115TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 115–933
Part 1

LOCAL COVERAGE DETERMINATION CLARIFICATION ACT OF 2018

SEPTEMBER 10, 2018.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BRADY of Texas, from the Committee on Ways and Means, submitted the following

R E P O R T

[To accompany H.R. 3635]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 3635) to amend title XVIII of the Social Security Act in order to improve the process whereby medicare administrative contractors issue local coverage determinations under the Medicare program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

79–006

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 "Local Coverage Determination Clarification Act of 2018".

SEC. 2. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS FOR SPECIFIED LCDS.

(a) LCD DEVELOPMENT PROCESS.—Section 1862(l)(5)(D) of the Social Security Act (42 U.S.C. 1395y(l)(5)(D)) is amended to read as follows:

"(D) PROCESS FOR ISSUING SPECIFIED LOCAL COVERAGE DETERMINATIONS.—

"(i) IN GENERAL.—In the case of a specified local coverage determination (as defined in clause (iii)) within an area by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, such intermediary or carrier must take the following actions with respect to such determination before such determination may take effect:

"(I) Publish on the public Internet website of the intermediary or carrier a proposed version of the specified local coverage determination (in this subparagraph referred to as a 'draft determination'), a written rationale for the draft determination, and a description of all evidence relied upon and considered by the intermediary or carrier in the development of the draft determination.

"(II) Not later than 60 days after the date on which the intermediary or carrier publishes the draft determination in accordance with subclause (I), convene one or more open, public meetings to review the draft determination, receive comments with respect to the draft determination, and secure the advice of an expert panel (such as a carrier advisory committee described in chapter 13 of the Medicare Program Integrity Manual in effect on August 31, 2015) with respect to the draft determination. The intermediary or carrier shall make available means for the public to attend such meetings remotely, such as via teleconference.

"(III) With respect to each meeting convened pursuant to subclause (II), post on the public Internet website of the intermediary or carrier, not later than 14 days after such meeting is convened, a record of the meeting minutes for such meeting.

"(IV) Provide a period for submission of written public comment on such draft determination that begins on the date on which all records required to be posted with respect to such draft determination under subclause (III) are so posted and that is not fewer than 30 days in duration.

"(ii) FINALIZING A SPECIFIED LOCAL COVERAGE DETERMINATION.—A fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A shall, with respect to a specified local coverage determination, post on the public Internet website of the fiscal intermediary or carrier the following information before the specified local coverage determination (in this subparagraph referred to as the 'final determination') takes effect—

"(I) a response to the issues raised at meetings convened pursuant to clause (i)(II) with respect to the draft determination;

"(II) the rationale for the final determination;

"(III) in the case that the intermediary or carrier considered qualifying evidence in the development of the determination that was not described in the written notice provided pursuant to clause (i)(I), a description of such qualifying evidence; and

"(IV) an effective date for the final determination that is not less than 30 days after the date on which such determination is so posted.

"(iii) SPECIFIED LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subparagraph, the term 'specified local coverage determination' means, with respect to a geographic area—

"(I) a new local coverage determination (regardless of whether such determination made by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A and is based upon a specified local coverage determination that previously has been made with respect to another geographic area, or by another such intermediary or carrier);

"(II) a revised local coverage determination for such geographic area that restricts one or more existing coverage criteria for such area (such as by adding non-covered indications to an existing local coverage determination or by deleting previously covered ICD–9 or ICD–10 codes);

"(III) a revised local coverage determination that makes a substantive revision to one or more existing local coverage determinations; or

"(IV) any other local coverage determination specified by the Secretary pursuant to regulations.

"(iv) QUALIFYING EVIDENCE DEFINED.—For purposes of this subparagraph, the term 'qualifying evidence' means either of the following:

"(I) Scientific evidence published in peer-reviewed medical literature, such as randomized clinical trials or other studies.

"(II) A general consensus of the applicable medical community (such as a consensus evinced through a recognized standard of practice in such medical community) that is supported by information provided by a recognized medical authority, such as a professional medical society.".

(b) LCD RECONSIDERATION PROCESS.—Section 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f)) is amended—

(1) in paragraph (2)(A), by inserting "(other than the reconsideration process described in paragraphs (8) and (9))" after "local coverage determination";

(2) in paragraph (5), by inserting "(other than under the reconsideration process described in paragraphs (8) and (9))" after "local coverage determination";

(3) by redesignating paragraph (8) as paragraph (13); and

(4) by inserting after paragraph (7) the following new paragraphs:

"(8) CARRIER OR FISCAL INTERMEDIARY RECONSIDERATION PROCESS FOR SPECIFIED LOCAL COVERAGE DETERMINATIONS.—Upon the filing of a request by an interested party with respect to a specified local coverage determination by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, the intermediary or carrier shall reconsider such determination in accordance with the following process:

"(A) Not later than 30 days after such a request is filed with the fiscal intermediary or carrier by the interested party with respect to such determination, the intermediary or carrier shall—

"(i) determine whether the request is an applicable request; and

"(ii) in the case that the request is not an applicable request, inform the interested party of the reasons why such request is not an applicable request.

"(B) In the case that the intermediary or carrier determines under subparagraph (A) that the request described in such subparagraph is an applicable request, the intermediary or carrier shall, not later than 90 days after the date on which the request was filed with the intermediary or carrier, take the actions described in subparagraphs (C), (D), and (E) with respect to the determination.

"(C) The action described in this subparagraph is the action of specifying whether any of the following statements is applicable to the determination:

"(i) The determination did not apply, or inaccurately applied, qualifying evidence relevant to such determination.

"(ii) The determination used language that exceeded the scope of the intended purpose of the determination.

"(iii) The determination was incorrect in its determination of whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

"(iv) The determination failed to describe, with respect to such an item or service, the clinical conditions to be used for purposes of determining whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

"(v) The determination does not apply with respect to items or services to which it was intended to apply.

"(vi) The determination is erroneous for another reason that the intermediary or carrier identifies.

"(D) The action described in this subparagraph, with respect to the determination, is the action of taking, based on the specification under subparagraph (C) of whether any of the statements in such subparagraph applied to such determination, one or more of the following actions:

"(i) Making no change in the determination.

"(ii) Rescinding a part of the determination (including, as applicable, the entire determination).

"(iii) Modifying the determination to restrict the coverage provided under this title for an item or service that is subject to the determination.

"(iv) Modifying the determination to expand the coverage provided under this title for an item or service that is subject to the determination.

"(E) The action described in this subparagraph is the action of making publicly available a written description of the action taken under subparagraph (D) with respect to the determination.

"(9) AGENCY EVALUATION OF RECONSIDERATION DECISION.—In the case that an interested party that filed an applicable request under paragraph (8) with respect to a specified local coverage determination files with the Secretary, on a date that is not later than 120 days after the date on which an intermediary or carrier takes an action described under paragraph (8)(D) with respect to such determination, an appeal with respect to such decision in such form and manner as the Secretary may require, the Secretary shall, not later than 30 days after such appeal is filed—

"(A) specify which, if any, of the statements in subparagraph (C) of paragraph (8) is applicable to the determination; and

"(B) based on such specification, take one of the actions described in subparagraph (D) of such paragraph with respect to the determination.

The Secretary shall apply subparagraph (A) as though the reference to 'the intermediary or carrier' in clause (vi) of paragraph (8)(C) were a reference to the Secretary.

"(10) RULE OF CONSTRUCTION.—Nothing in paragraph (8) or (9) may be construed as affecting the right of an aggrieved party to file a complaint under paragraph (2)(A) and receive a determination in accordance with the provisions of such paragraph.

"(11) DEFINITIONS APPLICABLE TO PARAGRAPHS (8) AND (9).—For purposes of paragraphs (8) and (9):

"(A) The term 'applicable request' means a request that is submitted in fiscal year 2019 or a subsequent fiscal year, that is solely with respect to a specified local coverage determination, and that includes a description of the rationale for such request and any evidence supporting such request. For purposes of the preceding sentence, the Secretary may not require, as a condition of treating a request with respect to such a determination as an applicable request, that the request contain qualifying evidence that was not considered in the development of such determination.

"(B) The term 'interested party' means, with respect to a specified local coverage determination within an area by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A—

"(i) a provider of services or supplier that, in such area, furnishes, provides, or supplies items or services that are subject to such determination; or

"(ii) an organization that represents such a provider of services or supplier.

