H(b)(4).

(5) INDEXING DOLLAR AMOUNTS.—

(A) FOR 2006.—The dollar amounts applied under paragraphs (1)(B) and (2)(B) for 2006 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase described in section 1860B(b)(5) for 2006.

(B) FOR SUBSEQUENT YEARS.—The dollar amounts applied under paragraphs (1)(B) and (2)(B) for a year after 2006 shall be the amounts (under this paragraph) applied under paragraph (1)(B) or (2)(B) for the preceding year increased by the annual percentage increase described in section 1860B(b)(5) (relating to growth in medicare prescription drug costs per beneficiary) for the year involved.

(b) PREMIUM SUBSIDY AMOUNT.—



(1) *IN GENERAL.*—The premium subsidy amount described in this subsection for an individual residing in an area is the benchmark bid amount (as defined in paragraph (2)) for qualified prescription drug coverage offered by the prescription drug plan or the Medicare+Choice plan in which the individual is enrolled.

(2) *BENCHMARK BID AMOUNT DEFINED.*—For purposes of this subsection, the term “benchmark bid amount” means, with respect to qualified prescription drug coverage offered under—

(A) a prescription drug plan that—

(i) provides standard coverage (or alternative prescription drug coverage the actuarial value is equivalent to that of standard coverage), the bid amount for enrollment under the plan under this part (determined without regard to any subsidy under this section or any late enrollment penalty under section 1860A(c)(2)(B)); or

(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the bid amount described in clause (i) multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

(B) a Medicare+Choice plan, the portion of the bid amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

(c) *RULES IN APPLYING COST-SHARING SUBSIDIES.*—

(1) *IN GENERAL.*—In applying subsections (a)(1)(B) and (a)(2)(B), nothing in this part shall be construed as preventing a plan or provider from waiving or reducing the amount of cost-sharing otherwise applicable.

(2) *LIMITATION ON CHARGES.*—In the case of an individual receiving cost-sharing subsidies under subsection (a)(1)(B) or (a)(2)(B), the PDP sponsor may not charge more than \$5 per prescription.

(3) *APPLICATION OF INDEXING RULES.*—The provisions of subsection (a)(4) shall apply to the dollar amount specified in paragraph (2) in the same manner as they apply to the dollar amounts specified in subsections (a)(1)(B) and (a)(2)(B).

(d) *ADMINISTRATION OF SUBSIDY PROGRAM.*—The Administrator shall provide a process whereby, in the case of an individual who is determined to be a subsidy eligible individual and who is enrolled in prescription drug plan or is enrolled in a Medicare+Choice plan under which qualified prescription drug coverage is provided—

(1) the Administrator provides for a notification of the PDP sponsor or Medicare+Choice organization involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

(2) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Administrator information on the amount of such reduction; and



(3) the Administrator periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions.

The reimbursement under paragraph (3) with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

(e) RELATION TO MEDICAID PROGRAM.—

(1) IN GENERAL.—For provisions providing for eligibility determinations, and additional financing, under the medicaid program, see section 1935.

(2) MEDICAID PROVIDING WRAP AROUND BENEFITS.—The coverage provided under this part is primary payor to benefits for prescribed drugs provided under the medicaid program under title XIX.

(3) COORDINATION.—The Administrator shall develop and implement a plan for the coordination of prescription drug benefits under this part with the benefits provided under the medicaid program under title XIX, with particular attention to insuring coordination of payments and prevention of fraud and abuse. In developing and implementing such plan, the Administrator shall involve the Secretary, the States, the data processing industry, pharmacists, and pharmaceutical manufacturers, and other experts.

SEC. 1860H. SUBSIDIES FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

(a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for all medicare beneficiaries consistent with an overall subsidy level of 65 percent, to reduce adverse selection among prescription drug plans and Medicare+Choice plans that provide qualified prescription drug coverage, and to promote the participation of PDP sponsors under this part, the Administrator shall provide in accordance with this section for payment to a qualifying entity (as defined in subsection (b)) of the following subsidies:

(1) DIRECT SUBSIDY.—In the case of an individual enrolled in a prescription drug plan, Medicare+Choice plan that provides qualified prescription drug coverage, or qualified retiree prescription drug plan, a direct subsidy equal to 35 percent of the total payments made by a qualifying entity for standard coverage under the respective plan.

(2) SUBSIDY THROUGH REINSURANCE.—The reinsurance payment amount (as defined in subsection (c)), which in the aggregate is 30 percent of such total payments, for excess costs incurred in providing qualified prescription drug coverage—

(A) for individuals enrolled with a prescription drug plan under this part;

(B) for individuals enrolled with a Medicare+Choice plan that provides qualified prescription drug coverage; and

(C) for individuals who are enrolled in a qualified retiree prescription drug plan.



This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Administrator to provide for the payment of amounts provided under this section.

(b) QUALIFYING ENTITY DEFINED.—For purposes of this section, the term “qualifying entity” means any of the following that has entered into an agreement with the Administrator to provide the Administrator with such information as may be required to carry out this section:

(1) A PDP sponsor offering a prescription drug plan under this part.

(2) A Medicare+Choice organization that provides qualified prescription drug coverage under a Medicare+Choice plan under part C.

(3) The sponsor of a qualified retiree prescription drug plan (as defined in subsection (f)).

(c) REINSURANCE PAYMENT AMOUNT.—

(1) IN GENERAL.—Subject to subsection (d)(1)(B) and paragraph (4), the reinsurance payment amount under this subsection for a qualifying covered individual (as defined in subsection (g)(1)) for a coverage year (as defined in subsection (g)(2)) is equal to the sum of the following:

(A) For the portion of the individual’s gross covered prescription drug costs (as defined in paragraph (3)) for the year that exceeds the initial copayment threshold specified in section 1860B(b)(2)(C), but does not exceed the initial coverage limit specified in section 1860B(b)(3), an amount equal to 30 percent of the allowable costs (as defined in paragraph (2)) attributable to such gross covered prescription drug costs.

(B) For the portion of the individual’s gross covered prescription drug costs for the year that exceeds the annual out-of-pocket threshold specified in 1860B(b)(4)(B), an amount equal to 80 percent of the allowable costs attributable to such gross covered prescription drug costs.

(2) ALLOWABLE COSTS.—For purposes of this section, the term “allowable costs” means, with respect to gross covered prescription drug costs under a plan described in subsection (b) offered by a qualifying entity, the part of such costs that are actually paid (net of average percentage rebates) under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were standard coverage.

(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term “gross covered prescription drug costs” means, with respect to an enrollee with a qualifying entity under a plan described in subsection (b) during a coverage year, the costs incurred under the plan (including costs attributable to administrative costs) for covered prescription drugs dispensed during the year, including costs relating to the deductible, whether paid by the enrollee or under the plan, regardless of whether the coverage under the plan exceeds standard coverage and regardless of when the payment for such drugs is made.

(4) INDEXING DOLLAR AMOUNTS.—



(A) AMOUNTS FOR 2005.—The dollar amounts applied under paragraph (1) for 2005 shall be the dollar amounts specified in such paragraph.

(B) FOR 2006.—The dollar amounts applied under paragraph (1) for 2006 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase described in section 1860B(b)(5) for 2006.

(C) FOR SUBSEQUENT YEARS.—The dollar amounts applied under paragraph (1) for a year after 2006 shall be the amounts (under this paragraph) applied under paragraph (1) for the preceding year increased by the annual percentage increase described in section 1860B(b)(5) (relating to growth in medicare prescription drug costs per beneficiary) for the year involved.

(D) ROUNDING.—Any amount, determined under the preceding provisions of this paragraph for a year, which is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

(d) ADJUSTMENT OF PAYMENTS.—

(1) ADJUSTMENT OF REINSURANCE PAYMENTS TO ASSURE 30 PERCENT LEVEL OF SUBSIDY THROUGH REINSURANCE.—

(A) ESTIMATION OF PAYMENTS.—The Administrator shall estimate—

(i) the total payments to be made (without regard to this subsection) during a year under subsections (a)(2) and (c); and

(ii) the total payments to be made by qualifying entities for standard coverage under plans described in subsection (b) during the year.

(B) ADJUSTMENT.—The Administrator shall proportionally adjust the payments made under subsections (a)(2) and (c) for a coverage year in such manner so that the total of the payments made under such subsections for the year is equal to 30 percent of the total payments described in subparagraph (A)(ii).

(2) RISK ADJUSTMENT FOR DIRECT SUBSIDIES.—To the extent the Administrator determines it appropriate to avoid risk selection, the payments made for direct subsidies under subsection (a)(1) are subject to adjustment based upon risk factors specified by the Administrator. Any such risk adjustment shall be designed in a manner as to not result in a change in the aggregate payments made under such subsection.

(e) PAYMENT METHODS.—

(1) IN GENERAL.—Payments under this section shall be based on such a method as the Administrator determines. The Administrator may establish a payment method by which interim payments of amounts under this section are made during a year based on the Administrator's best estimate of amounts that will be payable after obtaining all of the information.

(2) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Trust Fund.

(f) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN DEFINED.—



(1) *IN GENERAL.*—For purposes of this section, the term “qualified retiree prescription drug plan” means employment-based retiree health coverage (as defined in paragraph (3)(A)) if, with respect to an individual enrolled (or eligible to be enrolled) under this part who is covered under the plan, the following requirements are met:

(A) *ASSURANCE.*—The sponsor of the plan shall annually attest, and provide such assurances as the Administrator may require, that the coverage meets or exceeds the requirements for qualified prescription drug coverage.

(B) *AUDITS.*—The sponsor (and the plan) shall maintain, and afford the Administrator access to, such records as the Administrator may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage, and the accuracy of payments made.

(C) *PROVISION OF CERTIFICATION OF PRESCRIPTION DRUG COVERAGE.*—The sponsor of the plan shall provide for issuance of certifications of the type described in section 1860A(c)(2)(D).

(2) *LIMITATION ON BENEFIT ELIGIBILITY.*—No payment shall be provided under this section with respect to an individual who is enrolled under a qualified retiree prescription drug plan unless the individual is—

(A) enrolled under this part;

(B) is covered under the plan; and

(C) is eligible to obtain qualified prescription drug coverage under section 1860A but did not elect such coverage under this part (either through a prescription drug plan or through a Medicare+Choice plan).

(3) *DEFINITIONS.*—As used in this section:

(A) *EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.*—The term “employment-based retiree health coverage” means health insurance or other coverage of health care costs for individuals enrolled under this part (or for such individuals and their spouses and dependents) based on their status as former employees or labor union members.

(B) *SPONSOR.*—The term “sponsor” means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

(g) *GENERAL DEFINITIONS.*—For purposes of this section:

(1) *QUALIFYING COVERED INDIVIDUAL.*—The term “qualifying covered individual” means an individual who—

(A) is enrolled with a prescription drug plan under this part;

(B) is enrolled with a Medicare+Choice plan that provides qualified prescription drug coverage under part C; or

(C) is enrolled for benefits under this title and is covered under a qualified retiree prescription drug plan.

