115TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPT. 115–449
Part 1

PROSTATE CANCER MISDIAGNOSIS ELIMINATION ACT OF 2017

DECEMBER 6, 2017.—Committed to the Comittee of the Whole House on the State of the Union and ordered to be printed

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Mr. WALDEN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 2557]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2557) to amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of certain DNA Specimen Provenance Assay clinical diagnostic laboratory tests, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Prostate Cancer Misdiagnosis Elimination Act of 2017".

SEC. 2. COVERAGE OF CERTAIN DNA SPECIMEN PROVENANCE ASSAY CLINICAL DIAGNOSTIC LABORATORY TESTS UNDER MEDICARE.

(a) COVERAGE.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

(1) in subparagraph (O), by striking "and" at the end;

(2) in subparagraph (P), by striking the semicolon at the end and inserting ", and"; and

(3) by adding at the end the following new subparagraph:

"(Q) in the case of a DNA Specimen Provenance Assay clinical diagnostic laboratory test (DSPA test) furnished on or after the date specified in section 1834A(j)(4), unless the DSPA test is furnished to an individual enrolled under part B who has had a prostate cancer biopsy the results of which are positive, the DSPA test is furnished with respect to such biopsy, and the DSPA test is ordered by the physician who furnished the prostate cancer biopsy that obtained the specimen tested;".

(b) TEMPORARY PAYMENT AMOUNT FOR CERTAIN TESTS FURNISHED BEFORE 2028 AND RELATED REQUIREMENTS.—Section 1834A of the Social Security Act (42 U.S.C. 1395m–1) is amended—

(1) in subsection (b)(1)(A), by striking "and (d)" and inserting ", (d), and (j)"; and

(2) by adding at the end the following new subsection:

"(j) DNA SPECIMEN PROVENANCE ASSAY CLINICAL DIAGNOSTIC LABORATORY TESTS.—

"(1) TEMPORARY PAYMENT AMOUNT FOR CERTAIN TESTS FURNISHED BEFORE 2028.—With respect to a DNA Specimen Provenance Assay clinical diagnostic laboratory test furnished on or after the date specified in paragraph (4) and before January 1, 2028, the payment amount under this section for such test shall be equal to $200.

"(2) HCPCS CODE AND MODIFIER ASSIGNMENT.—

"(A) IN GENERAL.—The Secretary shall assign one or more HCPCS codes to the DNA Specimen Provenance Assay clinical diagnostic laboratory test and may use a modifier to facilitate making payment under this section with respect to such test.

"(B) IDENTIFICATION OF DNA MATCH ON CLAIM.—The Secretary shall require an indication on a claim for a DNA Specimen Provenance Assay clinical diagnostic laboratory test of whether the DNA of the prostate biopsy specimen for such test matches the DNA of the individual with respect to whom the test was ordered. Such indication may be made through use of a HCPCS code, a modifier, or other means, as determined appropriate by the Secretary.

"(3) DNA MATCH REVIEW.—

"(A) IN GENERAL.—The Secretary shall review at least three years of claims under part B for DNA Specimen Provenance Assay clinical diagnostic laboratory tests to identify whether the DNA of the prostate biopsy specimens for such tests matched the DNA of the individuals with respect to whom such tests were ordered.

"(B) POSTING ON INTERNET WEBSITE.—Not later than July 1, 2024, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the findings of the review conducted under subparagraph (A).

"(4) DATE SPECIFIED.—For purposes of paragraph (1) and section 1862(a)(1)(Q), the date specified in this paragraph is the first day of the second calendar quarter that begins at least 180 days after the date of the enactment of this subsection.".

PURPOSE AND SUMMARY

H.R. 2557 was introduced on May 19, 2017, by Rep. Larry Bucshon (R–IN). H.R. 2557 would provide Medicare coverage of DNA Specimen Provenance Assay (DPSA) testing for positive prostate biopsy tests to ensure that there are no specimen provenance complications. DPSA is a diagnostic tool that can address the chances of a false diagnosis, with the potential to prevent unnecessary and costly treatment protocols. DPSA compares the DNA of

the patient to the DNA of the tissue sample tested for cancer. Currently, this test is not covered under the Medicare payment program due to its classification as "quality assurance" rather than a diagnostic test.