"(C) The term 'qualifying evidence' has the meaning given such term by clause (iv) of section 1862(l)(5)(D).

"(D) The term 'specified local coverage determination' has the meaning given such term by clause (iii) of such section.

"(12) REPORT.—Not later than December 31 of each year (beginning with 2019), the Secretary shall submit to Congress a report containing the following:

"(A) The number of requests filed with fiscal intermediaries and carriers under paragraph (8), and the number of appeals filed with the Secretary under paragraph (9), during the 1-year period ending on such date.

"(B) With respect to such requests filed with such intermediaries and carriers under paragraph (8) during such period, the number of times that intermediaries and carriers took, with respect to the actions described in subparagraphs (C) through (E) of such paragraph, each such action.

"(C) With respect to such appeals filed with the Secretary under paragraph (9) during such period, the number of times that the Secretary took, with respect to the actions described in subparagraph (D) of paragraph (8), each such action.

"(D) Recommendations on ways to improve—

"(i) the efficacy and the efficiency of the process described in paragraph (8); and

"(ii) communication with individuals entitled to benefits under part A or enrolled under part B, providers of services, and suppliers regarding such process.".

SEC. 3. PROMULGATION OF REGULATIONS; APPLICATION DATE.

The Secretary of Health and Human Services shall promulgate regulations to carry out paragraph (5)(D) of section 1862(l) of the Social Security Act (42 U.S.C. 1395y(l)), as amended by subsection (a), and paragraphs (8) and (9) of section 1869(f) of such Act (42 U.S.C. 1395ff(f)), as inserted by subsection (b), in such a manner as to ensure that the processes described in such paragraphs are fully implemented by July 1, 2019.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 3635, the "Local Coverage Determination Clarification Act of 2018," as ordered reported by the Committee on Ways and Means on September 5, 2018, would establish transparency, certainty, and consistency for Medicare beneficiaries and providers through codifying and improving the process through which Medicare Administrative Contractors (MACs) make local coverage determinations (LCDs).

The bill would require MACs to institute an open process for developing LCDs, including publicly posting online proposed LCDs and the rationale and evidence relied on for making such determinations; convene open public meetings; solicit input from the public, including an expert panel; and establish a public comment period for developing draft policies and posting responses to comments received. H.R. 3635 would offer beneficiaries, providers, and suppliers a meaningful reconsideration process. Finally, H.R. 3635 would require the Secretary of Health and Human Services (HHS) to provide an annual report detailing the LCD process including the amount of applications and actions taken with respect to reconsideration.

B. BACKGROUND AND NEED FOR LEGISLATION

The Medicare Prescription Drug Improvement and Modernization Act of 2003 made reforms to the Medicare contracting process, including requiring the Secretary to replace private health insurers, previously known as Part A Fiscal Intermediaries (FI), and Part B carriers into a single organization called Medicare Administrative Contractors (MACs). MACs are responsible for processing both Part A and Part B claims and issuing local coverage determinations (LCDs), among other responsibilities.

There are 12 MAC regions throughout the country. MACs use LCDs to determine whether an item or service is covered under Medicare in the particular MAC region. When issuing an LCD, MACs evaluate whether an item or service is reasonable and necessary for Medicare beneficiaries, as required under Section 1862(a)(1)(A) of the Social Security Act. Additionally, MACs enroll

providers, educate them on the program's billing requirements, and answer provider and beneficiary inquiries.

The Committee reiterates that each MAC should review evidence independently before issuing a local coverage determination.While the reported legislation does not specifically address this issue, the Committee remains concerned that action may be necessary to ensure a thorough evidentiary review occurs for LCDs in each region.

C. Legislative History

Background

H.R. 3635 was introduced on August 4, 2017, and was referred to the Committee on Ways and Means and additionally the Committee on Energy and Commerce.

Committee hearings

On March 21, 2018, the Subcommittee on Health held a hearing on the implementation of MACRA, where members engaged the Administration on issues surrounding coverage decisions in Medicare.

On July 17, 2018, the Subcommittee on Oversight held a hearing on combatting fraud in Medicare, where MACs play a key role.

Committee action

The Committee on Ways and Means marked up H.R. 3635, the "Local Coverage Determination Act of 2018," on September 5, 2018, and ordered the bill, as amended, favorably reported (with a quorum being present).

II. EXPLANATION OF THE BILL

A. Local Coverage Determination Clarification Act of 2018

PRESENT LAW

Present law allows for the LCD process to be determined through regulation by the Centers for Medicare and Medicaid Services (CMS).

REASONS FOR CHANGE

While the regulations for the LCD process are described in detail in the CMS Program Integrity Manual, enhanced clarity and transparency is necessary in the LCD process, whether issuing a positive or negative determination.Placing these transparency requirements into statute will ensure that the process is fair.

EXPLANATION OF PROVISIONS

Section 1: Short Title: "Local Coverage Determination Clarification Act of 2018".

Section 2: Improvements in the Medicare Local Coverage (LCD) Process for Specified LCDs.

LCD development process

Open Meetings and Comment Period: This provision would require MACs to convene open, public meetings on a draft LCD, receive comments, and solicit expert advice, such as a Carrier Advi-

sory Committee. The public meetings would be recorded, with minutes posted on the MAC's website.

Upfront Disclosure: This provision would require MACs to make publicly available online a description of the rationale for the LCD, the evidence the MAC considered when developing the LCD, and a response to public comments on the LCD.

Meaningful reconsideration and options for appeal

This provision would create a reconsideration process for providers and suppliers to appeal a MAC's decision. The bill would also create a pathway for providers and suppliers to appeal an LCD to the Secretary of the Department of HHS. Nothing in this bill prevents an eligible aggrieved party, including patients, from availing themselves of an administrative law judge.

Report to Congress

This provision requires an annual report that would:

- Publicize information about the number of appeals filed with the MAC and CMS each year and the actions MACs take with respect to: (1) the appeals filed, (2) the number of times the Secretary took action in response to appeals filed with HHS, and (3) the responsiveness of the MACs
- Deliver recommendations to the Secretary on ways to improve the efficiency of the appeals process.

Section 3: Promulgation of Regulations; Application Date.

EFFECTIVE DATE

The Secretary will ensure that these processes are implemented by January 1, 2020.

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. 3635, the"Local Coverage Determination Clarification Act of 2018," on September 5, 2018.

The Chairman's amendment in the nature of a substitute was adopted by a voice vote (with a quorum being present).

The bill, H.R. 3635, was ordered favorably reported as amended by 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. 3635, 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 in-

volves no new or 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, September 10, 2018.

Hon. Kevin Brady,
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. 3635, the Local Coverage Determination Clarification Act of 2017.

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

Sincerely,

Keith Hall,
Director.

Enclosure.

H.R. 3635—Local Coverage Determination Clarification Act of 2017

Summary: H.R. 3635 would modify some processes by which private contractors develop coverage and payment policies within the Medicare program. CBO estimates that enacting the bill would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. H.R. 3635 would not affect spending subject to appropriation.

CBO estimates that enacting H.R. 3635 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

H.R. 3635 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Basis of estimate: Under current law, private entities known as Medicare Administrative Contractors (MACs) perform many activities necessary to manage Parts A and B of Medicare—the parts of the program that cover hospitalization, physician visits, and other inpatient and outpatient care.[1] The MACs determine Medicare coverage and payment parameters (local coverage decisions or LCDs) for health care services when there is no nationwide policy (national coverage decision or NCD). A contractor's LCDs are effective only for its geographic region and they must be consistent with the Medicare statute and NCDs.

H.R. 3635 would modify some of the processes that MACs use when promulgating LCDs. For example, MACs would be required to publish draft LCDs on a public website and convene public meetings about draft decisions within 60 days. MACs would also have

[1] Private health plans and firms separately manage Medicare Advantage (Part C) and the outpatient drug benefit (Part D). More information on MACs is available at https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC.html.

to publish responses to public comments and establish a process for responding to requests for review and reconsideration of LCDs. Some of the bill's requirements, such as public posting of draft LCDs, are substantially similar to existing MAC activities.

CBO estimates that the Centers for Medicare and Medicaid Services (CMS) and the MACs would not spend significant additional resources to meet the requirements of H.R. 3635. In addition, CBO does not expect any change in coverage of or payment for Medicare services, so H.R. 3635 would not affect direct spending.

Pay-As-You-Go considerations: None.

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 3635 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

Mandates: H.R. 3635 contains no intergovernmental or private-sector mandates as defined in UMRA.

