

PRESERVATION OF ACCESS FOR SENIORS IN MEDICARE
 ADVANTAGE ACT OF 2015

JUNE 16, 2015.—Committed to the Committee of the Whole House on the State of
 the Union and ordered to be printed

Mr. RYAN of Wisconsin, from the Committee on Ways and Means,
 submitted the following

R E P O R T

[To accompany H.R. 2581]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 2581) to amend title XVIII of the Social Security Act to establish a 3-year demonstration program to test the use of value-based insurance design methodologies under eligible Medicare Advantage plans, to preserve Medicare beneficiary choice under Medicare Advantage, to revise the treatment under the Medicare program of infusion drugs furnished through durable medical equipment, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Preservation of Access for Seniors in Medicare Advantage Act of 2015”.

SEC. 2. DEMONSTRATION PROGRAM.

(a) **IN GENERAL.**—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall establish a 3-year demonstration program to test the use of value-based insurance design methodologies (as defined in subsection (c)(1) under eligible Medicare Advantage plans offered by Medicare Advantage organizations under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.). The Secretary may extend the program to a duration of 4 or 5 years, as determined necessary by the Secretary in coordination with the Centers for Medicare and Medicaid Innovation.

(b) **DEMONSTRATION PROGRAM DESIGN.**—

(1) **SELECTION OF MEDICARE ADVANTAGE SITES AND ELIGIBLE MEDICARE ADVANTAGE PLANS.**—Not later than two years after the date of the enactment of this Act, the Secretary shall—

(A) select at least two Medicare Advantage sites with respect to which to conduct the demonstration program under this section; and

(B) approve eligible Medicare Advantage plans to participate in such demonstration program.

In selecting Medicare Advantage sites under subparagraph (A), the Secretary shall take into account area differences as well as the availability of health maintenance organization plans and preferred provider organization plans offered in such sites.

(2) **START OF DEMONSTRATION.**—The demonstration program shall begin not later than the third plan year beginning after the date of the enactment of this Act.

(3) **ELIGIBLE MEDICARE ADVANTAGE PLANS.**—For purposes of this section, the term “eligible Medicare Advantage plan” means a Medicare Advantage plan under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.) that meets the following requirements:

(A) The plan is an Medicare Advantage regional plan (as defined in paragraph (4) of section 1859(b) of such Act (42 U.S.C. 1395w–28(b))) or Medicare Advantage local plan (as defined in paragraph (5) of such section) offered in the Medicare Advantage region selected under paragraph (1)(A).

(B) The plan has—

(i) (I) a quality rating under section 1853(o) of such Act (42 U.S.C. 1395w–23(o)) of 4 stars or higher based on the most recent data available for such year, or (II) in the case of a specialized Medicare Advantage plan for special needs individuals, as defined in section 1859(b)(6)(A) of such Act (42 U.S.C. 1395w–28(b)(6)(A)), a quality rating under section 1853(o) of such Act (42 U.S.C. 1395w–23(o)) equal to or higher than the national average for special needs plans (excluding Institutional-Special needs plans) based on the most recent data available for such year; and

(ii) at least 20 percent of the population to whom the plan is offered in a service area consists of subsidy eligible individuals (as defined in section 1860D–14(a)(3)(A) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(A))).

(4) **DISCLOSURE TO BENEFICIARIES.**—The Secretary shall provide to each individual eligible to enroll under a Medicare Advantage plan approved to participate under the demonstration program during a plan year for which the plan is so selected—

(A) notification that the plan is participating in such demonstration program;

(B) background information on the demonstration program;

(C) clinical data derived from the studies resulting from the demonstration program; and

(D) notification of the potential benefits that the individual will receive, and of the other potential impacts that the individual will experience, on account of the participation of the plan in the demonstration program.

(c) VALUE-BASED INSURANCE DESIGN METHODOLOGIES.—

(1) DEFINITION.—For purposes of this section, the term “value-based insurance design methodology” means a methodology for identifying specific prescription medications, and clinical services that are payable under title XVIII of the Social Security Act, for which the reduction of copayments, coinsurance, or both, would improve the management of specific chronic clinical conditions because of the high value and effectiveness of such medications and services for such specific chronic clinical conditions, as approved by the Secretary.

(2) USE OF METHODOLOGIES TO REDUCE COPAYMENTS AND COINSURANCE.—A Medicare Advantage organization offering an eligible Medicare Advantage plan approved to participate under the demonstration program, for each plan year for which the plan is so selected and using value-based insurance design methodologies—

(A) shall identify each prescription medication and clinical service covered under such plan for which the plan proposes to reduce or eliminate the copayment or coinsurance, with respect to the management of specific chronic clinical conditions (as specified by the Secretary) of Medicare Advantage eligible individuals (as defined in section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w–21(a)(3))) enrolled under such plans, for such plan year;

(B) may, for such plan year, reduce or eliminate copayments, coinsurance, or both for such prescription medication and clinical services so identified with respect to the management of such conditions of such individuals—

(i) if such reduction or elimination is evidence-based and for the purpose of encouraging such individuals in such plan to use such prescription medications and clinical services (such as preventive care, primary care, specialty visits, diagnostic tests, procedures, and durable medical equipment) with respect to such conditions; and

(ii) for the purpose of encouraging such individuals in such plan to use health care providers that such organization has identified with respect to such plan year as being high value providers; and

(C) if a reduction or elimination is applied pursuant to subparagraph (B), with respect to such medication and clinical services, shall, for such plan year, count toward the deductible applicable to such individual under such plan amounts that would have been payable by the individual as copayment or coinsurance for such medication and services if the reduction or elimination had not been applied.

(3) PROHIBITION OF INCREASES OF COPAYMENTS AND COINSURANCE.—In no case may any Medicare Advantage plan participating in the demonstration program increase, for any plan year for which the plan is so participating, the amount of copayments or coinsurance for any item or service covered under such plan for purposes of discouraging the use of such item or service.

(d) REPORT ON IMPLEMENTATION.—

(1) IN GENERAL.—Not later than 1 year after the date on which the demonstration program under this section begins under subsection (b)(2), the Secretary shall submit to Congress a report on the status of the implementation of the demonstration program.

(2) ELEMENTS.—The report required by paragraph (1) shall, with respect to eligible Medicare Advantage plans participating in the demonstration program for the first plan year of such program, include the following:

(A) A list of each medication and service identified pursuant to subsection (c)(2)(A) for such plan with respect to such plan year.

(B) For each such medication or service so identified, the amount of the copayment or coinsurance required under such plan with respect to such plan year for such medication or service and the amount of the reduction of such copayment or coinsurance from a previous plan year.

(C) For each provider identified pursuant to subsection (c)(2)(B)(ii) for such plan with respect to such plan year, a statement of the amount of the copayment or coinsurance required under such plan with respect to such plan year and the amount of the reduction of such copayment or coinsurance from the previous plan year.

(e) REVIEW AND ASSESSMENT OF UTILIZATION OF VALUE-BASED INSURANCE DESIGN METHODOLOGIES.—

(1) IN GENERAL.—The Secretary shall enter into a contract or agreement with an independent entity to review and assess the implementation of the dem-

onstration program under this section. The review and assessment shall include the following:

(A) An assessment of the utilization of value-based insurance design methodologies by Medicare Advantage plans participating under such program.

(B) An analysis of whether reducing or eliminating the copayment or coinsurance for each medication and clinical service identified pursuant to subsection (c)(2)(A) resulted in increased adherence to medication regimens, increased service utilization, improvement in quality metrics, better health outcomes, and enhanced beneficiary experience.

(C) An analysis of the extent to which costs to Medicare Advantage plans under part C of title XVIII of the Social Security Act participating in the demonstration program is less than costs to Medicare Advantage plans under such part that are not participating in the demonstration program.

(D) An analysis of whether reducing or eliminating the copayment or coinsurance for providers identified pursuant to subsection (c)(2)(B)(ii) resulted in improvement in quality metrics, better health outcomes, and enhanced beneficiary experience.

(E) An analysis, for each provider so identified, the extent to which costs to Medicare Advantage plans under part C of title XVIII of the Social Security Act participating in the demonstration program is less than costs to Medicare Advantage plans under such part that are not participating in the demonstration program.

(F) Such other matters as the Secretary considers appropriate.

(2) REPORT.—The contract or agreement entered into under paragraph (1) shall require such entity to submit to the Secretary a report on the review and assessment conducted by the entity under such paragraph in time for the inclusion of the results of such report in the report required by paragraph (3). Such report shall include a description, in clear language, of the manner in which the entity conducted the review and assessment.

(3) REPORT TO CONGRESS.—Not later than 4 years after the date on which the demonstration program begins under subsection (b)(2), the Secretary shall submit to Congress a report on the review and assessment of the demonstration program conducted under this subsection. The report shall include the following:

(A) A description of the results of the review and assessment included in the report submitted pursuant to paragraph (2).

(B) Such recommendations as the Secretary considers appropriate for enhancing the utilization of the methodologies applied under the demonstration program to all Medicare Advantage plans under part C of title XVIII of the Social Security Act so as to reduce copayments and coinsurance under such plans paid by Medicare beneficiaries for high-value prescription medications and clinical services for which coverage is provided under such plans and to otherwise improve the quality of health care provided under such plans.

(4) OVERSIGHT REPORT.—Not later than three years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the demonstration program that includes an assessment, with respect to individuals enrolled under Medicare Advantage plans approved to participate under the demonstration program, of the impact that the age, co-morbidities, and geographic regions of such individuals had upon the implementation of the demonstration program by the plans with respect to such individuals.

(f) SAVINGS.—In no case may any reduction in beneficiary copayments or coinsurance resulting from the implementation of the demonstration program under this section result in expenditures under parts A, B, and D of the title XVIII of the Social Security Act that are greater than such expenditures without application of this section.

(g) EXPANSION OF DEMONSTRATION PROGRAM.—Taking into account the review and assessment conducted under subsection (e), the Secretary may, through notice and comment rulemaking, expand (including implementation on a nationwide basis) the duration and scope of the demonstration program under title XVIII of the Social Security Act, other than under the original medicare fee-for-service program under parts A and B of such title, to the extent determined appropriate by the Secretary, if the requirements of paragraphs (1), (2) and (3) of subsection (c) of section 1115A of the Social Security Act (42 U.S.C. 1315a), as applied to the testing of a model under subsection (b) of such section, applied to the demonstration under this section.

(h) **WAIVER AUTHORITY.**—The Secretary may waive such provisions of titles XI and XVIII of the Social Security Act as may be necessary to carry out the demonstration program under this section.

(i) **IMPLEMENTATION FUNDING.**—For purposes of carrying out the demonstration program under this section, the Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) and the Federal Supplementary Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t), including the Medicare Prescription Drug Account in such Trust Fund, in such proportion as determined appropriate by the Secretary, of such sums as may be necessary.

SEC. 3. PRESERVATION OF MEDICARE BENEFICIARY CHOICE UNDER MEDICARE ADVANTAGE.

Section 1851(e)(2) of the Social Security Act (42 U.S.C. 1395w–21(e)(2)) is amended—

(1) in subparagraph (C)—

(A) in the heading, by inserting “FROM 2011 THROUGH 2015” after “45-DAY PERIOD”; and

(B) by inserting “and ending with 2015” after “beginning with 2011”; and
(2) by adding at the end the following new subparagraph:

“(G) **CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN 2016 AND SUBSEQUENT YEARS.**—

“(i) **IN GENERAL.**—Subject to clause (ii) and subparagraph (D)—

“(I) in the case of an MA eligible individual who is enrolled in an MA plan, at any time during the first 3 months of a year (beginning with 2016); or

“(II) in the case of an individual who first becomes an MA eligible individual during a year (beginning with 2016) and enrolls in an MA plan, during the first 3 months during such year in which the individual is an MA eligible individual;

such MA eligible individual may change the election under subsection (a)(1).

“(ii) **LIMITATION OF ONE CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR.**—An individual may change the election pursuant to clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

“(iii) **LIMITED APPLICATION TO PART D.**—Clauses (i) and (ii) of this subparagraph shall only apply with respect to changes in enrollment in a prescription drug plan under part D in the case of an individual who, previous to such change in enrollment, is enrolled in a Medicare Advantage plan.

“(iv) **LIMITATIONS ON MARKETING.**—Pursuant to subsection (j), no unsolicited marketing or marketing materials may be sent to an individual described in clause (i) during the continuous open enrollment and disenrollment period established for the individual under such clause, notwithstanding marketing guidelines established by the Centers for Medicare & Medicaid Services.”.

SEC. 4. TREATMENT OF INFUSION DRUGS FURNISHED THROUGH DURABLE MEDICAL EQUIPMENT.

Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended—

(1) in subparagraph (C), by inserting “(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)” after “2005”; and

(2) in subparagraph (D)—

(A) by striking “infusion drugs” and inserting “infusion drugs or biologicals” each place it appears; and

(B) in clause (i)—

(i) by striking “2004” and inserting “2004, and before January 1, 2017”; and

(ii) by striking “for such drug”.

SEC. 5. SENSE OF CONGRESS REGARDING THE IMPLEMENTATION AND DISTRIBUTION OF QUALITY INCENTIVE PAYMENTS TO MEDICARE ADVANTAGE PLANS.

It is the sense of Congress that—

(1) the Secretary of Health and Human Services has incorrectly interpreted subsection (n) of section 1853 of the Social Security Act (42 U.S.C. 1395w–23) as prohibiting the provision of any Medicare quality incentive payments under

subsection (o) of such section with respect to Medicare Advantage plans that exceed the payment benchmark cap under such subsection (n) for the area served by such plans; and

(2) the Secretary should immediately apply quality incentive payments under such subsection (o) with respect to such Medicare Advantage plans without regard to the limits set forth in such subsection (n).

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 2581, as reported by the Committee on Ways and Means on June 2, 2015, establishes a demonstration program requiring the use of Value-Based Insurance Designs to demonstrate how a reduction in copayments or coinsurance charges to Medicare beneficiaries, when selecting high-value prescription medications and clinical services, can increase utilization and ultimately improve clinical outcomes and lower health care costs. The second section of the legislation further preserves beneficiary choice under Medicare Advantage by reinstating, with modifications, a second enrollment period for Medicare Advantage beneficiaries who need to change their plan. The bill also changes the payment methodology for drugs paid under Part B of the Medicare Program that are infused through durable medical equipment.

B. BACKGROUND AND NEED FOR LEGISLATION

On May 29, 2015, Representative Brady (R-TX), Chairman of Ways and Means Health Subcommittee, introduced H.R. 2581. H.R. 2581 establishes a demonstration program that provides Medicare beneficiaries with reduced copayments and coinsurance for Medicare beneficiaries to improve such a plans' ability to serve a varying beneficiary pool without running afoul of Anti-Discrimination Act concerns. H.R. 2581 reopens the Medicare Advantage second open enrollment period previously closed by the Patient Protection and Affordable Care Act due to concerns about plan churn and its impact on beneficiaries. With recent cuts to the Medicare Advantage program resulting in a narrowing of networks in certain service areas, the likelihood that beneficiaries would allow themselves to auto-enroll into a plan they have come to like unbeknownst to network changes. The Committee believes this legislation is necessary in order to protect seniors' ability to see the providers they choose and. The increased spending that result from these policies is offset by adjusting the payment methodology for Part B drugs that are infused through durable medical equipment from the 95% of the Average Wholesale Price (AWP) that was in effect on October 1, 2003 to the Average Sales Price plus six (ASP+6) methodology. The Department of Health and Human Services Office of the Inspector General, documenting that many DME infused drugs are overpaid under the AWP-based methodology, recommended this change starting in 2013.

C. LEGISLATIVE HISTORY

Background

H.R. 2581 was introduced on May 29, 2015, and was referred to the Committee on Ways and Means and subsequently to the Committee on Energy and Commerce.

Committee hearings

On July 24, 2014, the Committee on Ways and Means Subcommittee on Health held a hearing on the status of the Medicare Advantage program.

The panel of witnesses included the following:

Chris Wing, Chief Executive Officer, SCAN Health Plans
 Jeff Burnich, M.D., Senior Vice President & Executive Officer, Sutter Medical Network, (Sacramento, CA) on behalf of CAPG
 Robert Book, PhD, Senior Research Director, Health Systems Innovation Network, LLC, Outside Healthcare and Economics Expert, American Action Forum
 Joe Baker, President, Medicare Rights Center

Committee action

The Committee on Ways and Means marked up H.R. 2581, Preservation of Access for Seniors in Medicare Advantage Act of 2015, on June 2, 2015 and ordered the bill favorably reported to the House of Representatives, as amended by a voice-vote (with a quorum being present).

II. EXPLANATION OF THE BILL

PRESERVATION OF ACCESS FOR SENIORS IN MEDICARE ADVANTAGE
 ACT OF 2015

PRESENT LAW

This bill creates a new statutory demonstration program to be added to the Social Security Act (42 U.S.C. 1395w-21). No such program exists, nor is it prohibited.

Section 1851(e)(2) of the Social Security Act restricts disenrollment from Medicare Advantage plans to the first 45 days of the year and strictly prohibits open enrollment after initial selection of plans when an individual is Medicare eligible. Current legislation also disallows for changing of election of enrollment.

Section 1842(o)(1) of the Social Security Act currently states that payment for durable medical equipment related infused drugs is set at 95% of AWP in effect on October 1, 2003.

REASONS FOR CHANGE

The Committee believes that Congress has found certain Medicare beneficiaries do not utilize important aspects of their benefits, opting to ignore potential health issues (including use high value clinical services), due to associated high out-of-pocket costs. Studies have found that the use of such high value services can decrease hospitalization and emergency room visits. Due to the 'one-size fits all' necessity in Medicare Advantage to align with Anti-Discrimination Act concerns, plans must find a benefit structure that can be offered to all beneficiaries they enroll. This creates the need for Chronic Special Needs Plans (C-SNPs), instead of allowing plans flexibility to serve a varying beneficiary pool to their specific needs.

The Committee also believes that seniors should have the option to choose whether to enroll or withdraw from Medicare Advantage if their choice during the original enrollment period is not one that meets their needs, as many satisfied Medicare Advantage bene-

ficiaries regularly auto-enroll into the same plan without regard to whether their networks may have narrowed. However, current statute does not allow an individual to change their mind after enrolling, and the Committee believes that beneficiary choice should be restored in a modified fashion.

The HHS Office of Inspector has pointed out that AWP does not represent actual transaction prices and that use of the AWP-based methodology results in overpayment of many DME infused drugs in relation to the ASP. Paying for DME infused drugs at ASP +6% ensures payments reflect recent transaction prices, reduces total Medicare spending on these drugs, and lowers total beneficiary cost sharing for these drugs.

EXPLANATION OF PROVISIONS

Section 1. The Value Based Insurance Design for Better Care Act of 2015 establishes a demonstration program that allows for varying benefit structures under a plan's bid for the purpose of reducing out-of-pocket costs for seniors in Medicare Advantage that are accepted to participate, while specifically prohibiting increases to copayments and coinsurance of these sites. The demonstration is authorized for 3–5 years, depending on analysis by the Secretary in conjunction with the Center for Medicare and Medicaid Innovation, and once the demonstration is complete, Congress will receive a final analysis from the Secretary of Health and Human Services.

Section 2. The Medicare Beneficiary Preservation of Choice Act of 2015 allows for a modified second Medicare open enrollment period. It allows for one change during each year during the second enrollment period, January 1 to March 1, and also prohibits the use of unsolicited materials in marketing for this period.

Section 3. This section establishes the payment methodology for Part B DME infused drugs at ASP +6%.

EFFECTIVE DATE

Section 1 of this bill would take effect no more than two years after enactment.

Section 2 takes effect beginning of January 1, 2016.

Section 3 takes effect beginning of January 1, 2017.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 2581, Preservation of Access for Seniors in Medicare Advantage Act of 2015, on June 2, 2015.

The bill, H.R. 2581, was ordered favorably reported to the House of Representatives as amended by a voice vote (with a quorum being present).

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the bill, H.R. 2581, as reported.

The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO), which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 15, 2015.

Hon. PAUL RYAN,
*Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2581, the Preservation of Access for Seniors in Medicare Advantage Act of 2015.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Paul Masi.

Sincerely,

KEITH HALL,
Director.

Enclosure.

H.R. 2581—Preservation of Access for Seniors in Medicare Advantage Act of 2015

Summary: H.R. 2581 would establish a demonstration program in the Medicare Advantage (MA) program, modify the open enrollment period for that program, and change payment rates for prescription drugs that are administered through items of durable medical equipment (DME).