BACKGROUND AND NEED FOR LEGISLATION

Prostate cancer affects the lives of one in seven American men. The current method to diagnose prostate cancer is via needle biopsy of the prostate. Prostate cancer is diagnosed with a 10 to 12 samples needle biopsy to detect for cancerous cells, a protocol that became the clinical standard in 2010 and improved the detection rates of prostate cancer.[1] Over 800,000 prostate biopsies are performed on men each year. The Committee received testimony that the transposition of one patient's prostate biopsy specimen with another patient occurs at a higher rate than other testing due to the number of specimens collected at biopsy. Despite the most rigorous protocols for obtaining and handling specimens, peer-reviewed medical literature shows that about 2.5 percent of prostate biopsies are subject to specimen provenance complications, where a specimen from one patient is transposed with or contaminated by that of another patient.

This leads to patients receiving false-negatives, and losing the opportunity to treat their cancer at its earliest possible stage, but also patients receiving false-positives—an estimated 1.28 percent, according to peer-reviewed literature—are erroneously told they have prostate cancer when they do not. This can result in unnecessary, expensive, and invasive procedures, including radical prostatectomy and radiation therapy. An April 2016 report by Milliman projects that $539 million will be spent by Medicare on prostate cancer treatment over the next 10 years for the 1.28 percent of beneficiaries who are erroneously told they have prostate cancer due to specimen provenance complications.

DSPA testing matches each patient's unique genetic profile to that of the diagnostic tissue read by a pathologist in order to rule out the presence of undetected provenance complications prior to treatment. This ensures the proper patient is matched to his specimen. Medicare currently does not provide coverage of these tests. H.R. 2557 would provide coverage in conjunction with a positive biopsy.

COMMITTEE ACTION

On July 20, 2017, the Subcommittee on Health held a hearing on H.R. 2557. The hearing was entitled "Examining Bipartisan Legislation to Improve the Medicare Program." The Subcommittee received testimony from:

- Christel Aprigliano, CEO, Diabetes Patient Advocacy Coalition;
- Lisa Bardach, Speech-Language Pathologist, ALS of Michigan;
- K. Eric De Jonge, President-Elect, American Academy of Home Care Medicine (AAHCM);
- Cletis Earle, Chairman-Elect, CHIME Board of Trustees;
- Mary Grealy, President, Healthcare Leadership Council;

- Deepak A. Kapoor, Chairman and CEO, Integrated Medical Professionals;
- Brett Kissela, Chair, Department of Neurology and Rehabilitation Medicine, University of Cincinnati Gardner Neuroscience Institute, on behalf of American Academy of Neurology;
- Justin Moore, CEO, American Physical Therapy Association;
- Alan E. Morrison, Chair, Diagnostic Services Committee, National Association for the Support of Long Term Care (NASL);
- Varner Richards, Board Chair, National Home Infusion Association; and
- Stacy Sanders, Federal Policy Director, Medicare Rights Center.

On September 13, 2017, the Subcommittee on Health met in open markup session and forwarded H.R. 2557, without amendment, to the full Committee by a voice vote. On October 4, 2017, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 2557, as amended, favorably reported to the House by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 2557 reported.

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 2557 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 24, 2017.

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2557, the Prostate Cancer Misdiagnosis Elimination Act of 2017.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Lara Robillard and Rebecca Yip.

Sincerely,

KEITH HALL,
Director.

Enclosure.

H.R. 2557—Prostate Cancer Misdiagnosis Elimination Act of 2017

Summary: H.R. 2557 would require the Medicare program to cover a certain type of laboratory test for beneficiaries who test positive for prostate cancer. CBO estimates that H.R. 2557 would, on net, decrease direct spending by $7 million over the 2018–2027 period.

Enacting H.R. 2557 would affect direct spending; therefore, pay-as-you-go procedures apply. The legislation would not affect revenues.

CBO estimates that enacting H.R. 2557 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

H.R. 2557 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 2557 is shown in the following table. The costs of this legislation fall within budget function 570 (Medicare).