Estimate prepared by: Federal costs: Lara Robillard, Mandates: Andrew Laughlin.

Estimate reviewed by: Tom Bradley, Chief, Medicare and Health Systems Cost Estimate Unit; Susan Willie, Chief, Mandates Unit; Theresa Gullo, 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, the Committee made findings and recommendations that are reflected in this report.

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 Domestic 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. CORRESPONDENCE

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

September 7, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden,

I write to you regarding several health bills the Committee on Ways and Means ordered favorably reported to the House. The following bills were also referred to the Committee on Energy and Commerce.

I ask that the Committee on Energy and Commerce waive formal consideration of the following bills so that they may proceed expeditiously to the House Floor:

- H.R. 6662, Empowering Seniors' Enrollment Decision Act of 2018;
- H.R. 6690, Fighting Fraud to Protect Care for Seniors Act of 2018;
- H.R. 6561, Comprehensive Care for Seniors Act of 2018; and
- H.R. 3635, Local Coverage Determination Clarification Act of 2018.

I acknowledge that by waiving formal consideration of the bills, the Committee on Energy and Commerce is in no way waiving its jurisdiction over the subject matter contained in those provisions of the bills that fall within your Rule X jurisdiction. I would support your effort to seek appointment of an appropriate number of conferees on any House-Senate conference involving this legislation.

I will include a copy of our letters in the *Congressional Record* during consideration of this legislation on the House floor.

Sincerely,

Kevin Brady
Chairman

cc: The Honorable Paul Ryan, Speaker
The Honorable Richard E. Neal
The Honorable Frank Pallone
Thomas J. Wickham, Jr., Parliamentarian

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

September 7, 2018

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Brady:

Thank you for your letter regarding H.R. 3635, Local Coverage Determination Clarification Act of 2018; H.R. 6561, Comprehensive Care for Seniors Act of 2018; H.R. 6662, Empowering Seniors' Enrollment Decision Act of 2018; and H.R. 6690, Fighting Fraud to Protect Care for Seniors Act of 2018.

The Committee on Energy and Commerce will forgo consideration of both bills so that they may proceed expeditiously to the House Floor.

I appreciate your assurance that by forgoing action on these bills, the Committee is in no way waiving its jurisdiction over the subject matter contained in the bills. I also appreciate your offer of support for the appointment of conferees from the Committee to any House-Senate conference involving this legislation.

Sincerely,

Greg Walden
Chairman

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

A. 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):

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and 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 E—MISCELLANEOUS PROVISIONS

* * * * * * *

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1)), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1861(s)(10), which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6),

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1834(c)(2) or which is not conducted by a facility described in section 1834(c)(1)(B), in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1861(nn), and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu),

(G) in the case of prostate cancer screening tests (as defined in section 1861(oo)), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d),

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive area under section 1847B, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B,

(L) in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1)), which are performed more frequently than is covered under section 1861(xx)(2),

(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3),

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA),

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg)), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1861(hhh)(1)), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this Act and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1861(aa)(1), in the case of Federally qualified health center services, as defined in section 1861(aa)(3), in the case of services for which payment may be made under section 1880(e), and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1814(f) and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this title, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12);

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and

services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of title XI) or a carrier under section 1842 has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1848(i)(2)(B) applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997;

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a)) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1888(e)(2)(A)(i) and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1802(b);

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A)), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1861) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for 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 is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier (as defined in section 1861(d)), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B);

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) MEDICARE AS SECONDARY PAYER.—

(1) REQUIREMENTS OF GROUP HEALTH PLANS.—

(A) WORKING AGED UNDER GROUP HEALTH PLANS.—

(i) IN GENERAL.—A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a), and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) EXCLUSION OF GROUP HEALTH PLAN OF A SMALL EMPLOYER.—Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar

weeks in the current calendar year or the preceding calendar year.

(iii) EXCEPTION FOR SMALL EMPLOYERS IN MULTIEMPLOYER OR MULTIPLE EMPLOYER GROUP HEALTH PLANS.—Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(v) GROUP HEALTH PLAN DEFINED.—In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code

(B) DISABLED INDIVIDUALS IN LARGE GROUP HEALTH PLANS.—

(i) IN GENERAL.—A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(b).

(ii) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(iii) LARGE GROUP HEALTH PLAN DEFINED.—In this subparagraph, the term "large group health plan" has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code.

(C) INDIVIDUALS WITH END STAGE RENAL DISEASE.—A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is entitled to or eligible for benefits under this title under section 226A during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the pro-

visions of section 226A, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section 226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18- month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears.

(D) TREATMENT OF CERTAIN MEMBERS OF RELIGIOUS ORDERS.—In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.

(E) GENERAL PROVISIONS.—For purposes of this subsection:

(i) AGGREGATION RULES.—

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of such Code.

In applying sections of the Internal Revenue Code of 1986 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) CURRENT EMPLOYMENT STATUS DEFINED.—An individual has "current employment status" with an employer if the individual is an employee, is the em-

ployer, or is associated with the employer in a business relationship.

(iii) TREATMENT OF SELF-EMPLOYED PERSONS AS EMPLOYERS.—The term "employer" includes a self-employed person.

(F) LIMITATION ON BENEFICIARY LIABILITY.—An individual who is entitled to benefits under this title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) MEDICARE SECONDARY PAYER.—

(A) IN GENERAL.—Payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In the subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) CONDITIONAL PAYMENT.—

(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) REPAYMENT REQUIRED.—Subject to paragraph (9), a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's com-

promise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) ACTION BY UNITED STATES.—In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan. An action may not be brought by the United States under this clause with respect to payment owed unless the complaint is filed not later than 3 years after the date of the receipt of notice of a settlement, judgment, award, or other payment made pursuant to paragraph (8) relating to such payment owed.

(iv) SUBROGATION RIGHTS.—The United States shall be subrogated (to the extent of payment made under this title for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) WAIVER OF RIGHTS.—The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Sec-

retary determines that the waiver is in the best interests of the program established under this title.

(vi) CLAIMS-FILING PERIOD.—Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(vii) USE OF WEBSITE TO DETERMINE FINAL CONDITIONAL REIMBURSEMENT AMOUNT.—

(I) NOTICE TO SECRETARY OF EXPECTED DATE OF A SETTLEMENT, JUDGMENT, ETC.—In the case of a payment made by the Secretary pursuant to clause (i) for items and services provided to the claimant, the claimant or applicable plan (as defined in paragraph (8)(F)) may at any time beginning 120 days before the reasonably expected date of a settlement, judgment, award, or other payment, notify the Secretary that a payment is reasonably expected and the expected date of such payment.

(II) SECRETARIAL PROVIDING ACCESS TO CLAIMS INFORMATION THROUGH A WEBSITE.—The Secretary shall maintain and make available to individuals to whom items and services are furnished under this title (and to authorized family or other representatives recognized under regulations and to an applicable plan which has obtained the consent of the individual) access to information on the claims for such items and services (including payment amounts for such claims), including those claims that relate to a potential settlement, judgment, award, or other payment. Such access shall be provided to an individual, representative, or plan through a website that requires a password to gain access to the information. The Secretary shall update the information on claims and payments on such website in as timely a manner as possible but not later than 15 days after the date that payment is made. Information related to claims and payments subject to the notice under subclause (I) shall be maintained and made available consistent with the following:

(aa) The information shall be as complete as possible and shall include provider or supplier name, diagnosis codes (if any), dates of service, and conditional payment amounts.

(bb) The information accurately identifies those claims and payments that are related to a potential settlement, judgment, award, or

other payment to which the provisions of this subsection apply.

(cc) The website provides a method for the receipt of secure electronic communications with the individual, representative, or plan involved.

(dd) The website provides that information is transmitted from the website in a form that includes an official time and date that the information is transmitted.

(ee) The website shall permit the individual, representative, or plan to download a statement of reimbursement amounts (in this clause referred to as a "statement of reimbursement amount") on payments for claims under this title relating to a potential settlement, judgment, award, or other payment.

(III) USE OF TIMELY WEB DOWNLOAD AS BASIS FOR FINAL CONDITIONAL AMOUNT.—If an individual (or other claimant or applicable plan with the consent of the individual) obtains a statement of reimbursement amount from the website during the protected period as defined in subclause (V) and the related settlement, judgment, award or other payment is made during such period, then the last statement of reimbursement amount that is downloaded during such period and within 3 business days before the date of the settlement, judgment, award, or other payment shall constitute the final conditional amount subject to recovery under clause (ii) related to such settlement, judgment, award, or other payment.