CBO estimates that enacting H.R. 2581 would decrease direct spending relative to current law by \$225 million over the 2016–2025 period. Pay-as-you-go procedures apply because the bill would affect direct spending. Enacting the bill would not affect revenues.

H.R. 2581 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 2581 is shown in the following table. The costs of this legislation fall within budget function 570 (Medicare).

	By fiscal year, in millions of dollars—											
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016–2020	2016–2025
CHANGES IN DIRECT SPENDING (Outlays ^a)												
Value-Based Insurance Design Demonstration Program	0	0	20	20	20	20	20	30	40	40	60	210
Medicare Advantage Open Enrollment Period	0	5	10	10	10	10	15	15	15	15	35	105
Durable Medical Equipment Drugs	0	-55	-75	-80	-55	-50	-55	-55	-55	-60	-265	-540
NET DECREASE IN THE DEFICIT FROM CHANGES IN DIRECT SPENDING												
Impact on the Deficit	0	-50	-45	-50	-25	-20	-20	-10	0	-5	-170	-225

^a Budget authority is equal to outlays.

Basis of estimate: H.R. 2581 would require the Secretary of Health and Human Services to conduct a demonstration program, modify the open enrollment period for the Medicare Advantage program, and change how payment rates for certain prescription drugs are set. In aggregate, CBO estimates those changes would reduce direct spending for Medicare by \$225 million over the 2016–2025 period.

Value-based insurance design demonstration program

The legislation would require the Secretary to conduct a demonstration program to test the effectiveness of permitting private health insurance plans participating in the Medicare Advantage program to vary cost-sharing for Medicare beneficiaries with certain conditions in order to encourage the use of certain services and providers. As with models tested through the Center for Medicare and Medicaid Innovation (CMMI), the Secretary would be permitted to expand the program if, after evaluation of the results of the demonstration program, the Chief Actuary of the Centers for Medicare and Medicaid Services certifies that expansion would not increase Medicare spending and the Secretary determines that the expansion would not reduce quality of care.

Based on the priority areas announced by the CMMI program and information provided by stakeholders, CBO expects that CMMI will conduct a demonstration program under current law that is substantially similar to the program proposed under the legislation. The CMMI program has considerable flexibility in designing the models it tests, and to modify those models during the testing process. That flexibility increases the likelihood that a model tested by CMMI will be successful in either reducing spending without harming quality of care or improving quality of care without increasing spending.

In contrast, the legislation would codify several features of the demonstration program that the Secretary would be required to conduct. In CBO's judgment, that codification would have the effect of limiting the Secretary's flexibility in designing and modifying the demonstration, and could result in a model that is less successful in achieving the cost-reducing objective of the CMMI program. CBO expects that limiting that flexibility would be unlikely to result in greater cost savings than a similar model designed and refined under the existing CMMI program. Based on that one-sided effect on potential savings, CBO concludes that the middle of the

range of expected outcomes would be an increase in Medicare spending. CBO estimates that replacing the CMMI model with the demonstration program would increase Medicare spending by about \$20 million a year during the testing period, rising to about \$40 million a year during years when a successful model would be expanded. In particular, CBO estimates that the projected savings for the cohort of projects beginning in 2017 would be reduced by around 5 percent under the legislation. In total, CBO estimates the demonstration program required by H.R. 2581 would increase direct spending for Medicare by \$210 million over the 2016–2025 period.

Medicare advantage open enrollment period:

H.R. 2581 would establish an additional open enrollment period annually for beneficiaries already enrolled in a Medicare Advantage plan, beginning in 2016. Those beneficiaries would be permitted to enroll in a different plan during January through March of each year. CBO expects that the opportunity to switch plans would result in slightly more beneficiaries selecting plans that receive quality-bonus payments, increasing Medicare's costs for those beneficiaries by around 3 percent. That assessment reflects CBO's observation that beneficiaries tend to choose plans with higher quality ratings when given an opportunity to do so. CBO estimates that the additional enrollment period would increase direct spending for Medicare by \$105 million over the 2016–2025 period.

Durable medical equipment drugs

Under current law, Medicare's payment rate for prescription drugs delivered through an item of durable medical equipment (such as an infusion pump) is 95 percent of the average wholesale price (AWP) that was in effect as of October 1, 2003. As of January 1, 2017, the bill would base payment for those drugs on the Average Sales Price (ASP), which reflects actual transaction prices paid to manufacturers. CBO estimates that Medicare spent more than \$700 million for these drugs in FY 2014 and, absent the change in law, CBO projects that Medicare will spend more than \$1 billion annually on these drugs by 2025. For some drugs, the new payment rate would be higher than under current law, but the new payment rate would be lower for the majority of drugs. CBO estimates that this provision would reduce direct spending for Medicare by about \$540 million over the 2016–2025 period.

Pay-as-you-go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 2581, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON WAYS AND MEANS ON JUNE 2, 2015

	By fiscal year, in millions of dollars												
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016- 2020	2016- 2025
Statutory Pay-As-You-Go Impact	0	0	-50	-45	-50	-25	-20	-20	-10	0	-5	-170	-225
NET DECREASE (-) IN THE DEFICIT													
Statutory Pay-As-You-Go Impact	0	0	-50	-45	-50	-25	-20	-20	-10	0	-5	-170	-225

Intergovernmental and private-sector impact: H.R. 2581 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local or tribal governments.

Estimate prepared by: Federal Costs: Paul Masi and Lara Robillard; Impact on State, Local, and Tribal Governments: J'nell Blanco Suchy; Impact on the Private Sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives (relating to oversight findings), the Committee advises that it was as a result of the Committee's review of the provisions of H.R. 2581 that the Committee concluded that it is appropriate to report the bill, as amended, favorably to the House of Representatives with the recommendation that the bill do pass.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

C. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104-4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

E. DUPLICATION OF FEDERAL PROGRAMS

In compliance with Sec. 3(g)(2) of H. Res. 5 (114th Congress), the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139; or (3) a program related to a program identified in the most recent Catalog of Federal Do-

mestic Assistance, published pursuant to the Federal Program Information Act (Pub. L. No. 95–220, as amended by Pub. L. No. 98–169).

F. DISCLOSURE OF DIRECTED RULE MAKINGS

In compliance with Sec. 3(i) of H. Res. 5 (114th Congress), the following statement is made concerning directed rule makings: The Committee estimates that the bill requires no directed rule makings within the meaning of such section.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

A. TEXT OF EXISTING LAW AMENDED OR REPEALED BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(A) of rule XIII of the Rules of the House of Representatives, the text of each section proposed to be amended or repealed by the bill, as reported, is shown below:

SOCIAL SECURITY ACT

* * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * *

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

* * * * *

PROVISIONS RELATING TO THE ADMINISTRATION OF PART B

SEC. 1842. (a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.

(b)

(2)

(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 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.

(3) The Secretary—

(A) 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) 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 medicare administrative contractor, and such payment will (except as otherwise provided in section 1870(f)) be made—

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this title is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B), and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1862(a), and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title (except in the case of physicians' services and ambulance service furnished as described in section 1862(a)(4), other than for purposes of section 1870(f));

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the period ending 1 calendar year after the date of service;

(F) 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) 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) determine, prior to making payment, whether the amount billed for such service exceeds the limiting charge applicable under section 1848(g)(2);

(ii) notify the physician, supplier, or other person periodically (but not less often than once every 30 days) of determinations that amounts billed exceeded such applicable limiting charges; and

(iii) provide for prompt response to inquiries of physicians, suppliers, and other persons concerning the accuracy of such limiting charges for their services;

(H) shall implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the 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

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians;

(L) 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.

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 (including 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. In applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph.

(4)(A)(i) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(ii)(I) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(II) In determining the prevailing charge levels under the fourth sentence of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall permit an additional one percentage point increase in the increase otherwise permitted under that sentence.

(iii) In determining the maximum allowable prevailing charges which may be recognized consistent with the index described in the fourth sentence of paragraph (3) for physicians' services furnished on or after January 1, 1987, by participating physicians, the Sec-

retary shall treat the maximum allowable prevailing charges recognized as of December 31, 1986, under such sentence with respect to participating physicians as having been justified by economic changes.

(iv) The reasonable charge for physicians' services furnished on or after January 1, 1987, and before January 1, 1992, by a non-participating physician shall be no greater than the applicable percent of the prevailing charge levels established under the third and fourth sentences of paragraph (3) (or under any other applicable provision of law affecting the prevailing charge level). In the previous sentence, the term "applicable percent" means for services furnished (I) on or after January 1, 1987, and before April 1, 1988, 96 percent, (II) on or after April 1, 1988, and before January 1, 1989, 95.5 percent, and (III) on or after January 1, 1989, 95 percent.

(v) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning January 1, 1987.

(vi) Before each year (beginning with 1989), the Secretary shall establish a prevailing charge floor for primary care services (as defined in subsection (i)(4)) equal to 60 percent of the estimated average prevailing charge levels based on the best available data (determined, under the third and fourth sentences of paragraph (3) and under paragraph (4), without regard to this clause and without regard to physician specialty) for such service for all localities in the United States (weighted by the relative frequency of the service in each locality) for the year.

(vii) Beginning with 1987, the percentage increase in the MEI (as defined in subsection (i)(3)) for each year shall be the same for non-participating physicians as for participating physicians.

(B)(i) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983.

(ii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services—

(I) if the physician was not a participating physician at any time during the 12-month period beginning on October 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983, and

(II) if the physician was a participating physician at any time during the 12-month period beginning on October 1, 1984, the physician's customary charges shall be determined based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985.

(iii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the customary charges shall be the same

customary charges as were recognized under this section for the 12-month period beginning January 1, 1987.

(iv) In determining the reasonable charge under paragraph (3) for physicians' services (other than primary care services, as defined in subsection (i)(4)) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section for the 9-month period beginning April 1, 1990. In a case in which subparagraph (F) applies (relating to new physicians) so as to limit the customary charges of a physician during 1990 to a percent of prevailing charges, the previous sentence shall not prevent such limit on customary charges under such subparagraph from increasing in 1991 to a higher percent of such prevailing charges.

(C) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during periods beginning after September 30, 1985, the Secretary shall treat the level as set under subparagraph (A)(i) as having fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(i).

(D)(i) In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1)) on September 30, 1985, the Secretary shall not recognize increases in actual charges for services furnished during the 15-month period beginning on July 1, 1984, above the level of the physician's actual charges billed in the 3-month period ending on June 30, 1984.

(ii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, by a physician who is not a participating physician (as defined in subsection (h)(1)) on April 30, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 7-month period beginning on October 1, 1985, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, or January 1, 1988, by a physician who is not a participating physician (as defined in subsection (h)(1)) on December 31, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 8-month period beginning on May 1, 1986, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iv) In determining the customary charges for a physicians' service furnished on or after January 1, 1988, if a physician was a non-participating physician in a previous year (beginning with 1987), the Secretary shall not recognize any amount of such actual charges (for that service furnished during such previous year) that exceeds the maximum allowable actual charge for such service established under subsection (j)(1)(C).

(E)(i) For purposes of this part for physicians' services furnished in 1987, the percentage increase in the MEI is 3.2 percent.

- (ii) For purposes of this part for physicians' services furnished in 1988, on or after April 1, the percentage increase in the MEI is—
 - (I) 3.6 percent for primary care services (as defined in subsection (i)(4)), and
 - (II) 1 percent for other physicians' services.
 - (iii) For purposes of this part for physicians' services furnished in 1989, the percentage increase in the MEI is—
 - (I) 3.0 percent for primary care services, and
 - (II) 1 percent for other physicians' services.
 - (iv) For purposes of this part for items and services furnished in 1990, after March 31, 1990, the percentage increase in the MEI is—
 - (I) 0 percent for radiology services, for anesthesia services, and for other services specified in the list referred to in paragraph (14)(C)(i),
 - (II) 2 percent for other services (other than primary care services), and
 - (III) such percentage increase in the MEI (as defined in subsection (i)(3)) as would be otherwise determined for primary care services (as defined in subsection (i)(4)).
 - (v) For purposes of this part for items and services furnished in 1991, the percentage increase in the MEI is—
 - (I) 0 percent for services (other than primary care services), and
 - (II) 2 percent for primary care services (as defined in subsection (i)(4)).
- (6) No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to any 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 under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate, (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 assist-

ant, (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 or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the 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), (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, and (H) in the case of services described in section 1861(aa)(3) that are furnished by a health care professional under contract with a Federally qualified health center, payment shall be made to the center. 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 entity as described in subparagraph (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 Secretary shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) unless—

(I) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought,

(II) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this title, and

(III) at least 25 percent of the hospital's patients (during a representative past period, as determined by the Secretary) who were not entitled to benefits under this title and who were furnished services described in subclauses (I) and (II) paid all or a substantial part of charges (other than nominal charges) imposed for such services; and

(ii) to the extent that the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B).

(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 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 Secretary shall base payment under this title on the greatest of—

(I) the charges (other than nominal charges) which are most frequently collected in full or substantial part with respect to patients who were not entitled to benefits under this title and who were furnished services described in subclauses (I) and (II) of subparagraph (A)(i),

(II) the mean of the charges (other than nominal charges) which were collected in full or substantial part with respect to such patients, or

(III) 85 percent of the prevailing charges paid for similar services in the same locality.

(iii) If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished to patients in such hospital on an assignment-related basis, the customary charge for such services shall be equal to 90 percent of the prevailing charges paid for similar services in the same locality.

(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 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).

(D)(i) 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), no payment shall be made under this part for services of assistants at surgery with respect to a surgical procedure if such hospital has a training program relating to the medical specialty required for such surgical procedure and a qualified individual on the staff of the hospital is available to provide such services; except that payment may be made under this part for such services, to the extent that such payment is otherwise allowed under this paragraph, if such services, as determined under regulations of the Secretary—

(I) are required due to exceptional medical circumstances,

(II) are performed by team physicians needed to perform complex medical procedures, or

(III) constitute concurrent medical care relating to a medical condition which requires the presence of, and active care by, a physician of another specialty during surgery,

and under such other circumstances as the Secretary determines by regulation to be appropriate.

(ii) For purposes of this subparagraph, the term "assistant at surgery" means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(iii) The Secretary shall determine appropriate methods of reimbursement of assistants at surgery where such services are reimbursable under this part.

(8)(A)(i) The Secretary shall by regulation—

(I) describe the factors to be used in determining the cases (of particular items or services) in which the application of this title to payment under this part (other than to physicians' services paid under section 1848) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and

(II) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.

(ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

(B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if—

(i) the Secretary's determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,

(ii) the Secretary's determination takes into account the potential impacts described in subparagraph (D), and

(iii) the Secretary complies with the procedural requirements of paragraph (9).

(C) The factors described in this subparagraph are as follows:

(i) The programs established under this title and title XIX are the sole or primary sources of payment for an item or service.

(ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.

(iii) The payment amount for an item or service under this part is substantially higher or lower than the payment made for the item or service by other purchasers.

(D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.

(9)(A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.

(B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register—

(i) specifying the payment amount proposed to be established with respect to an item or service,

(ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and

(iii) explaining the potential impacts described in paragraph (8)(D).

(C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.

(D)(i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (8)(B) with respect to the payment amount to be established with respect to the item or service.

(ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.

(10)(A)(i) In determining the reasonable charge for procedures described in subparagraph (B) and performed during the 9-month period beginning on April 1, 1988, the prevailing charge for such procedure shall be the prevailing charge otherwise recognized for such procedure for 1987—

(I) subject to clause (iii), reduced by 2.0 percent, and

(II) further reduced by the applicable percentage specified in clause (ii).

(ii) For purposes of clause (i), the applicable percentage specified in this clause is—

(I) 15 percent, in the case of a prevailing charge otherwise recognized (without regard to this paragraph and determined

without regard to physician specialty) that is at least 150 percent of the weighted national average (as determined by the Secretary) of such prevailing charges for such procedure for all localities in the United States for 1987;

(II) 0 percent, in the case of a prevailing charge that does not exceed 85 percent of such weighted national average; and

(III) in the case of any other prevailing charge, a percent determined on the basis of a straight line sliding scale, equal to $3\frac{1}{3}$ of a percentage point for each percent by which the prevailing charge exceeds 85 percent of such weighted national average.

(iii) In no case shall the reduction under clause (i) for a procedure result in a prevailing charge in a locality for 1988 which is less than 85 percent of the Secretary's estimate of the weighted national average of such prevailing charges for such procedure for all localities in the United States for 1987 (based upon the best available data and determined without regard to physician specialty) after making the reduction described in clause (i)(I).

(B) The procedures described in this subparagraph are as follows: bronchoscopy, carpal tunnel repair, cataract surgery (including subsequent insertion of an intraocular lens), coronary artery bypass surgery, diagnostic and/or therapeutic dilation and curettage, knee arthroscopy, knee arthroplasty, pacemaker implantation surgery, total hip replacement, suprapubic prostatectomy, transurethral resection of the prostate, and upper gastrointestinal endoscopy.

(C) In the case of a reduction in the reasonable charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(D) There shall be no administrative or judicial review under section 1869 or otherwise of any determination under subparagraph (A) or under paragraph (11)(B)(ii).

(11)(A) In providing payment for cataract eyeglasses and cataract contact lenses, and professional services relating to them, under this part, each carrier shall—

(i) provide for separate determinations of the payment amount for the eyeglasses and lenses and of the payment amount for the professional services of a physician (as defined in section 1861(r)), and

(ii) not recognize as reasonable for such eyeglasses and lenses more than such amount as the Secretary establishes in guidelines relating to the inherent reasonableness of charges for such eyeglasses and lenses.

(B)(i) In determining the reasonable charge under paragraph (3) for a cataract surgical procedure, subject to clause (ii), the prevailing charge for such procedure otherwise recognized for participating and nonparticipating physicians shall be reduced by 10 percent with respect to procedures performed in 1987.

(ii) In no case shall the reduction under clause (i) for a surgical procedure result in a prevailing charge in a locality for a year which is less than 75 percent of the weighted national average of such prevailing charges for such procedure for all the localities in the United States for 1986.

(C)(i) The prevailing charge level determined with respect to A-mode ophthalmic ultrasound procedures may not exceed 5 percent of the prevailing charge level established with respect to extracapsular cataract removal with lens insertion.

(ii) The reasonable charge for an intraocular lens inserted during or subsequent to cataract surgery in a physician's office may not exceed the actual acquisition cost for the lens (taking into account any discount) plus a handling fee (not to exceed 5 percent of such actual acquisition cost).

(D) In the case of a reduction in the reasonable charge for a physicians' service or item under subparagraph (B) or (C), if a non-participating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(13)(A) In determining payments under section 1833(l) and section 1848 for anesthesia services furnished on or after January 1, 1994, the methodology for determining the base and time units used shall be the same for services furnished by physicians, for medical direction by physicians of two, three, or four certified registered nurse anesthetists, or for services furnished by a certified registered nurse anesthetist (whether or not medically directed) and shall be based on the methodology in effect, for anesthesia services furnished by physicians, as of the date of the enactment of the Omnibus Budget Reconciliation Act of 1993.

(B) The Secretary shall require claims for physicians' services for medical direction of nurse anesthetists during the periods in which the provisions of subparagraph (A) apply to indicate the number of such anesthetists being medically directed concurrently at any time during the procedure, the name of each nurse anesthetist being directed, and the type of procedure for which the services are provided.

(14)(A)(i) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during the 9-month period beginning on April 1, 1990, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for 1989 reduced by 15 percent or, if less, $\frac{1}{3}$ of the percent (if any) by which the prevailing charge otherwise applied in the locality in 1989 exceeds the locally-adjusted reduced prevailing amount (as determined under subparagraph (B)(i)) for the service.

(ii) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during 1991, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for the period during 1990 beginning on April 1, reduced by the same amount as the amount of the reduction effected under this paragraph (as amended by the Omnibus Budget Reconciliation Act of 1990) for such service during such period.