	By fiscal year, in millions of dollars—											
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2018–2022	2018–2027
INCREASES OR DECREASES (−) IN DIRECT SPENDING												
Estimated Budget Authority	0	1	1	0	0	−1	−1	−2	−2	−3	2	−7
Estimated Outlays	0	1	1	0	0	−1	−1	−2	−2	−3	2	−7

Basis of estimate: For this estimate, CBO assumes that H.R. 2557 will be enacted early in fiscal year 2018.

H.R. 2557 would establish Medicare coverage of and payment for the DNA specimen provenance assay (DSPA) laboratory test. The DSPA tests genetic material in a prostate cancer biopsy specimen to ensure that the sample came from the beneficiary to whom it is attributed.

CBO analyzed Medicare utilization data and estimates that Medicare paid for about 148,000 prostate biopsies in 2016. Based on discussions with stakeholders and a review of clinical literature, CBO estimates that about 40 percent of biopsies are positive. CBO expects that it would take some time for clinicians to adopt the DSPA technology. By the end of the 2018–2027 period, CBO estimates that about half of all positive biopsies would lead to a DSPA test. H.R. 2557 would set the Medicare payment for DSPA at $200 until January 1, 2028, after which it would be paid under the Medicare's fee schedule for clinical laboratory tests. CBO estimates that Medicare would spend $46 million over the 2018–2028 period on DSPA tests.

When men are diagnosed with prostate cancer, they can choose either active treatment (including surgery, radiation, and chemotherapy) or they can choose active surveillance, also called watchful

waiting. CBO estimates that the average annual cost of prostate cancer treatment, accounting for both active treatment and active surveillance, is about $13,000. Clinical data indicate that some prostate biopsies yield false positives, resulting in treatment for men who do not actually have the disease. CBO expects that Medicare coverage would lead to more DSPA testing, which would reduce the number of false positives and thus fewer men would be treated for prostate cancer they do not have. Based on clinical information and discussions with stakeholders, CBO estimates that about 1.5 percent of these tests would reveal a false positive and prevent some men from receiving unnecessary treatment. CBO estimates the number of men who are not treated because of DSPA results would rise from about 60 in 2019 to 450 in 2027. Over the 2018–2027 period, CBO expects that Medicare coverage of DSPA would reduce treatment costs associated with false positive tests by about $51 million.

On net, taking into account both increased spending for the DSPA test and averted treatment costs, CBO estimates that H.R. 2557 would decrease Medicare spending for patients in the fee-for-service sector by $5 million. After taking into account interactions with the Part B premium and payments to Medicare Advantage plans, CBO estimates that the legislation would reduce net direct spending by $7 million over the 2018–2027 period.

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

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 2557, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON OCTOBER 4, 2017

	By fiscal year, in millions of dollars—											
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2018–2022	2018–2027
NET INCREASE OR DECREASE (−) IN THE DEFICIT												
Statutory Pay-As-You-Go Impact	0	1	1	0	0	−1	−1	−2	−2	−3	2	−7

Increase in long-term direct spending and deficits: CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

Intergovernmental and private-sector impact: H.R. 2557 contains no intergovernmental or private-sector mandates as defined in UMRA.

Estimate prepared by: Federal costs: Lara Robillard and Rebecca Yip; Impact on state, local, and tribal governments and the private sector: Amy Petz.

Estimate approved by: Theresa Gullo, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to provide Medicare coverage of DPSA testing for positive prostate biopsy tests to ensure that there are no specimen provenance complications.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 2557 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 2557 contains no earmarks, limited tax benefits, or limited tariff benefits.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the Committee finds that H.R. 2557 contains no directed rule makings.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the "Prostate Cancer Misdiagnosis Elimination Act."

Section 2. Coverage of certain DNA specimen provenance assay clinical diagnostic laboratory tests under medicare

Section 2 provides for coverage of DNA Specimen Provenance Assay (DPSA) testing beginning January 1, 2018, setting the payment rate for the test and mandating the assignment of an HCPCS code to the test. This section also allows the use of a modifier to facilitate payment. Finally, the section mandates a post-payment

review, which is to be made public on the Centers for Medicare and Medicaid Services website no later than July 1, 2019.