(2) *COVERAGE YEAR.*—The term “coverage year” means a calendar year in which covered outpatient drugs are dispensed if a claim for payment is made under the plan for such drugs, regardless of when the claim is paid.



SEC. 1860I. MEDICARE PRESCRIPTION DRUG TRUST FUND.

(a) *IN GENERAL.*—There is created on the books of the Treasury of the United States a trust fund to be known as the “Medicare Prescription Drug Trust Fund” (in this section referred to as the “Trust Fund”). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, such fund as provided in this part. Except as otherwise provided in this section, the provisions of subsections (b) through (i) of section 1841 shall apply to the Trust Fund in the same manner as they apply to the Federal Supplementary Medical Insurance Trust Fund under such section.

(b) *PAYMENTS FROM TRUST FUND.*—

(1) *IN GENERAL.*—The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Administrator certifies are necessary to make—

(A) payments under section 1860G (relating to low-income subsidy payments);

(B) payments under section 1860H (relating to subsidy payments); and

(C) payments with respect to administrative expenses under this part in accordance with section 201(g).

(2) *TRANSFERS TO MEDICAID ACCOUNT FOR INCREASED ADMINISTRATIVE COSTS.*—The Managing Trustee shall transfer from time to time from the Trust Fund to the Grants to States for Medicaid account amounts the Administrator certifies are attributable to increases in payment resulting from the application of a higher Federal matching percentage under section 1935(b).

(c) *DEPOSITS INTO TRUST FUND.*—

(1) *LOW-INCOME TRANSFER.*—There is hereby transferred to the Trust Fund, from amounts appropriated for Grants to States for Medicaid, amounts equivalent to the aggregate amount of the reductions in payments under section 1903(a)(1) attributable to the application of section 1935(c).

(2) *APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.*—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Trust Fund, an amount equivalent to the amount of payments made from the Trust Fund under subsection (b), reduced by the amount transferred to the Trust Fund under paragraph (1).

(d) *RELATION TO SOLVENCY REQUIREMENTS.*—Any provision of law that relates to the solvency of the Trust Fund under this part shall take into account the Trust Fund and amounts receivable by, or payable from, the Trust Fund.

SEC. 1860J. DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C.

(a) *DEFINITIONS.*—For purposes of this part:

(1) *COVERED OUTPATIENT DRUGS.*—The term “covered outpatient drugs” is defined in section 1860B(f).

(2) *INITIAL COVERAGE LIMIT.*—The term “initial coverage limit” means such limit as established under section 1860B(b)(3), or, in the case of coverage that is not standard cov-



erage, the comparable limit (if any) established under the coverage.

(3) *MEDICARE PRESCRIPTION DRUG TRUST FUND.*—The term “Medicare Prescription Drug Trust Fund” means the Trust Fund created under section 1860I(a).

(4) *PDP SPONSOR.*—The term “PDP sponsor” means an entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

(5) *PRESCRIPTION DRUG PLAN.*—The term “prescription drug plan” means health benefits coverage that—

(A) is offered under a policy, contract, or plan by a PDP sponsor pursuant to, and in accordance with, a contract between the Administrator and the sponsor under section 1860D(b);

(B) provides qualified prescription drug coverage; and

(C) meets the applicable requirements of the section 1860C for a prescription drug plan.

(6) *QUALIFIED PRESCRIPTION DRUG COVERAGE.*—The term “qualified prescription drug coverage” is defined in section 1860B(a).

(7) *STANDARD COVERAGE.*—The term “standard coverage” is defined in section 1860B(b).

(b) *APPLICATION OF MEDICARE+CHOICE PROVISIONS UNDER THIS PART.*—For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

(1) any reference to a Medicare+Choice plan included a reference to a prescription drug plan;

(2) any reference to a provider-sponsored organization included a reference to a PDP sponsor;

(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D(b); and

(4) any reference to part C included a reference to this part.

PART [D] E—MISCELLANEOUS PROVISIONS

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

Spell of Illness

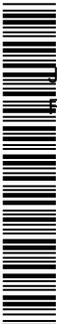
(a) * * *

* * * * *

Supplier

(d) The term “supplier” means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

* * * * *



Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services:

(1) * * *

(2)(A) * * *

* * * * *

(U) screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes; [and]

(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who—

(i) * * *

* * * * *

(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

(W) an initial preventive physical examination (as defined in subsection (ww)); and

(X) cholesterol and other blood lipid screening tests (as defined in subsection (XX));

* * * * *

Hospice Care; Hospice Program

(dd)(1) * * *

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which—

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals *and services described in section 1812(a)(5),*

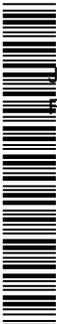
* * * * *

(5)(A) * * *

* * * * *

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

* * * * *



Initial Preventive Physical Examination

(ww) The term "initial preventive physical examination" means physicians' services consisting of a physical examination with the goal of health promotion and disease detection and includes items and services specified by the Secretary in regulations.

Cholesterol and Other Blood Lipid Screening Test

(xx)(1) The term "cholesterol and other blood lipid screening test" means diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels.

(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cholesterol and other blood lipid screening tests, except that such frequency may not be more often than once every 2 years.

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) * * *

* * * * *

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d), [and]

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation[;],

(J) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual's first coverage period begins under part B; and

(K) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(xx)(1)), which is performed more frequently than is covered under section 1861(xx)(2).

* * * * *

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraph (B), (F), (G), [or (H)] (H), or (J) of paragraph (1));

* * * * *

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees [established under section 1114(f)] with respect to the determina-



tion are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

* * * * *
(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

* * * * *
(h)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

* * * * *
[(i)] (j)(1) Any advisory committee appointed [under subsection (f)] to advise the Secretary on matters relating to the interpretation, application, or implementation of [section 1862(a)(1)] subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or serv-



ices directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

* * * * *

AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT PROCESSES

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

(A) * * *

* * * * *

(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification, [and]

(S) in the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1861(ee)(2)(H)(ii), or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on—

(i) * * *

* * * * *

(iii) the percentage of such individuals who received such services from such provider (or another such provider) [.] and

(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).

In the case of a hospital which has an agreement in effect with an organization described in subparagraph (F), which organization's contract with the Secretary under part B of title XI is terminated on or after October 1, 1984, the hospital shall not be determined to be out of compliance with the requirement of such subparagraph during the six month period beginning on the date of the termination of that contract.

(2)(A) A provider of services may charge such individual or other person (i) the amount of any deduction [or coinsurance], co-insurance, or copayment amount imposed pursuant to section 1813(a)(1), (a)(3), [or (a)(4)] (a)(4), or (a)(5), section 1833(b), or section 1861(y)(3) with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (not in excess of 20 per centum of the amount customarily charged for such items and



services by such provider) for which payment is made under part B or which are durable medical equipment furnished as home health services (but in the case of items and services furnished to individuals with end-stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary). In the case of items and services described in section 1833(c), clause (ii) of the preceding sentence shall be applied by substituting for 20 percent the proportion which is appropriate under such section. A provider of services may not impose a charge under clause (ii) of the first sentence of this subparagraph with respect to items and services described in section 1861(s)(10)(A) and with respect to clinical diagnostic laboratory tests for which payment is made under part B. Notwithstanding the first sentence of this subparagraph, a home health agency may charge such an individual or person, with respect to covered items subject to payment under section 1834(a), the amount of any deduction imposed under section 1833(b) and 20 percent of the payment basis described in section 1834(a)(1)(B). In the case of items and services for which payment is made under part B under the prospective payment system established under section 1833(t), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1833(t)(5). In the case of services described in section 1833(a)(8) or section 1833(a)(9) for which payment is made under part B under section 1834(k), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge for such services 20 percent of the lesser of the actual charge or the applicable fee schedule amount (as defined in such section) for such services.

* * * * *

(b)(1) * * *

* * * * *

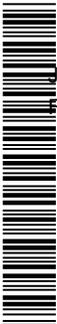
(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

* * * * *

(h)(1)(A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Sec-



retary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

* * * * *

(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) ENROLLMENT PROCESS.—

(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

* * * * *

EXAMINATION AND TREATMENT FOR EMERGENCY MEDICAL CONDITIONS AND WOMEN IN LABOR

SEC. 1867. (a) * * *

* * * * *

(d) ENFORCEMENT.—



(1) * * *

* * * * *

(3) CONSULTATION WITH PEER REVIEW ORGANIZATIONS.—In considering allegations of violations of the requirements of this section in imposing sanctions under paragraph (1) or in terminating a hospital's participation under this title, the Secretary shall request the appropriate utilization and quality control peer review organization (with a contract under part B of title XI) to assess whether the individual involved had an emergency medical condition which had not been stabilized, and provide a report on its findings. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction under paragraph (1) and shall provide a period of at least 60 days for such review. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.

(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.

PRACTICING PHYSICIANS ADVISORY COUNCIL; MEDICARE PROVIDER OMBUDSMAN

SEC. 1868. (a) PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1) The Secretary shall appoint, based upon nominations submitted by medical organizations representing physicians, a Practicing Physicians Advisory Council (in this [section] subsection referred to as the "Council") to be composed of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under this title in the previous year. At least 11 of the members of the Council shall be physicians described in section 1861(r)(1) and the members of the Council shall include both participating and nonparticipating physicians and physicians practicing in rural areas and underserved urban areas.

[(b)] (2) The Council shall meet once during each calendar quarter to discuss certain proposed changes in regulations and carrier manual instructions related to physician services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, such consultation shall occur before the publication of such proposed changes.

[(c)] (3) Members of the Council shall be entitled to receive reimbursement of expenses and per diem in lieu of subsistence in the same manner as other members of advisory councils appointed by the Secretary are provided such reimbursement and per diem under this title.



(b) *MEDICARE PROVIDER OMBUDSMAN.*—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(c) *COUNCIL FOR TECHNOLOGY AND INNOVATION.*—

(1) *ESTABLISHMENT.*—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as “CMS”).

(2) *COMPOSITION.*—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

(3) *DUTIES.*—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

(4) *EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.*—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.



DETERMINATIONS; APPEALS

SEC. 1869. (a) INITIAL DETERMINATIONS.—

(1) * * *

* * * * *

(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS AND RE-DETERMINATIONS.—A written notice of a determination on an initial determination or on a redetermination, insofar as such determination or redetermination results in a denial of a claim for benefits, shall include—

(A) the specific reasons for the determination, including—

(i) upon request, the provision of the policy, manual, or regulation used in making the determination; and

(ii) as appropriate in the case of a redetermination, a summary of the clinical or scientific evidence used in making the determination;

(B) the procedures for obtaining additional information concerning the determination or redetermination; and

(C) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination or appeal under this section.

The written notice on a redetermination shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both.