(IV) RESOLUTION OF DISCREPANCIES.—If the individual (or authorized representative) believes there is a discrepancy with the statement of reimbursement amount, the Secretary shall provide a timely process to resolve the discrepancy. Under such process the individual (or representative) must provide documentation explaining the discrepancy and a proposal to resolve such discrepancy. Within 11 business days after the date of receipt of such documentation, the Secretary shall determine whether there is a reasonable basis to include or remove claims on the statement of reimbursement. If the Secretary does not make such determination within the 11 business-day period, then the proposal to resolve the discrepancy shall be accepted. If the Secretary determines within such period that there is not a reasonable basis to include or remove claims on the statement of reimbursement, the proposal shall be rejected. If the Secretary determines within such period that there is a reasonable basis to conclude there is a discrepancy, the Secretary must respond in a timely manner by agreeing to the proposal to re-

solve the discrepancy or by providing documentation showing with good cause why the Secretary is not agreeing to such proposal and establishing an alternate discrepancy resolution. In no case shall the process under this subclause be treated as an appeals process or as establishing a right of appeal for a statement of reimbursement amount and there shall be no administrative or judicial review of the Secretary's determinations under this subclause.

(V) PROTECTED PERIOD.—In subclause (III), the term "protected period" means, with respect to a settlement, judgment, award or other payment relating to an injury or incident, the portion (if any) of the period beginning on the date of notice under subclause (I) with respect to such settlement, judgment, award, or other payment that is after the end of a Secretarial response period beginning on the date of such notice to the Secretary. Such Secretarial response period shall be a period of 65 days, except that such period may be extended by the Secretary for a period of an additional 30 days if the Secretary determines that additional time is required to address claims for which payment has been made. Such Secretarial response period shall be extended and shall not include any days for any part of which the Secretary determines (in accordance with regulations) that there was a failure in the claims and payment posting system and the failure was justified due to exceptional circumstances (as defined in such regulations). Such regulations shall define exceptional circumstances in a manner so that not more than 1 percent of the repayment obligations under this subclause would qualify as exceptional circumstances.

(VI) EFFECTIVE DATE.—The Secretary shall promulgate final regulations to carry out this clause not later than 9 months after the date of the enactment of this clause.

(VII) WEBSITE INCLUDING SUCCESSOR TECHNOLOGY.—In this clause, the term "website" includes any successor technology.

(viii) RIGHT OF APPEAL FOR SECONDARY PAYER DETERMINATIONS RELATING TO LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—The Secretary shall promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this title for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan (as defined in paragraph (8)(F)) that is a primary plan under subsection (A)(ii), under which the applicable plan involved, or an attorney, agent, or third party administrator on behalf

of such plan, may appeal such determination. The individual furnished such an item or service shall be notified of the plan's intent to appeal such determination

(C) TREATMENT OF QUESTIONNAIRES.—The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) ENFORCEMENT.—

(A) PRIVATE CAUSE OF ACTION.—There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) REFERENCE TO EXCISE TAX WITH RESPECT TO NONCONFORMING GROUP HEALTH PLANS.—For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of the Internal Revenue Code of 1986.

(C) PROHIBITION OF FINANCIAL INCENTIVES NOT TO ENROLL IN A GROUP HEALTH PLAN OR A LARGE GROUP HEALTH PLAN.—It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this title not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(4) COORDINATION OF BENEFITS.—Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this title (without regard to deductibles and coinsurance under this title) for the remainder of such charge, but—

(A) payment under this title may not exceed an amount which would be payable under this title for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this title, when combined with the amount payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this title on the basis of reasonable cost (or other cost-related basis) or under section 1886, the amount which would be payable under this title on such basis, and

(ii) in the case of an item or service for which payment is authorized under this title on another basis—

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this title (without regard to deductibles and coinsurance under this title),

whichever is greater.

(5) IDENTIFICATION OF SECONDARY PAYER SITUATIONS.—

(A) REQUESTING MATCHING INFORMATION.—

(i) COMMISSIONER OF SOCIAL SECURITY.—The Commissioner of Social Security shall, not less often that annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(l)(12) of the Internal Revenue Code of 1986) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) ADMINISTRATOR.—The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of section 6103(l)(12) of the Internal Revenue Code of 1986.

(B) DISCLOSURE TO FISCAL INTERMEDIARIES AND CARRIERS.—In addition to any other information provided under this title to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) CONTACTING EMPLOYERS.—

(i) IN GENERAL.—With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) EMPLOYER RESPONSE.—Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of

not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provision of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) OBTAINING INFORMATION FROM BENEFICIARIES.—Before an individual applies for benefits under part A or enrolls under part B, the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(E) END DATE.—The provisions of this paragraph shall not apply to information required to be provided on or after July 1, 2016.

(6) SCREENING REQUIREMENTS FOR PROVIDERS AND SUPPLIERS.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, no payment may be made for any item or service furnished under part B unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) PENALTIES.—An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7) REQUIRED SUBMISSION OF INFORMATION BY GROUP HEALTH PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph, an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall—

(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been a primary plan to the program under this title; and

(ii) submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) ENFORCEMENT.—

(i) IN GENERAL.—An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817.

(C) SHARING OF INFORMATION.—Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary—

(i) shall share information on entitlement under Part A and enrollment under Part B under this title with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii) may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii) may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(8) REQUIRED SUBMISSION OF INFORMATION BY OR ON BEHALF OF LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph, an applicable plan shall—

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this title on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form

and manner (including frequency) specified by the Secretary.

(B) REQUIRED INFORMATION.—The information described in this subparagraph is—

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

Not later than 18 months after the date of enactment of this sentence, the Secretary shall modify the reporting requirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary payer program under this subsection. Any such deadline extension notice shall include information on the progress being made in implementing such modification and the anticipated implementation date for such modification.

(C) TIMING.—Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) CLAIMANT.—For purposes of subparagraph (A), the term "claimant" includes—

(i) an individual filing a claim directly against the applicable plan; and

(ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) ENFORCEMENT.—

(i) IN GENERAL.—An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant may be subject to a civil money penalty of up to $1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) APPLICABLE PLAN.—In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) SHARING OF INFORMATION.—The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(H) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(I) REGULATIONS.—Not later than 60 days after the date of the enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for the specification of practices for which sanctions will and will not be imposed under subparagraph (E), including not imposing sanctions for good faith efforts to identify a beneficiary pursuant to this paragraph under an applicable entity responsible for reporting information. After considering the proposals so submitted, the Secretary, in consultation with the Attorney General, shall publish in the Federal Register, including a 60-day period for comment, proposed specified practices for which such sanctions will and will not be imposed. After considering any public comments received during such period, the Secretary shall issue final rules specifying such practices.

(9) EXCEPTION.—

(A) IN GENERAL.—Clause (ii) of paragraph (2)(B) and any reporting required by paragraph (8) shall not apply with respect to any settlement, judgment, award, or other payment by an applicable plan arising from liability insurance (including self-insurance) and from alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) constituting a total payment obligation to a claimant of not more than the single threshold amount calculated by the Secretary under subparagraph (B) for the year involved.

(B) ANNUAL COMPUTATION OF THRESHOLD.—

(i) IN GENERAL.—Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single threshold amount for a year shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject

to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for 2014, the Secretary shall inform, and seek review of, the Comptroller General of the United States with regard to such amount.

(ii) PUBLICATION.—The Secretary shall include, as part of such publication for a year—

(I) the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents; and

(II) a summary of the methodology and data used by the Secretary in computing such threshold amount and such cost of collection.

(C) EXCLUSION OF ONGOING EXPENSES.—For purposes of this paragraph and with respect to a settlement, judgment, award, or other payment not otherwise addressed in clause (ii) of paragraph (2)(B) that includes ongoing responsibility for medical payments (excluding settlements, judgments, awards, or other payments made by a workers' compensation law or plan or no fault insurance), the amount utilized for calculation of the threshold described in subparagraph (A) shall include only the cumulative value of the medical payments made under this title.