(B) For purposes of this paragraph:

(i) The "locally-adjusted reduced prevailing amount" for a locality for a physicians' service is equal to the product of—

(I) the reduced national weighted average prevailing charge for the service (specified under clause (ii)), and

- (II) the adjustment factor (specified under clause (iii)) for the locality.
- (ii) The “reduced national weighted average prevailing charge” for a physicians’ service is equal to the national weighted average prevailing charge for the service (specified in subparagraph (C)(ii)) reduced by the percentage change (specified in subparagraph (C)(iii)) for the service.
- (iii) The “adjustment factor”, for a physicians’ service for a locality, is the sum of—
- (I) the practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101–M, 101st Congress, 1st Session) for the service, multiplied by the geographic practice cost index value (specified in subparagraph (C)(iv)) for the locality, and
- (II) 1 minus the practice expense component (percent), divided by 100.
- (C) For purposes of this paragraph:
- (i) The physicians’ services specified in this clause are the procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission which specification is of physicians’ services that have been identified as overvalued by at least 10 percent based on a comparison of payments for such services under a resource- based relative value scale and of the national average prevailing charges under this part.
- (ii) The “national weighted average prevailing charge” specified in this clause, for a physicians’ service specified in clause (i), is the national weighted average prevailing charge for the service in 1989 as determined by the Secretary using the best data available.
- (iii) The “percentage change” specified in this clause, for a physicians’ service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list referred to in clause (i).
- (iv) The geographic practice cost index value specified in this clause for a locality is the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research).
- (D) In the case of a reduction in the prevailing charge for a physicians’ service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician’s actual charge is subject to a limit under subsection (j)(1)(D).
- (15)(A) In determining the reasonable charge for surgery, radiology, and diagnostic physicians’ services which the Secretary shall

designate (based on their high volume of expenditures under this part) and for which the prevailing charge (but for this paragraph) differs by physician specialty, the prevailing charge for such a service may not exceed the prevailing charge or fee schedule amount for that specialty of physicians that furnish the service most frequently nationally.

(B) In the case of a reduction in the prevailing charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of the reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(16)(A) In determining the reasonable charge for all physicians' services other than physicians' services specified in subparagraph (B) furnished during 1991, the prevailing charge for a locality shall be 6.5 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(B) For purposes of subparagraph (A), the physicians' services specified in this subparagraph are as follows:

(i) Radiology, anesthesia and physician pathology services, the technical components of diagnostic tests specified in paragraph (17) and physicians' services specified in paragraph (14)(C)(i).

(ii) Primary care services specified in subsection (i)(4), hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

(iii) Partial mastectomy; tendon sheath injections and small joint arthrocentesis; femoral fracture and trochanteric fracture treatments; endotracheal intubation; thoracentesis; thoracostomy; aneurysm repair; cystourethroscopy; transurethral fulguration and resection; tympanoplasty with mastoidectomy; and ophthalmoscopy.

(17) With respect to payment under this part for the technical (as distinct from professional) component of diagnostic tests (other than clinical diagnostic laboratory tests, tests specified in paragraph (14)(C)(i), and radiology services, including portable X-ray services) which the Secretary shall designate (based on their high volume of expenditures under this part), the reasonable charge for such technical component (including the applicable portion of a global service) may not exceed the national median of such charges for all localities, as estimated by the Secretary using the best available data.

(18)(A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part on a reasonable charge or fee schedule basis may only be made under this part on an assignment-related basis.

(B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the

same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j)(2) in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(C) A practitioner described in this subparagraph is any of the following:

- (i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)).
- (ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)).
- (iii) A certified nurse-midwife (as defined in section 1861(gg)(2)).
- (iv) A clinical social worker (as defined in section 1861(hh)(1)).
- (v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)).
- (vi) A registered dietitian or nutrition professional.

(D) For purposes of this paragraph, a service furnished by a practitioner described in subparagraph (C) includes any services and supplies furnished as incident to the service as would otherwise be covered under this part if furnished by a physician or as incident to a physician's service.

(19) For purposes of section 1833(a)(1), the reasonable charge for ambulance services (as described in section 1861(s)(7)) provided during calendar year 1998 and calendar year 1999 may not exceed the reasonable charge for such services provided during the previous calendar year (after application of this paragraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved reduced by 1.0 percentage point.

(c)

(2)(A) Each 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) which are clean claims, and
- (ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(ii) The term "applicable number of calendar days" means—

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days (or 19 calendar days with respect to claims submitted by participating physicians),

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days (or 18 calendar days with respect to claims submitted by participating physicians),

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days (or 17 calendar days with respect to claims submitted by participating physicians), and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received, interest shall be paid at the rate used for purposes of section 3902(a) of title 31, United States Code (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3)(A) Each contract under this section which provides for the disbursement of funds, as described in 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.

(B) In this paragraph, the term “applicable number of calendar days” means—

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 28 days.

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

(A) for the filing of claims related to physicians’ services,

(B) for an error in filing a claim relating to physicians’ services or for such a claim which is denied,

(C) for any appeal under this title with respect to physicians’ services,

(D) for applying for (or obtaining) a unique identifier under subsection (r), or

(E) for responding to inquiries respecting physicians’ services or for providing information with respect to medical review of such services.

(g) The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a 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) Any physician or supplier may voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. For purposes of this section, the term “participating physician or supplier” means a physician or supplier (excluding any provider of services) who, before the beginning of any year begin-

ning with 1984, enters into an agreement with the Secretary which provides that such physician or supplier will accept payment under this part on an assignment-related basis for all items and services furnished to individuals enrolled under this part during such year. In the case of a newly licensed physician or a physician who begins a practice in a new area, or in the case of a new supplier who begins a new business, or in such similar cases as the Secretary may specify, such physician or supplier may enter into such an agreement after the beginning of a year, for items and services furnished during the remainder of the year.

(2) 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). The Secretary shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which 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 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 medicare administrative contractor with a contract under this section, 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 medicare administrative contractor, whether electronically or otherwise, and such user fees shall be collected and retained by the contractor.

(4) At the beginning of each year the Secretary shall publish directories (for appropriate local geographic areas) containing the name, address, and specialty of all participating physicians and suppliers (as defined in paragraph (1)) for that area for that year. Each directory shall be organized to make the most useful presentation of the information (as determined by the Secretary) for individuals enrolled under this part. Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation pro-

gram 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 medicare administrative contractors, and to senior citizen organizations.

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

- (i) a description of the participation program,
- (ii) an explanation of the advantages to beneficiaries of obtaining covered services through a participating physician or supplier,
- (iii) an explanation of the assistance offered by medicare administrative contractors in obtaining the names of participating physicians and suppliers, and
- (iv) the toll-free telephone number under paragraph (2)(A) for inquiries concerning the program and for requests for free copies of appropriate directories.

(6) The Secretary shall provide that the directories shall be available for purchase by the public. The Secretary shall provide that each appropriate area directory is sent to each participating physician located in that area and that an appropriate number of copies of each such directory is sent to hospitals located in the area. Such copies shall be sent free of charge.

(7) The Secretary shall provide that each explanation of benefits provided under this part for services furnished in the United States, in conjunction with the payment of claims under section 1833(a)(1) (made other than on an assignment-related basis), shall include—

(A) a prominent reminder of the participating physician and supplier program established under this subsection (including the limitation on charges that may be imposed by such physicians and suppliers and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part),

(B) the toll-free telephone number or numbers, maintained under paragraph (2), at which an individual enrolled under this part may obtain information on participating physicians and suppliers,

(C)(i) an offer of assistance to such an individual in obtaining the names of participating physicians of appropriate specialty and (ii) an offer to provide a free copy of the appropriate participating physician directory, and

(D) in the case of services for which the billed amount exceeds the limiting charge imposed under section 1848(g), information regarding such applicable limiting charge (including information concerning the right to a refund under section 1848(g)(1)(A)(iv)).

(8) The Secretary may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(9) The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under

section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.

(i) For purposes of this title:

(1) A claim is considered to be paid on an “assignment-related basis” if the claim is paid on the basis of an assignment described in subsection (b)(3)(B)(ii), in accordance with subsection (b)(6)(B), or under the procedure described in section 1870(f)(1).

(2) The term “participating physician” refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is a participating physician (under subsection (h)(1)); the term “nonparticipating physician” refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is not a participating physician; and the term “nonparticipating supplier or other person” means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (h)(1)).

(3) The term “percentage increase in the MEI” means, with respect to physicians’ services furnished in a year, the percentage increase in the medicare economic index (referred to in the fourth sentence of subsection (b)(3)) applicable to such services furnished as of the first day of that year.

(4) The term “primary care services” means physicians’ services which constitute office medical services, emergency department services, home medical services, skilled nursing, intermediate care, and long-term care medical services, or nursing home, boarding home, domiciliary, or custodial care medical services.

(j)(1)(A) In the case of a physician who is not a participating physician for items and services furnished during a portion of the 30-month period beginning July 1, 1984, the Secretary shall monitor the physician’s actual charges to individuals enrolled under this part for physicians’ services during that portion of that period. If such physician knowingly and willfully bills individuals enrolled under this part for actual charges in excess of such physician’s actual charges for the calendar quarter beginning on April 1, 1984, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(B)(i) During any period (on or after January 1, 1987, and before the date specified in clause (ii)), during which a physician is a nonparticipating physician, the Secretary shall monitor the actual charges of each such physician for physicians’ services furnished to individuals enrolled under this part. If such physician knowingly and willfully bills on a repeated basis for such a service an actual charge in excess of the maximum allowable actual charge determined under subparagraph (C) for that service, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(ii) Clause (i) shall not apply to services furnished after December 31, 1990.

(C)(i) For a particular physicians' service furnished by a non-participating physician to individuals enrolled under this part during a year, for purposes of subparagraph (B), the maximum allowable actual charge is determined as follows: If the physician's maximum allowable actual charge for that service in the previous year was—

(I) less than 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge for the year involved is the greater of the maximum allowable actual charge described in subclause (II) or the charge described in clause (ii), or

(II) equal to, or greater than, 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge is 101 percent of the physician's maximum allowable actual charge for the service for the previous year.

(ii) For purposes of clause (i)(I), the charge described in this clause for a particular physicians' service furnished in a year is the maximum allowable actual charge for the service of the physician for the previous year plus the product of (I) the applicable fraction (as defined in clause (iii)) and (II) the amount by which 115 percent of the prevailing charge for the year involved for such service furnished by nonparticipating physicians, exceeds the physician's maximum allowable actual charge for the service for the previous year.

(iii) In clause (ii), the "applicable fraction" is—

(I) for 1987, $\frac{1}{4}$,

(II) for 1988, $\frac{1}{3}$,

(III) for 1989, $\frac{1}{2}$, and

(IV) for any subsequent year, 1.

(iv) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for 1987, in the case of a physicians' service for which the physician has actual charges for the calendar quarter beginning on April 1, 1984, the "maximum allowable actual charge" for 1986 is the physician's actual charge for such service furnished during such quarter.

(v) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for a year after 1986, in the case of a physicians' service for which the physician has no actual charges for the calendar quarter beginning on April 1, 1984, and for which a maximum allowable actual charge has not been previously established under this clause, the "maximum allowable actual charge" for the previous year shall be the 50th percentile of the customary charges for the service (weighted by frequency of the service) performed by nonparticipating physicians in the locality during the 12-month period ending June 30 of that previous year.

(vi) For purposes of this subparagraph, a "physician's actual charge" for a physicians' service furnished in a year or other period is the weighted average (or, at the option of the Secretary for a service furnished in the calendar quarter beginning April 1, 1984, the median) of the physician's charges for such service furnished in the year or other period.

(vii) In the case of a nonparticipating physician who was a participating physician during a previous period, for the purpose of

computing the physician's maximum allowable actual charge during the physician's period of nonparticipation, the physician shall be deemed to have had a maximum allowable actual charge during the period of participation, and such deemed maximum allowable actual charge shall be determined according to clauses (i) through (vi).

(viii) Notwithstanding any other provision of this subparagraph, the maximum allowable actual charge for a particular physician's service furnished by a nonparticipating physician to individuals enrolled under this part during the 3-month period beginning on January 1, 1988, shall be the amount determined under this subparagraph for 1987. The maximum allowable actual charge for any such service otherwise determined under this subparagraph for 1988 shall take effect on April 1, 1988.

(ix) If there is a reduction under subsection (b)(13) in the reasonable charge for medical direction furnished by a nonparticipating physician, the maximum allowable actual charge otherwise permitted under this subsection for such services shall be reduced in the same manner and in the same percentage as the reduction in such reasonable charge.

(D)(i) If an action described in clause (ii) results in a reduction in a reasonable charge for a physicians' service or item and a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such action, the physician may not charge the individual more than 125 percent of the reduced payment allowance (as defined in clause (iii)) plus (for services or items furnished during the 12-month period (or 9-month period in the case of an action described in clause (ii)(II)) beginning on the effective date of the action) $\frac{1}{2}$ of the amount by which the physician's maximum allowable actual charge for the service or item for the previous 12-month period exceeds such 125 percent level.

(ii) The first sentence of clause (i) shall apply to—

(I) an adjustment under subsection (b)(8)(B) (relating to inherent reasonableness),

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) (relating to certain overpriced procedures),

(III) a reduction under subsection (b)(11)(B) (relating to certain cataract procedures),

(IV) a prevailing charge limit established under subsection (b)(11)(C)(i) or (b)(15)(A),

(V) a reasonable charge limit established under subsection (b)(11)(C)(ii), and

(VI) an adjustment under section 1833(l)(3)(B) (relating to physician supervision of certified registered nurse anesthetists).

(iii) In clause (i), the term "reduced payment allowance" means, with respect to an action—

(I) under subsection (b)(8)(B), the inherently reasonable charge established under subsection (b)(8);

(II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) or under section 1833(l)(3)(B), the prevailing charge for the service after the action; or

(III) under subsection (b)(11)(C)(ii), the payment allowance established under such subsection.

(iv) If a physician knowingly and willfully bills in violation of clause (i) (whether or not such charge violates subparagraph (B)), the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(v) Clause (i) shall not apply to items and services furnished after December 31, 1990.

(2) Subject to paragraph (3), the sanctions which the Secretary may apply under this paragraph are—

(A) excluding a physician from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128, or

(B) civil monetary penalties and assessments, in the same manner as such penalties and assessments are authorized under section 1128A(a),

or both. The provisions of section 1128A (other than the first 2 sentences of subsection (a) and other than subsection (b)) shall apply to a civil money penalty and assessment under subparagraph (B) in the same manner as such provisions apply to a penalty, assessment, or proceeding under section 1128A(a), except to the extent such provisions are inconsistent with subparagraph (A) or paragraph (3).

(3)(A) The Secretary may not exclude a physician pursuant to paragraph (2)(A) if such physician is a sole community physician or sole source of essential specialized services in a community.

(B) The Secretary shall take into account access of beneficiaries to physicians' services for which payment may be made under this part in determining whether to bar a physician from participation under paragraph (2)(A).

(4) The Secretary may, out of any civil monetary penalty or assessment collected from a physician pursuant to this subsection, make a payment to a beneficiary enrolled under this part in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be an excess charge under paragraph (1).

(k)(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges for services as an assistant at surgery for which payment may not be made by reason of section 1862(a)(15), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1862(a)(15), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

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

(i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part,

(ii) payment for such services is not accepted on an assignment-related basis,

(iii)(I) a medicare administrative contractor determines under this part or a quality improvement 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

(iv) the physician has collected any amounts for such services,

the physician shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts so collected.

(B) A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the physician receives notice of an adverse determination on reconsideration or appeal.

(C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (A)(iii)(I) if—

(i) the physician establishes that the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1862(a)(1), or

(ii) before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that service.

(2) Each medicare administrative contractor with a contract in effect under this section with respect to physicians and each quality improvement 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 requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(m)(1) In the case of a nonparticipating physician who—

(A) performs an elective surgical procedure for an individual enrolled for benefits under this part and for which the physician's actual charge is at least \$500, and

(B) does not accept payment for such procedure on an assignment-related basis,

the physician must disclose to the individual, in writing and in a form approved by the Secretary, the physician's estimated actual charge for the procedure, the estimated approved charge under this part for the procedure, the excess of the physician's actual charge over the approved charge, and the coinsurance amount applicable

to the procedure. The written estimate may not be used as the basis for, or evidence in, a civil suit.

(2) A physician who fails to make a disclosure required under paragraph (1) with respect to a procedure shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected for the procedure in excess of the charges recognized and approved under this part.

(3) If a physician knowingly and willfully fails to comply with paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(4) The Secretary shall provide for such monitoring of requests for payment for physicians' services to which paragraph (1) applies as is necessary to assure compliance with paragraph (2).

(n)(1) If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

(2) A physician may not bill an individual enrolled under this part—

(A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or

(B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).

(3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with section 1842(j)(2).

(o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to the following:

(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

(i) A drug or biological furnished before January 1, 2004.

(ii) Blood clotting factors furnished during 2004.

(iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.

(iv) A vaccine described in subparagraph (A) or (B) of section 1861(s)(10) furnished on or after January 1, 2004.

(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(B) In the case of a drug or biological furnished during 2004 that is not described in—

(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

(ii) subparagraph (D)(i), or

(iii) subparagraph (F),

the amount determined under paragraph (4).

(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005, the amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13), as the case may be for the drug or biological.

(D)(i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1847 on or after January 1, 2007, the amount provided under section 1847.

(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished—

(i) in 2004, the amount of payment provided under paragraph (4); and

(ii) in 2005 and subsequent years, the amount of payment provided under section 1847A.

(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1861(n) that are furnished—

(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and

(ii) in 2005 and subsequent years, the amount provided under section 1847A for the drug or biological.

(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. This paragraph shall not apply in the case of payment under paragraph (1)(C).

(3)(A) Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

(B) The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to

services furnished by a practitioner described in subsection (b)(18)(C).

(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled "Average of GAO and OIG data (percent)" in the table entitled "Table 3.—Medicare Part B Drugs in the Most Recent GAO and OIG Studies" published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.

(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled "Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost", provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1861(s)(2) and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).

(7) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).

(p)(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.

(2) In the case of a request for payment for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) on an assignment-related basis which does not include the code (or codes) required under paragraph (1), payment may be denied under this part.

(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 medicare administrative contractor, the physician may be subject to a civil money penalty in an amount not to exceed \$2,000, and

(B) if the physician knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection, to include the code (or codes) required under paragraph (1), the physician may be subject to the sanction described in section 1842(j)(2)(A).

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(4) In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1861(s) ordered by a physician or a practitioner specified in subsection (b)(18)(C), but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

(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 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.

(B) For physician anesthesia services furnished under this part during 1991, the prevailing charge conversion factor used in a locality under this subsection shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:

(i) The Secretary shall estimate the national weighted average of the prevailing charge conversion factors used under this subsection for services furnished during 1990 after March 31, using the best available data.

(ii) The national weighted average estimated under clause (i) shall be reduced by 7 percent.

(iii) The adjusted prevailing charge conversion factor for a locality is the sum of—

(I) the product of (a) the portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause, 70 percent of the prevailing charge conversion factor shall be considered to be attributable to physician work.

(iv) The prevailing charge conversion factor to be applied to a locality under this subparagraph shall not be reduced by more than 15 percent below the prevailing charge conversion factor applied in the locality for the period during 1990 after March 31, but in no case shall the prevailing charge conversion factor be less than 60 percent of the national weighted average of the prevailing charge conversion factors (computed under clause (i)).

(2) For purposes of payment for anesthesia services (whether furnished by physicians or by certified registered nurse anesthetists) under this part, the time units shall be counted based on actual time rather than rounded to full time units.

(r) The Secretary shall establish a system which provides for a unique identifier for each physician who furnishes services for which payment may be made under this title. Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.

(s)(1)(A) Subject to paragraph (3), the Secretary may implement a statewide or other areawide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis.

(B) Any fee schedule established under this paragraph for such item or service shall be updated—

(i) for years before 2011—

(I) subject to subclause (II), by the percentage increase in the consumer price index for all urban

consumers (United States city average) for the 12-month period ending with June of the preceding year; and

(II) for items and services described in paragraph (2)(D) for 2009, section 1834(a)(14)(J) shall apply under this paragraph instead of the percentage increase otherwise applicable; and

(ii) for 2011 and subsequent years—

(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (B)(ii)(II) may result in the update under this paragraph being less than 0.0 for a year, and may result in payment rates under any fee schedule established under this paragraph for a year being less than such payment rates for the preceding year.

(2) The items and services described in this paragraph are as follows:

(A) Medical supplies.

(B) Home dialysis supplies and equipment (as defined in section 1881(b)(8)).

(D) Parenteral and enteral nutrients, equipment, and supplies.

(E) Electromyogram devices.

(F) Salivation devices.

(G) Blood products.

(H) Transfusion medicine.

(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

(t)(1) Each request for payment, or bill submitted, for an item or service furnished to an individual who is a resident of a skilled nursing facility for which payment may be made under this part shall include the facility's medicare provider number.

(2) Each request for payment, or bill submitted, for therapy services described in paragraph (1) or (3) of section 1833(g), including services described in section 1833(a)(8)(B), furnished on or after October 1, 2012, for which payment may be made under this part shall include the national provider identifier of the physician who periodically reviews the plan for such services under section 1861(p)(2).