(b) APPEAL RIGHTS.—

(1) IN GENERAL.—

(A) RECONSIDERATION OF INITIAL DETERMINATION.—

Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 205(b) and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g). For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (l) of section 205 shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

* * * * *

(F) EXPEDITED [PROCEEDINGS.—

[(i) EXPEDITED DETERMINATION] DETERMINATIONS AND RECONSIDERATIONS.—In the case of an individual who has received notice from a provider of services that such provider plans—

[(I)] (i) to terminate services provided to an individual and a physician certifies that failure to con-



tinue the provision of such services is likely to place the individual's health at significant risk, or

【(II)】 *(ii)* to discharge the individual from the provider of services,

the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1), as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

【(ii) EXPEDITED HEARING.—In a hearing by the Secretary under this section, in which the moving party alleges that no material issues of fact are in dispute, the Secretary shall make an expedited determination as to whether any such facts are in dispute and, if not, shall render a decision expeditiously.】

* * * * *

(2) *EXPEDITED ACCESS TO JUDICIAL REVIEW.—*

(A) *IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case of an appeal.*

(B) *PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.*

(C) *ACCESS TO JUDICIAL REVIEW.—*

(i) *IN GENERAL.—If the appropriate review panel—*

(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B);



then the appellant may bring a civil action as described in this subparagraph.

(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

(iv) INTEREST ON AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this Act.

(D) REVIEW PANELS.—For purposes of this subsection, a “review panel” is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.

(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

* * * * *
(c) CONDUCT OF RECONSIDERATIONS BY INDEPENDENT CONTRACTORS.—

(1) * * *

* * * * *



(3) REQUIREMENTS.—Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) IN GENERAL.—The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have [sufficient training and expertise in medical science and legal matters] *sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing* to make reconsiderations under this subsection.

(B) RECONSIDERATIONS.—

(i) IN GENERAL.—The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (*including the medical records of the individual involved*) and medical, technical, and scientific evidence.

* * * * *

[(D) LIMITATION ON INDIVIDUAL REVIEWING DETERMINATIONS.—

[(i) PHYSICIANS AND HEALTH CARE PROFESSIONAL.—No physician or health care professional under the employ of a qualified independent contractor may review—

[(I) determinations regarding health care services furnished to a patient if the physician or health care professional was directly responsible for furnishing such services; or

[(II) determinations regarding health care services provided in or by an institution, organization, or agency, if the physician or any member of the family of the physician or health care professional has, directly or indirectly, a significant financial interest in such institution, organization, or agency.

[(ii) FAMILY DESCRIBED.—For purposes of this paragraph, the family of a physician or health care professional includes the spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance), children (including stepchildren and legally adopted children), grandchildren, parents, and grandparents of the physician or health care professional.]



(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).

(E) EXPLANATION OF DECISION.—Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, *be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate) and shall include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section* and in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)) an explanation of the medical and scientific rationale for the decision.

* * * * *

(I) DATA COLLECTION.—

(i) * * *

(ii) TYPE OF DATA COLLECTED.—Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) * * *

* * * * *

(III) Situations suggesting the need for changes in national or local coverage [policy] *determination.*

(IV) Situations suggesting the need for changes in local [medical review policies] *coverage determinations.*

(J) HEARINGS BY THE SECRETARY.—The qualified independent contractor shall (i) [prepare] *submit* such information as is required for an appeal of a decision of the contractor [with respect to a reconsideration to the Secretary for a hearing, including as necessary, explanations of issues involved in the decision and relevant policies], and (ii) participate in such hearings as required by the Secretary.

(K) INDEPENDENCE REQUIREMENTS.—

(i) IN GENERAL.—*Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—*

(I) is not a related party (as defined in subsection (g)(5));

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and



(III) does not otherwise have a conflict of interest with such a party.

(ii) EXCEPTION FOR REASONABLE COMPENSATION.— Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) LIMITATIONS ON ENTITY COMPENSATION.— Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

* * * * *

(d) DEADLINES FOR HEARINGS BY THE SECRETARY; NOTICE.—

(1) * * *

* * * * *

(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

* * * * *

(f) REVIEW OF COVERAGE DETERMINATIONS.—

(1) * * *

(2) LOCAL COVERAGE DETERMINATION.—

(A) IN GENERAL.—Review of any local coverage determination shall be subject to the following limitations:

(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge [of the Social Security Administration]. The administrative law judge—

(I) * * *

* * * * *

(4) PENDING NATIONAL COVERAGE DETERMINATIONS.—

(A) IN GENERAL.—In the event the Secretary has not issued a national coverage or noncoverage determination with respect to a particular type or class of items or services, an aggrieved person (as described in paragraph (5)) may submit to the Secretary a request to make such a determination with respect to such items or services. By not later than the end of the 90-day period beginning on the date the Secretary receives such a request (notwithstanding the receipt by the Secretary of new evidence (if



any) during such 90-day period), the Secretary shall take one of the following actions:

(i) * * *

* * * * *

(iv) Issue a notice that states that the Secretary has not completed a review of the request for a national coverage determination and that includes an identification of the remaining steps in the Secretary's review process and a deadline by which the Secretary will complete the review and take an action described in [subclause (I), (II), or (III)] clause (i), (ii), or (iii).

(B) DEEMED ACTION BY THE SECRETARY.—In the case of an action described in [clause (i)(IV)] subparagraph (A)(iv), if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have taken an action described in [clause (i)(III)] subparagraph (A)(iii) as of the deadline.

(C) EXPLANATION OF DETERMINATION.—When issuing a determination under [clause (i)] subparagraph (A), the Secretary shall include an explanation of the basis for the determination. An action taken under clause (i) (other than [subclause (IV)] clause (iv)) is deemed to be a national coverage determination for purposes of review under [subparagraph (A)] paragraph (1)(A).

* * * * *

(g) QUALIFICATIONS OF REVIEWERS.—

(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

(A) each individual conducting a review shall meet the qualifications of paragraph (2);

(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a "reviewing professional"), each reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), each reviewing professional shall be a physician (allopathic or osteopathic).

(2) INDEPENDENCE.—

(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

(iii) not otherwise have a conflict of interest with such a party.



(B) *EXCEPTION.*—Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

(I) the individual is not involved in the provision of items or services in the case under review;

(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term “participation agreement” means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(3) *LIMITATIONS ON REVIEWER COMPENSATION.*—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

(4) *LICENSURE AND EXPERTISE.*—Each reviewing professional shall be—

(A) a physician (allopathic or osteopathic) 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 that is appropriate for the items or services at issue; or

(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

(5) *RELATED PARTY DEFINED.*—For purposes of this section, the term “related party” means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:



(A) *The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.*

(B) *The individual (or authorized representative).*

(C) *The health care professional that provides the items or services involved in the case.*

(D) *The institution at which the items or services (or treatment) involved in the case are provided.*

(E) *The manufacturer of any drug or other item that is included in the items or services involved in the case.*

(F) *Any other party determined under any regulations to have a substantial interest in the case involved.*

(h) *PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—*

(1) *ESTABLISHMENT OF PROCESS.—*

(A) *IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to eligible items and services described in subparagraph (C), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.*

(B) *ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:*

(i) *A physician, but only with respect to eligible items and services for which the physician may be paid directly.*

(ii) *An individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives, from the physician who may be paid directly for the item or service, an advance beneficiary notice under section 1879(a) that payment may not be made (or may no longer be made) for the item or service under this title.*

(C) *ELIGIBLE ITEMS AND SERVICES.—For purposes of this subsection and subject to paragraph (2), eligible items and services are items and services which are physicians' services (as defined in paragraph (4)(A) of section 1848(f) for purposes of calculating the sustainable growth rate under such section).*

(2) *SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.*

(3) *REQUEST FOR PRIOR DETERMINATION.—*

(A) *IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of an eligible item or serv-*



ice involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the item or service, supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(4) RESPONSE TO REQUEST.—

(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

- (i) the item or service is so covered;*
- (ii) the item or service is not so covered; or*
- (iii) the contractor lacks sufficient information to make a coverage determination.*

If the contractor makes the determination described in clause (iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

(C) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service and have a claim submitted for the item or service.

(5) EFFECT OF DETERMINATIONS.—

(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

- (I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and*
- (II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determina-*



tion (if any) the determination is based, and the right to such a redetermination.

(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

(6) LIMITATION ON FURTHER REVIEW.—

(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

(i) decides not to seek a prior determination under this subsection with respect to items or services; or

(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii), from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determination under this subsection with respect to such items or services.

* * * * *

REGULATIONS

SEC. 1871. (a)(1) * * *

* * * * *

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall 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.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such



regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes notice of proposed rulemaking relating to a regulation (including an interim final regulation), insofar as such final regulation includes a provision that is not a logical outgrowth of such notice of proposed rulemaking, that provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

* * * * *

(d)(1) Subject to paragraph (2), the Secretary shall issue proposed or final (including interim final) regulations to carry out this title only on one business day of every month.

(2) The Secretary may issue a proposed or final regulation described in paragraph (1) on any other day than the day described in paragraph (1) if the Secretary—

(A) finds that issuance of such regulation on another day is necessary to comply with requirements under law; or

(B) finds that with respect to that regulation the limitation of issuance on the date described in paragraph (1) is contrary to the public interest.

If the Secretary makes a finding under this paragraph, the Secretary shall include such finding, and brief statement of the reasons for such finding, in the issuance of such regulation.

(3) The Secretary shall coordinate issuance of new regulations described in paragraph (1) relating to a category of provider of services or suppliers based on an analysis of the collective impact of regulatory changes on that category of providers or suppliers.

(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.



(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the



Secretary determines appropriate to further reduce such inconsistency or conflicts.

* * * * *

CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

SEC. 1874A. (a) AUTHORITY.—

(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

(A) the entity has demonstrated capability to carry out such function;

(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

(C) the entity has sufficient assets to financially support the performance of such function; and

(D) the entity meets such other requirements as the Secretary may impose.

(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

(A) IN GENERAL.—The term “medicare administrative contractor” means an agency, organization, or other person with a contract under this section.

(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the “appropriate” medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.



(B) *MAKING PAYMENTS.*—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

(C) *BENEFICIARY EDUCATION AND ASSISTANCE.*—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

(D) *PROVIDER CONSULTATIVE SERVICES.*—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.

(E) *COMMUNICATION WITH PROVIDERS.*—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

(F) *PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.*—Performing the functions relating to provider education, training, and technical assistance.

(G) *ADDITIONAL FUNCTIONS.*—Performing such other functions as are necessary to carry out the purposes of this title.

(5) *RELATIONSHIP TO MIP CONTRACTS.*—

(A) *NONDUPLICATION OF DUTIES.*—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

(B) *CONSTRUCTION.*—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

(6) *APPLICATION OF FEDERAL ACQUISITION REGULATION.*—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

(b) *CONTRACTING REQUIREMENTS.*—

(1) *USE OF COMPETITIVE PROCEDURES.*—

(A) *IN GENERAL.*—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

(B) *RENEWAL OF CONTRACTS.*—The Secretary may renew a contract with a medicare administrative contractor



under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

(3) PERFORMANCE REQUIREMENTS.—

(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection (a)(4).

(B) CONSULTATION.— In developing such requirements, the Secretary may consult with providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, or both, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements;

(ii) shall be used for evaluating contractor performance under the contract; and

(iii) shall be consistent with the written statement of work provided under the contract.