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

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

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SEC. 1834A. IMPROVING POLICIES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

(a) REPORTING OF PRIVATE SECTOR PAYMENT RATES FOR ESTABLISHMENT OF MEDICARE PAYMENT RATES.—

(1) IN GENERAL.—Beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary, applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

(2) DEFINITION OF APPLICABLE LABORATORY.—In this section, the term "applicable laboratory" means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

(3) APPLICABLE INFORMATION DEFINED.—

(A) IN GENERAL.—In this section, subject to subparagraph (B), the term "applicable information" means, with respect to a laboratory test for a data collection period, the following:

(i) The payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period.

(ii) The volume of such tests for each such payor for the period.

(B) EXCEPTION FOR CERTAIN CONTRACTUAL ARRANGEMENTS.—Such term shall not include information with respect to a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

(4) DATA COLLECTION PERIOD DEFINED.—In this section, the term "data collection period" means a period of time, such as a previous 12 month period, specified by the Secretary.

(5) TREATMENT OF DISCOUNTS.—The payment rate reported by a laboratory under this subsection shall reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3).

(6) ENSURING COMPLETE REPORTING.—In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

(7) CERTIFICATION.—An officer of the laboratory shall certify the accuracy and completeness of the information reported under this subsection.

(8) PRIVATE PAYOR DEFINED.—In this section, the term "private payor" means the following:

(A) A health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act).

(B) A Medicare Advantage plan under part C.

(C) A medicaid managed care organization (as defined in section 1903(m)).

(9) CIVIL MONEY PENALTY.—

(A) IN GENERAL.—If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information under this subsection with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

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

(10) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by a laboratory under this subsection is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except—

(A) as the Secretary determines to be necessary to carry out this section;

(B) to permit the Comptroller General to review the information provided;

(C) to permit the Director of the Congressional Budget Office to review the information provided; and

(D) to permit the Medicare Payment Advisory Commission to review the information provided.

(11) PROTECTION FROM PUBLIC DISCLOSURE.—A payor shall not be identified on information reported under this subsection. The name of an applicable laboratory under this subsection shall be exempt from disclosure under section 552(b)(3) of title 5, United States Code.

(12) REGULATIONS.—Not later than June 30, 2015, the Secretary shall establish through notice and comment rulemaking parameters for data collection under this subsection.

(b) PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.—

(1) USE OF PRIVATE PAYOR RATE INFORMATION TO DETERMINE MEDICARE PAYMENT RATES.—

(A) IN GENERAL.—Subject to paragraph (3) and subsections (c) **[**and (d)**]**, *(d), and (j)*, in the case of a clinical diagnostic laboratory test furnished on or after January 1, 2017, the payment amount under this section shall be equal to the weighted median determined for the test under paragraph (2) for the most recent data collection period.

(B) APPLICATION OF PAYMENT AMOUNTS TO HOSPITAL LABORATORIES.—The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately, and not as part of a bundled payment under section 1833(t).

(2) CALCULATION OF WEIGHTED MEDIAN.—For each laboratory test with respect to which information is reported under subsection (a) for a data collection period, the Secretary shall calculate a weighted median for the test for the period, by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory.

(3) PHASE-IN OF REDUCTIONS FROM PRIVATE PAYOR RATE IMPLEMENTATION.—

(A) IN GENERAL.—Payment amounts determined under this subsection for a clinical diagnostic laboratory test for each of 2017 through 2022 shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than the applicable percent (as defined in subparagraph (B)) of the amount of payment for the test for the preceding year.

(B) APPLICABLE PERCENT DEFINED.—In this paragraph, the term "applicable percent" means—

(i) for each of 2017 through 2019, 10 percent; and

(ii) for each of 2020 through 2022, 15 percent.

(C) NO APPLICATION TO NEW TESTS.—This paragraph shall not apply to payment amounts determined under this section for either of the following.

(i) A new test under subsection (c).

(ii) A new advanced diagnostic test (as defined in subsection (d)(5)) under subsection (d).