(u) Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection

with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.

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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, and may elect qualified prescription drug coverage in accordance with section 1860D-1.

(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 (INCLUDING REGIONAL PLANS).—

(i) IN GENERAL.—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 regional or local preferred provider organization plans (including MA regional plans).

(ii) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—Specialized MA plans for special needs individuals (as defined in section 1859(b)(6)) may be any type of coordinated care plan.

(B) COMBINATION OF MSA PLAN AND CONTRIBUTIONS TO MEDICARE+CHOICE MSA.—An MSA plan, as defined in section 1859(b)(3), and a contribution into a Medicare+Choice medical savings account (MSA).

(C) PRIVATE FEE-FOR-SERVICE PLANS.—A Medicare+Choice private fee-for-service plan, as defined in section 1859(b)(2).

(3) MEDICARE+CHOICE ELIGIBLE INDIVIDUAL.—

(A) IN GENERAL.—In this title, subject to subparagraph (B), the term “Medicare+Choice eligible individual” means an individual who is entitled to benefits under part A and enrolled under part B.

(B) SPECIAL RULE FOR END-STAGE RENAL DISEASE.—Such term shall not include an individual medically determined to have end-stage renal disease, except that—

(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan; and

(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in subsection (e)(4)(A), then the individual will be treated as a “Medicare+Choice eligible individual” for purposes of electing to continue enrollment in another Medicare+Choice plan.

An individual who develops end-stage renal disease while enrolled in a reasonable cost reimbursement contract under section 1876(h) shall be treated as an MA eligible individual for purposes of applying the deemed enrollment under subsection (c)(4).

(b) SPECIAL RULES.—

(1) RESIDENCE REQUIREMENT.—

(A) IN GENERAL.—Except as the Secretary may otherwise provide and except as provided in subparagraph (C), an individual is eligible to elect a Medicare+Choice plan offered by a Medicare+Choice organization only if the plan serves the geographic area in which the individual resides.

(B) CONTINUATION OF ENROLLMENT PERMITTED.—Pursuant to rules specified by the Secretary, the Secretary shall provide that an MA local plan may offer to all individuals residing in a geographic area the option to continue enrollment in the plan, notwithstanding that the individual no longer resides in the service area of the plan, so long as the plan provides that individuals exercising this option have, as part of the benefits under the original medicare fee-for-service program option, reasonable access within that geographic area to the full range of basic benefits, subject to reasonable cost sharing liability in obtaining such benefits.

(C) CONTINUATION OF ENROLLMENT PERMITTED WHERE SERVICE CHANGED.—Notwithstanding subparagraph (A) and in addition to subparagraph (B), if a Medicare+Choice organization eliminates from its service area a Medicare+Choice payment area that was previously within its service area, the organization may elect to offer individuals residing in all or portions of the affected area who would otherwise be ineligible to continue enrollment the option to continue enrollment in an MA local plan it offers so long as—

(i) the enrollee agrees to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively at facilities designated by the organization within the plan service area; and

(ii) there is no other Medicare+Choice plan offered in the area in which the enrollee resides at the time of the organization’s election.

(2) SPECIAL RULE FOR CERTAIN INDIVIDUALS COVERED UNDER FEHBP OR ELIGIBLE FOR VETERANS OR MILITARY HEALTH BENEFITS, VETERANS.—

(A) FEHBP.—An individual who is enrolled in a health benefit plan under chapter 89 of title 5, United States Code, is not eligible to enroll in an MSA plan until such

time as the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted policies which will ensure that the enrollment of such individuals in such plans will not result in increased expenditures for the Federal Government for health benefit plans under such chapter.

(B) VA AND DOD.—The Secretary may apply rules similar to the rules described in subparagraph (A) in the case of individuals who are eligible for health care benefits under chapter 55 of title 10, United States Code, or under chapter 17 of title 38 of such Code.

(3) LIMITATION ON ELIGIBILITY OF QUALIFIED MEDICARE BENEFICIARIES AND OTHER MEDICAID BENEFICIARIES TO ENROLL IN AN MSA PLAN.—An individual who is a qualified medicare beneficiary (as defined in section 1905(p)(1)), a qualified disabled and working individual (described in section 1905(s)), an individual described in section 1902(a)(10)(E)(iii), or otherwise entitled to medicare cost-sharing under a State plan under title XIX is not eligible to enroll in an MSA plan.

(4) COVERAGE UNDER MSA PLANS.—

(A) IN GENERAL.—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.

(B) EVALUATION.—The Secretary shall regularly evaluate the impact of permitting enrollment in MSA plans under this part on selection (including adverse selection), use of preventive care, access to care, and the financial status of the Trust Funds under this title.

(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).

(c) PROCESS FOR EXERCISING CHOICE.—

(1) IN GENERAL.—The Secretary shall establish a process through which elections described in subsection (a) are made and changed, including the form and manner in which such elections are made and changed. Subject to paragraph (4), such elections shall be made or changed only during coverage election periods specified under subsection (e) and shall become effective as provided in subsection (f).

(2) COORDINATION THROUGH MEDICARE+CHOICE ORGANIZATIONS.—

(A) ENROLLMENT.—Such process shall permit an individual who wishes to elect a Medicare+Choice plan offered by a Medicare+Choice organization to make such election through the filing of an appropriate election form with the organization.

(B) DISENROLLMENT.—Such process shall permit an individual, who has elected a Medicare+Choice plan offered by a Medicare+Choice organization and who wishes to terminate such election, to terminate such election through the

filing of an appropriate election form with the organization.

(3) DEFAULT.—

(A) INITIAL ELECTION.—

(i) IN GENERAL.—Subject to clause (ii), an individual who fails to make an election during an initial election period under subsection (e)(1) is deemed to have chosen the original medicare fee-for-service program option.

(ii) SEAMLESS CONTINUATION OF COVERAGE.—The Secretary may establish procedures under which an individual who is enrolled in a health plan (other than Medicare+Choice plan) offered by a Medicare+Choice organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the Medicare+Choice plan offered by the organization (or, if the organization offers more than one such plan, such plan or plans as the Secretary identifies under such procedures).

(B) CONTINUING PERIODS.—An individual who has made (or is deemed to have made) an election under this section is considered to have continued to make such election until such time as—

(i) the individual changes the election under this section, or

(ii) the Medicare+Choice plan with respect to which such election is in effect is discontinued or, subject to subsection (b)(1)(B), no longer serves the area in which the individual resides.

(4) DEEMED ENROLLMENT RELATING TO CONVERTED REASONABLE COST REIMBURSEMENT CONTRACTS.—

(A) IN GENERAL.—On the first day of the annual, coordinated election period under subsection (e)(3) for plan years beginning on or after January 1, 2017, an MA eligible individual described in clause (i) or (ii) of subparagraph (B) is deemed, unless the individual elects otherwise, to have elected to receive benefits under this title through an applicable MA plan (and shall be enrolled in such plan) beginning with such plan year, if—

(i) the individual is enrolled in a reasonable cost reimbursement contract under section 1876(h) in the previous plan year;

(ii) such reasonable cost reimbursement contract was extended or renewed for the last reasonable cost reimbursement contract year of the contract (as described in subclause (I) of section 1876(h)(5)(C)(iv)) pursuant to such section;

(iii) the eligible organization that is offering such reasonable cost reimbursement contract provided the notice described in subclause (III) of such section that the contract was to be converted;

(iv) the applicable MA plan—

(I) is the plan that was converted from the reasonable cost reimbursement contract described in clause (iii);

(II) is offered by the same entity (or an organization affiliated with such entity that has a common ownership interest of control) that entered into such contract; and

(III) is offered in the service area where the individual resides;

(v) in the case of reasonable cost reimbursement contracts that provide coverage under parts A and B (and, to the extent the Secretary determines it to be feasible, contracts that provide only part B coverage), the difference between the estimated individual costs (as determined applicable by the Secretary) for the applicable MA plan and such costs for the predecessor cost plan does not exceed a threshold established by the Secretary; and

(vi) the applicable MA plan—

(I) provides coverage for enrollees transitioning from the converted reasonable cost reimbursement contract to such plan to maintain current providers of services and suppliers and course of treatment at the time of enrollment for a period of at least 90 days after enrollment; and

(II) during such period, pays such providers of services and suppliers for items and services furnished to the enrollee an amount that is not less than the amount of payment applicable for such items and services under the original Medicare fee-for-service program under parts A and B.

(B) MA ELIGIBLE INDIVIDUALS DESCRIBED.—

(i) WITHOUT PRESCRIPTION DRUG COVERAGE.—An MA eligible individual described in this clause, with respect to a plan year, is an MA eligible individual who is enrolled in a reasonable cost reimbursement contract under section 1876(h) in the previous plan year and who is not, for such previous plan year, enrolled in a prescription drug plan under part D, including coverage under section 1860D-22.

(ii) WITH PRESCRIPTION DRUG COVERAGE.—An MA eligible individual described in this clause, with respect to a plan year, is an MA eligible individual who is enrolled in a reasonable cost reimbursement contract under section 1876(h) in the previous plan year and who, for such previous plan year, is enrolled in a prescription drug plan under part D—

(I) through such contract; or

(II) through a prescription drug plan, if the sponsor of such plan is the same entity (or an organization affiliated with such entity) that entered into such contract.

(C) APPLICABLE MA PLAN DEFINED.—In this paragraph, the term “applicable MA plan” means, in the case of an individual described in—

(i) subparagraph (B)(i), an MA plan that is not an MA–PD plan; and

(ii) subparagraph (B)(ii), an MA–PD plan.

(D) IDENTIFICATION AND NOTIFICATION OF DEEMED INDIVIDUALS.—Not later than 45 days before the first day of the annual, coordinated election period under subsection (e)(3) for plan years beginning on or after January 1, 2017, the Secretary shall identify and notify the individuals who will be subject to deemed elections under subparagraph (A) on the first day of such period.

(d) PROVIDING INFORMATION TO PROMOTE INFORMED CHOICE.—

(1) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to medicare beneficiaries (and prospective medicare beneficiaries) on the coverage options provided under this section in order to promote an active, informed selection among such options.

(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. Such information shall be presented in a comparative form.

(iii) ADDITIONAL INFORMATION.—Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1804.

(B) NOTIFICATION TO NEWLY ELIGIBLE MEDICARE+CHOICE ELIGIBLE INDIVIDUALS.—To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial Medicare+Choice enrollment period for an individual described in subsection (e)(1), mail to the individual the information described in subparagraph (A).

(ii) NOTIFICATION RELATED TO CERTAIN DEEMED ELECTIONS.—The Secretary shall require a Medicare Advantage organization that is offering a Medicare Advantage plan that has been converted from a reasonable cost reimbursement contract pursuant to section 1876(h)(5)(C)(iv) to mail, not later than 30 days prior to the first day of the annual, coordinated election period under subsection (e)(3) of a year, to any individual enrolled under such contract and identified by the Secretary under subsection (c)(4)(D) for such year—

(I) a notification that such individual will, on such day, be deemed to have made an election

with respect to such plan to receive benefits under this title through an MA plan or MA-PD plan (and shall be enrolled in such plan) for the next plan year under subsection (c)(4)(A), but that the individual may make a different election during the annual, coordinated election period for such year;

(II) the information described in subparagraph (A);

(III) a description of the differences between such MA plan or MA-PD plan and the reasonable cost reimbursement contract in which the individual was most recently enrolled with respect to benefits covered under such plans, including cost-sharing, premiums, drug coverage, and provider networks;

(IV) information about the special period for elections under subsection (e)(2)(F); and

(V) other information the Secretary may specify.

(C) FORM.—The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

(D) PERIODIC UPDATING.—The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of Medicare+Choice plans and the benefits and Medicare+Choice monthly basic and supplemental beneficiary premiums for such plans.

(3) GENERAL INFORMATION.—General information under this paragraph, with respect to coverage under this part during a year, shall include the following:

(A) BENEFITS UNDER ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—A general description of the benefits covered under the original medicare fee-for-service program under parts A and B, including—

- (i) covered items and services,
- (ii) beneficiary cost sharing, such as deductibles, co-insurance, and copayment amounts, and
- (iii) any beneficiary liability for balance billing.

(B) ELECTION PROCEDURES.—Information and instructions on how to exercise election options under this section.

(C) RIGHTS.—A general description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program and the Medicare+Choice program and the right to be protected against discrimination based on health status-related factors under section 1852(b).

(D) INFORMATION ON MEDIGAP AND MEDICARE SELECT.—A general description of the benefits, enrollment rights, and other requirements applicable to medicare supplemental policies under section 1882 and provisions relating to medicare select policies described in section 1882(t).

(E) POTENTIAL FOR CONTRACT TERMINATION.—The fact that a Medicare+Choice organization may terminate its contract, refuse to renew its contract, or reduce the service

area included in its contract, under this part, and the effect of such a termination, nonrenewal, or service area reduction may have on individuals enrolled with the Medicare+Choice plan under this part.

(F) CATASTROPHIC COVERAGE AND SINGLE DEDUCTIBLE.—

In the case of an MA regional plan, a description of the catastrophic coverage and single deductible applicable under the plan.

(4) INFORMATION COMPARING PLAN OPTIONS.—Information under this paragraph, with respect to a Medicare+Choice plan for a year, shall include the following:

(A) BENEFITS.—The benefits covered under the plan, including the following:

(i) Covered items and services beyond those provided under the original medicare fee-for-service program.

(ii) Any beneficiary cost sharing, including information on the single deductible (if applicable) under section 1858(b)(1).

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an MSA plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

(v) In the case of a Medicare+Choice private fee-for-service plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vii) The extent to which an enrollee may select among in-network providers and the types of providers participating in the plan's network.

(viii) The organization's coverage of emergency and urgently needed care.

(B) PREMIUMS.—

(i) IN GENERAL.—The monthly amount of the premium charged to an individual.

(ii) REDUCTIONS.—The reduction in part B premiums, if any.

(C) SERVICE AREA.—The service area of the plan.

(D) QUALITY AND PERFORMANCE.—To the extent available, plan quality and performance indicators for the benefits under the plan (and how they compare to such indicators under the original medicare fee-for-service program under parts A and B in the area involved), including—

(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan's service area),

(ii) information on medicare enrollee satisfaction,

(iii) information on health outcomes, and

(iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

(E) SUPPLEMENTAL BENEFITS.—Supplemental health care benefits, including any reductions in cost-sharing under section 1852(a)(3) and the terms and conditions (including premiums) for such benefits.

(5) MAINTAINING A TOLL-FREE NUMBER AND INTERNET SITE.—The Secretary shall maintain a toll-free number for inquiries regarding Medicare+Choice options and the operation of this part in all areas in which Medicare+Choice plans are offered and an Internet site through which individuals may electronically obtain information on such options and Medicare+Choice plans.

(6) USE OF NON-FEDERAL ENTITIES.—The Secretary may enter into contracts with non-Federal entities to carry out activities under this subsection.

(7) PROVISION OF INFORMATION.—A Medicare+Choice organization shall provide the Secretary with such information on the organization and each Medicare+Choice plan it offers as may be required for the preparation of the information referred to in paragraph (2)(A).

(e) COVERAGE ELECTION PERIODS.—

(1) INITIAL CHOICE UPON ELIGIBILITY TO MAKE ELECTION IF MEDICARE+CHOICE PLANS AVAILABLE TO INDIVIDUAL.—If, at the time an individual first becomes entitled to benefits under part A and enrolled under part B, there is one or more Medicare+Choice plans offered in the area in which the individual resides, the individual shall make the election under this section during a period specified by the Secretary such that if the individual elects a Medicare+Choice plan during the period, coverage under the plan becomes effective as of the first date on which the individual may receive such coverage. If any portion of an individual's initial enrollment period under part B occurs after the end of the annual, coordinated election period described in paragraph (3)(B)(iii), the initial enrollment period under this part shall further extend through the end of the individual's initial enrollment period under part B.

(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5)—

(A) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2005.—At any time during the period beginning January 1, 1998, and ending on December 31, 2005, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

(B) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 6 MONTHS DURING 2006.—

(i) IN GENERAL.—Subject to clause (ii), subparagraph(C)(iii), and subparagraph (D), at any time during the first 6 months of 2006, or, if the individual first becomes a Medicare+Choice eligible individual during 2006, during the first 6 months during 2006 in which the individual is a Medicare+Choice eligible individual, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

(ii) LIMITATION OF ONE CHANGE.—An individual may exercise the right under clause (i) only once. The limitation under this clause shall not apply to changes in

elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under the first sentence of paragraph (4).

(C) ANNUAL 45-DAY PERIOD FROM 2011 THROUGH 2015 FOR DISENROLLMENT FROM MA PLANS TO ELECT TO RECEIVE BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM.—Subject to subparagraph (D), at any time during the first 45 days of a year (beginning with 2011 and ending with 2015), an individual who is enrolled in a Medicare Advantage plan may change the election under subsection (a)(1), but only with respect to coverage under the original medicare fee-for-service program under parts A and B, and may elect qualified prescription drug coverage in accordance with section 1860D-1.

(D) CONTINUOUS OPEN ENROLLMENT FOR INSTITUTIONALIZED INDIVIDUALS.—At any time after 2005 in the case of a Medicare+Choice eligible individual who is institutionalized (as defined by the Secretary), the individual may elect under subsection (a)(1)—

(i) to enroll in a Medicare+Choice plan; or

(ii) to change the Medicare+Choice plan in which the individual is enrolled.

(E) LIMITED CONTINUOUS OPEN ENROLLMENT OF ORIGINAL FEE-FOR-SERVICE ENROLLEES IN MEDICARE ADVANTAGE NON-PRESCRIPTION DRUG PLANS.—

(i) IN GENERAL.—On any date during the period beginning on January 1, 2007, and ending on July 31, 2007, on which a Medicare Advantage eligible individual is an unenrolled fee-for-service individual (as defined in clause (ii)), the individual may elect under subsection (a)(1) to enroll in a Medicare Advantage plan that is not an MA-PD plan.

(ii) UNENROLLED FEE-FOR-SERVICE INDIVIDUAL DEFINED.—In this subparagraph, the term “unenrolled fee-for-service individual” means, with respect to a date, a Medicare Advantage eligible individual who—

(I) is receiving benefits under this title through enrollment in the original medicare fee-for-service program under parts A and B;

(II) is not enrolled in an MA plan on such date; and

(III) as of such date is not otherwise eligible to elect to enroll in an MA plan.

(iii) LIMITATION OF ONE CHANGE DURING THE APPLICABLE PERIOD.—An individual may exercise the right under clause (i) only once during the period described in such clause.

(iv) NO EFFECT ON COVERAGE UNDER A PRESCRIPTION DRUG PLAN.—Nothing in this subparagraph shall be construed as permitting an individual exercising the right under clause (i)—

(I) who is enrolled in a prescription drug plan under part D, to disenroll from such plan or to enroll in a different prescription drug plan; or

(II) who is not enrolled in a prescription drug plan, to enroll in such a plan.

(F) SPECIAL PERIOD FOR CERTAIN DEEMED ELECTIONS.—

(i) IN GENERAL.—At any time during the period beginning after the last day of the annual, coordinated election period under paragraph (3) in which an individual is deemed to have elected to enroll in an MA plan or MA–PD plan under subsection (c)(4) and ending on the last day of February of the first plan year for which the individual is enrolled in such plan, such individual may change the election under subsection (a)(1) (including changing the MA plan or MA–PD plan in which the individual is enrolled).

(ii) LIMITATION OF ONE CHANGE.—An individual may exercise the right under clause (i) only once during the applicable period described in such clause. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

(3) ANNUAL, COORDINATED ELECTION PERIOD.—

(A) IN GENERAL.—Subject to paragraph (5), each individual who is eligible to make an election under this section may change such election during an annual, coordinated election period.

(B) ANNUAL, COORDINATED ELECTION PERIOD.—For purposes of this section, the term “annual, coordinated election period” means—

(i) with respect to a year before 2002, the month of November before such year;

(ii) with respect to 2002, 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year;

(iii) with respect to 2006, the period beginning on November 15, 2005, and ending on May 15, 2006;

(iv) with respect to 2007, 2008, 2009, and 2010, the period beginning on November 15 and ending on December 31 of the year before such year; and

(v) with respect to 2012 and succeeding years, the period beginning on October 15 and ending on December 7 of the year before such year.