(4) *INFORMATION REQUIREMENTS.*—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

(5) *SURETY BOND.*—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

(c) *TERMS AND CONDITIONS.*—

(1) *IN GENERAL.*—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

(2) *PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.*—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

(d) *LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.*—

(1) *CERTIFYING OFFICER.*—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by the individual under this section.

(2) *DISBURSING OFFICER.*—No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

(3) *LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.*—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless in connection with such payment or in the supervision of or selection of such officer the medicare administrative contractor acted with gross negligence.

(4) *INDEMNIFICATION BY SECRETARY.*—



(A) *IN GENERAL.*—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

(B) *CONDITIONS.*—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

(C) *SCOPE OF INDEMNIFICATION.*—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

(D) *WRITTEN APPROVAL FOR SETTLEMENTS.*—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

(E) *CONSTRUCTION.*—Nothing in this paragraph shall be construed—

(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.

(e) *REQUIREMENTS FOR INFORMATION SECURITY.*—

(1) *DEVELOPMENT OF INFORMATION SECURITY PROGRAM.*—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under section 3534(b)(2) of title 44, United



States Code (other than requirements under subparagraphs (B)(ii), (F)(iii), and (F)(iv) of such section).

(2) INDEPENDENT AUDITS.—

(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

(ii) test the effectiveness of information security control techniques for an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines.

(B) DEADLINE FOR INITIAL EVALUATION.—

(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

(C) REPORTS ON EVALUATIONS.—

(i) TO THE INSPECTOR GENERAL.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services.

(ii) TO CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations.

(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—In order to give medicare administrative contractors an incentive to implement effective education and outreach programs for providers of services and suppliers, the Secretary shall develop and implement a methodology to



measure the specific claims payment error rates of such contractors in the processing or reviewing of medicare claims.

(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

(4) MONITORING OF CONTRACTOR RESPONSES.—

(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

(B) DEVELOPMENT OF STANDARDS.—

(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of



services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.

(h) CONDUCT OF PREPAYMENT REVIEW.—

(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term “random prepayment review” means a demand for the production of records or documentation absent cause with respect to a claim.

(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).

(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.

* * * * *

PAYMENTS TO HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS

SEC. 1876. (a) * * *

* * * * *



(h)(1) * * *

* * * * *

(5)(A) * * *

* * * * *

(C)(i) The Secretary may not extend or renew a reasonable cost reimbursement contract under this subsection for any period beyond December 31, 2004, except (subject to clause (ii)) in the case of a contract for an area which is not covered in the service area of 1 or more coordinated care Medicare+Choice plans under part C. (ii) In the case in which—

(I) a reasonable cost reimbursement contract includes an area in its service area as of a date that is after December 31, 2003;

(II) such area is no longer included in such service area after such date by reason of the operation of clause (i) because of the inclusion of such area within the service area of a Medicare+Choice plan; and

(III) all Medicare+Choice plans subsequently terminate coverage in such area;

such reasonable cost reimbursement contract may be extended and renewed to cover such area (so long as it is not included in the service area of any Medicare+Choice plan).

* * * * *

MEDICARE COVERAGE FOR END STAGE RENAL DISEASE PATIENTS

SEC. 1881. (a) * * *

(b)(1) * * *

* * * * *

(7) The Secretary shall provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home. Such method (or methods) shall provide for the prospective determination of a rate (or rates) for each mode of care based on a single composite weighted formula (which takes into account the mix of patients who receive dialysis services at a facility or at home and the relative costs of providing such services in such settings) for hospital-based facilities and such a single composite weighted formula for other renal dialysis facilities, or based on such other method or combination of methods which differentiate between hospital-based facilities and other renal dialysis facilities and which the Secretary determines, after detailed analysis, will more effectively encourage the more efficient delivery of dialysis services and will provide greater incentives for increased use of home dialysis than through the single composite weighted formulas. The amount of a payment made under any method other than a method based on a single composite weighted formula may not exceed the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent of the amount) of the median payment that would have been made under the formula for hospital-based facilities. [The Secretary] Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection



Act of 2000, the Secretary shall provide for such exceptions to such methods as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed. The Secretary may provide that such method will serve in lieu of any target reimbursement rate that would otherwise be established under paragraph (6). The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2). The Secretary shall provide that amounts paid under the previous sentence shall be distributed to the organizations described in subsection (c)(1)(A) to ensure equitable treatment of all such network organizations. The Secretary in distributing any such payments to network organizations shall take into account—

(A) * * *

* * * * *

CERTIFICATION OF MEDICARE SUPPLEMENTAL HEALTH INSURANCE POLICIES

SEC. 1882. (a) * * *

* * * * *

(v) *COVERAGE OF PRESCRIPTION DRUGS.—*

(1) *IN GENERAL.—Notwithstanding any other provision of law, except as provided in paragraph (3) no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under this section on or after January 1, 2005, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs.*

(2) *ISSUANCE OF SUBSTITUTE POLICIES IF OBTAIN PRESCRIPTION DRUG COVERAGE UNDER PART D.—*

(A) *IN GENERAL.—The issuer of a medicare supplemental policy—*

(i) *may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as "A", "B", "C", "D", "E", "F", or "G" (under the standards established under subsection (p)(2)) and that is offered and is available for issuance to new enrollees by such issuer;*

(ii) *may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and*

(iii) *may not impose an exclusion of benefits based on a pre-existing condition under such policy, in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days*



after the date of the termination of enrollment described in such paragraph and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

(B) *INDIVIDUAL COVERED.*—An individual described in this subparagraph is an individual who—

(i) enrolls in a prescription drug plan under part D; and

(ii) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as “H”, “I”, or “J” under the standards referred to in subparagraph (A)(i) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

(C) *ENFORCEMENT.*—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of this paragraph in the same manner as they apply to the requirements of such subsection.

(3) *NEW STANDARDS.*—In applying subsection (p)(1)(E) (including permitting the NAIC to revise its model regulations in response to changes in law) with respect to the change in benefits resulting from title I of the Medicare Modernization and Prescription Drug Act of 2002, with respect to policies issued to individuals who are enrolled under part D, the changes in standards shall only provide for substituting for the benefit packages that included coverage for prescription drugs two benefit packages that may provide for coverage of cost-sharing with respect to qualified prescription drug coverage under such part, except that such coverage may not cover the prescription drug deductible under such part. The two benefit packages shall be consistent with the following:

(A) *FIRST NEW POLICY.*—The policy described in this subparagraph has the following benefits, notwithstanding any other provision of this section relating to a core benefit package:

(i) Coverage of 50 percent of the cost-sharing otherwise applicable, except coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

(ii) No coverage of the part B deductible.

(iii) Coverage for all hospital coinsurance for long stays (as in the current core benefit package).

(iv) A limitation on annual out-of-pocket expenditures to \$4,000 in 2005 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

(B) *SECOND NEW POLICY.*—The policy described in this subparagraph has the same benefits as the policy described in subparagraph (A), except as follows:

(i) Substitute “75 percent” for “50 percent” in clause (i) of such subparagraph.



(ii) Substitute "\$2,000" for "\$4,000" in clause (iv) of such subparagraph.

(4) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met through the offering of other coverage under this subsection.

* * * * *

PAYMENT TO HOSPITALS FOR INPATIENT HOSPITAL SERVICES

SEC. 1886. (a) * * *

(b)(1) * * *

* * * * *

(3)(A) * * *

(B)(i) For purposes of subsection (d) and subsection (j) for discharges occurring during a fiscal year, the "applicable percentage increase" shall be—

(I) * * *

* * * * *

[(XVIII) for fiscal year 2003, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas, and]

(XVIII) for fiscal year 2003, the market basket percentage increase for sole community hospitals and such increase minus 0.25 percentage points for other hospitals, and

* * * * *

(d)(1) * * *

* * * * *

(3) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in a fiscal year after fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine a regional adjusted DRG prospective payment rate for such discharges in each region for which payment may be made under part A of this title. Each such rate shall be determined for hospitals located in large urban, other urban, or rural areas within the United States and within each such region, respectively, as follows:

(A) UPDATING PREVIOUS STANDARDIZED AMOUNTS.—

(i) * * *

* * * * *

[(iv) For discharges] (iv)(I) Subject to the succeeding provisions of this clause, for discharges occurring in a fiscal year beginning on or after October 1, 1995, the Secretary shall compute an average standardized amount for hospitals located in a large urban area and for hospitals located in other areas within the United States and within each region equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.



(II) For discharges occurring during fiscal year 2003, the average standardized amount for hospitals located other than in a large urban area shall be increased by 1/2 of the difference between the average standardized amount determined under subclause (I) for hospitals located in large urban areas for such fiscal year and such amount determined (without regard to this subclause) for other hospitals for such fiscal year.

(III) For discharges occurring in a fiscal year beginning with fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in any area within the United States and within each region equal to the average standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for hospitals located in any area) increased by the applicable percentage increase under subsection (b)(3)(B)(i).

* * * * *

(5)(A) * * *

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2), except as follows:

(i) * * *

(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor is equal to $c \times ((1+r) \text{ to the } n\text{th power}) - 1$, where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds and "n" equals .405. For discharges occurring—

(I) * * *

* * * * *

(VI) during fiscal year 2002, "c" is equal to 1.6; [and] (VII) during fiscal year 2003, "c" is equal to 1.47; (VIII) during fiscal year 2004, "c" is equal to 1.45; and [(VII)] (IX) on or after October 1, [2002] 2004, "c" is equal to 1.35.

* * * * *

(v) In determining the adjustment with respect to a hospital for discharges occurring on or after October 1, 1997, the total number of full-time equivalent interns and residents in the fields of allopathic and osteopathic medicine in either a hospital or nonhospital setting may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent interns and residents in the hospital with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996. Rules similar to the rules of subsection (h)(4)(F)(ii) shall apply for purposes of this clause. The provisions of clause (i) of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentence of this clause in the same manner as it applies



with respect to subparagraph (F) of such subsection, but the provisions of clause (ii) of such subparagraph shall not apply.