(D) REPORT TO CONGRESS.—Not later than November 15 before each year, the Secretary shall submit to the Congress a report on the single threshold amount for settlements, judgments, awards, or other payments for conditional payment obligations arising from liability insurance (including self-insurance) and alleged incidents described in subparagraph (A) for that year and on the establishment and application of similar thresholds for such payments for conditional payment obligations arising from worker compensation cases and from no fault insurance cases subject to this section for the year. For each such report, the Secretary shall—

(i) calculate the threshold amount by using the methodology applicable to certain liability claims described in subparagraph (B); and

(ii) include a summary of the methodology and data used in calculating each threshold amount and the amount of estimated savings under this title achieved by the Secretary implementing each such threshold.

(c) No payment may be made under part B for any expenses incurred for—

(1) a drug product—

(A) which is described in section 107(c)(3) of the Drug Amendments of 1962,

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

(D) for which the Secretary has not determined there is a compelling justification for its medical need; and

(2) any other drug product—

(A) which is identical, related, or similar (as determined in accordance with section 310.6 of title 21 of the Code of Federal Regulations) to a drug product described in paragraph (1), and

(B) for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e)(1) No payment may be made under this title with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this title submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this title, pursuant to section 1128, 1128A, 1156, 1160 (as in effect on September 2, 1982), 1842(j)(2), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or l866, and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this title, and notwith-

standing such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection (a), under part A or part B for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g) The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with quality improvement organizations pursuant to part B of title XI of this Act.

(h)(1) The Secretary—

(A) shall waive the application of subsection (a)(22) in cases in which—

(i) there is no method available for the submission of claims in an electronic form; or

(ii) the entity submitting the claim is a small provider of services or supplier; and

(B) may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term "small provider of services or supplier" means—

(A) a provider of services with fewer than 25 full-time equivalent employees; or

(B) a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) with respect to such a procedure if the Secretary finds that—

(1) such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2) research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3) such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

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

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

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

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

(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

(l) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—

(A) PERIOD FOR PROPOSED DECISION.—Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a re-

quest for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-DAY PERIOD FOR FINAL DECISION.—Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

(i) make a final decision on the request;

(ii) include in such final decision summaries of the public comments received and responses to such comments;

(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

(5) LOCAL COVERAGE DETERMINATION PROCESS.—

(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

[(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

[(i) Such determination in its entirety.

[(ii) Where and when the proposed determination was first made public.

[(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

[(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

[(v) An explanation of the rationale that supports such determination.]

(D) PROCESS FOR ISSUING SPECIFIED LOCAL COVERAGE DETERMINATIONS.—

(i) IN GENERAL.—In the case of a specified local coverage determination (as defined in clause (iii)) within an area by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, such intermediary or carrier must take the following actions with respect to such determination before such determination may take effect:

(I) Publish on the public Internet website of the intermediary or carrier a proposed version of the specified local coverage determination (in this subparagraph referred to as a "draft determination"), a written rationale for the draft determination, and a description of all evidence relied upon and considered by the intermediary or carrier in the development of the draft determination.

(II) Not later than 60 days after the date on which the intermediary or carrier publishes the draft determination in accordance with subclause (I), convene one or more open, public meetings to review the draft determination, receive comments with respect to the draft determination, and secure the advice of an expert panel (such as a carrier advisory committee described in chapter 13 of the Medicare Program Integrity Manual in effect on August 31, 2015) with respect to the draft determination. The intermediary or carrier shall make available means for the public to attend such meetings remotely, such as via teleconference.

(III) With respect to each meeting convened pursuant to subclause (II), post on the public Internet website of the intermediary or carrier, not later than 14 days after such meeting is convened, a record of the meeting minutes for such meeting.

(IV) Provide a period for submission of written public comment on such draft determination that begins on the date on which all records required to be posted with respect to such draft determination under subclause (III) are so posted and that is not fewer than 30 days in duration.

(ii) FINALIZING A SPECIFIED LOCAL COVERAGE DETERMINATION.—A fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A shall, with respect to a specified local coverage determination, post on the public Internet website of the fiscal intermediary or carrier the following infor-

mation before the specified local coverage determination (in this subparagraph referred to as the "final determination") takes effect—

(I) a response to the issues raised at meetings convened pursuant to clause (i)(II) with respect to the draft determination;

(II) the rationale for the final determination;

(III) in the case that the intermediary or carrier considered qualifying evidence in the development of the determination that was not described in the written notice provided pursuant to clause (i)(I), a description of such qualifying evidence; and

(IV) an effective date for the final determination that is not less than 30 days after the date on which such determination is so posted.

(iii) SPECIFIED LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subparagraph, the term "specified local coverage determination" means, with respect to a geographic area—

(I) a new local coverage determination (regardless of whether such determination made by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A and is based upon a specified local coverage determination that previously has been made with respect to another geographic area, or by another such intermediary or carrier);

(II) a revised local coverage determination for such geographic area that restricts one or more existing coverage criteria for such area (such as by adding non-covered indications to an existing local coverage determination or by deleting previously covered ICD–9 or ICD–10 codes);

(III) a revised local coverage determination that makes a substantive revision to one or more existing local coverage determinations; or

(IV) any other local coverage determination specified by the Secretary pursuant to regulations.

(iv) QUALIFYING EVIDENCE DEFINED.—For purposes of this subparagraph, the term "qualifying evidence" means either of the following:

(I) Scientific evidence published in peer-reviewed medical literature, such as randomized clinical trials or other studies.

(II) A general consensus of the applicable medical community (such as a consensus evinced through a recognized standard of practice in such medical community) that is supported by information provided by a recognized medical authority, such as a professional medical society.

(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection—

(A) NATIONAL COVERAGE DETERMINATION.—The term "national coverage determination" means a determination by the Secretary with respect to whether or not a par-

ticular item or service is covered nationally under this title.

(B) LOCAL COVERAGE DETERMINATION.—The term "local coverage determination" has the meaning given that in section 1869(f)(2)(B).

(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

(1) IN GENERAL.—In the case of an individual entitled to benefits under part A, or enrolled under part B, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) CATEGORY A CLINICAL TRIAL.—For purposes of paragraph (1), a "category A clinical trial" means a trial of a medical device if—

(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

(n) REQUIREMENT OF A SURETY BOND FOR CERTAIN PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) IN GENERAL.—The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

(2) PROVIDER OF SERVICES OR SUPPLIER DESCRIBED.—A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1834(a)(16)(B) and 1861(o)(7)(C).

(o) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD.—

(1) IN GENERAL.—The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

(2) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Serv-

ices in determining whether there is a credible allegation of fraud against a provider of services or supplier.

(3) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out this subsection and section 1903(i)(2)(C).

* * * * * * *

DETERMINATIONS; APPEALS

SEC. 1869. (a) INITIAL DETERMINATIONS.—

(1) PROMULGATIONS OF REGULATIONS.—The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A or part B in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a quality improvement organization under section 1154(a)(2), and an initial determination made by an entity pursuant to a contract (other than a contract under section 1852) with the Secretary to administer provisions of this title or title XI.

(2) DEADLINES FOR MAKING INITIAL DETERMINATIONS.—

(A) IN GENERAL.—Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits from an individual as described in paragraph (1). Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 45-day period.

(B) CLEAN CLAIMS.—Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1816(c)(2) or 1842(c)(2).

(3) REDETERMINATIONS.—

(A) IN GENERAL.—In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) LIMITATIONS.—

(i) APPEAL RIGHTS.—No initial determination may be reconsidered or appealed under subsection (b) unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) DECISIONMAKER.—No redetermination may be made by any individual involved in the initial determination.

(C) DEADLINES.—

(i) FILING FOR REDETERMINATION.—A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) CONCLUDING REDETERMINATIONS.—Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) CONSTRUCTION.—For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the determination shall include—

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the redetermination shall include—

(i) the specific reasons for the redetermination;

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) APPEAL RIGHTS.—

(1) IN GENERAL.—

(A) RECONSIDERATION OF INITIAL DETERMINATION.—Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 205(b) and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g). For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (l) of section 205 shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

(B) REPRESENTATION BY PROVIDER OR SUPPLIER.—

(i) IN GENERAL.—Sections 206(a), 1102, and 1871 shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this section by a person that furnishes or supplies the individual, directly or indirectly, with services or items, solely on the basis that the person furnishes or supplies the individual with such a service or item.

(ii) MANDATORY WAIVER OF RIGHT TO PAYMENT FROM BENEFICIARY.—Any person that furnishes services or items to an individual may not represent an individual under this section with respect to the issue described in section 1879(a)(2) unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal.