(C) MEDICARE+CHOICE HEALTH INFORMATION FAIRS.—During the fall season of each year (beginning with 1999) and during the period described in subparagraph (B)(iii), in conjunction with the annual coordinated election period defined in subparagraph (B), the Secretary shall provide for a nationally coordinated educational and publicity campaign to inform Medicare+Choice eligible individuals about Medicare+Choice plans and the election process provided under this section.

(D) SPECIAL INFORMATION CAMPAIGNS.—During November 1998 the Secretary shall provide for an educational and publicity campaign to inform Medicare+Choice eligible individuals about the availability of Medicare+Choice plans, and eligible organizations with risk-sharing con-

tracts under section 1876, offered in different areas and the election process provided under this section. During the period described in subparagraph (B)(iii), the Secretary shall provide for an educational and publicity campaign to inform MA eligible individuals about the availability of MA plans (including MA–PD plans) offered in different areas and the election process provided under this section.

(4) SPECIAL ELECTION PERIODS.—Effective as of January 1, 2006, an individual may discontinue an election of a Medicare+Choice plan offered by a Medicare+Choice organization other than during an annual, coordinated election period and make a new election under this section if—

(A)(i) the certification of the organization or plan under this part has been terminated, or the organization or plan has notified the individual of an impending termination of such certification; or

(ii) the organization has terminated or otherwise discontinued providing the plan in the area in which the individual resides, or has notified the individual of an impending termination or discontinuation of such plan;

(B) the individual is no longer eligible to elect the plan because of a change in the individual's place of residence or other change in circumstances (specified by the Secretary, but not including termination of the individual's enrollment on the basis described in clause (i) or (ii) of subsection (g)(3)(B));

(C) the individual demonstrates (in accordance with guidelines established by the Secretary) that—

(i) the organization offering the plan substantially violated a material provision of the organization's contract under this part in relation to the individual (including the failure to provide an enrollee on a timely basis medically necessary care for which benefits are available under the plan or the failure to provide such covered care in accordance with applicable quality standards); or

(ii) the organization (or an agent or other entity acting on the organization's behalf) materially misrepresented the plan's provisions in marketing the plan to the individual; or

(D) the individual meets such other exceptional conditions as the Secretary may provide.

Effective as of January 1, 2006, an individual who, upon first becoming eligible for benefits under part A at age 65, enrolls in a Medicare+Choice plan under this part, the individual may discontinue the election of such plan, and elect coverage under the original fee-for-service plan, at any time during the 12-month period beginning on the effective date of such enrollment.

(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);

(B) subject to subparagraph (C), may not discontinue an election of an MSA plan except during the periods described in clause (ii) or (iii) of subparagraph (A) and under the first sentence of paragraph (4); and

(C) who elects an MSA plan during an annual, coordinated election period, and who never previously had elected such a plan, may revoke such election, in a manner determined by the Secretary, by not later than December 15 following the date of the election.

(6) OPEN ENROLLMENT PERIODS.—Subject to paragraph (5), a Medicare+Choice organization—

(A) shall accept elections or changes to elections during the initial enrollment periods described in paragraph (1), during the period described in paragraph (2)(F), during the month of November 1998 and during the annual, coordinated election period under paragraph (3) for each subsequent year, and during special election periods described in the first sentence of paragraph (4); and

(B) may accept other changes to elections at such other times as the organization provides.

(f) EFFECTIVENESS OF ELECTIONS AND CHANGES OF ELECTIONS.—

(1) DURING INITIAL COVERAGE ELECTION PERIOD.—An election of coverage made during the initial coverage election period under subsection (e)(1) shall take effect upon the date the individual becomes entitled to benefits under part A and enrolled under part B, except as the Secretary may provide (consistent with section 1838) in order to prevent retroactive coverage.

(2) DURING CONTINUOUS OPEN ENROLLMENT PERIODS.—An election or change of coverage made under subsection (e)(2) shall take effect with the first day of the first calendar month following the date on which the election or change is made.

(3) ANNUAL, COORDINATED ELECTION PERIOD.—An election or change of coverage made during an annual, coordinated election period (as defined in subsection (e)(3)(B), other than the period described in clause (iii) of such subsection) in a year shall take effect as of the first day of the following year.

(4) OTHER PERIODS.—An election or change of coverage made during any other period under subsection (e)(4) shall take effect in such manner as the Secretary provides in a manner consistent (to the extent practicable) with protecting continuity of health benefit coverage.

(g) GUARANTEED ISSUE AND RENEWAL.—

(1) IN GENERAL.—Except as provided in this subsection, 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.

(2) PRIORITY.—If the Secretary determines that a Medicare+Choice organization, in relation to a Medicare+Choice plan it offers, has a capacity limit and the number of Medicare+Choice eligible individuals who elect the

plan under this section exceeds the capacity limit, the organization may limit the election of individuals of the plan under this section but only if priority in election is provided—

(A) first to such individuals as have elected the plan at the time of the determination, and

(B) then to other such individuals in such a manner that does not discriminate, on a basis described in section 1852(b), among the individuals (who seek to elect the plan).

The preceding sentence shall not apply if it would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the medicare population in the service area of the plan.

(3) LIMITATION ON TERMINATION OF ELECTION.—

(A) IN GENERAL.—Subject to subparagraph (B), a Medicare+Choice organization may not for any reason terminate the election of any individual under this section for a Medicare+Choice plan it offers.

(B) BASIS FOR TERMINATION OF ELECTION.—A Medicare+Choice organization may terminate an individual's election under this section with respect to a Medicare+Choice plan it offers if—

(i) any Medicare+Choice monthly basic and supplemental beneficiary premiums required with respect to such plan are not paid on a timely basis (consistent with standards under section 1856 that provide for a grace period for late payment of such premiums),

(ii) the individual has engaged in disruptive behavior (as specified in such standards), or

(iii) the plan is terminated with respect to all individuals under this part in the area in which the individual resides.

(C) CONSEQUENCE OF TERMINATION.—

(i) TERMINATIONS FOR CAUSE.—Any individual whose election is terminated under clause (i) or (ii) of subparagraph (B) is deemed to have elected the original medicare fee-for-service program option described in subsection (a)(1)(A).

(ii) TERMINATION BASED ON PLAN TERMINATION OR SERVICE AREA REDUCTION.—Any individual whose election is terminated under subparagraph (B)(iii) shall have a special election period under subsection (e)(4)(A) in which to change coverage to coverage under another Medicare+Choice plan. Such an individual who fails to make an election during such period is deemed to have chosen to change coverage to the original medicare fee-for-service program option described in subsection (a)(1)(A).

(D) ORGANIZATION OBLIGATION WITH RESPECT TO ELECTION FORMS.—Pursuant to a contract under section 1857, each Medicare+Choice organization receiving an election form under subsection (c)(2) shall transmit to the Secretary (at such time and in such manner as the Secretary may specify) a copy of such form or such other information respecting the election as the Secretary may specify.

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

(1) SUBMISSION.—No marketing material or application form may be distributed by a Medicare+Choice organization to (or for the use of) Medicare+Choice eligible individuals unless—

(A) at least 45 days (or 10 days in the case described in paragraph (5)) before the date of distribution the organization has submitted the material or form to the Secretary for review, and

(B) the Secretary has not disapproved the distribution of such material or form.

(2) REVIEW.—The standards established under section 1856 shall include guidelines for the review of any material or form submitted and under such guidelines the Secretary shall disapprove (or later require the correction of) such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(3) DEEMED APPROVAL (1-STOP SHOPPING).—In the case of material or form that is submitted under paragraph (1)(A) to the Secretary or a regional office of the Department of Health and Human Services and the Secretary or the office has not disapproved the distribution of marketing material or form under paragraph (1)(B) with respect to a Medicare+Choice plan in an area, the Secretary is deemed not to have disapproved such distribution in all other areas covered by the plan and organization except with regard to that portion of such material or form that is specific only to an area involved.

(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, subject to subsection (j)(2)(C), cash, gifts, prizes, or other monetary rebates as an inducement for enrollment or otherwise;

(B) may include a prohibition against a Medicare+Choice organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual;

(C) shall not permit a Medicare Advantage organization (or the agents, brokers, and other third parties representing such organization) to conduct the prohibited activities described in subsection (j)(1); and

(D) shall only permit a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization) to conduct the activities described in subsection (j)(2) in accordance with the limitations established under such subsection.

(5) SPECIAL TREATMENT OF MARKETING MATERIAL FOLLOWING MODEL MARKETING LANGUAGE.—In the case of marketing material of an organization that uses, without modification, proposed model language specified by the Secretary, the period specified in paragraph (1)(A) shall be reduced from 45 days to 10 days.

(6) REQUIRED INCLUSION OF PLAN TYPE IN PLAN NAME.—For plan years beginning on or after January 1, 2010, a Medicare Advantage organization must ensure that the name of each Medicare Advantage plan offered by the Medicare Advantage organization includes the plan type of the plan (using standard terminology developed by the Secretary).

(7) STRENGTHENING THE ABILITY OF STATES TO ACT IN COLLABORATION WITH THE SECRETARY TO ADDRESS FRAUDULENT OR INAPPROPRIATE MARKETING PRACTICES.—

(A) APPOINTMENT OF AGENTS AND BROKERS.—Each Medicare Advantage organization shall—

(i) only use agents and brokers who have been licensed under State law to sell Medicare Advantage plans offered by the Medicare Advantage organization;

(ii) in the case where a State has a State appointment law, abide by such law; and

(iii) report to the applicable State the termination of any such agent or broker, including the reasons for such termination (as required under applicable State law).

(B) COMPLIANCE WITH STATE INFORMATION REQUESTS.—Each Medicare Advantage organization shall comply in a timely manner with any request by a State for information regarding the performance of a licensed agent, broker, or other third party representing the Medicare Advantage organization as part of an investigation by the State into the conduct of the agent, broker, or other third party.

(i) EFFECT OF ELECTION OF MEDICARE+CHOICE PLAN OPTION.—

(1) PAYMENTS TO ORGANIZATIONS.—Subject to sections 1852(a)(5), 1853(a)(4), 1853(g), 1853(h), 1886(d)(11), 1886(h)(3)(D), and 1853(m), payments under a contract with a Medicare+Choice organization under section 1853(a) with respect to an individual electing a Medicare+Choice plan offered by the organization shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under parts A and B for items and services furnished to the individual.

(2) ONLY ORGANIZATION ENTITLED TO PAYMENT.—Subject to sections 1853(a)(4), 1853(e), 1853(g), 1853(h), 1857(f)(2), 1858(h), 1886(d)(11), and 1886(h)(3)(D), only the Medicare+Choice organization shall be entitled to receive payments from the Secretary under this title for services furnished to the individual.

(j) PROHIBITED ACTIVITIES DESCRIBED AND LIMITATIONS ON THE CONDUCT OF CERTAIN OTHER ACTIVITIES.—

(1) PROHIBITED ACTIVITIES DESCRIBED.—The following prohibited activities are described in this paragraph:

(A) UNSOLICITED MEANS OF DIRECT CONTACT.—Any unsolicited means of direct contact of prospective enrollees, including soliciting door-to-door or any outbound telemarketing without the prospective enrollee initiating contact.

(B) CROSS-SELLING.—The sale of other non-health related products (such as annuities and life insurance) dur-

ing any sales or marketing activity or presentation conducted with respect to a Medicare Advantage plan.

(C) MEALS.—The provision of meals of any sort, regardless of value, to prospective enrollees at promotional and sales activities.

(D) SALES AND MARKETING IN HEALTH CARE SETTINGS AND AT EDUCATIONAL EVENTS.—Sales and marketing activities for the enrollment of individuals in Medicare Advantage plans that are conducted—

(i) in health care settings in areas where health care is delivered to individuals (such as physician offices and pharmacies), except in the case where such activities are conducted in common areas in health care settings; and

(ii) at educational events.

(2) LIMITATIONS.—The Secretary shall establish limitations with respect to at least the following:

(A) SCOPE OF MARKETING APPOINTMENTS.—The scope of any appointment with respect to the marketing of a Medicare Advantage plan. Such limitation shall require advance agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement by the Medicare Advantage organization. In the case where the marketing appointment is in person, such documentation shall be in writing.

(B) CO-BRANDING.—The use of the name or logo of a co-branded network provider on Medicare Advantage plan membership and marketing materials.

(C) LIMITATION OF GIFTS TO NOMINAL DOLLAR VALUE.—The offering of gifts and other promotional items other than those that are of nominal value (as determined by the Secretary) to prospective enrollees at promotional activities.

(D) COMPENSATION.—The use of compensation other than as provided under guidelines established by the Secretary. Such guidelines shall ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.

(E) REQUIRED TRAINING, ANNUAL RETRAINING, AND TESTING OF AGENTS, BROKERS, AND OTHER THIRD PARTIES.—The use by a Medicare Advantage organization of any individual as an agent, broker, or other third party representing the organization that has not completed an initial training and testing program and does not complete an annual retraining and testing program.

* * * * *

B. CHANGES IN EXISTING LAW PROPOSED BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed 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 italic, existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

**TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND
DISABLED**

* * * * *

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

* * * * *

PROVISIONS RELATING TO THE ADMINISTRATION OF PART B

SEC. 1842. (a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.

(b)

(2)

(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 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.

(3) The Secretary—

(A) 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) 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 medicare administrative contractor, and such payment will (except as otherwise provided in section 1870(f)) be made—

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this title is denied under section 1154(a)(2) by reason of a termination under section 1154(a)(1)(B), and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1862(a),

and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title (except in the case of physicians' services and ambulance service furnished as described in section 1862(a)(4), other than for purposes of section 1870(f));

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the period ending 1 calendar year after the date of service;

(F) 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) 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) determine, prior to making payment, whether the amount billed for such service exceeds the limiting charge applicable under section 1848(g)(2);

(ii) notify the physician, supplier, or other person periodically (but not less often than once every 30 days) of determinations that amounts billed exceeded such applicable limiting charges; and

(iii) provide for prompt response to inquiries of physicians, suppliers, and other persons concerning the accuracy of such limiting charges for their services;

(H) shall implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the 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

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians;

(L) 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.

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 (including 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. In applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph.

(4)(A)(i) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(ii)(I) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(II) In determining the prevailing charge levels under the fourth sentence of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall permit an additional one percentage point increase in the increase otherwise permitted under that sentence.

(iii) In determining the maximum allowable prevailing charges which may be recognized consistent with the index described in the fourth sentence of paragraph (3) for physicians' services furnished on or after January 1, 1987, by participating physicians, the Secretary shall treat the maximum allowable prevailing charges recognized as of December 31, 1986, under such sentence with respect to participating physicians as having been justified by economic changes.

(iv) The reasonable charge for physicians' services furnished on or after January 1, 1987, and before January 1, 1992, by a non-participating physician shall be no greater than the applicable percent of the prevailing charge levels established under the third and fourth sentences of paragraph (3) (or under any other applicable provision of law affecting the prevailing charge level). In the previous sentence, the term "applicable percent" means for services furnished (I) on or after January 1, 1987, and before April 1, 1988, 96 percent, (II) on or after April 1, 1988, and before January 1, 1989, 95.5 percent, and (III) on or after January 1, 1989, 95 percent.

(v) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services fur-

nished during the 3-month period beginning January 1, 1988, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning January 1, 1987.

(vi) Before each year (beginning with 1989), the Secretary shall establish a prevailing charge floor for primary care services (as defined in subsection (i)(4)) equal to 60 percent of the estimated average prevailing charge levels based on the best available data (determined, under the third and fourth sentences of paragraph (3) and under paragraph (4), without regard to this clause and without regard to physician specialty) for such service for all localities in the United States (weighted by the relative frequency of the service in each locality) for the year.

(vii) Beginning with 1987, the percentage increase in the MEI (as defined in subsection (i)(3)) for each year shall be the same for non-participating physicians as for participating physicians.

(B)(i) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983.

(ii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services—

(I) if the physician was not a participating physician at any time during the 12-month period beginning on October 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983, and

(II) if the physician was a participating physician at any time during the 12-month period beginning on October 1, 1984, the physician's customary charges shall be determined based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985.

(iii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning January 1, 1987.

(iv) In determining the reasonable charge under paragraph (3) for physicians' services (other than primary care services, as defined in subsection (i)(4)) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section for the 9-month period beginning April 1, 1990. In a case in which subparagraph (F) applies (relating to new physicians) so as to limit the customary charges of a physician during 1990 to a percent of prevailing charges, the previous sentence shall not prevent such limit on customary charges under such subparagraph from increasing in 1991 to a higher percent of such prevailing charges.

(C) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during periods beginning after September 30, 1985, the Secretary shall treat the level as set under subparagraph (A)(i) as hav-

ing fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(i).

(D)(i) In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1)) on September 30, 1985, the Secretary shall not recognize increases in actual charges for services furnished during the 15-month period beginning on July 1, 1984, above the level of the physician's actual charges billed in the 3-month period ending on June 30, 1984.

(ii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, by a physician who is not a participating physician (as defined in subsection (h)(1)) on April 30, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 7-month period beginning on October 1, 1985, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, or January 1, 1988, by a physician who is not a participating physician (as defined in subsection (h)(1)) on December 31, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 8-month period beginning on May 1, 1986, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iv) In determining the customary charges for a physicians' service furnished on or after January 1, 1988, if a physician was a non-participating physician in a previous year (beginning with 1987), the Secretary shall not recognize any amount of such actual charges (for that service furnished during such previous year) that exceeds the maximum allowable actual charge for such service established under subsection (j)(1)(C).

(E)(i) For purposes of this part for physicians' services furnished in 1987, the percentage increase in the MEI is 3.2 percent.

(ii) For purposes of this part for physicians' services furnished in 1988, on or after April 1, the percentage increase in the MEI is—

(I) 3.6 percent for primary care services (as defined in subsection (i)(4)), and

(II) 1 percent for other physicians' services.

(iii) For purposes of this part for physicians' services furnished in 1989, the percentage increase in the MEI is—

(I) 3.0 percent for primary care services, and

(II) 1 percent for other physicians' services.

(iv) For purposes of this part for items and services furnished in 1990, after March 31, 1990, the percentage increase in the MEI is—

(I) 0 percent for radiology services, for anesthesia services, and for other services specified in the list referred to in paragraph (14)(C)(i),

(II) 2 percent for other services (other than primary care services), and

(III) such percentage increase in the MEI (as defined in subsection (i)(3)) as would be otherwise determined for primary care services (as defined in subsection (i)(4)).

(v) For purposes of this part for items and services furnished in 1991, the percentage increase in the MEI is—

(I) 0 percent for services (other than primary care services), and

(II) 2 percent for primary care services (as defined in subsection (i)(4)).

(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 under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate, (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 or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the 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), (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, and (H) in the case of services described in section 1861(aa)(3) that are furnished by a health care professional under contract with a Federally qualified health center, payment shall be made to the center. 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 entity as described in subparagraph (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 Secretary shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) unless—

(I) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought,

(II) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this title, and

(III) at least 25 percent of the hospital's patients (during a representative past period, as determined by the Secretary) who were not entitled to benefits under this title and who were furnished services described in subclauses (I) and (II) paid all or a substantial part of charges (other than nominal charges) imposed for such services; and

(ii) to the extent that the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B).

(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 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 Secretary shall base payment under this title on the greatest of—

(I) the charges (other than nominal charges) which are most frequently collected in full or substantial part with respect to patients who were not entitled to benefits under this title and who were furnished services described in subclauses (I) and (II) of subparagraph (A)(i),

(II) the mean of the charges (other than nominal charges) which were collected in full or substantial part with respect to such patients, or

(III) 85 percent of the prevailing charges paid for similar services in the same locality.

(iii) If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished to patients in such hospital on an assignment-related basis, the customary charge for such services shall be equal to 90 percent of the prevailing charges paid for similar services in the same locality.

(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 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).

(D)(i) 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), no payment shall be made under this part for services of assistants at surgery with respect to a surgical procedure if such hospital has a training program relating to the medical spe-

cialty required for such surgical procedure and a qualified individual on the staff of the hospital is available to provide such services; except that payment may be made under this part for such services, to the extent that such payment is otherwise allowed under this paragraph, if such services, as determined under regulations of the Secretary—

(I) are required due to exceptional medical circumstances,

(II) are performed by team physicians needed to perform complex medical procedures, or

(III) constitute concurrent medical care relating to a medical condition which requires the presence of, and active care by, a physician of another specialty during surgery,

and under such other circumstances as the Secretary determines by regulation to be appropriate.

(ii) For purposes of this subparagraph, the term “assistant at surgery” means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(iii) The Secretary shall determine appropriate methods of reimbursement of assistants at surgery where such services are reimbursable under this part.