* * * * *
(F)(i) * * *

* * * * *
(iv) The disproportionate share adjustment percentage for a cost reporting period for a hospital that is not described in clause (i)(II) and that—

(I) * * *
(II) is located in an urban area and has less than 100 beds, is equal to 5 percent or, *subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xiii);*

(III) is located in a rural area and is not described in subclause (IV) or (V) or in the second sentence of clause (v), is equal to 4 percent or, *subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii);*

(IV) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is classified as a sole community hospital under subparagraph (D), is equal to 10 percent or, if greater, the percent determined in accordance with the applicable formula described in clause (viii) or, *subject to clause (xiv) and for discharges occurring on or after April 1, 2001, the greater of the percentages determined under clause (x) or (xi);*

(V) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is not classified as a sole community hospital under subparagraph (D), is equal to the percent determined in accordance with the applicable formula described in clause (viii) or, *subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xi); or*

(VI) is located in a rural area, is classified as a sole community hospital under subparagraph (D), and is not classified as a rural referral center under subparagraph (C), is 10 percent or, *subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (x).*

* * * * *
(viii) **[The formula]** *Subject to clause (xiv), the formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(IV) or (iv)(V) is the percentage determined in accordance with the following formula: (P-30)(.6) + 4.0, where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).*

* * * * *
(x) **[For purposes]** *Subject to clause (xiv), for purposes of clause (iv)(VI) (relating to sole community hospitals), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—*



(I) * * *

* * * * *

(xi) **【For purposes】** *Subject to clause (xiv), for purposes of clause (iv)(V) (relating to rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—*

(I) * * *

* * * * *

(xii) **【For purposes】** *Subject to clause (xiv), for purposes of clause (iv)(III) (relating to small rural hospitals generally), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—*

(I) * * *

* * * * *

(xiii) **【For purposes】** *Subject to clause (xiv), for purposes of clause (iv)(II) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—*

(I) * * *

* * * * *

(xiv)(I) In the case of discharges in a fiscal year beginning on or after October 1, 2002, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the old blend proportion (specified under subclause (III)) of the disproportionate share adjustment percentage otherwise determined under the respective clause and 100 percent minus such old blend proportion of the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 10 percent for a hospital that is not classified as a rural referral center under subparagraph (C).

(III) For purposes of subclause (I), the old blend proportion for fiscal year 2003 is 80 percent, for each subsequent year (through 2006) is the old blend proportion under this subclause for the previous year minus 20 percentage points, and for each year beginning with 2007 is 0 percent.

* * * * *

(K)(i) Effective for discharges beginning on or after October 1, 2001, the Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection. Such mechanism shall be established after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise). *Such mechanism shall be modified to meet the requirements of clause (viii).*

(ii) The mechanism established pursuant to clause (i) shall—

(I) apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective pay-



ment rate otherwise applicable to such discharges under this subsection is inadequate (*applying a threshold specified by the Secretary that is the lesser of 50 percent of the national average standardized amount for operating costs of inpatient hospital services for all hospitals and all diagnosis-related groups or one standard deviation for the diagnosis-related group involved*);

* * * * *

(III) subject to paragraph (4)(C)(iii), provide for additional payment to be made under this subsection with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average cost of such service or technology (*based on the marginal rate applied to costs under subparagraph (A)*); and

* * * * *

(vi)(I) For purposes of this subparagraph and subparagraph (L), a medical service or technology will be considered a "new medical service or technology" if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment.

(II) *Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-year period that begins on the effective date of implementation of a code under ICD-9-CM (or a successor coding methodology) that enables the identification of a significant sample of specific discharges in which the service or technology has been used.*

(III) *The Secretary shall by regulation provide for further clarification of the criteria applied to determine whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries. Under such criteria, in determining whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries, the Secretary shall deem a service or technology as meeting such requirement if the service or technology is a drug or biological that is designated under section 506 or 526 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of title 21, Code of Federal Regulations, or designated for priority review when the marketing application for such drug or biological was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority review has been provided under section 515(d)(5) of such Act.*

(vii) *Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.*

(viii) *The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described*



in the second sentence of clause (vi)(III) represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries as follows:

(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, medicare beneficiaries, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.

(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. In such case, no add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).

* * * * *

(9)(A) Notwithstanding section 1814(b) but subject to the provisions of section 1813, the amount of the payment with respect to the operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges is equal to the sum of—

(i) [for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)] the applicable Puerto Rico percentage (specified in subparagraph (E)) of the Puerto Rico adjusted DRG prospective payment rate (determined under subparagraph (B) or (C)) for such discharges, and

(ii) [for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)] the applicable Federal percentage (specified in subparagraph (E)) of the discharge-weighted average of—

*(I) * * **

* * * * *

(E) For purposes of subparagraph (A), for discharges occurring—

(i) between October 1, 1987, and September 30, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;



(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

(iii) during fiscal year 2004, the applicable Puerto Rico percentage is 45 percent and the applicable Federal percentage is 55 percent;

(iv) during fiscal year 2005, the applicable Puerto Rico percentage is 40 percent and the applicable Federal percentage is 60 percent;

(v) during fiscal year 2006, the applicable Puerto Rico percentage is 35 percent and the applicable Federal percentage is 65 percent;

(vi) during fiscal year 2007, the applicable Puerto Rico percentage is 30 percent and the applicable Federal percentage is 70 percent; and

(vii) on or after October 1, 2007, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.

* * * * *

(h) PAYMENTS FOR DIRECT GRADUATE MEDICAL EDUCATION COSTS.—

(1) * * *

(2) DETERMINATION OF HOSPITAL-SPECIFIC APPROVED FTE RESIDENT AMOUNTS.—The Secretary shall determine, for each hospital with an approved medical residency training program, an approved FTE resident amount for each cost reporting period beginning on or after July 1, 1985, as follows:

(A) * * *

* * * * *

(D) AMOUNT FOR SUBSEQUENT COST REPORTING PERIODS.—

(i) * * *

* * * * *

(iv) ADJUSTMENT IN RATE OF INCREASE FOR HOSPITALS WITH FTE APPROVED AMOUNT ABOVE 140 PERCENT OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—

(I) FREEZE FOR FISCAL YEARS 2001 [AND 2002] THROUGH 2012.—For a cost reporting period beginning [during fiscal year 2001 or fiscal year 2002] during the period beginning with fiscal year 2001 and ending with fiscal year 2012, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and period, [subject to subclause (III),] the approved FTE resident amount for the period involved shall be the same as the approved FTE resident amount for the hospital for such preceding cost reporting period.



[(II) 2 PERCENT DECREASE IN UPDATE FOR FISCAL YEARS 2003, 2004, AND 2005.—For a cost reporting period beginning during fiscal year 2003, fiscal year 2004, or fiscal year 2005, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and preceding period, the approved FTE resident amount for the period involved shall be updated in the manner described in subparagraph (D)(i) except that, subject to subclause (III), the consumer price index applied for a 12-month period shall be reduced (but not below zero) by 2 percentage points.]

[(III)] (II) NO ADJUSTMENT BELOW 140 PERCENT.—In no case shall subclause (I) [or (II)] reduce an approved FTE resident amount for a hospital for a cost reporting period below 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for such hospital and period.

* * * * *
(4) DETERMINATION OF FULL-TIME-EQUIVALENT RESIDENTS.—

(A) * * *

* * * * *
(F) LIMITATION ON NUMBER OF RESIDENTS IN ALLOPATHIC AND OSTEOPATHIC MEDICINE.—

(i) IN GENERAL.—Such rules shall provide that for purposes of a cost reporting period beginning on or after October 1, 1997, *subject to subparagraph (I)*, the total number of full-time equivalent residents before application of weighting factors (as determined under this paragraph) with respect to a hospital's approved medical residency training program in the fields of allopathic medicine and osteopathic medicine may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent residents for the hospital's most recent cost reporting period ending on or before December 31, 1996.

* * * * *
(H) SPECIAL RULES FOR APPLICATION OF SUBPARAGRAPHS (F) AND (G).—

(i) NEW FACILITIES.—The Secretary shall, consistent with the principles of subparagraphs (F) and (G), *subject to subparagraph (I)*, prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995. In promulgating such rules for purposes of subparagraph (F), the Secretary shall give



special consideration to facilities that meet the needs of underserved rural areas.

* * * * *

(I) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—
(i) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

(I) IN GENERAL.—If a hospital's resident level (as defined in clause (iii)(I)) is less than the otherwise applicable resident limit (as defined in clause (iii)(II)) for each of the reference periods (as defined in subclause (II)), effective for cost reporting periods beginning on or after January 1, 2003, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in subclause (III) (or subclause (IV) if applicable).

(II) REFERENCE PERIODS DEFINED.—In this clause, the term "reference periods" means, for a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not, submitted) on or before September 30, 2001.

(III) REFERENCE RESIDENT LEVEL.—Subject to subclause (IV), the reference resident level specified in this subclause for a hospital is the highest resident level for the hospital during any of the reference periods.

(IV) ADJUSTMENT PROCESS.—Upon the timely request of a hospital, the Secretary may adjust the reference resident level for a hospital to be the resident level for the hospital for the cost reporting period that includes July 1, 2002.

(ii) REDISTRIBUTION.—

(I) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in such limits attributable to clause (i) (without taking into account any adjustment under subclause (IV) of such clause).

(II) EFFECTIVE DATE.—No increase under subclause (I) shall be permitted or taken into account for a hospital for any portion of a cost reporting period that occurs before July 1, 2003, or before the date of the hospital's application for an increase under this clause. No such increase shall be permitted for a hospital unless the hospital has applied to the Secretary for such increase by December 31, 2004.

(III) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall take into account the need for such an increase by specialty



and location involved, consistent with subclause (IV).

(IV) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall first distribute the increase to programs of hospitals located in rural areas or in urban areas that are not large urban areas (as defined for purposes of subsection (d)) on a first-come-first-served basis (as determined by the Secretary) based on a demonstration that the hospital will fill the positions made available under this clause and not to exceed an increase of 25 full-time equivalent positions with respect to any hospital.

(V) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this clause, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital.

(VI) CONSTRUCTION.—Nothing in this clause shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6) or as affecting the ability of a hospital to establish new medical residency training programs under subparagraph (H).

(iii) RESIDENT LEVEL AND LIMIT DEFINED.—In this subparagraph:

(I) RESIDENT LEVEL.—The term “resident level” means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under this paragraph), in the fields of allopathic and osteopathic medicine for the hospital.

(II) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term “otherwise applicable resident limit” means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.

PAYMENT TO SKILLED NURSING FACILITIES FOR ROUTINE SERVICE COSTS

SEC. 1888. (a) * * *

* * * * *

(e) PROSPECTIVE PAYMENT.—



(1) * * *

* * * * *

[(12) PAYMENT RULE FOR CERTAIN FACILITIES.—

[(A) IN GENERAL.—In the case of a qualified acute skilled nursing facility described in subparagraph (B), the per diem amount of payment shall be determined by applying the non-Federal percentage and Federal percentage specified in paragraph (2)(C)(ii).

[(B) FACILITY DESCRIBED.—For purposes of subparagraph (A), a qualified acute skilled nursing facility is a facility that—

[(i) was certified by the Secretary as a skilled nursing facility eligible to furnish services under this title before July 1, 1992;

[(ii) is a hospital-based facility; and

[(iii) for the cost reporting period beginning in fiscal year 1998, the facility had more than 60 percent of total patient days comprised of patients who are described in subparagraph (C).

[(C) DESCRIPTION OF PATIENTS.—For purposes of subparagraph (B), a patient described in this subparagraph is an individual who—

[(i) is entitled to benefits under part A; and

[(ii) is immuno-compromised secondary to an infectious disease, with specific diagnoses as specified by the Secretary.]

(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable shall be increased by 128 percent to reflect increased costs associated with such residents.

(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.

PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.