(iii) PROHIBITION ON PAYMENT FOR REPRESENTATION.—If a person furnishes services or items to an individual and represents the individual under this section, the person may not impose any financial liability on such individual in connection with such representation.

(iv) REQUIREMENTS FOR REPRESENTATIVES OF A BENEFICIARY.—The provisions of section 205(j) and of section 206 (other than subsection (a)(4) of such section) regarding representation of claimants shall apply to representation of an individual with respect to appeals under this section in the same manner as they apply

to representation of an individual under those sections.

(C) SUCCESSION OF RIGHTS IN CASES OF ASSIGNMENT.—The right of an individual to an appeal under this section with respect to an item or service may be assigned to the provider of services or supplier of the item or service upon the written consent of such individual using a standard form established by the Secretary for such an assignment.

(D) TIME LIMITS FOR FILING APPEALS.—

(i) RECONSIDERATIONS.—Reconsideration under subparagraph (A) shall be available only if the individual described in subparagraph (A) files notice with the Secretary to request reconsideration by not later than the end of the 180-day period beginning on the date the individual receives notice of the redetermination under subsection (a)(3), or within such additional time as the Secretary may allow.

(ii) HEARINGS CONDUCTED BY THE SECRETARY.—The Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 205 and 206.

(E) AMOUNTS IN CONTROVERSY.—

(i) IN GENERAL.—A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than $100, and judicial review shall not be available to the individual if the amount in controversy is less than $1,000.

(ii) AGGREGATION OF CLAIMS.—In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve—

(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or

(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

(iii) ADJUSTMENT OF DOLLAR AMOUNTS.—For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(F) EXPEDITED PROCEEDINGS.—

(i) EXPEDITED DETERMINATION.—In the case of an individual who has received notice from a provider of services that such provider plans—

(I) to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or

(II) to discharge the individual from the provider of services,

the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1), as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

(ii) REFERENCE TO EXPEDITED ACCESS TO JUDICIAL REVIEW.—For the provision relating to expedited access to judicial review, see paragraph (2).

(G) REOPENING AND REVISION OF DETERMINATIONS.—The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

(C) ACCESS TO JUDICIAL REVIEW.—

(i) IN GENERAL.—If the appropriate review entity—

(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B),

then the appellant may bring a civil action as described in this subparagraph.

(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

(iv) INTEREST ON ANY AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this title.

(D) REVIEW ENTITY DEFINED.—For purposes of this subsection, the term "review entity" means an entity of up to three reviewers who are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.

(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(c) CONDUCT OF RECONSIDERATIONS BY INDEPENDENT CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into contracts with qualified independent contractors to conduct reconsiderations of initial determinations made under subparagraphs (B) and (C) of subsection (a)(1). Contracts shall be for an initial term of three years and shall be renewable on a triennial basis thereafter.

(2) QUALIFIED INDEPENDENT CONTRACTOR.—For purposes of this subsection, the term "qualified independent contractor" means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1), and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) REQUIREMENTS.—Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) IN GENERAL.—The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing to make reconsiderations under this subsection.

(B) RECONSIDERATIONS.—

(i) IN GENERAL.—The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.

(ii) EFFECT OF NATIONAL AND LOCAL COVERAGE DETERMINATIONS.—

(I) NATIONAL COVERAGE DETERMINATIONS.—If the Secretary has made a national coverage determination pursuant to the requirements established under the third sentence of section 1862(a), such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section.

(II) LOCAL COVERAGE DETERMINATIONS.—If the Secretary has made a local coverage determination, such determination shall not be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section. Notwithstanding the previous sentence, the qualified independent contractor shall consider the local coverage determination in making such decision.

(III) ABSENCE OF NATIONAL OR LOCAL COVERAGE DETERMINATION.—In the absence of such a national coverage determination or local coverage determination, the qualified independent contractor shall make a decision with respect to the reconsid-

eration based on applicable information, including clinical experience and medical, technical, and scientific evidence.

(C) DEADLINES FOR DECISIONS.—

(i) RECONSIDERATIONS.—Except as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration under subparagraph (B), and mail the notice of the decision with respect to the reconsideration by not later than the end of the 60-day period beginning on the date a request for reconsideration has been timely filed.

(ii) CONSEQUENCES OF FAILURE TO MEET DEADLINE.—In the case of a failure by the qualified independent contractor to mail the notice of the decision by the end of the period described in clause (i) or to provide notice by the end of the period described in clause (iii), as the case may be, the party requesting the reconsideration or appeal may request a hearing before the Secretary, notwithstanding any requirements for a reconsidered determination for purposes of the party's right to such hearing.

(iii) EXPEDITED RECONSIDERATIONS.—The qualified independent contractor shall perform an expedited reconsideration under subsection (b)(1)(F) as follows:

(I) DEADLINE FOR DECISION.—Notwithstanding section 216(j) and subject to clause (iv), not later than the end of the 72-hour period beginning on the date the qualified independent contractor has received a request for such reconsideration and has received such medical or other records needed for such reconsideration, the qualified independent contractor shall provide notice (by telephone and in writing) to the individual and the provider of services and attending physician of the individual of the results of the reconsideration. Such reconsideration shall be conducted regardless of whether the provider of services or supplier will charge the individual for continued services or whether the individual will be liable for payment for such continued services.

(II) CONSULTATION WITH BENEFICIARY.—In such reconsideration, the qualified independent contractor shall solicit the views of the individual involved.

(III) SPECIAL RULE FOR HOSPITAL DISCHARGES.—A reconsideration of a discharge from a hospital shall be conducted under this clause in accordance with the provisions of paragraphs (2), (3), and (4) of section 1154(e) as in effect on the date that precedes the date of the enactment of this subparagraph.

(iv) EXTENSION.—An individual requesting a reconsideration under this subparagraph may be granted such additional time as the individual specifies (not to

exceed 14 days) for the qualified independent contractor to conclude the reconsideration. The individual may request such additional time orally or in writing.

(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).

(E) EXPLANATION OF DECISION.—Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate) and shall include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section and in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)) an explanation of the medical and scientific rationale for the decision.

(F) NOTICE REQUIREMENTS.—Whenever a qualified independent contractor makes a decision with respect to a reconsideration under this subsection, the qualified independent contractor shall promptly notify the entity responsible for the payment of claims under part A or part B of such decision.

(G) DISSEMINATION OF DECISIONS ON RECONSIDERATIONS.—Each qualified independent contractor shall make available all decisions with respect to reconsiderations of such qualified independent contractors to fiscal intermediaries (under section 1816), carriers (under section 1842), quality improvement organizations (under part B of title XI), Medicare+Choice organizations offering Medicare+Choice plans under part C, other entities under contract with the Secretary to make initial determinations under part A or part B or title XI, and to the public. The Secretary shall establish a methodology under which qualified independent contractors shall carry out this subparagraph.

(H) ENSURING CONSISTENCY IN DECISIONS.—Each qualified independent contractor shall monitor its decisions with respect to reconsiderations to ensure the consistency of such decisions with respect to requests for reconsideration of similar or related matters.

(I) DATA COLLECTION.—

(i) IN GENERAL.—Consistent with the requirements of clause (ii), a qualified independent contractor shall collect such information relevant to its functions, and keep and maintain such records in such form and manner as the Secretary may require to carry out the purposes of this section and shall permit access to and use of any such information and records as the Secretary may require for such purposes.

(ii) TYPE OF DATA COLLECTED.—Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) Specific claims that give rise to appeals.

(II) Situations suggesting the need for increased education for providers of services, physicians, or suppliers.

(III) Situations suggesting the need for changes in national or local coverage determination.

(IV) Situations suggesting the need for changes in local coverage determinations.

(iii) ANNUAL REPORTING.—Each qualified independent contractor shall submit annually to the Secretary (or otherwise as the Secretary may request) records maintained under this paragraph for the previous year.

(J) HEARINGS BY THE SECRETARY.—The qualified independent contractor shall (i) submit such information as is required for an appeal of a decision of the contractor, and (ii) participate in such hearings as required by the Secretary.

(K) INDEPENDENCE REQUIREMENTS.—

(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

(I) is not a related party (as defined in subsection (g)(5));

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—The Secretary shall enter into contracts with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection.

(5) LIMITATION ON QUALIFIED INDEPENDENT CONTRACTOR LIABILITY.—No qualified independent contractor having a contract with the Secretary under this subsection and no person

who is employed by, or who has a fiduciary relationship with, any such qualified independent contractor or who furnishes professional services to such qualified independent contractor, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this subsection or to a valid contract entered into under this subsection, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(d) DEADLINES FOR HEARINGS BY THE SECRETARY; NOTICE.—

(1) HEARING BY ADMINISTRATIVE LAW JUDGE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.