(8)(A)(i) The Secretary shall by regulation—

(I) describe the factors to be used in determining the cases (of particular items or services) in which the application of this title to payment under this part (other than to physicians’ services paid under section 1848) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and

(II) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.

(ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

(B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if—

(i) the Secretary’s determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,

(ii) the Secretary’s determination takes into account the potential impacts described in subparagraph (D), and

(iii) the Secretary complies with the procedural requirements of paragraph (9).

(C) The factors described in this subparagraph are as follows:

(i) The programs established under this title and title XIX are the sole or primary sources of payment for an item or service.

(ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.

(iii) The payment amount for an item or service under this part is substantially higher or lower than the payment made for the item or service by other purchasers.

(D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.

(9)(A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.

(B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register—

(i) specifying the payment amount proposed to be established with respect to an item or service,

(ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and

(iii) explaining the potential impacts described in paragraph (8)(D).

(C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.

(D)(i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (8)(B) with respect to the payment amount to be established with respect to the item or service.

(ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.

(10)(A)(i) In determining the reasonable charge for procedures described in subparagraph (B) and performed during the 9-month period beginning on April 1, 1988, the prevailing charge for such procedure shall be the prevailing charge otherwise recognized for such procedure for 1987—

(I) subject to clause (iii), reduced by 2.0 percent, and

(II) further reduced by the applicable percentage specified in clause (ii).

(ii) For purposes of clause (i), the applicable percentage specified in this clause is—

(I) 15 percent, in the case of a prevailing charge otherwise recognized (without regard to this paragraph and determined without regard to physician specialty) that is at least 150 percent of the weighted national average (as determined by the Secretary) of such prevailing charges for such procedure for all localities in the United States for 1987;

(II) 0 percent, in the case of a prevailing charge that does not exceed 85 percent of such weighted national average; and

(III) in the case of any other prevailing charge, a percent determined on the basis of a straight line sliding scale, equal to $3\frac{1}{3}$ of a percentage point for each percent by which the prevailing charge exceeds 85 percent of such weighted national average.

(iii) In no case shall the reduction under clause (i) for a procedure result in a prevailing charge in a locality for 1988 which is less than 85 percent of the Secretary's estimate of the weighted national average of such prevailing charges for such procedure for all localities in the United States for 1987 (based upon the best avail-

able data and determined without regard to physician specialty) after making the reduction described in clause (i)(I).

(B) The procedures described in this subparagraph are as follows: bronchoscopy, carpal tunnel repair, cataract surgery (including subsequent insertion of an intraocular lens), coronary artery bypass surgery, diagnostic and/or therapeutic dilation and curettage, knee arthroscopy, knee arthroplasty, pacemaker implantation surgery, total hip replacement, suprapubic prostatectomy, transurethral resection of the prostate, and upper gastrointestinal endoscopy.

(C) In the case of a reduction in the reasonable charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(D) There shall be no administrative or judicial review under section 1869 or otherwise of any determination under subparagraph (A) or under paragraph (11)(B)(ii).

(11)(A) In providing payment for cataract eyeglasses and cataract contact lenses, and professional services relating to them, under this part, each carrier shall—

(i) provide for separate determinations of the payment amount for the eyeglasses and lenses and of the payment amount for the professional services of a physician (as defined in section 1861(r)), and

(ii) not recognize as reasonable for such eyeglasses and lenses more than such amount as the Secretary establishes in guidelines relating to the inherent reasonableness of charges for such eyeglasses and lenses.

(B)(i) In determining the reasonable charge under paragraph (3) for a cataract surgical procedure, subject to clause (ii), the prevailing charge for such procedure otherwise recognized for participating and nonparticipating physicians shall be reduced by 10 percent with respect to procedures performed in 1987.

(ii) In no case shall the reduction under clause (i) for a surgical procedure result in a prevailing charge in a locality for a year which is less than 75 percent of the weighted national average of such prevailing charges for such procedure for all the localities in the United States for 1986.

(C)(i) The prevailing charge level determined with respect to A-mode ophthalmic ultrasound procedures may not exceed 5 percent of the prevailing charge level established with respect to extracapsular cataract removal with lens insertion.

(ii) The reasonable charge for an intraocular lens inserted during or subsequent to cataract surgery in a physician's office may not exceed the actual acquisition cost for the lens (taking into account any discount) plus a handling fee (not to exceed 5 percent of such actual acquisition cost).

(D) In the case of a reduction in the reasonable charge for a physician's service or item under subparagraph (B) or (C), if a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(13)(A) In determining payments under section 1833(l) and section 1848 for anesthesia services furnished on or after January 1, 1994, the methodology for determining the base and time units used shall be the same for services furnished by physicians, for medical direction by physicians of two, three, or four certified registered nurse anesthetists, or for services furnished by a certified registered nurse anesthetist (whether or not medically directed) and shall be based on the methodology in effect, for anesthesia services furnished by physicians, as of the date of the enactment of the Omnibus Budget Reconciliation Act of 1993.

(B) The Secretary shall require claims for physicians' services for medical direction of nurse anesthetists during the periods in which the provisions of subparagraph (A) apply to indicate the number of such anesthetists being medically directed concurrently at any time during the procedure, the name of each nurse anesthetist being directed, and the type of procedure for which the services are provided.

(14)(A)(i) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during the 9-month period beginning on April 1, 1990, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for 1989 reduced by 15 percent or, if less, $\frac{1}{3}$ of the percent (if any) by which the prevailing charge otherwise applied in the locality in 1989 exceeds the locally-adjusted reduced prevailing amount (as determined under subparagraph (B)(i)) for the service.

(ii) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during 1991, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for the period during 1990 beginning on April 1, reduced by the same amount as the amount of the reduction effected under this paragraph (as amended by the Omnibus Budget Reconciliation Act of 1990) for such service during such period.

(B) For purposes of this paragraph:

(i) The "locally-adjusted reduced prevailing amount" for a locality for a physicians' service is equal to the product of—

(I) the reduced national weighted average prevailing charge for the service (specified under clause (ii)), and

(II) the adjustment factor (specified under clause (iii)) for the locality.

(ii) The "reduced national weighted average prevailing charge" for a physicians' service is equal to the national weighted average prevailing charge for the service (specified in subparagraph (C)(ii)) reduced by the percentage change (specified in subparagraph (C)(iii)) for the service.

(iii) The "adjustment factor", for a physicians' service for a locality, is the sum of—

(I) the practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101-M, 101st Congress, 1st Ses-

sion) for the service, multiplied by the geographic practice cost index value (specified in subparagraph (C)(iv)) for the locality, and

(II) 1 minus the practice expense component (percent), divided by 100.

(C) For purposes of this paragraph:

(i) The physicians' services specified in this clause are the procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission which specification is of physicians' services that have been identified as overvalued by at least 10 percent based on a comparison of payments for such services under a resource-based relative value scale and of the national average prevailing charges under this part.

(ii) The "national weighted average prevailing charge" specified in this clause, for a physicians' service specified in clause (i), is the national weighted average prevailing charge for the service in 1989 as determined by the Secretary using the best data available.

(iii) The "percentage change" specified in this clause, for a physicians' service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list referred to in clause (i).

(iv) The geographic practice cost index value specified in this clause for a locality is the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research).

(D) In the case of a reduction in the prevailing charge for a physicians' service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(15)(A) In determining the reasonable charge for surgery, radiology, and diagnostic physicians' services which the Secretary shall designate (based on their high volume of expenditures under this part) and for which the prevailing charge (but for this paragraph) differs by physician specialty, the prevailing charge for such a service may not exceed the prevailing charge or fee schedule amount for that specialty of physicians that furnish the service most frequently nationally.

(B) In the case of a reduction in the prevailing charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of the reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(16)(A) In determining the reasonable charge for all physicians' services other than physicians' services specified in subparagraph (B) furnished during 1991, the prevailing charge for a locality shall be 6.5 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(B) For purposes of subparagraph (A), the physicians' services specified in this subparagraph are as follows:

(i) Radiology, anesthesia and physician pathology services, the technical components of diagnostic tests specified in paragraph (17) and physicians' services specified in paragraph (14)(C)(i).

(ii) Primary care services specified in subsection (i)(4), hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

(iii) Partial mastectomy; tendon sheath injections and small joint arthrocentesis; femoral fracture and trochanteric fracture treatments; endotracheal intubation; thoracentesis; thoracostomy; aneurysm repair; cystourethroscopy; transurethral fulguration and resection; tympanoplasty with mastoidectomy; and ophthalmoscopy.

(17) With respect to payment under this part for the technical (as distinct from professional) component of diagnostic tests (other than clinical diagnostic laboratory tests, tests specified in paragraph (14)(C)(i), and radiology services, including portable X-ray services) which the Secretary shall designate (based on their high volume of expenditures under this part), the reasonable charge for such technical component (including the applicable portion of a global service) may not exceed the national median of such charges for all localities, as estimated by the Secretary using the best available data.

(18)(A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part on a reasonable charge or fee schedule basis may only be made under this part on an assignment-related basis.

(B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j)(2) in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(C) A practitioner described in this subparagraph is any of the following:

(i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)).

(ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)).

(iii) A certified nurse-midwife (as defined in section 1861(gg)(2)).

(iv) A clinical social worker (as defined in section 1861(hh)(1)).

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)).

(vi) A registered dietitian or nutrition professional.

(D) For purposes of this paragraph, a service furnished by a practitioner described in subparagraph (C) includes any services and supplies furnished as incident to the service as would otherwise be covered under this part if furnished by a physician or as incident to a physician's service.

(19) For purposes of section 1833(a)(1), the reasonable charge for ambulance services (as described in section 1861(s)(7)) provided during calendar year 1998 and calendar year 1999 may not exceed the reasonable charge for such services provided during the previous calendar year (after application of this paragraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved reduced by 1.0 percentage point.

(c)

(2)(A) Each 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) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(ii) The term "applicable number of calendar days" means—

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days (or 19 calendar days with respect to claims submitted by participating physicians),

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days (or 18 calendar days with respect to claims submitted by participating physicians),

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days (or 17 calendar days with respect to claims submitted by participating physicians), and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause

(i) of such subparagraph) is received, interest shall be paid at the rate used for purposes of section 3902(a) of title 31, United States Code (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3)(A) Each contract under this section which provides for the disbursement of funds, as described in 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.

(B) In this paragraph, the term “applicable number of calendar days” means—

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 28 days.

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

(A) for the filing of claims related to physicians’ services,

(B) for an error in filing a claim relating to physicians’ services or for such a claim which is denied,

(C) for any appeal under this title with respect to physicians’ services,

(D) for applying for (or obtaining) a unique identifier under subsection (r), or

(E) for responding to inquiries respecting physicians’ services or for providing information with respect to medical review of such services.

(g) The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a 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) Any physician or supplier may voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. For purposes of this section, the term “participating physician or supplier” means a physician or supplier (excluding any provider of services) who, before the beginning of any year beginning with 1984, enters into an agreement with the Secretary which provides that such physician or supplier will accept payment under this part on an assignment-related basis for all items and services furnished to individuals enrolled under this part during such year. In the case of a newly licensed physician or a physician who begins a practice in a new area, or in the case of a new supplier who begins a new business, or in such similar cases as the Secretary may specify, such physician or supplier may enter into such an agreement after the beginning of a year, for items and services furnished during the remainder of the year.

(2) 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). The Secretary

shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which 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 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 medicare administrative contractor with a contract under this section, 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 medicare administrative contractor, whether electronically or otherwise, and such user fees shall be collected and retained by the contractor.

(4) At the beginning of each year the Secretary shall publish directories (for appropriate local geographic areas) containing the name, address, and specialty of all participating physicians and suppliers (as defined in paragraph (1)) for that area for that year. Each directory shall be organized to make the most useful presentation of the information (as determined by the Secretary) for individuals enrolled under this part. Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.

(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 medicare administrative contractors, and to senior citizen organizations.

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

- (i) a description of the participation program,
- (ii) an explanation of the advantages to beneficiaries of obtaining covered services through a participating physician or supplier,
- (iii) an explanation of the assistance offered by medicare administrative contractors in obtaining the names of participating physicians and suppliers, and

(iv) the toll-free telephone number under paragraph (2)(A) for inquiries concerning the program and for requests for free copies of appropriate directories.

(6) The Secretary shall provide that the directories shall be available for purchase by the public. The Secretary shall provide that each appropriate area directory is sent to each participating physician located in that area and that an appropriate number of copies of each such directory is sent to hospitals located in the area. Such copies shall be sent free of charge.

(7) The Secretary shall provide that each explanation of benefits provided under this part for services furnished in the United States, in conjunction with the payment of claims under section 1833(a)(1) (made other than on an assignment-related basis), shall include—

(A) a prominent reminder of the participating physician and supplier program established under this subsection (including the limitation on charges that may be imposed by such physicians and suppliers and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part),

(B) the toll-free telephone number or numbers, maintained under paragraph (2), at which an individual enrolled under this part may obtain information on participating physicians and suppliers,

(C)(i) an offer of assistance to such an individual in obtaining the names of participating physicians of appropriate specialty and (ii) an offer to provide a free copy of the appropriate participating physician directory, and

(D) in the case of services for which the billed amount exceeds the limiting charge imposed under section 1848(g), information regarding such applicable limiting charge (including information concerning the right to a refund under section 1848(g)(1)(A)(iv)).

(8) The Secretary may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(9) The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.

(i) For purposes of this title:

(1) A claim is considered to be paid on an “assignment-related basis” if the claim is paid on the basis of an assignment described in subsection (b)(3)(B)(ii), in accordance with subsection (b)(6)(B), or under the procedure described in section 1870(f)(1).

(2) The term “participating physician” refers, with respect to the furnishing of services, to a physician who at the time of

furnishing the services is a participating physician (under subsection (h)(1)); the term “nonparticipating physician” refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is not a participating physician; and the term “nonparticipating supplier or other person” means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (h)(1)).

(3) The term “percentage increase in the MEI” means, with respect to physicians’ services furnished in a year, the percentage increase in the medicare economic index (referred to in the fourth sentence of subsection (b)(3)) applicable to such services furnished as of the first day of that year.

(4) The term “primary care services” means physicians’ services which constitute office medical services, emergency department services, home medical services, skilled nursing, intermediate care, and long-term care medical services, or nursing home, boarding home, domiciliary, or custodial care medical services.

(j)(1)(A) In the case of a physician who is not a participating physician for items and services furnished during a portion of the 30-month period beginning July 1, 1984, the Secretary shall monitor the physician’s actual charges to individuals enrolled under this part for physicians’ services during that portion of that period. If such physician knowingly and willfully bills individuals enrolled under this part for actual charges in excess of such physician’s actual charges for the calendar quarter beginning on April 1, 1984, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(B)(i) During any period (on or after January 1, 1987, and before the date specified in clause (ii)), during which a physician is a nonparticipating physician, the Secretary shall monitor the actual charges of each such physician for physicians’ services furnished to individuals enrolled under this part. If such physician knowingly and willfully bills on a repeated basis for such a service an actual charge in excess of the maximum allowable actual charge determined under subparagraph (C) for that service, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(ii) Clause (i) shall not apply to services furnished after December 31, 1990.

(C)(i) For a particular physicians’ service furnished by a nonparticipating physician to individuals enrolled under this part during a year, for purposes of subparagraph (B), the maximum allowable actual charge is determined as follows: If the physician’s maximum allowable actual charge for that service in the previous year was—

(I) less than 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge for the year involved is the greater of the maximum allowable actual charge described in subclause (II) or the charge described in clause (ii), or

(II) equal to, or greater than, 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing

charge for the year and service involved, the maximum allowable actual charge is 101 percent of the physician's maximum allowable actual charge for the service for the previous year.

(ii) For purposes of clause (i)(I), the charge described in this clause for a particular physicians' service furnished in a year is the maximum allowable actual charge for the service of the physician for the previous year plus the product of (I) the applicable fraction (as defined in clause (iii)) and (II) the amount by which 115 percent of the prevailing charge for the year involved for such service furnished by nonparticipating physicians, exceeds the physician's maximum allowable actual charge for the service for the previous year.

(iii) In clause (ii), the "applicable fraction" is—

(I) for 1987, $\frac{1}{4}$,

(II) for 1988, $\frac{1}{3}$,

(III) for 1989, $\frac{1}{2}$, and

(IV) for any subsequent year, 1.

(iv) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for 1987, in the case of a physicians' service for which the physician has actual charges for the calendar quarter beginning on April 1, 1984, the "maximum allowable actual charge" for 1986 is the physician's actual charge for such service furnished during such quarter.

(v) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for a year after 1986, in the case of a physicians' service for which the physician has no actual charges for the calendar quarter beginning on April 1, 1984, and for which a maximum allowable actual charge has not been previously established under this clause, the "maximum allowable actual charge" for the previous year shall be the 50th percentile of the customary charges for the service (weighted by frequency of the service) performed by nonparticipating physicians in the locality during the 12-month period ending June 30 of that previous year.

(vi) For purposes of this subparagraph, a "physician's actual charge" for a physicians' service furnished in a year or other period is the weighted average (or, at the option of the Secretary for a service furnished in the calendar quarter beginning April 1, 1984, the median) of the physician's charges for such service furnished in the year or other period.

(vii) In the case of a nonparticipating physician who was a participating physician during a previous period, for the purpose of computing the physician's maximum allowable actual charge during the physician's period of nonparticipation, the physician shall be deemed to have had a maximum allowable actual charge during the period of participation, and such deemed maximum allowable actual charge shall be determined according to clauses (i) through (vi).

(viii) Notwithstanding any other provision of this subparagraph, the maximum allowable actual charge for a particular physician's service furnished by a nonparticipating physician to individuals enrolled under this part during the 3-month period beginning on January 1, 1988, shall be the amount determined under this subparagraph for 1987. The maximum allowable actual charge for any such service otherwise determined under this subparagraph for 1988 shall take effect on April 1, 1988.

(ix) If there is a reduction under subsection (b)(13) in the reasonable charge for medical direction furnished by a nonparticipating physician, the maximum allowable actual charge otherwise permitted under this subsection for such services shall be reduced in the same manner and in the same percentage as the reduction in such reasonable charge.

(D)(i) If an action described in clause (ii) results in a reduction in a reasonable charge for a physicians' service or item and a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such action, the physician may not charge the individual more than 125 percent of the reduced payment allowance (as defined in clause (iii)) plus (for services or items furnished during the 12-month period (or 9-month period in the case of an action described in clause (ii)(II)) beginning on the effective date of the action) $\frac{1}{2}$ of the amount by which the physician's maximum allowable actual charge for the service or item for the previous 12-month period exceeds such 125 percent level.

(ii) The first sentence of clause (i) shall apply to—

(I) an adjustment under subsection (b)(8)(B) (relating to inherent reasonableness),

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) (relating to certain overpriced procedures),

(III) a reduction under subsection (b)(11)(B) (relating to certain cataract procedures),

(IV) a prevailing charge limit established under subsection (b)(11)(C)(i) or (b)(15)(A),

(V) a reasonable charge limit established under subsection (b)(11)(C)(ii), and

(VI) an adjustment under section 1833(l)(3)(B) (relating to physician supervision of certified registered nurse anesthetists).

(iii) In clause (i), the term "reduced payment allowance" means, with respect to an action—

(I) under subsection (b)(8)(B), the inherently reasonable charge established under subsection (b)(8);

(II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) or under section 1833(l)(3)(B), the prevailing charge for the service after the action; or

(III) under subsection (b)(11)(C)(ii), the payment allowance established under such subsection.

(iv) If a physician knowingly and willfully bills in violation of clause (i) (whether or not such charge violates subparagraph (B)), the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(v) Clause (i) shall not apply to items and services furnished after December 31, 1990.

(2) Subject to paragraph (3), the sanctions which the Secretary may apply under this paragraph are—

(A) excluding a physician from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128, or

(B) civil monetary penalties and assessments, in the same manner as such penalties and assessments are authorized under section 1128A(a), or both. The provisions of section 1128A (other than the first 2 sentences of subsection (a) and other than subsection (b)) shall apply to a civil money penalty and assessment under subparagraph (B) in the same manner as such provisions apply to a penalty, assessment, or proceeding under section 1128A(a), except to the extent such provisions are inconsistent with subparagraph (A) or paragraph (3).

(3)(A) The Secretary may not exclude a physician pursuant to paragraph (2)(A) if such physician is a sole community physician or sole source of essential specialized services in a community.