(b) ENHANCED EDUCATION AND TRAINING.—

(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) \$25,000,000 for each of fiscal years 2004 and 2005 and such sums as may be necessary for succeeding fiscal years.



(2) *USE.*—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

(c) *TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.*—

(1) *IN GENERAL.*—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

(2) *SMALL PROVIDER OF SERVICES OR SUPPLIER.*—In this subsection, the term “small provider of services or supplier” means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(d) *INTERNET SITES; FAQs.*—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet site which—

(1) provides answers in an easily accessible format to frequently asked questions, and

(2) includes other published materials of the contractor, that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).

(e) *ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.*—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(f) *CONSTRUCTION.*—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

(g) *DEFINITIONS.*—For purposes of this section, the term “medicare contractor” includes the following:

(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

(2) An eligible entity with a contract under section 1893. Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.

* * * * *



MEDICARE INTEGRITY PROGRAM

SEC. 1893. (a) * * *

* * * * *

(f) RECOVERY OF OVERPAYMENTS.—

(1) USE OF REPAYMENT PLANS.—

(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

(B) HARDSHIP.—

(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or



(ii) there is an indication of fraud or abuse committed against the program.

(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

(2) LIMITATION ON RECOUPMENT.—

(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term “medicare contractor” has the meaning given such term in section 1889(g).

(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) CONSENT SETTLEMENT REFORMS.—



(A) *IN GENERAL.*—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

(B) *OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.*—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

(i) communicate to the provider of services or supplier—

(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

(II) the nature of the problems identified in such evaluation; and

(III) the steps that the provider of services or supplier should take to address the problems; and

(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

(C) *CONSENT SETTLEMENT OFFER.*—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

(I) the opportunity for a statistically valid random sample; or

(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

(D) *CONSENT SETTLEMENT DEFINED.*—For purposes of this paragraph, the term “consent settlement” means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

(6) *NOTICE OF OVER-UTILIZATION OF CODES.*—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).



(7) PAYMENT AUDITS.—

(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

* * * * *

PROSPECTIVE PAYMENT FOR HOME HEALTH SERVICES

SEC. 1895. (a) * * *

(b) SYSTEM OF PROSPECTIVE PAYMENT FOR HOME HEALTH SERVICES.—

(1) * * *

* * * * *

(3) PAYMENT BASIS.—

[(A) INITIAL BASIS.—

[(i) IN GENERAL.—Under such system the Secretary shall provide for computation of a standard prospective payment amount (or amounts) as follows:

[(I) Such amount (or amounts) shall initially be based on the most current audited cost report data available to the Secretary and shall be computed in a manner so that the total amounts pay-



able under the system for the 12-month period beginning on the date the Secretary implements the system shall be equal to the total amount that would have been made if the system had not been in effect.

[(II) For the 12-month period beginning after the period described in subclause (I), such amount (or amounts) shall be equal to the amount (or amounts) determined under subclause (I), updated under subparagraph (B).

[(III) For periods beginning after the period described in subclause (II), such amount (or amounts) shall be equal to the amount (or amounts) that would have been determined under subclause (I) that would have been made for fiscal year 2001 if the system had not been in effect and if section 1861(v)(1)(L)(ix) had not been enacted but if the reduction in limits described in clause (ii) had been in effect, updated under subparagraph (B).

Each such amount shall be standardized in a manner that eliminates the effect of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner consistent with the case mix and wage level adjustments provided under paragraph (4)(A). Under the system, the Secretary may recognize regional differences or differences based upon whether or not the services or agency are in an urbanized area.

[(ii) REDUCTION.—The reduction described in this clause is a reduction by 15 percent in the cost limits and per beneficiary limits described in section 1861(v)(1)(L), as those limits are in effect on September 30, 2000.]

(A) INITIAL BASIS.—Under such system the Secretary shall provide for computation of a standard prospective payment amount (or amounts) as follows:

(i) Such amount (or amounts) shall initially be based on the most current audited cost report data available to the Secretary and shall be computed in a manner so that the total amounts payable under the system for fiscal year 2001 shall be equal to the total amount that would have been made if the system had not been in effect and if section 1861(v)(1)(L)(ix) had not been enacted.

(ii) For fiscal year 2002 and for the first quarter of fiscal year 2003, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for the previous fiscal year, updated under subparagraph (B).

(iii) For 2003, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for fiscal year 2002, updated under subparagraph (B) for 2003.



(iv) For 2004 and each subsequent year, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for the previous year, updated under subparagraph (B).

Each such amount shall be standardized in a manner that eliminates the effect of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner consistent with the case mix and wage level adjustments provided under paragraph (4)(A). Under the system, the Secretary may recognize regional differences or differences based upon whether or not the services or agency are in an urbanized area.

(B) ANNUAL UPDATE.—

(i) IN GENERAL.—The standard prospective payment amount (or amounts) shall be adjusted for [each fiscal year (beginning with fiscal year 2002)] *fiscal year 2002 and for each subsequent year (beginning with 2003)* in a prospective manner specified by the Secretary by the home health applicable increase percentage (as defined in clause (ii)) applicable to the fiscal year *or year* involved.

(ii) HOME HEALTH APPLICABLE INCREASE PERCENTAGE.—For purposes of this subparagraph, the term “home health applicable increase percentage” means, with respect to—

(I) [each of fiscal years 2002 and 2003] *fiscal year 2002, the home health market basket percentage increase (as defined in clause (iii)) minus 1.1 percentage points;*

(II) 2003, [the home health market basket percentage increase (as defined in clause (iii)) minus 1.1 percentage points] *2.0 percentage points; [or]*

(III) 2004, *1.1 percentage points;*

(IV) 2005, *2.7 percentage points; or*

[(II)] (V) any subsequent [fiscal] year, the home health market basket percentage increase.

(iii) HOME HEALTH MARKET BASKET PERCENTAGE INCREASE.—For purposes of this subsection, the term “home health market basket percentage increase” means, with respect to a fiscal year *or year*, a percentage (estimated by the Secretary before the beginning of the fiscal year *or year*) determined and applied with respect to the mix of goods and services included in home health services in the same manner as the market basket percentage increase under section 1886(b)(3)(B)(iii) is determined and applied to the mix of goods and services comprising inpatient hospital services for the fiscal year *or year*.

(iv) ADJUSTMENT FOR CASE MIX CHANGES.—Insofar as the Secretary determines that the adjustments under paragraph (4)(A)(i) for a previous fiscal year *or year* (or estimates that such adjustments for a future fiscal year *or year*) did (or are likely to) result in a



change in aggregate payments under this subsection during the fiscal year *or year* that are a result of changes in the coding or classification of different units of services that do not reflect real changes in case mix, the Secretary may adjust the standard prospective payment amount (or amounts) under paragraph (3) for subsequent fiscal years *or years* so as to eliminate the effect of such coding or classification changes.

* * * * *

(5) OUTLIERS.—The Secretary may provide for an addition or adjustment to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. The total amount of the additional payments or payment adjustments made under this paragraph with respect to a fiscal year *or year* may not exceed [5] 3 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year.

* * * * *

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) * * *

* * * * *

(64) provide, not later than 1 year after the date of the enactment of this paragraph, a mechanism to receive reports from beneficiaries and others and compile data concerning alleged instances of waste, fraud, and abuse relating to the operation of this title; [and]

(65) provide that the State shall issue provider numbers for all suppliers of medical assistance consisting of durable medical equipment, as defined in section 1861(n), and the State shall not issue or renew such a supplier number for any such supplier unless—

(A) * * *

* * * * *

(B) a surety bond in a form specified by the Secretary under section 1834(a)(16)(B) and in an amount that is not less than \$50,000 or such comparable surety bond as the Secretary may permit under the second sentence of such section[.]; and

(66) provide for making eligibility determinations under section 1935(a).

Notwithstanding paragraph (5), if on January 1, 1965, and on the date on which a State submits its plan for approval under this title, the State agency which administered or supervised the administration of the plan of such State approved under title X (or title XVI, insofar as it relates to the blind) was different from the



State agency which administered or supervised the administration of the State plan approved under title I (or title XVI, insofar as it relates to the aged), the State agency which administered or supervised the administration of such plan approved under title X (or title XVI, insofar as it relates to the blind) may be designated to administer or supervise the administration of the portion of the State plan for medical assistance which relates to blind individuals and a different State agency may be established or designated to administer or supervise the administration of the rest of the State plan for medical assistance; and in such case the part of the plan which each such agency administers, or the administration of which each such agency supervises, shall be regarded as a separate plan for purposes of this title (except for purposes of paragraph (10)). The provisions of paragraphs (9)(A), (31), and (33) and of section 1903(i)(4) shall not apply to a religious nonmedical health care institution (as defined in section 1861(ss)(1)).

For purposes of paragraph (10) any individual who, for the month of August 1972, was eligible for or receiving aid or assistance under a State plan approved under title I, X, XIV, or XVI, or part A of title IV and who for such month was entitled to monthly insurance benefits under title II shall for purposes of this title only be deemed to be eligible for financial aid or assistance for any month thereafter if such individual would have been eligible for financial aid or assistance for such month had the increase in monthly insurance benefits under title II resulting from enactment of Public Law 92-336 not been applicable to such individual.

The requirement of clause (A) of paragraph (37) with respect to a State plan may be waived by the Secretary if he finds that the State has exercised good faith in trying to meet such requirement. For purposes of this title, any child who meets the requirements of paragraph (1) or (2) of section 473(b) shall be deemed to be a dependent child as defined in section 406 and shall be deemed to be a recipient of aid to families with dependent children under part A of title IV in the State where such child resides. Notwithstanding paragraph (10)(B) or any other provision of this subsection, a State plan shall provide medical assistance with respect to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law only in accordance with section 1903(v).

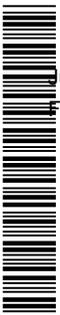
* * * * *

PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966—

(1) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b), subject to subsections (g) and (j) of this section and subsection 1923(f) of the total amount expended during such quarter as medical assistance under the State plan, *reduced by the amount computed under section 1935(c)(1) for the State and the quarter*; plus

* * * * *



SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG
BENEFIT

SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a) subject to subsection (e), a State shall—

(1) make determinations of eligibility for premium and cost-sharing subsidies under (and in accordance with) section 1860G;

(2) inform the Administrator of the Medicare Benefits Administration of such determinations in cases in which such eligibility is established; and

(3) otherwise provide such Administrator with such information as may be required to carry out part D of title XVIII (including section 1860G).

(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE COSTS.—

(1) IN GENERAL.—The amounts expended by a State in carrying out subsection (a) are, subject to paragraph (2), expenditures reimbursable under the appropriate paragraph of section 1903(a); except that, notwithstanding any other provision of such section, the applicable Federal matching rates with respect to such expenditures under such section shall be increased as follows (but in no case shall the rate as so increased exceed 100 percent):

(A) For expenditures attributable to costs incurred during 2005, the otherwise applicable Federal matching rate shall be increased by 10 percent of the percentage otherwise payable (but for this subsection) by the State.