(B) WAIVER OF DEADLINE BY PARTY SEEKING HEARING.—The 90-day period under subparagraph (A) shall not apply in the case of a motion or stipulation by the party requesting the hearing to waive such period.

(2) DEPARTMENTAL APPEALS BOARD REVIEW.—

(A) IN GENERAL.—The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.

(B) DAB HEARING PROCEDURE.—In reviewing a decision on a hearing under this paragraph, the Departmental Appeals Board shall review the case de novo.

(3) CONSEQUENCES OF FAILURE TO MEET DEADLINES.—

(A) HEARING BY ADMINISTRATIVE LAW JUDGE.—In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party's right to such a review.

(B) DEPARTMENTAL APPEALS BOARD REVIEW.—In the case of a failure by the Departmental Appeals Board to render a decision by the end of the period described in paragraph (2), the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review.

(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

(e) ADMINISTRATIVE PROVISIONS.—

(1) LIMITATION ON REVIEW OF CERTAIN REGULATIONS.—A regulation or instruction that relates to a method for determining the amount of payment under part B and that was initially issued before January 1, 1981, shall not be subject to judicial review.

(2) OUTREACH.—The Secretary shall perform such outreach activities as are necessary to inform individuals entitled to benefits under this title and providers of services and suppliers with respect to their rights of, and the process for, appeals made under this section. The Secretary shall use the toll-free telephone number maintained by the Secretary under section 1804(b) to provide information regarding appeal rights and respond to inquiries regarding the status of appeals.

(3) CONTINUING EDUCATION REQUIREMENT FOR QUALIFIED INDEPENDENT CONTRACTORS AND ADMINISTRATIVE LAW JUDGES.—The Secretary shall provide to each qualified independent contractor, and, in consultation with the Commissioner of Social Security, to administrative law judges that decide appeals of reconsiderations of initial determinations or other decisions or determinations under this section, such continuing education with respect to coverage of items and services under this title or policies of the Secretary with respect to part B of title XI as is necessary for such qualified independent contractors and administrative law judges to make informed decisions with respect to appeals.

(4) REPORTS.—

(A) ANNUAL REPORT TO CONGRESS.—The Secretary shall submit to Congress an annual report describing the number of appeals for the previous year, identifying issues that require administrative or legislative actions, and including any recommendations of the Secretary with respect to such actions. The Secretary shall include in such report an analysis of determinations by qualified independent contractors with respect to inconsistent decisions and an analysis of the causes of any such inconsistencies.

(B) SURVEY.—Not less frequently than every 5 years, the Secretary shall conduct a survey of a valid sample of individuals entitled to benefits under this title who have filed appeals of determinations under this section, providers of services, and suppliers to determine the satisfaction of such individuals or entities with the process for appeals of determinations provided for under this section and education and training provided by the Secretary with respect to that process. The Secretary shall submit to Congress a report describing the results of the survey, and shall in-

clude any recommendations for administrative or legislative actions that the Secretary determines appropriate.

(f) REVIEW OF COVERAGE DETERMINATIONS.—

(1) NATIONAL COVERAGE DETERMINATIONS.—

(A) IN GENERAL.—Review of any national coverage determination shall be subject to the following limitations:

(i) Such a determination shall not be reviewed by any administrative law judge.

(ii) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of title 5, United States Code, or section 1871(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.

(iii) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services. In conducting such a review, the Departmental Appeals Board—

(I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the Board determines that the record is incomplete or lacks adequate information to support the validity of the determination;

(II) may, as appropriate, consult with appropriate scientific and clinical experts; and

(III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(iv) The Secretary shall implement a decision of the Departmental Appeals Board within 30 days of receipt of such decision.

(v) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) DEFINITION OF NATIONAL COVERAGE DETERMINATION.—For purposes of this section, the term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.

(2) LOCAL COVERAGE DETERMINATION.—

(A) IN GENERAL.—Review of any local coverage determination *(other than the reconsideration process described in paragraphs (8) and (9))* shall be subject to the following limitations:

(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge. The administrative law judge—

(I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the administrative law judge determines that the record is incomplete or lacks adequate information to support the validity of the determination;

(II) may, as appropriate, consult with appropriate scientific and clinical experts; and

(III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(ii) Upon the filing of a complaint by an aggrieved party, a decision of an administrative law judge under clause (i) shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services.

(iii) The Secretary shall implement a decision of the administrative law judge or the Departmental Appeals Board within 30 days of receipt of such decision.

(iv) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) DEFINITION OF LOCAL COVERAGE DETERMINATION.—For purposes of this section, the term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).

(C) LOCAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.—For provisions relating to local coverage determinations for clinical diagnostic laboratory tests, see section 1834A(g).

(3) NO MATERIAL ISSUES OF FACT IN DISPUTE.—In the case of a determination that may otherwise be subject to review under paragraph (1)(A)(iii) or paragraph (2)(A)(i), where the moving party alleges that—

(A) there are no material issues of fact in dispute, and

(B) the only issue of law is the constitutionality of a provision of this title, or that a regulation, determination, or ruling by the Secretary is invalid,

the moving party may seek review by a court of competent jurisdiction without filing a complaint under such paragraph and without otherwise exhausting other administrative remedies.

(4) PENDING NATIONAL COVERAGE DETERMINATIONS.—

(A) IN GENERAL.—In the event the Secretary has not issued a national coverage or noncoverage determination with respect to a particular type or class of items or services, an aggrieved person (as described in paragraph (5)) may submit to the Secretary a request to make such a determination with respect to such items or services. By not later than the end of the 90-day period beginning on the date the Secretary receives such a request (notwithstanding the receipt by the Secretary of new evidence (if

any) during such 90-day period), the Secretary shall take one of the following actions:

(i) Issue a national coverage determination, with or without limitations.

(ii) Issue a national noncoverage determination.

(iii) Issue a determination that no national coverage or noncoverage determination is appropriate as of the end of such 90-day period with respect to national coverage of such items or services.

(iv) Issue a notice that states that the Secretary has not completed a review of the request for a national coverage determination and that includes an identification of the remaining steps in the Secretary's review process and a deadline by which the Secretary will complete the review and take an action described in clause (i), (ii), or (iii).

(B) DEEMED ACTION BY THE SECRETARY.—In the case of an action described in subparagraph (A)(iv), if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have taken an action described in subparagraph (A)(iii) as of the deadline.

(C) EXPLANATION OF DETERMINATION.—When issuing a determination under subparagraph (A), the Secretary shall include an explanation of the basis for the determination. An action taken under clause (i) (other than clause (iv)) is deemed to be a national coverage determination for purposes of review under paragraph (1)(A).

(5) STANDING.—An action under this subsection seeking review of a national coverage determination or local coverage determination *(other than under the reconsideration process described in paragraphs (8) and (9))* may be initiated only by individuals entitled to benefits under part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination.

(6) PUBLICATION ON THE INTERNET OF DECISIONS OF HEARINGS OF THE SECRETARY.—Each decision of a hearing by the Secretary with respect to a national coverage determination shall be made public, and the Secretary shall publish each decision on the Medicare Internet site of the Department of Health and Human Services. The Secretary shall remove from such decision any information that would identify any individual, provider of services, or supplier.

(7) ANNUAL REPORT ON NATIONAL COVERAGE DETERMINATIONS.—

(A) IN GENERAL.—Not later than December 1 of each year, beginning in 2001, the Secretary shall submit to Congress a report that sets forth a detailed compilation of the actual time periods that were necessary to complete and fully implement national coverage determinations that were made in the previous fiscal year for items, services, or medical devices not previously covered as a benefit under this title, including, with respect to each new item, service, or medical device, a statement of the time taken by the Secretary to make and implement the necessary

coverage, coding, and payment determinations, including the time taken to complete each significant step in the process of making and implementing such determinations.

(B) PUBLICATION OF REPORTS ON THE INTERNET.—The Secretary shall publish each report submitted under clause (i) on the medicare Internet site of the Department of Health and Human Services.