(4) APPLICATION OF MARKET RATES.—

(A) IN GENERAL.—Subject to paragraph (3), once established for a year following a data collection period, the payment amounts under this subsection shall continue to apply until the year following the next data collection period.

(B) OTHER ADJUSTMENTS NOT APPLICABLE.—The payment amounts under this section shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

(5) SAMPLE COLLECTION FEE.—In the case of a sample collected from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, the nominal fee that would otherwise apply under section 1833(h)(3)(A) shall be increased by $2.

(c) PAYMENT FOR NEW TESTS THAT ARE NOT ADVANCED DIAGNOSTIC LABORATORY TESTS.—

(1) PAYMENT DURING INITIAL PERIOD.—In the case of a clinical diagnostic laboratory test that is assigned a new or substantially revised HCPCS code on or after the date of enactment of this section, and which is not an advanced diagnostic laboratory test (as defined in subsection (d)(5)), during an initial period until payment rates under subsection (b) are established for the test, payment for the test shall be determined—

(A) using cross-walking (as described in section 414.508(a) of title 42, Code of Federal Regulations, or any successor regulation) to the most appropriate existing test under the fee schedule under this section during that period; or

(B) if no existing test is comparable to the new test, according to the gapfilling process described in paragraph (2).

(2) GAPFILLING PROCESS DESCRIBED.—The gapfilling process described in this paragraph shall take into account the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges.

(B) Resources required to perform the test.

(C) Payment amounts determined by other payors.

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(E) Other criteria the Secretary determines appropriate.

(3) ADDITIONAL CONSIDERATION.—In determining the payment amount under crosswalking or gapfilling processes under this subsection, the Secretary shall consider recommendations from the panel established under subsection (f)(1).

(4) EXPLANATION OF PAYMENT RATES.—In the case of a clinical diagnostic laboratory test for which payment is made under this subsection, the Secretary shall make available to the public an explanation of the payment rate for the test, including an explanation of how the criteria described in paragraph (2) and paragraph (3) are applied.

(d) PAYMENT FOR NEW ADVANCED DIAGNOSTIC LABORATORY TESTS.—

(1) PAYMENT DURING INITIAL PERIOD.—

(A) IN GENERAL.—In the case of an advanced diagnostic laboratory test for which payment has not been made under the fee schedule under section 1833(h) prior to the date of enactment of this section, during an initial period of three quarters, the payment amount for the test for such period shall be based on the actual list charge for the laboratory test.

(B) ACTUAL LIST CHARGE.—For purposes of subparagraph (A), the term "actual list charge", with respect to a laboratory test furnished during such period, means the publicly available rate on the first day at which the test is available for purchase by a private payor.

(2) SPECIAL RULE FOR TIMING OF INITIAL REPORTING.—With respect to an advanced diagnostic laboratory test described in paragraph (1)(A), an applicable laboratory shall initially be required to report under subsection (a) not later than the last day of the second quarter of the initial period under such paragraph.

(3) APPLICATION OF MARKET RATES AFTER INITIAL PERIOD.—Subject to paragraph (4), data reported under paragraph (2) shall be used to establish the payment amount for an advanced diagnostic laboratory test after the initial period under paragraph (1)(A) using the methodology described in subsection (b). Such payment amount shall continue to apply until the year following the next data collection period.

(4) RECOUPMENT IF ACTUAL LIST CHARGE EXCEEDS MARKET RATE.—With respect to the initial period described in paragraph (1)(A), if, after such period, the Secretary determines that the payment amount for an advanced diagnostic laboratory test under paragraph (1)(A) that was applicable during the period was greater than 130 percent of the payment amount for the test established using the methodology described in subsection (b) that is applicable after such period, the Secretary shall recoup the difference between such payment amounts for tests furnished during such period.

(5) ADVANCED DIAGNOSTIC LABORATORY TEST DEFINED.—In this subsection, the term "advanced diagnostic laboratory test" means a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:

(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.

(B) The test is cleared or approved by the Food and Drug Administration.

(C) The test meets other similar criteria established by the Secretary.