(B) The Secretary shall take into account access of beneficiaries to physicians' services for which payment may be made under this part in determining whether to bar a physician from participation under paragraph (2)(A).

(4) The Secretary may, out of any civil monetary penalty or assessment collected from a physician pursuant to this subsection, make a payment to a beneficiary enrolled under this part in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be an excess charge under paragraph (1).

(k)(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges for services as an assistant at surgery for which payment may not be made by reason of section 1862(a)(15), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1862(a)(15), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

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

(i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part,

(ii) payment for such services is not accepted on an assignment-related basis,

(iii)(I) a medicare administrative contractor determines under this part or a quality improvement 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

(iv) the physician has collected any amounts for such services,

the physician shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts so collected.

(B) A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the physician receives notice of an adverse determination on reconsideration or appeal.

(C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (A)(iii)(I) if—

(i) the physician establishes that the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1862(a)(1), or

(ii) before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that service.

(2) Each medicare administrative contractor with a contract in effect under this section with respect to physicians and each quality improvement 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 requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(m)(1) In the case of a nonparticipating physician who—

(A) performs an elective surgical procedure for an individual enrolled for benefits under this part and for which the physician's actual charge is at least \$500, and

(B) does not accept payment for such procedure on an assignment-related basis,

the physician must disclose to the individual, in writing and in a form approved by the Secretary, the physician's estimated actual charge for the procedure, the estimated approved charge under this part for the procedure, the excess of the physician's actual charge over the approved charge, and the coinsurance amount applicable to the procedure. The written estimate may not be used as the basis for, or evidence in, a civil suit.

(2) A physician who fails to make a disclosure required under paragraph (1) with respect to a procedure shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected for the procedure in excess of the charges recognized and approved under this part.

(3) If a physician knowingly and willfully fails to comply with paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(4) The Secretary shall provide for such monitoring of requests for payment for physicians' services to which paragraph (1) applies as is necessary to assure compliance with paragraph (2).

(n)(1) If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

(2) A physician may not bill an individual enrolled under this part—

(A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or

(B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).

(3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with section 1842(j)(2).

(o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to the following:

(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

(i) A drug or biological furnished before January 1, 2004.

(ii) Blood clotting factors furnished during 2004.

(iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.

(iv) A vaccine described in subparagraph (A) or (B) of section 1861(s)(10) furnished on or after January 1, 2004.

(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(B) In the case of a drug or biological furnished during 2004 that is not described in—

(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

(ii) subparagraph (D)(i), or

(iii) subparagraph (F),
the amount determined under paragraph (4).

(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005 (*and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017*), the amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13), as the case may be for the drug or biological.

(D)(i) Except as provided in clause (ii), in the case of [infusion drugs] *infusion drugs or biologicals* furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, [2004] *2004, and before January 1, 2017*, 95 percent of the average wholesale price [for such drug] in effect on October 1, 2003.

(ii) In the case of such [infusion drugs] *infusion drugs or biologicals* furnished in a competitive acquisition area under section 1847 on or after January 1, 2007, the amount provided under section 1847.

(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished—

(i) in 2004, the amount of payment provided under paragraph (4); and

(ii) in 2005 and subsequent years, the amount of payment provided under section 1847A.

(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1861(n) that are furnished—

(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and

(ii) in 2005 and subsequent years, the amount provided under section 1847A for the drug or biological.

(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. This paragraph shall not apply in the case of payment under paragraph (1)(C).

(3)(A) Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

(B) The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C).

(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled “Average

of GAO and OIG data (percent)” in the table entitled “Table 3.— Medicare Part B Drugs in the Most Recent GAO and OIG Studies” published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.

(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled “Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost”, provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1861(s)(2) and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).

(7) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).

(p)(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.

(2) In the case of a request for payment for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) on an assignment-related basis which does not include the code (or codes) required under paragraph (1), payment may be denied under this part.

(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 medicare administrative contractor, the physician may be subject to a civil money penalty in an amount not to exceed \$2,000, and

(B) if the physician knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection, to include the code (or codes) required under paragraph (1), the physician may be subject to the sanction described in section 1842(j)(2)(A).

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(4) In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1861(s) ordered by a physician or a practitioner specified in subsection (b)(18)(C), but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

(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 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.

(B) For physician anesthesia services furnished under this part during 1991, the prevailing charge conversion factor used in a locality under this subsection shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:

(i) The Secretary shall estimate the national weighted average of the prevailing charge conversion factors used under this subsection for services furnished during 1990 after March 31, using the best available data.

(ii) The national weighted average estimated under clause (i) shall be reduced by 7 percent.

(iii) The adjusted prevailing charge conversion factor for a locality is the sum of—

(I) the product of (a) the portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause, 70 percent of the prevailing charge conversion factor shall be considered to be attributable to physician work.

(iv) The prevailing charge conversion factor to be applied to a locality under this subparagraph shall not be reduced by more than 15 percent below the prevailing charge conversion factor applied in the locality for the period during 1990 after March 31, but in no case shall the prevailing charge conversion factor be less than 60 percent of the national weighted average of the prevailing charge conversion factors (computed under clause (i)).

(2) For purposes of payment for anesthesia services (whether furnished by physicians or by certified registered nurse anesthetists) under this part, the time units shall be counted based on actual time rather than rounded to full time units.

(r) The Secretary shall establish a system which provides for a unique identifier for each physician who furnishes services for which payment may be made under this title. Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.

(s)(1)(A) Subject to paragraph (3), the Secretary may implement a statewide or other areawide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis.

(B) Any fee schedule established under this paragraph for such item or service shall be updated—

(i) for years before 2011—

(I) subject to subclause (II), by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year; and

(II) for items and services described in paragraph (2)(D) for 2009, section 1834(a)(14)(J) shall apply under this paragraph instead of the percentage increase otherwise applicable; and

(ii) for 2011 and subsequent years—

(I) the percentage increase in the consumer price index for all urban consumers (United States

city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (B)(ii)(II) may result in the update under this paragraph being less than 0.0 for a year, and may result in payment rates under any fee schedule established under this paragraph for a year being less than such payment rates for the preceding year.

(2) The items and services described in this paragraph are as follows:

(A) Medical supplies.

(B) Home dialysis supplies and equipment (as defined in section 1881(b)(8)).

(D) Parenteral and enteral nutrients, equipment, and supplies.

(E) Electromyogram devices.

(F) Salivation devices.

(G) Blood products.

(H) Transfusion medicine.

(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

(t)(1) Each request for payment, or bill submitted, for an item or service furnished to an individual who is a resident of a skilled nursing facility for which payment may be made under this part shall include the facility's medicare provider number.

(2) Each request for payment, or bill submitted, for therapy services described in paragraph (1) or (3) of section 1833(g), including services described in section 1833(a)(8)(B), furnished on or after October 1, 2012, for which payment may be made under this part shall include the national provider identifier of the physician who periodically reviews the plan for such services under section 1861(p)(2).

(u) Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.

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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, and may elect qualified prescription drug coverage in accordance with section 1860D-1.

(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 (INCLUDING REGIONAL PLANS).—

(i) IN GENERAL.—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 regional or local preferred provider organization plans (including MA regional plans).

(ii) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—Specialized MA plans for special needs individuals (as defined in section 1859(b)(6)) may be any type of coordinated care plan.

(B) COMBINATION OF MSA PLAN AND CONTRIBUTIONS TO MEDICARE+CHOICE MSA.—An MSA plan, as defined in section 1859(b)(3), and a contribution into a Medicare+Choice medical savings account (MSA).

(C) PRIVATE FEE-FOR-SERVICE PLANS.—A Medicare+Choice private fee-for-service plan, as defined in section 1859(b)(2).

(3) MEDICARE+CHOICE ELIGIBLE INDIVIDUAL.—

(A) IN GENERAL.—In this title, subject to subparagraph (B), the term “Medicare+Choice eligible individual” means an individual who is entitled to benefits under part A and enrolled under part B.

(B) SPECIAL RULE FOR END-STAGE RENAL DISEASE.—Such term shall not include an individual medically determined to have end-stage renal disease, except that—

(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan; and

(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in subsection (e)(4)(A), then the individual will be treated as a “Medicare+Choice eligible individual” for purposes of

electing to continue enrollment in another Medicare+Choice plan.

An individual who develops end-stage renal disease while enrolled in a reasonable cost reimbursement contract under section 1876(h) shall be treated as an MA eligible individual for purposes of applying the deemed enrollment under subsection (c)(4).

(b) SPECIAL RULES.—

(1) RESIDENCE REQUIREMENT.—

(A) IN GENERAL.—Except as the Secretary may otherwise provide and except as provided in subparagraph (C), an individual is eligible to elect a Medicare+Choice plan offered by a Medicare+Choice organization only if the plan serves the geographic area in which the individual resides.

(B) CONTINUATION OF ENROLLMENT PERMITTED.—Pursuant to rules specified by the Secretary, the Secretary shall provide that an MA local plan may offer to all individuals residing in a geographic area the option to continue enrollment in the plan, notwithstanding that the individual no longer resides in the service area of the plan, so long as the plan provides that individuals exercising this option have, as part of the benefits under the original medicare fee-for-service program option, reasonable access within that geographic area to the full range of basic benefits, subject to reasonable cost sharing liability in obtaining such benefits.

(C) CONTINUATION OF ENROLLMENT PERMITTED WHERE SERVICE CHANGED.—Notwithstanding subparagraph (A) and in addition to subparagraph (B), if a Medicare+Choice organization eliminates from its service area a Medicare+Choice payment area that was previously within its service area, the organization may elect to offer individuals residing in all or portions of the affected area who would otherwise be ineligible to continue enrollment the option to continue enrollment in an MA local plan it offers so long as—

(i) the enrollee agrees to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively at facilities designated by the organization within the plan service area; and

(ii) there is no other Medicare+Choice plan offered in the area in which the enrollee resides at the time of the organization's election.

(2) SPECIAL RULE FOR CERTAIN INDIVIDUALS COVERED UNDER FEHBP OR ELIGIBLE FOR VETERANS OR MILITARY HEALTH BENEFITS, VETERANS.—

(A) FEHBP.—An individual who is enrolled in a health benefit plan under chapter 89 of title 5, United States Code, is not eligible to enroll in an MSA plan until such time as the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted policies which will ensure that the enrollment of such individuals in such plans will not result in increased expenditures for the Federal Government for health benefit plans under such chapter.

(B) VA AND DOD.—The Secretary may apply rules similar to the rules described in subparagraph (A) in the case of individuals who are eligible for health care benefits under chapter 55 of title 10, United States Code, or under chapter 17 of title 38 of such Code.

(3) LIMITATION ON ELIGIBILITY OF QUALIFIED MEDICARE BENEFICIARIES AND OTHER MEDICAID BENEFICIARIES TO ENROLL IN AN MSA PLAN.—An individual who is a qualified medicare beneficiary (as defined in section 1905(p)(1)), a qualified disabled and working individual (described in section 1905(s)), an individual described in section 1902(a)(10)(E)(iii), or otherwise entitled to medicare cost-sharing under a State plan under title XIX is not eligible to enroll in an MSA plan.

(4) COVERAGE UNDER MSA PLANS.—

(A) IN GENERAL.—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.

(B) EVALUATION.—The Secretary shall regularly evaluate the impact of permitting enrollment in MSA plans under this part on selection (including adverse selection), use of preventive care, access to care, and the financial status of the Trust Funds under this title.

(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).

(c) PROCESS FOR EXERCISING CHOICE.—

(1) IN GENERAL.—The Secretary shall establish a process through which elections described in subsection (a) are made and changed, including the form and manner in which such elections are made and changed. Subject to paragraph (4), such elections shall be made or changed only during coverage election periods specified under subsection (e) and shall become effective as provided in subsection (f).

(2) COORDINATION THROUGH MEDICARE+CHOICE ORGANIZATIONS.—

(A) ENROLLMENT.—Such process shall permit an individual who wishes to elect a Medicare+Choice plan offered by a Medicare+Choice organization to make such election through the filing of an appropriate election form with the organization.

(B) DISENROLLMENT.—Such process shall permit an individual, who has elected a Medicare+Choice plan offered by a Medicare+Choice organization and who wishes to terminate such election, to terminate such election through the filing of an appropriate election form with the organization.

(3) DEFAULT.—

(A) INITIAL ELECTION.—

(i) IN GENERAL.—Subject to clause (ii), an individual who fails to make an election during an initial election period under subsection (e)(1) is deemed to have cho-

sen the original medicare fee-for-service program option.

(ii) SEAMLESS CONTINUATION OF COVERAGE.—The Secretary may establish procedures under which an individual who is enrolled in a health plan (other than Medicare+Choice plan) offered by a Medicare+Choice organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the Medicare+Choice plan offered by the organization (or, if the organization offers more than one such plan, such plan or plans as the Secretary identifies under such procedures).

(B) CONTINUING PERIODS.—An individual who has made (or is deemed to have made) an election under this section is considered to have continued to make such election until such time as—

(i) the individual changes the election under this section, or

(ii) the Medicare+Choice plan with respect to which such election is in effect is discontinued or, subject to subsection (b)(1)(B), no longer serves the area in which the individual resides.

(4) DEEMED ENROLLMENT RELATING TO CONVERTED REASONABLE COST REIMBURSEMENT CONTRACTS.—

(A) IN GENERAL.—On the first day of the annual, coordinated election period under subsection (e)(3) for plan years beginning on or after January 1, 2017, an MA eligible individual described in clause (i) or (ii) of subparagraph (B) is deemed, unless the individual elects otherwise, to have elected to receive benefits under this title through an applicable MA plan (and shall be enrolled in such plan) beginning with such plan year, if—

(i) the individual is enrolled in a reasonable cost reimbursement contract under section 1876(h) in the previous plan year;

(ii) such reasonable cost reimbursement contract was extended or renewed for the last reasonable cost reimbursement contract year of the contract (as described in subclause (I) of section 1876(h)(5)(C)(iv)) pursuant to such section;

(iii) the eligible organization that is offering such reasonable cost reimbursement contract provided the notice described in subclause (III) of such section that the contract was to be converted;

(iv) the applicable MA plan—

(I) is the plan that was converted from the reasonable cost reimbursement contract described in clause (iii);

(II) is offered by the same entity (or an organization affiliated with such entity that has a common ownership interest of control) that entered into such contract; and

(III) is offered in the service area where the individual resides;

(v) in the case of reasonable cost reimbursement contracts that provide coverage under parts A and B (and, to the extent the Secretary determines it to be feasible, contracts that provide only part B coverage), the difference between the estimated individual costs (as determined applicable by the Secretary) for the applicable MA plan and such costs for the predecessor cost plan does not exceed a threshold established by the Secretary; and

(vi) the applicable MA plan—

(I) provides coverage for enrollees transitioning from the converted reasonable cost reimbursement contract to such plan to maintain current providers of services and suppliers and course of treatment at the time of enrollment for a period of at least 90 days after enrollment; and

(II) during such period, pays such providers of services and suppliers for items and services furnished to the enrollee an amount that is not less than the amount of payment applicable for such items and services under the original Medicare fee-for-service program under parts A and B.

(B) MA ELIGIBLE INDIVIDUALS DESCRIBED.—

(i) WITHOUT PRESCRIPTION DRUG COVERAGE.—An MA eligible individual described in this clause, with respect to a plan year, is an MA eligible individual who is enrolled in a reasonable cost reimbursement contract under section 1876(h) in the previous plan year and who is not, for such previous plan year, enrolled in a prescription drug plan under part D, including coverage under section 1860D–22.

(ii) WITH PRESCRIPTION DRUG COVERAGE.—An MA eligible individual described in this clause, with respect to a plan year, is an MA eligible individual who is enrolled in a reasonable cost reimbursement contract under section 1876(h) in the previous plan year and who, for such previous plan year, is enrolled in a prescription drug plan under part D—

(I) through such contract; or

(II) through a prescription drug plan, if the sponsor of such plan is the same entity (or an organization affiliated with such entity) that entered into such contract.

(C) APPLICABLE MA PLAN DEFINED.—In this paragraph, the term “applicable MA plan” means, in the case of an individual described in—

(i) subparagraph (B)(i), an MA plan that is not an MA–PD plan; and

(ii) subparagraph (B)(ii), an MA–PD plan.

(D) IDENTIFICATION AND NOTIFICATION OF DEEMED INDIVIDUALS.—Not later than 45 days before the first day of the annual, coordinated election period under subsection (e)(3) for plan years beginning on or after January 1, 2017, the Secretary shall identify and notify the individuals who

will be subject to deemed elections under subparagraph (A) on the first day of such period.

(d) PROVIDING INFORMATION TO PROMOTE INFORMED CHOICE.—

(1) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to medicare beneficiaries (and prospective medicare beneficiaries) on the coverage options provided under this section in order to promote an active, informed selection among such options.

(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. Such information shall be presented in a comparative form.

(iii) ADDITIONAL INFORMATION.—Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1804.

(B) NOTIFICATION TO NEWLY ELIGIBLE MEDICARE+CHOICE ELIGIBLE INDIVIDUALS.—To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial Medicare+Choice enrollment period for an individual described in subsection (e)(1), mail to the individual the information described in subparagraph (A).

(ii) NOTIFICATION RELATED TO CERTAIN DEEMED ELECTIONS.—The Secretary shall require a Medicare Advantage organization that is offering a Medicare Advantage plan that has been converted from a reasonable cost reimbursement contract pursuant to section 1876(h)(5)(C)(iv) to mail, not later than 30 days prior to the first day of the annual, coordinated election period under subsection (e)(3) of a year, to any individual enrolled under such contract and identified by the Secretary under subsection (c)(4)(D) for such year—

(I) a notification that such individual will, on such day, be deemed to have made an election with respect to such plan to receive benefits under this title through an MA plan or MA–PD plan (and shall be enrolled in such plan) for the next plan year under subsection (c)(4)(A), but that the individual may make a different election during the annual, coordinated election period for such year;

(II) the information described in subparagraph (A);

(III) a description of the differences between such MA plan or MA-PD plan and the reasonable cost reimbursement contract in which the individual was most recently enrolled with respect to benefits covered under such plans, including cost-sharing, premiums, drug coverage, and provider networks;

(IV) information about the special period for elections under subsection (e)(2)(F); and

(V) other information the Secretary may specify.

(C) FORM.—The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

(D) PERIODIC UPDATING.—The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of Medicare+Choice plans and the benefits and Medicare+Choice monthly basic and supplemental beneficiary premiums for such plans.

(3) GENERAL INFORMATION.—General information under this paragraph, with respect to coverage under this part during a year, shall include the following:

(A) BENEFITS UNDER ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—A general description of the benefits covered under the original medicare fee-for-service program under parts A and B, including—

(i) covered items and services,

(ii) beneficiary cost sharing, such as deductibles, co-insurance, and copayment amounts, and

(iii) any beneficiary liability for balance billing.

(B) ELECTION PROCEDURES.—Information and instructions on how to exercise election options under this section.

(C) RIGHTS.—A general description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program and the Medicare+Choice program and the right to be protected against discrimination based on health status-related factors under section 1852(b).

(D) INFORMATION ON MEDIGAP AND MEDICARE SELECT.—A general description of the benefits, enrollment rights, and other requirements applicable to medicare supplemental policies under section 1882 and provisions relating to medicare select policies described in section 1882(t).

(E) POTENTIAL FOR CONTRACT TERMINATION.—The fact that a Medicare+Choice organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract, under this part, and the effect of such a termination, nonrenewal, or service area reduction may have on individuals enrolled with the Medicare+Choice plan under this part.

(F) CATASTROPHIC COVERAGE AND SINGLE DEDUCTIBLE.—In the case of an MA regional plan, a description of the

catastrophic coverage and single deductible applicable under the plan.

(4) INFORMATION COMPARING PLAN OPTIONS.—Information under this paragraph, with respect to a Medicare+Choice plan for a year, shall include the following:

(A) BENEFITS.—The benefits covered under the plan, including the following:

(i) Covered items and services beyond those provided under the original medicare fee-for-service program.

(ii) Any beneficiary cost sharing, including information on the single deductible (if applicable) under section 1858(b)(1).

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an MSA plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

(v) In the case of a Medicare+Choice private fee-for-service plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vii) The extent to which an enrollee may select among in-network providers and the types of providers participating in the plan's network.

(viii) The organization's coverage of emergency and urgently needed care.

(B) PREMIUMS.—

(i) IN GENERAL.—The monthly amount of the premium charged to an individual.

(ii) REDUCTIONS.—The reduction in part B premiums, if any.

(C) SERVICE AREA.—The service area of the plan.