(8) CARRIER OR FISCAL INTERMEDIARY RECONSIDERATION PROCESS FOR SPECIFIED LOCAL COVERAGE DETERMINATIONS.—Upon the filing of a request by an interested party with respect to a specified local coverage determination by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, the intermediary or carrier shall reconsider such determination in accordance with the following process:

(A) Not later than 30 days after such a request is filed with the fiscal intermediary or carrier by the interested party with respect to such determination, the intermediary or carrier shall—

(i) determine whether the request is an applicable request; and

(ii) in the case that the request is not an applicable request, inform the interested party of the reasons why such request is not an applicable request.

(B) In the case that the intermediary or carrier determines under subparagraph (A) that the request described in such subparagraph is an applicable request, the intermediary or carrier shall, not later than 90 days after the date on which the request was filed with the intermediary or carrier, take the actions described in subparagraphs (C), (D), and (E) with respect to the determination.

(C) The action described in this subparagraph is the action of specifying whether any of the following statements is applicable to the determination:

(i) The determination did not apply, or inaccurately applied, qualifying evidence relevant to such determination.

(ii) The determination used language that exceeded the scope of the intended purpose of the determination.

(iii) The determination was incorrect in its determination of whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

(iv) The determination failed to describe, with respect to such an item or service, the clinical conditions to be used for purposes of determining whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

(v) The determination does not apply with respect to items or services to which it was intended to apply.

(vi) The determination is erroneous for another reason that the intermediary or carrier identifies.

(D) The action described in this subparagraph, with respect to the determination, is the action of taking, based on

the specification under subparagraph (C) of whether any of the statements in such subparagraph applied to such determination, one or more of the following actions:

(i) Making no change in the determination.

(ii) Rescinding a part of the determination (including, as applicable, the entire determination).

(iii) Modifying the determination to restrict the coverage provided under this title for an item or service that is subject to the determination.

(iv) Modifying the determination to expand the coverage provided under this title for an item or service that is subject to the determination.

(E) The action described in this subparagraph is the action of making publicly available a written description of the action taken under subparagraph (D) with respect to the determination.

(9) AGENCY EVALUATION OF RECONSIDERATION DECISION.—In the case that an interested party that filed an applicable request under paragraph (8) with respect to a specified local coverage determination files with the Secretary, on a date that is not later than 120 days after the date on which an intermediary or carrier takes an action described under paragraph (8)(D) with respect to such determination, an appeal with respect to such decision in such form and manner as the Secretary may require, the Secretary shall, not later than 30 days after such appeal is filed—

(A) specify which, if any, of the statements in subparagraph (C) of paragraph (8) is applicable to the determination; and

(B) based on such specification, take one of the actions described in subparagraph (D) of such paragraph with respect to the determination.

The Secretary shall apply subparagraph (A) as though the reference to "the intermediary or carrier" in clause (vi) of paragraph (8)(C) were a reference to the Secretary.

(10) RULE OF CONSTRUCTION.—Nothing in paragraph (8) or (9) may be construed as affecting the right of an aggrieved party to file a complaint under paragraph (2)(A) and receive a determination in accordance with the provisions of such paragraph.

(11) DEFINITIONS APPLICABLE TO PARAGRAPHS (8) AND (9).—For purposes of paragraphs (8) and (9):

(A) The term "applicable request" means a request that is submitted in fiscal year 2019 or a subsequent fiscal year, that is solely with respect to a specified local coverage determination, and that includes a description of the rationale for such request and any evidence supporting such request. For purposes of the preceding sentence, the Secretary may not require, as a condition of treating a request with respect to such a determination as an applicable request, that the request contain qualifying evidence that was not considered in the development of such determination.

(B) The term "interested party" means, with respect to a specified local coverage determination within an area by a

fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A—

(i) a provider of services or supplier that, in such area, furnishes, provides, or supplies items or services that are subject to such determination; or

(ii) an organization that represents such a provider of services or supplier.

(C) The term "qualifying evidence" has the meaning given such term by clause (iv) of section 1862(l)(5)(D).

(D) The term "specified local coverage determination" has the meaning given such term by clause (iii) of such section.

(12) REPORT.—Not later than December 31 of each year (beginning with 2019), the Secretary shall submit to Congress a report containing the following:

(A) The number of requests filed with fiscal intermediaries and carriers under paragraph (8), and the number of appeals filed with the Secretary under paragraph (9), during the 1-year period ending on such date.

(B) With respect to such requests filed with such intermediaries and carriers under paragraph (8) during such period, the number of times that intermediaries and carriers took, with respect to the actions described in subparagraphs (C) through (E) of such paragraph, each such action.

(C) With respect to such appeals filed with the Secretary under paragraph (9) during such period, the number of times that the Secretary took, with respect to the actions described in subparagraph (D) of paragraph (8), each such action.

(D) Recommendations on ways to improve—

(i) the efficacy and the efficiency of the process described in paragraph (8); and

(ii) communication with individuals entitled to benefits under part A or enrolled under part B, providers of services, and suppliers regarding such process.

[(8)**]** *(13)* CONSTRUCTION.—Nothing in this subsection shall be construed as permitting administrative or judicial review pursuant to this section insofar as such review is explicitly prohibited or restricted under another provision of law.

(g) QUALIFICATIONS OF REVIEWERS.—

(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

(A) each individual conducting a review shall meet the qualifications of paragraph (2);

(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a "reviewing professional"), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a re-

viewing professional shall be a physician (allopathic or osteopathic).

(2) INDEPENDENCE.—

(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

(iii) not otherwise have a conflict of interest with such a party.

(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

(I) the individual is not involved in the provision of items or services in the case under review;

(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, or such individual's authorized representative, and neither party objects; and

(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term "participation agreement" means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

(5) RELATED PARTY DEFINED.—For purposes of this section, the term "related party" means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

(B) The individual (or authorized representative).

(C) The health care professional that provides the items or services involved in the case.

(D) The institution at which the items or services (or treatment) involved in the case are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

(F) Any other party determined under any regulations to have a substantial interest in the case involved.

(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

(1) ESTABLISHMENT OF PROCESS.—

(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to physicians' services (as defined in section 1848(j)(3)), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:

(i) A participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under this title and who has consented to the physician making the request under this subsection for those physicians' services.

(ii) An individual entitled to benefits under this title, but only with respect to a physicians' service for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a).

(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the physicians' services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the physicians' service, administrative costs and burdens, and other relevant factors.

(3) REQUEST FOR PRIOR DETERMINATION.—

(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of a physicians' service, as to whether the physicians' service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the physicians' service, supporting documentation relating to the medical necessity for the physicians' service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(4) RESPONSE TO REQUEST.—

(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

(i) the physicians' service is so covered;

(ii) the physicians' service is not so covered; or

(iii) the contractor lacks sufficient information to make a coverage determination with respect to the physicians' service.

(B) CONTENTS OF NOTICE FOR CERTAIN DETERMINATIONS.—

(i) NONCOVERAGE.—If the contractor makes the determination described in subparagraph (A)(ii), the contractor shall include in the notice a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and a description of any applicable rights under subsection (a).

(ii) INSUFFICIENT INFORMATION.—If the contractor makes the determination described in subparagraph (A)(iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

(C) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

(D) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request by a participating physician under paragraph (1)(B)(i), the process shall provide that the individual to whom the physicians' service is proposed to be furnished shall be informed of any determination described in subparagraph (A)(ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the physicians' service and have a claim submitted for the physicians' service.

(5) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph

(4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(6) LIMITATION ON FURTHER REVIEW.—

(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (relating to pre-service claims) are not subject to further administrative appeal or judicial review under this section or otherwise.

(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

(i) decides not to seek a prior determination under this subsection with respect to physicians' services; or

(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such physicians' services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to physicians' service shall not be taken into account in such administrative or judicial review.

(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided physicians' services, there shall be no prior determination under this subsection with respect to such physicians' services.

(i) MEDIATION PROCESS FOR LOCAL COVERAGE DETERMINATIONS.—

(1) ESTABLISHMENT OF PROCESS.—The Secretary shall establish a mediation process under this subsection through the use of a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

(2) RESPONSIBILITY OF MEDIATOR.—Under the process established in paragraph (1), such a mediator shall mediate in disputes between groups representing providers of services, suppliers (as defined in section 1861(d)), and the medical director for a medicare administrative contractor whenever the regional administrator (as defined by the Secretary) involved determines that there was a systematic pattern and a large volume of complaints from such groups regarding decisions of such director or there is a complaint from the co-chair of the advisory committee for that contractor to such regional administrator regarding such dispute.

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