(e) CODING.—

(1) TEMPORARY CODES FOR CERTAIN NEW TESTS.—

(A) IN GENERAL.—The Secretary shall adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests (as defined in subsection (d)(5)) and new laboratory tests that are cleared or approved by the Food and Drug Administration.

(B) DURATION.—

(i) IN GENERAL.—Subject to clause (ii), the temporary code shall be effective until a permanent HCPCS code is established (but not to exceed 2 years).

(ii) EXCEPTION.—The Secretary may extend the temporary code or establish a permanent HCPCS code, as the Secretary determines appropriate.

(2) EXISTING TESTS.—Not later than January 1, 2016, for each existing advanced diagnostic laboratory test (as so defined) and each existing clinical diagnostic laboratory test that is cleared or approved by the Food and Drug Administration for which payment is made under this part as of the date of enactment of this section, if such test has not already been assigned a unique HCPCS code, the Secretary shall—

(A) assign a unique HCPCS code for the test; and

(B) publicly report the payment rate for the test.

(3) ESTABLISHMENT OF UNIQUE IDENTIFIER FOR CERTAIN TESTS.—For purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an advanced diagnostic laboratory test (as so defined) or a laboratory test that is cleared or approved by the Food and Drug Administration, the Secretary shall utilize a means to uniquely track such test through a mechanism such as a HCPCS code or modifier.

(f) INPUT FROM CLINICIANS AND TECHNICAL EXPERTS.—

(1) IN GENERAL.—The Secretary shall consult with an expert outside advisory panel, established by the Secretary not later than July 1, 2015, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics, in issues related to clinical diagnostic laboratory tests, which may include the development, validation, performance, and application of such tests, to provide—

(A) input on—

(i) the establishment of payment rates under this section for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and

(ii) the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and

(B) recommendations to the Secretary under this section.

(2) COMPLIANCE WITH FACA.—The panel shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(3) CONTINUATION OF ANNUAL MEETING.—The Secretary shall continue to convene the annual meeting described in section 1833(h)(8)(B)(iii) after the implementation of this section for purposes of receiving comments and recommendations (and

data on which the recommendations are based) as described in such section on the establishment of payment amounts under this section.

(g) COVERAGE.—

(1) ISSUANCE OF COVERAGE POLICIES.—

(A) IN GENERAL.—A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1869(f)(2)(B)), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations).

(B) NO EFFECT ON NATIONAL COVERAGE DETERMINATION PROCESS.—This paragraph shall not apply to the national coverage determination process (as defined in section 1869(f)(1)(B)).

(C) EFFECTIVE DATE.—This paragraph shall apply to coverage policies issued on or after January 1, 2015.

(2) DESIGNATION OF ONE OR MORE MEDICARE ADMINISTRATIVE CONTRACTORS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.—The Secretary may designate one or more (not to exceed 4) medicare administrative contractors to either establish coverage policies or establish coverage policies and process claims for payment for clinical diagnostic laboratory tests, as determined appropriate by the Secretary.

(h) IMPLEMENTATION.—

(1) IMPLEMENTATION.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the establishment of payment amounts under this section.

(2) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to information collected under this section.

(3) FUNDING.—For purposes of implementing this section, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to the Centers for Medicare & Medicaid Services Program Management Account, for each of fiscal years 2014 through 2018, $4,000,000, and for each of fiscal years 2019 through 2023, $3,000,000. Amounts transferred under the preceding sentence shall remain available until expended.

(i) TRANSITIONAL RULE.—During the period beginning on the date of enactment of this section and ending on December 31, 2016, with respect to advanced diagnostic laboratory tests under this part, the Secretary shall use the methodologies for pricing, coding, and coverage in effect on the day before such date of enactment, which may include cross-walking or gapfilling methods.

(j) DNA SPECIMEN PROVENANCE ASSAY CLINICAL DIAGNOSTIC LABORATORY TESTS.—

(1) TEMPORARY PAYMENT AMOUNT FOR CERTAIN TESTS FURNISHED BEFORE 2028.—With respect to a DNA Specimen Provenance Assay clinical diagnostic laboratory test furnished on or after the date specified in paragraph (4) and before January 1, 2028, the payment amount under this section for such test shall be equal to $200.