(D) QUALITY AND PERFORMANCE.—To the extent available, plan quality and performance indicators for the benefits under the plan (and how they compare to such indicators under the original medicare fee-for-service program under parts A and B in the area involved), including—

(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan's service area),

(ii) information on medicare enrollee satisfaction,

(iii) information on health outcomes, and

(iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

(E) SUPPLEMENTAL BENEFITS.—Supplemental health care benefits, including any reductions in cost-sharing under section 1852(a)(3) and the terms and conditions (including premiums) for such benefits.

(5) MAINTAINING A TOLL-FREE NUMBER AND INTERNET SITE.—The Secretary shall maintain a toll-free number for inquiries regarding Medicare+Choice options and the operation of this

part in all areas in which Medicare+Choice plans are offered and an Internet site through which individuals may electronically obtain information on such options and Medicare+Choice plans.

(6) USE OF NON-FEDERAL ENTITIES.—The Secretary may enter into contracts with non-Federal entities to carry out activities under this subsection.

(7) PROVISION OF INFORMATION.—A Medicare+Choice organization shall provide the Secretary with such information on the organization and each Medicare+Choice plan it offers as may be required for the preparation of the information referred to in paragraph (2)(A).

(e) COVERAGE ELECTION PERIODS.—

(1) INITIAL CHOICE UPON ELIGIBILITY TO MAKE ELECTION IF MEDICARE+CHOICE PLANS AVAILABLE TO INDIVIDUAL.—If, at the time an individual first becomes entitled to benefits under part A and enrolled under part B, there is one or more Medicare+Choice plans offered in the area in which the individual resides, the individual shall make the election under this section during a period specified by the Secretary such that if the individual elects a Medicare+Choice plan during the period, coverage under the plan becomes effective as of the first date on which the individual may receive such coverage. If any portion of an individual's initial enrollment period under part B occurs after the end of the annual, coordinated election period described in paragraph (3)(B)(iii), the initial enrollment period under this part shall further extend through the end of the individual's initial enrollment period under part B.

(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5)—

(A) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2005.—At any time during the period beginning January 1, 1998, and ending on December 31, 2005, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

(B) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 6 MONTHS DURING 2006.—

(i) IN GENERAL.—Subject to clause (ii), subparagraph(C)(iii), and subparagraph (D), at any time during the first 6 months of 2006, or, if the individual first becomes a Medicare+Choice eligible individual during 2006, during the first 6 months during 2006 in which the individual is a Medicare+Choice eligible individual, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

(ii) LIMITATION OF ONE CHANGE.—An individual may exercise the right under clause (i) only once. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under the first sentence of paragraph (4).

(C) ANNUAL 45-DAY PERIOD FROM 2011 THROUGH 2015 FOR DISENROLLMENT FROM MA PLANS TO ELECT TO RECEIVE BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE

PROGRAM.—Subject to subparagraph (D), at any time during the first 45 days of a year (beginning with 2011 *and ending with 2015*), an individual who is enrolled in a Medicare Advantage plan may change the election under subsection (a)(1), but only with respect to coverage under the original medicare fee-for-service program under parts A and B, and may elect qualified prescription drug coverage in accordance with section 1860D-1.

(D) CONTINUOUS OPEN ENROLLMENT FOR INSTITUTIONALIZED INDIVIDUALS.—At any time after 2005 in the case of a Medicare+Choice eligible individual who is institutionalized (as defined by the Secretary), the individual may elect under subsection (a)(1)—

- (i) to enroll in a Medicare+Choice plan; or
- (ii) to change the Medicare+Choice plan in which the individual is enrolled.

(E) LIMITED CONTINUOUS OPEN ENROLLMENT OF ORIGINAL FEE-FOR-SERVICE ENROLLEES IN MEDICARE ADVANTAGE NON-PRESCRIPTION DRUG PLANS.—

(i) IN GENERAL.—On any date during the period beginning on January 1, 2007, and ending on July 31, 2007, on which a Medicare Advantage eligible individual is an unenrolled fee-for-service individual (as defined in clause (ii)), the individual may elect under subsection (a)(1) to enroll in a Medicare Advantage plan that is not an MA-PD plan.

(ii) UNENROLLED FEE-FOR-SERVICE INDIVIDUAL DEFINED.—In this subparagraph, the term “unenrolled fee-for-service individual” means, with respect to a date, a Medicare Advantage eligible individual who—

(I) is receiving benefits under this title through enrollment in the original medicare fee-for-service program under parts A and B;

(II) is not enrolled in an MA plan on such date; and

(III) as of such date is not otherwise eligible to elect to enroll in an MA plan.

(iii) LIMITATION OF ONE CHANGE DURING THE APPLICABLE PERIOD.—An individual may exercise the right under clause (i) only once during the period described in such clause.

(iv) NO EFFECT ON COVERAGE UNDER A PRESCRIPTION DRUG PLAN.—Nothing in this subparagraph shall be construed as permitting an individual exercising the right under clause (i)—

(I) who is enrolled in a prescription drug plan under part D, to disenroll from such plan or to enroll in a different prescription drug plan; or

(II) who is not enrolled in a prescription drug plan, to enroll in such a plan.

(F) SPECIAL PERIOD FOR CERTAIN DEEMED ELECTIONS.—

(i) IN GENERAL.—At any time during the period beginning after the last day of the annual, coordinated election period under paragraph (3) in which an individual is deemed to have elected to enroll in an MA

plan or MA–PD plan under subsection (c)(4) and ending on the last day of February of the first plan year for which the individual is enrolled in such plan, such individual may change the election under subsection (a)(1) (including changing the MA plan or MA–PD plan in which the individual is enrolled).

(ii) **LIMITATION OF ONE CHANGE.**—An individual may exercise the right under clause (i) only once during the applicable period described in such clause. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

(G) **CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN 2016 AND SUBSEQUENT YEARS.**—

(i) **IN GENERAL.**—Subject to clause (ii) and subparagraph (D)—

(I) *in the case of an MA eligible individual who is enrolled in an MA plan, at any time during the first 3 months of a year (beginning with 2016); or*

(II) *in the case of an individual who first becomes an MA eligible individual during a year (beginning with 2016) and enrolls in an MA plan, during the first 3 months during such year in which the individual is an MA eligible individual; such MA eligible individual may change the election under subsection (a)(1).*

(ii) **LIMITATION OF ONE CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR.**—An individual may change the election pursuant to clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

(iii) **LIMITED APPLICATION TO PART D.**—Clauses (i) and (ii) of this subparagraph shall only apply with respect to changes in enrollment in a prescription drug plan under part D in the case of an individual who, previous to such change in enrollment, is enrolled in a Medicare Advantage plan.

(iv) **LIMITATIONS ON MARKETING.**—Pursuant to subsection (j), no unsolicited marketing or marketing materials may be sent to an individual described in clause (i) during the continuous open enrollment and disenrollment period established for the individual under such clause, notwithstanding marketing guidelines established by the Centers for Medicare & Medicaid Services.

(3) **ANNUAL, COORDINATED ELECTION PERIOD.**—

(A) **IN GENERAL.**—Subject to paragraph (5), each individual who is eligible to make an election under this sec-

tion may change such election during an annual, coordinated election period.

(B) ANNUAL, COORDINATED ELECTION PERIOD.—For purposes of this section, the term “annual, coordinated election period” means—

- (i) with respect to a year before 2002, the month of November before such year;
- (ii) with respect to 2002, 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year;
- (iii) with respect to 2006, the period beginning on November 15, 2005, and ending on May 15, 2006;
- (iv) with respect to 2007, 2008, 2009, and 2010, the period beginning on November 15 and ending on December 31 of the year before such year; and
- (v) with respect to 2012 and succeeding years, the period beginning on October 15 and ending on December 7 of the year before such year.

(C) MEDICARE+CHOICE HEALTH INFORMATION FAIRS.—During the fall season of each year (beginning with 1999) and during the period described in subparagraph (B)(iii), in conjunction with the annual coordinated election period defined in subparagraph (B), the Secretary shall provide for a nationally coordinated educational and publicity campaign to inform Medicare+Choice eligible individuals about Medicare+Choice plans and the election process provided under this section.

(D) SPECIAL INFORMATION CAMPAIGNS.—During November 1998 the Secretary shall provide for an educational and publicity campaign to inform Medicare+Choice eligible individuals about the availability of Medicare+Choice plans, and eligible organizations with risk-sharing contracts under section 1876, offered in different areas and the election process provided under this section. During the period described in subparagraph (B)(iii), the Secretary shall provide for an educational and publicity campaign to inform MA eligible individuals about the availability of MA plans (including MA–PD plans) offered in different areas and the election process provided under this section.

(4) SPECIAL ELECTION PERIODS.—Effective as of January 1, 2006, an individual may discontinue an election of a Medicare+Choice plan offered by a Medicare+Choice organization other than during an annual, coordinated election period and make a new election under this section if—

- (A)(i) the certification of the organization or plan under this part has been terminated, or the organization or plan has notified the individual of an impending termination of such certification; or
- (ii) the organization has terminated or otherwise discontinued providing the plan in the area in which the individual resides, or has notified the individual of an impending termination or discontinuation of such plan;

(B) the individual is no longer eligible to elect the plan because of a change in the individual’s place of residence or other change in circumstances (specified by the Sec-

retary, but not including termination of the individual's enrollment on the basis described in clause (i) or (ii) of subsection (g)(3)(B));

(C) the individual demonstrates (in accordance with guidelines established by the Secretary) that—

(i) the organization offering the plan substantially violated a material provision of the organization's contract under this part in relation to the individual (including the failure to provide an enrollee on a timely basis medically necessary care for which benefits are available under the plan or the failure to provide such covered care in accordance with applicable quality standards); or

(ii) the organization (or an agent or other entity acting on the organization's behalf) materially misrepresented the plan's provisions in marketing the plan to the individual; or

(D) the individual meets such other exceptional conditions as the Secretary may provide.

Effective as of January 1, 2006, an individual who, upon first becoming eligible for benefits under part A at age 65, enrolls in a Medicare+Choice plan under this part, the individual may discontinue the election of such plan, and elect coverage under the original fee-for-service plan, at any time during the 12-month period beginning on the effective date of such enrollment.

(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);

(B) subject to subparagraph (C), may not discontinue an election of an MSA plan except during the periods described in clause (ii) or (iii) of subparagraph (A) and under the first sentence of paragraph (4); and

(C) who elects an MSA plan during an annual, coordinated election period, and who never previously had elected such a plan, may revoke such election, in a manner determined by the Secretary, by not later than December 15 following the date of the election.

(6) OPEN ENROLLMENT PERIODS.—Subject to paragraph (5), a Medicare+Choice organization—

(A) shall accept elections or changes to elections during the initial enrollment periods described in paragraph (1), during the period described in paragraph (2)(F), during the month of November 1998 and during the annual, coordinated election period under paragraph (3) for each subsequent year, and during special election periods described in the first sentence of paragraph (4); and

(B) may accept other changes to elections at such other times as the organization provides.

(f) EFFECTIVENESS OF ELECTIONS AND CHANGES OF ELECTIONS.—

(1) DURING INITIAL COVERAGE ELECTION PERIOD.—An election of coverage made during the initial coverage election period under subsection (e)(1) shall take effect upon the date the individual becomes entitled to benefits under part A and enrolled under part B, except as the Secretary may provide (consistent with section 1838) in order to prevent retroactive coverage.

(2) DURING CONTINUOUS OPEN ENROLLMENT PERIODS.—An election or change of coverage made under subsection (e)(2) shall take effect with the first day of the first calendar month following the date on which the election or change is made.

(3) ANNUAL, COORDINATED ELECTION PERIOD.—An election or change of coverage made during an annual, coordinated election period (as defined in subsection (e)(3)(B), other than the period described in clause (iii) of such subsection) in a year shall take effect as of the first day of the following year.

(4) OTHER PERIODS.—An election or change of coverage made during any other period under subsection (e)(4) shall take effect in such manner as the Secretary provides in a manner consistent (to the extent practicable) with protecting continuity of health benefit coverage.

(g) GUARANTEED ISSUE AND RENEWAL.—

(1) IN GENERAL.—Except as provided in this subsection, 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.

(2) PRIORITY.—If the Secretary determines that a Medicare+Choice organization, in relation to a Medicare+Choice plan it offers, has a capacity limit and the number of Medicare+Choice eligible individuals who elect the plan under this section exceeds the capacity limit, the organization may limit the election of individuals of the plan under this section but only if priority in election is provided—

(A) first to such individuals as have elected the plan at the time of the determination, and

(B) then to other such individuals in such a manner that does not discriminate, on a basis described in section 1852(b), among the individuals (who seek to elect the plan).

The preceding sentence shall not apply if it would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the medicare population in the service area of the plan.

(3) LIMITATION ON TERMINATION OF ELECTION.—

(A) IN GENERAL.—Subject to subparagraph (B), a Medicare+Choice organization may not for any reason terminate the election of any individual under this section for a Medicare+Choice plan it offers.

(B) BASIS FOR TERMINATION OF ELECTION.—A Medicare+Choice organization may terminate an individual's election under this section with respect to a Medicare+Choice plan it offers if—

(i) any Medicare+Choice monthly basic and supplemental beneficiary premiums required with respect to such plan are not paid on a timely basis (consistent with standards under section 1856 that provide for a grace period for late payment of such premiums),

(ii) the individual has engaged in disruptive behavior (as specified in such standards), or

(iii) the plan is terminated with respect to all individuals under this part in the area in which the individual resides.

(C) CONSEQUENCE OF TERMINATION.—

(i) TERMINATIONS FOR CAUSE.—Any individual whose election is terminated under clause (i) or (ii) of subparagraph (B) is deemed to have elected the original medicare fee-for-service program option described in subsection (a)(1)(A).

(ii) TERMINATION BASED ON PLAN TERMINATION OR SERVICE AREA REDUCTION.—Any individual whose election is terminated under subparagraph (B)(iii) shall have a special election period under subsection (e)(4)(A) in which to change coverage to coverage under another Medicare+Choice plan. Such an individual who fails to make an election during such period is deemed to have chosen to change coverage to the original medicare fee-for-service program option described in subsection (a)(1)(A).

(D) ORGANIZATION OBLIGATION WITH RESPECT TO ELECTION FORMS.—Pursuant to a contract under section 1857, each Medicare+Choice organization receiving an election form under subsection (c)(2) shall transmit to the Secretary (at such time and in such manner as the Secretary may specify) a copy of such form or such other information respecting the election as the Secretary may specify.

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

(1) SUBMISSION.—No marketing material or application form may be distributed by a Medicare+Choice organization to (or for the use of) Medicare+Choice eligible individuals unless—

(A) at least 45 days (or 10 days in the case described in paragraph (5)) before the date of distribution the organization has submitted the material or form to the Secretary for review, and

(B) the Secretary has not disapproved the distribution of such material or form.

(2) REVIEW.—The standards established under section 1856 shall include guidelines for the review of any material or form submitted and under such guidelines the Secretary shall disapprove (or later require the correction of) such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(3) DEEMED APPROVAL (1-STOP SHOPPING).—In the case of material or form that is submitted under paragraph (1)(A) to the Secretary or a regional office of the Department of Health and Human Services and the Secretary or the office has not disapproved the distribution of marketing material or form under

paragraph (1)(B) with respect to a Medicare+Choice plan in an area, the Secretary is deemed not to have disapproved such distribution in all other areas covered by the plan and organization except with regard to that portion of such material or form that is specific only to an area involved.

(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, subject to subsection (j)(2)(C), cash, gifts, prizes, or other monetary rebates as an inducement for enrollment or otherwise;

(B) may include a prohibition against a Medicare+Choice organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual;

(C) shall not permit a Medicare Advantage organization (or the agents, brokers, and other third parties representing such organization) to conduct the prohibited activities described in subsection (j)(1); and

(D) shall only permit a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization) to conduct the activities described in subsection (j)(2) in accordance with the limitations established under such subsection.

(5) SPECIAL TREATMENT OF MARKETING MATERIAL FOLLOWING MODEL MARKETING LANGUAGE.—In the case of marketing material of an organization that uses, without modification, proposed model language specified by the Secretary, the period specified in paragraph (1)(A) shall be reduced from 45 days to 10 days.

(6) REQUIRED INCLUSION OF PLAN TYPE IN PLAN NAME.—For plan years beginning on or after January 1, 2010, a Medicare Advantage organization must ensure that the name of each Medicare Advantage plan offered by the Medicare Advantage organization includes the plan type of the plan (using standard terminology developed by the Secretary).

(7) STRENGTHENING THE ABILITY OF STATES TO ACT IN COLLABORATION WITH THE SECRETARY TO ADDRESS FRAUDULENT OR INAPPROPRIATE MARKETING PRACTICES.—

(A) APPOINTMENT OF AGENTS AND BROKERS.—Each Medicare Advantage organization shall—

(i) only use agents and brokers who have been licensed under State law to sell Medicare Advantage plans offered by the Medicare Advantage organization;

(ii) in the case where a State has a State appointment law, abide by such law; and

(iii) report to the applicable State the termination of any such agent or broker, including the reasons for such termination (as required under applicable State law).

(B) COMPLIANCE WITH STATE INFORMATION REQUESTS.—Each Medicare Advantage organization shall comply in a

timely manner with any request by a State for information regarding the performance of a licensed agent, broker, or other third party representing the Medicare Advantage organization as part of an investigation by the State into the conduct of the agent, broker, or other third party.

(i) EFFECT OF ELECTION OF MEDICARE+CHOICE PLAN OPTION.—

(1) PAYMENTS TO ORGANIZATIONS.—Subject to sections 1852(a)(5), 1853(a)(4), 1853(g), 1853(h), 1886(d)(11), 1886(h)(3)(D), and 1853(m), payments under a contract with a Medicare+Choice organization under section 1853(a) with respect to an individual electing a Medicare+Choice plan offered by the organization shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under parts A and B for items and services furnished to the individual.

(2) ONLY ORGANIZATION ENTITLED TO PAYMENT.—Subject to sections 1853(a)(4), 1853(e), 1853(g), 1853(h), 1857(f)(2), 1858(h), 1886(d)(11), and 1886(h)(3)(D), only the Medicare+Choice organization shall be entitled to receive payments from the Secretary under this title for services furnished to the individual.

(j) PROHIBITED ACTIVITIES DESCRIBED AND LIMITATIONS ON THE CONDUCT OF CERTAIN OTHER ACTIVITIES.—

(1) PROHIBITED ACTIVITIES DESCRIBED.—The following prohibited activities are described in this paragraph:

(A) UNSOLICITED MEANS OF DIRECT CONTACT.—Any unsolicited means of direct contact of prospective enrollees, including soliciting door-to-door or any outbound telemarketing without the prospective enrollee initiating contact.

(B) CROSS-SELLING.—The sale of other non-health related products (such as annuities and life insurance) during any sales or marketing activity or presentation conducted with respect to a Medicare Advantage plan.

(C) MEALS.—The provision of meals of any sort, regardless of value, to prospective enrollees at promotional and sales activities.

(D) SALES AND MARKETING IN HEALTH CARE SETTINGS AND AT EDUCATIONAL EVENTS.—Sales and marketing activities for the enrollment of individuals in Medicare Advantage plans that are conducted—

(i) in health care settings in areas where health care is delivered to individuals (such as physician offices and pharmacies), except in the case where such activities are conducted in common areas in health care settings; and

(ii) at educational events.

(2) LIMITATIONS.—The Secretary shall establish limitations with respect to at least the following:

(A) SCOPE OF MARKETING APPOINTMENTS.—The scope of any appointment with respect to the marketing of a Medicare Advantage plan. Such limitation shall require advance agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement by the Medicare Advantage organization. In the

case where the marketing appointment is in person, such documentation shall be in writing.

(B) CO-BRANDING.—The use of the name or logo of a co-branded network provider on Medicare Advantage plan membership and marketing materials.

(C) LIMITATION OF GIFTS TO NOMINAL DOLLAR VALUE.—The offering of gifts and other promotional items other than those that are of nominal value (as determined by the Secretary) to prospective enrollees at promotional activities.

(D) COMPENSATION.—The use of compensation other than as provided under guidelines established by the Secretary. Such guidelines shall ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.

(E) REQUIRED TRAINING, ANNUAL RETRAINING, AND TESTING OF AGENTS, BROKERS, AND OTHER THIRD PARTIES.—The use by a Medicare Advantage organization of any individual as an agent, broker, or other third party representing the organization that has not completed an initial training and testing program and does not complete an annual retraining and testing program.

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