(B)(i) For expenditures attributable to costs incurred during 2006 and each subsequent year through 2013, the otherwise applicable Federal matching rate shall be increased by the applicable percent (as defined in clause (ii)) of the percentage otherwise payable (but for this subsection) by the State.

(ii) For purposes of clause (i), the “applicable percent” for—

(I) 2006 is 20 percent; or

(II) a subsequent year is the applicable percent under this clause for the previous year increased by 10 percentage points.

(C) For expenditures attributable to costs incurred after 2013, the otherwise applicable Federal matching rate shall be increased to 100 percent.

(2) COORDINATION.—The State shall provide the Administrator with such information as may be necessary to properly allocate administrative expenditures described in paragraph (1) that may otherwise be made for similar eligibility determinations.

(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALY-ELIGIBLE BENEFICIARIES.—

(1) IN GENERAL.—For purposes of section 1903(a)(1) subject to subsection (e), for a State that is one of the 50 States or the



District of Columbia for a calendar quarter in a year (beginning with 2005) the amount computed under this subsection is equal to the product of the following:

(A) *MEDICARE SUBSIDIES.*—*The total amount of payments made in the quarter under section 1860G (relating to premium and cost-sharing prescription drug subsidies for low-income medicare beneficiaries) that are attributable to individuals who are residents of the State and are entitled to benefits with respect to prescribed drugs under the State plan under this title (including such a plan operating under a waiver under section 1115).*

(B) *STATE MATCHING RATE.*—*A proportion computed by subtracting from 100 percent the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State and the quarter.*

(C) *PHASE-OUT PROPORTION.*—*The phase-out proportion (as defined in paragraph (2)) for the quarter.*

(2) *PHASE-OUT PROPORTION.*—*For purposes of paragraph (1)(C), the “phase-out proportion” for a calendar quarter in—*

(A) *2005 is 90 percent;*

(B) *a subsequent year before 2014, is the phase-out proportion for calendar quarters in the previous year decreased by 10 percentage points; or*

(C) *a year after 2013 is 0 percent.*

(d) *ADDITIONAL PROVISIONS.*—

(1) *MEDICAID AS SECONDARY PAYOR.*—*In the case of an individual who is entitled to qualified prescription drug coverage under a prescription drug plan under part D of title XVIII (or under a Medicare+Choice plan under part C of such title) and medical assistance for prescribed drugs under this title, medical assistance shall continue to be provided under this title for prescribed drugs to the extent payment is not made under the prescription drug plan or the Medicare+Choice plan selected by the individual.*

(2) *CONDITION.*—*A State may require, as a condition for the receipt of medical assistance under this title with respect to prescription drug benefits for an individual eligible to obtain qualified prescription drug coverage described in paragraph (1), that the individual elect qualified prescription drug coverage under section 1860A.*

(e) *TREATMENT OF TERRITORIES.*—

(1) *IN GENERAL.*—*In the case of a State, other than the 50 States and the District of Columbia—*

(A) *the previous provisions of this section shall not apply to residents of such State; and*

(B) *if the State establishes a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in paragraph (3).*

(2) *PLAN.*—*The plan described in this paragraph is a plan that—*



(A) provides medical assistance with respect to the provision of covered outpatient drugs (as defined in section 1860B(f) to low-income medicare beneficiaries; and

(B) assures that additional amounts received by the State that are attributable to the operation of this subsection are used only for such assistance.

(3) INCREASED AMOUNT.—

(A) IN GENERAL.—The amount specified in this paragraph for a State for a year is equal to the product of—

(i) the aggregate amount specified in subparagraph (B); and

(ii) the amount specified in section 1108(g)(1) for that State, divided by the sum of the amounts specified in such section for all such States.

(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for—

(i) 2005, is equal to \$20,000,000; or

(ii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860B(b)(5) for the year involved.

(4) REPORT.—The Administrator shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Administrator deems appropriate.

REFERENCES TO LAWS DIRECTLY AFFECTING MEDICAID PROGRAM

SEC. [1935.] 1936. (a) AUTHORITY OR REQUIREMENTS TO COVER ADDITIONAL INDIVIDUALS.—For provisions of law which make additional individuals eligible for medical assistance under this title, see the following:

(1) * * *

* * * * *

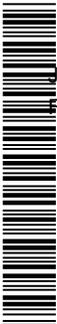
SECTION 4018 OF THE OMNIBUS BUDGET RECONCILIATION ACT OF 1987

SEC. 4018. SPECIAL RULES.

(a) * * *

(b) EXTENSION OF WAIVERS FOR SOCIAL HEALTH MAINTENANCE ORGANIZATIONS.—

(1) The Secretary of Health and Human Services shall extend without interruption, through [the date that is 30 months after the date that the Secretary submits to Congress the report described in section 4014(c) of the Balanced Budget Act of 1997] December 31, 2004, the approval of waivers granted under subsection (a) of section 2355 of the Deficit Reduction Act of 1984 for the demonstration project described in subsection (b) of that section, subject to the terms and conditions



(other than duration of the project) established under that section (as amended by paragraph (2) of this subsection).

* * * * *

SECTION 9215 OF THE CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985

SEC. 9215. EXTENSION OF CERTAIN MEDICARE MUNICIPAL HEALTH SERVICES DEMONSTRATION PROJECTS.

(a) The Secretary of Health and Human Services shall extend through December 31, 1997, approval of four municipal health services demonstration projects (located in Baltimore, Cincinnati, Milwaukee, and San Jose) authorized under section 402(a) of the Social Security Amendments of 1967. The Secretary shall submit a report to Congress on the waiver program with respect to the quality of health care, beneficiary costs, costs to the medicaid program and other payers, access to care, outcomes, beneficiary satisfaction, utilization differences among the different populations served by the projects, and such other factors as may be appropriate. Subject to subsection (c), the Secretary may further extend such demonstration projects through [December 31, 2004, but only with respect to individuals who received at least one service during the period beginning on January 1, 1996, and ending on the date of the enactment of the Balanced Budget Act of 1997.] *December 31, 2009, but only with respect to individuals who reside in the city in which the project is operated and so long as the total number of individuals participating in the project does not exceed the number of such individuals participating as of January 1, 1996.*

* * * * *

MEDICARE, MEDICAID, AND SCHIP BENEFITS IMPROVEMENT AND PROTECTION ACT OF 2000 (BIPA)

* * * * *

TITLE III—PROVISIONS RELATING TO PART A

* * * * *

Subtitle B—Adjustments to PPS Payments for Skilled Nursing Facilities

* * * * *

SEC. 312. INCREASE IN NURSING COMPONENT OF PPS FEDERAL RATE.

(a) IN GENERAL.—The Secretary of Health and Human Services shall increase by 16.66 percent the nursing component of the case-mix adjusted Federal prospective payment rate specified in



Tables 3 and 4 of the final rule published in the Federal Register by the Health Care Financing Administration on July 31, 2000 (65 Fed. Reg. 46770) and as subsequently updated, effective for services furnished on or after April 1, 2001, and before October 1, 2002. *The Secretary of Health and Human Services shall increase by 12, 10, and 8 percent the nursing component of the case-mix adjusted Federal prospective payment rate specified in Tables 3 and 4 of the final rule published in the Federal Register by the Health Care Financing Administration on July 31, 2000 (65 Fed. Reg. 46770) and as subsequently updated under section 1888(e)(4)(E)(ii) of the Social Security Act (42 U.S.C. 1395yy(e)(4)(E)(ii)), effective for services furnished during fiscal years 2003, 2004, and 2005, respectively.*

* * * * *

TITLE IV—PROVISIONS RELATING TO PART B

* * * * *

Subtitle C—Other Services

* * * * *

SEC. 422. UPDATE IN RENAL DIALYSIS COMPOSITE RATE.

(a) UPDATE.—

(1) * * *

(2) PROHIBITION ON EXCEPTIONS.—

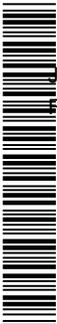
(A) IN GENERAL.—Subject to subparagraphs (B) [and (C)], (C), and (D), the Secretary of Health and Human Services may not provide for an exception under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)) on or after December 31, 2000.

(B) DEADLINE FOR NEW APPLICATIONS.—[In the case] *Subject to subparagraph (D), in the case of a facility that during 2000 did not file for an exception rate under such section, the facility may submit an application for an exception rate by not later than July 1, 2001.*

* * * * *

(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term “pediatric facility” means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.

* * * * *



TITLE V—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

* * * * *

SEC. 508. TEMPORARY INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) [24-MONTH INCREASE BEGINNING APRIL 1, 2001] *IN GENERAL.*—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) on or after April 1, 2001, and before [April 1, 2003] *January 1, 2005*, the Secretary of Health and Human Services shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 10 percent.

* * * * *

Subtitle E—Other Provisions

* * * * *

SEC. 542. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE.

(a) * * *

* * * * *

(c) *EFFECTIVE DATE.*—This section shall apply to services furnished during the [2-year period] *3-year period* beginning on January 1, 2001.

* * * * *

SEC. 547. CLARIFICATION OF APPLICATION OF TEMPORARY PAYMENT INCREASES FOR 2001.

(a) * * *

* * * * *

(c) *HOME HEALTH SERVICES.*—

(1) * * *

(2) *TEMPORARY INCREASE FOR RURAL HOME HEALTH SERVICES.*—The payment increase provided under section 508(a) for [the period beginning on April 1, 2001, and ending on September 30, 2002.] *a period under such section* shall not apply to episodes and visits ending after such period, and shall not be taken into account in calculating the payment amounts applicable for episodes and visits occurring after such period.

* * * * *

TITLE 5, UNITED STATES CODE

* * * * *



PART III—EMPLOYEES

* * * * *

Subpart D—Pay and Allowances

* * * * *

CHAPTER 53—PAY RATES AND SYSTEMS

* * * * *

SUBCHAPTER II—EXECUTIVE SCHEDULE PAY RATES

* * * * *

§ 5314. Positions at level III

Level III of the Executive Schedule applies to the following positions, for which the annual rate of basic pay shall be the rate determined with respect to such level under chapter 11 of title 2, as adjusted by section 5318 of this title:

- Solicitor General of the United States.
- Under Secretary of Commerce, Under Secretary of Commerce for Economic Affairs, Under Secretary of Commerce for Export Administration and Under Secretary of Commerce for Travel and Tourism.

* * * * *

- Administrator of the Centers for Medicare & Medicaid Services .*
- Administrator of the Medicare Benefits Administration.*

§ 5315. Positions at level IV

Level IV of the Executive Schedule applies to the following positions, for which the annual rate of basic pay shall be the rate determined with respect to such level under chapter 11 of title 2, as adjusted by section 5318 of this title:

- Deputy Administrator of General Services.

* * * * *

- [Administrator of the Health Care Financing Administration.]**

* * * * *

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:



(a) * * *

* * * * *

(bb) *The failure to post information required under section 503B(b)(2) or for knowingly making a materially false statement when posting such information as required under such section or violating section 503B(b)(4).*

* * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * *

SEC. 503B. INTERNET PRESCRIPTION DRUG SALES.