(2) HCPCS CODE AND MODIFIER ASSIGNMENT.—

(A) IN GENERAL.—The Secretary shall assign one or more HCPCS codes to the DNA Specimen Provenance Assay clinical diagnostic laboratory test and may use a modifier to facilitate making payment under this section with respect to such test.

(B) IDENTIFICATION OF DNA MATCH ON CLAIM.—The Secretary shall require an indication on a claim for a DNA Specimen Provenance Assay clinical diagnostic laboratory test of whether the DNA of the prostate biopsy specimen for such test matches the DNA of the individual with respect to whom the test was ordered. Such indication may be made through use of a HCPCS code, a modifier, or other means, as determined appropriate by the Secretary.

(3) DNA MATCH REVIEW.—

(A) IN GENERAL.—The Secretary shall review at least three years of claims under part B for DNA Specimen Provenance Assay clinical diagnostic laboratory tests to identify whether the DNA of the prostate biopsy specimens for such tests matched the DNA of the individuals with respect to whom such tests were ordered.

(B) POSTING ON INTERNET WEBSITE.—Not later than July 1, 2024, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the findings of the review conducted under subparagraph (A).

(4) DATE SPECIFIED.—For purposes of paragraph (1) and section 1862(a)(1)(Q), the date specified in this paragraph is the first day of the second calendar quarter that begins at least 180 days after the date of the enactment of this subsection.

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PART E—MISCELLANEOUS PROVISIONS

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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**[**;**]**, *and*

(Q) in the case of a DNA Specimen Provenance Assay clinical diagnostic laboratory test (DSPA test) furnished on or after the date specified in section 1834A(j)(4), unless the DSPA test is furnished to an individual enrolled under part B who has had a prostate cancer biopsy the results of which are positive, the DSPA test is furnished with respect to such biopsy, and the DSPA test is ordered by the physician who furnished the prostate cancer biopsy that obtained the specimen tested;

(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 Sec-

retary) 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 indi-

vidual) 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 provisions 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 employer, 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 compromise, 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 Secretary 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 resolve 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 Sec-

retary 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) sub-

ject 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 notwithstanding 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 request 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.

(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 particular 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 Services 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).

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EXCHANGE OF LETTERS WITH ADDITIONAL COMMITTEES OF REFERRAL

Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
1102 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-3625
Washington, DC 20515-0548
http://waysandmeans.house.gov

December 5, 2017

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

Dear Chairman Walden,

I am writing with respect to H.R. 2557, the "Prostate Cancer Misdiagnosis Elimination Act of 2017," on which the Committee on Ways and Means was granted an additional referral.

As a result of your having consulted with us on provisions in H.R. 2557 that fall within the Rule X jurisdiction of the Committee on Ways and Means, I agree to waive formal consideration of this bill so that it may move expeditiously to the floor. The Committee on Ways and Means takes this action with the mutual understanding that we do not waive any jurisdiction over the subject matter contained in this or similar legislation, and the Committee will be appropriately consulted and involved as the bill or similar legislation moves forward so that we may address any remaining issues that fall within our jurisdiction. The Committee also reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, and requests your support for such request.

Finally, I would appreciate your response to this letter confirming this understanding, and would ask that a copy of our exchange of letters on this matter be included in the *Congressional Record* during floor consideration of H.R. 2557.

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

December 5, 2017

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. 2557, Prostate Cancer Misdiagnosis Elimination Act of 2017, on which the Committee on Ways and Means was granted an additional referral.

I appreciate your agreeing to waive formal consideration of H.R. 2557 in order to allow the bill to move expeditiously to the House floor.

I agree that by foregoing consideration on H.R. 2557 at this time, the Committee on Ways and Means does not waive any jurisdiction over subject matter contained in this or similar legislation, and that the Committee will be appropriately consulted and involved as this bill or similar legislation moves forward. I also agree that the Committee reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, and I will support any such request.

Finally, I will include a copy of your letter and this response in the Congressional Record during the floor consideration of this bill.

Sincerely,

Greg Walden
Chairman

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