(a) *DEFINITIONS.—For purposes of this section:*

(1) *CONSUMER.—The term “consumer” means a person (other than an entity licensed or otherwise authorized under Federal or State law as a pharmacy or to dispense or distribute prescription drugs) that purchases or seeks to purchase prescription drugs through the Internet.*

(2) *HOME PAGE.—The term “home page” means the entry point or main web page for an Internet site.*

(3) *INTERNET.—The term “Internet” means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio, including electronic mail.*

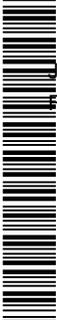
(4) *INTERSTATE INTERNET SELLER.—*

(A) *IN GENERAL.—The term “interstate Internet seller” means a person whether in the United States or abroad, that engages in, offers to engage in, or causes the delivery or sale of a prescription drug through the Internet and has such drug delivered directly to the consumer via the Postal Service, or any private or commercial interstate carrier to a consumer in the United States who is residing in a State other than the State in which the seller’s place of business is located. This definition excludes a person who only delivers a prescription drug to a consumer, such as an interstate carrier service.*

(B) *EXEMPTION.—With respect to the consumer involved, the term “interstate Internet seller” does not include a person described in subparagraph (A) whose place of business is located within 75 miles of the consumer.*

(5) *LINK.—The term “link” means either a textual or graphical marker on a web page that, when clicked on, takes the consumer to another part of the Internet, such as to another web page or a different area on the same web page, or from an electronic message to a web page.*

(6) *PHARMACY.—The term “pharmacy” means any place licensed or otherwise authorized as a pharmacy under State law.*



(7) *PRESCRIBER.*—The term “prescriber” means an individual, licensed or otherwise authorized under applicable Federal and State law to issue prescriptions for prescription drugs.

(8) *PRESCRIPTION DRUG.*—The term “prescription drug” means a drug under section 503(b)(1).

(9) *VALID PRESCRIPTION.*—The term “valid prescription” means a prescription that meets the requirements of section 503(b)(1) and other applicable Federal and State law.

(10) *WEB SITE; SITE.*—The terms “web site” and “site” mean a specific location on the Internet that is determined by Internet protocol numbers or by a domain name.

(b) *REQUIREMENTS FOR INTERSTATE INTERNET SELLERS.*—

(1) *IN GENERAL.*—Each interstate Internet seller shall comply with the requirements of this subsection with respect to the sale of, or the offer to sell, prescription drugs through the Internet and shall at all times display on its web site information in accordance with paragraph (2).

(2) *WEB SITE DISCLOSURE INFORMATION.*—An interstate Internet seller shall post in a visible and clear manner (as determined by regulation) on the home page of its web site, or on a page directly linked to such home page—

(A) the street address of the interstate Internet seller’s place of business, and the telephone number of such place of business;

(B) each State in which the interstate Internet seller is licensed or otherwise authorized as a pharmacy, or if the interstate Internet seller is not licensed or otherwise authorized by a State as a pharmacy, each State in which the interstate Internet seller is licensed or otherwise authorized to dispense prescription drugs, and the type of State license or authorization;

(C) in the case of an interstate Internet seller that makes referrals to or solicits on behalf of a prescriber, the name of each prescriber, the street address of each such prescriber’s place of business, the telephone number of such place of business, each State in which each such prescriber is licensed or otherwise authorized to prescribe prescription drugs, and the type of such license or authorization; and

(D) a statement that the interstate Internet seller will dispense prescription drugs only upon a valid prescription.

(3) *DATE OF POSTING.*—Information required to be posted under paragraph (2) shall be posted by an interstate Internet seller—

(A) not later than 90 days after the effective date of this section if the web site of such seller is in operation as of such date; or

(B) on the date of the first day of operation of such seller’s web site if such site goes into operation after such date.

(4) *QUALIFYING STATEMENTS.*—An interstate Internet seller shall not indicate in any manner that posting disclosure information on its web site signifies that the Federal Government has made any determination on the legitimacy of the interstate Internet seller or its business.



(5) *DISCLOSURE TO STATE LICENSING BOARDS.*—An interstate Internet seller licensed or otherwise authorized to dispense prescription drugs in accordance with applicable State law shall notify each State entity that granted such licensure or authorization that it is an interstate Internet seller, the name of its business, the Internet address of its business, the street address of its place of business, and the telephone number of such place of business.

(6) *REGULATIONS.*—The Secretary is authorized to promulgate such regulations as are necessary to carry out the provisions of this subsection. In issuing such regulations, the Secretary—

(A) shall take into consideration disclosure formats used by existing interstate Internet seller certification programs; and

(B) shall in defining the term “place of business” include provisions providing that such place is a single location at which employees of the business perform job functions, and not a post office box or similar locale.

* * * * *

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * *

PART P—ADDITIONAL PROGRAMS

* * * * *

SEC. 3990. GRANTS TO HEALTH CARE PROVIDERS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS.

(a) *IN GENERAL.*—The Secretary is authorized to make grants for the purpose of assisting health care providers who prescribe drugs and biologicals in implementing electronic prescription programs described in section 1860C(d)(3) of the Social Security Act.

(b) *APPLICATION.*—No grant may be made under this section except pursuant to a grant application that is submitted in a time, manner, and form approved by the Secretary.

(c) *AUTHORIZATION OF APPROPRIATIONS.*—There are authorized to be appropriated for fiscal year 2004, such sums as may be appropriate to carry out this section.

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

* * * * *



OFFICE OF RARE DISEASES

SEC. 404F. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Rare Diseases (in this section referred to as the “Office”), which shall be headed by a Director (in this section referred to as the “Director”), appointed by the Director of NIH.

(b) DUTIES.—

(1) IN GENERAL.—The Director of the Office shall carry out the following:

(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 404G.

(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

(G) The Director shall prepare the NIH Director’s annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.

(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

(c) DEFINITION.—For purposes of this section, the term “rare disease” means any disease or condition that affects less than 200,000 persons in the United States.



(d) *AUTHORIZATION OF APPROPRIATIONS.*—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$4,000,000 for each of the fiscal years 2003 through 2006.

RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

SEC. 404G. (a) *COOPERATIVE AGREEMENTS AND GRANTS.*—

(1) *IN GENERAL.*—The Director of the Office of Rare Diseases (in this section referred to as the “Director”), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private non-profit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

(2) *POLICIES.*—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

(b) *COORDINATION WITH OTHER INSTITUTES.*—The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

(c) *USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.*—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

(d) *PERIOD OF SUPPORT; ADDITIONAL PERIODS.*—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(e) *AUTHORIZATION OF APPROPRIATIONS.*—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$20,000,000 for each of the fiscal years 2003 through 2006.

* * * * *



**TITLE VII—HEALTH PROFESSIONS
EDUCATION**

* * * * *

**PART E—HEALTH PROFESSIONS AND PUBLIC
HEALTH WORKFORCE**

* * * * *

Subpart 3—Pharmacist Workforce Programs

SEC. 771. PUBLIC SERVICE ANNOUNCEMENTS.

(a) *PUBLIC SERVICE ANNOUNCEMENTS.*—

(1) *IN GENERAL.*—The Secretary shall develop and issue public service announcements that advertise and promote the pharmacist profession, highlight the advantages and rewards of being a pharmacist, and encourage individuals to enter the pharmacist profession.

(2) *METHOD.*—The public service announcements described in subsection (a) shall be broadcast through appropriate media outlets, including television or radio, in a manner intended to reach as wide and diverse an audience as possible.

(b) *STATE AND LOCAL PUBLIC SERVICE ANNOUNCEMENTS.*—

(1) *IN GENERAL.*—The Secretary shall award grants to entities to support State and local advertising campaigns through appropriate media outlets to promote the pharmacist profession, highlight the advantages and rewards of being a pharmacist, and encourage individuals to enter the pharmacist profession.

(2) *USE OF FUNDS.*—An entity that receives a grant under subsection (a) shall use funds received through such grant to acquire local television and radio time, place advertisements in local newspapers, and post information on billboards or on the Internet, in order to—

(A) advertise and promote the pharmacist profession;

(B) promote pharmacist education programs;

(C) inform the public of public assistance regarding such education programs;

(D) highlight individuals in the community that are presently practicing as pharmacists to recruit new pharmacists; and

(E) provide any other information to recruit individuals for the pharmacist profession.

(3) *METHOD.*—The campaigns described in subsection (a) shall be broadcast on television or radio, placed in newspapers as advertisements, or posted on billboards or the Internet, in a manner intended to reach as wide and diverse an audience as possible.

SEC. 772. DEMONSTRATION PROJECT.

(a) *IN GENERAL.*—The Secretary shall establish a demonstration project to enhance the participation of individuals who are



pharmacists in the National Health Service Corps Loan Repayment Program described in section 338B.

(b) SERVICES.—Services that may be provided by pharmacists pursuant to the demonstration project established under this section include medication therapy management services to assure that medications are used appropriately by patients, to enhance patients' understanding of the appropriate use of medications, to increase patients' adherence to prescription medication regimens, to reduce the risk of adverse events associated with medications, and to reduce the need for other costly medical services through better management of medication therapy. Such services may include case management, disease management, drug therapy management, patient training and education, counseling, drug therapy problem resolution, medication administration, the provision of special packaging, or other services that enhance the use of prescription medications.

(c) PROCEDURE.—The Secretary may not provide assistance to an individual under this section unless the individual agrees to comply with all requirements described in sections 338B and 338D.

(d) LIMITATIONS.—The demonstration project described in this section shall provide for the participation of—

(1) individuals to provide services in rural and urban areas; and

(2) enough individuals to allow the Secretary to properly analyze the effectiveness of such project.

(e) DESIGNATIONS.—The demonstration project described in this section, and any pharmacists who are selected to participate in such project, shall not be considered by the Secretary in the designation of a health professional shortage area under section 332 during fiscal years 2003 through 2005.

(f) RULE OF CONSTRUCTION.—This section shall not be construed to require any State to participate in the project described in this section.

(g) REPORT.—The Secretary shall prepare and submit a report on the project to—

(1) the Committee on Health, Education, Labor, and Pensions of the Senate;

(2) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the Senate;

(3) the Committee on Energy and Commerce of the House of Representatives; and

(4) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the House of Representatives.

SEC. 773. INFORMATION TECHNOLOGY.

(a) GRANTS AND CONTRACTS.—The Secretary may make awards of grants or contracts to qualifying schools of pharmacy for the purpose of assisting such schools in acquiring and installing computer-based systems to provide pharmaceutical education. Education provided through such systems may be graduate education, professional education, or continuing education. The computer-based systems may be designed to provide on-site education, or education at remote sites (commonly referred to as distance learning), or both.



(b) QUALIFYING SCHOOL OF PHARMACY.—For purposes of this section, the term “qualifying school of pharmacy” means a school of pharmacy (as defined in section 799B) that requires students to serve in a clinical rotation in which pharmacist services are part of the curriculum.

SEC. 774. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2006.

