

SEC. 216. IMPROVING MEDICARE POLICIES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

(a) IN GENERAL.—Title XVIII of the Social Security Act is amended by inserting after section 1834 (42 U.S.C. 1395m) the following new section:

“SEC. 1834A. IMPROVING POLICIES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS. 42 USC 1395m–1.

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

“(1) IN GENERAL.—Beginning January 1, 2016, and every Effective date. 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 ARRANGE-

MENTS.—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

Effective date. 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.—

Determination. “(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.

Deadline. “(12) REGULATIONS.—Not later than June 30, 2015, the Secretary shall establish through notice and comment rule-making parameters for data collection under this subsection. “(b) PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.—

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

“(A) IN GENERAL.—Subject to paragraph (3) and subsections (c) and (d), 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 labora

tory 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 DIAG

NOSTIC 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 pay

ment amount under crosswalking or gapfilling processes under this subsection, the Secretary shall consider recommendations from the panel established under subsection (f)(1).

Public information.

“(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.

Definition.

“(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 Determination. 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 Deadline. 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 Public information. purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an advanced

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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.—

Consultation.
Establishment.
Deadline.

“(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 ADMINISTRATION 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 Time period.

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.”.

(b) CONFORMING AMENDMENTS.—

(1) Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(A) in paragraph (1)(D)—

(i) by striking “(i) on the basis” and inserting “(i)(I) on the basis”;

(ii) in subclause (I), as added by clause (i), by striking “subsection (h)(1)” and inserting “subsection (h)(1) (for tests furnished before January 1, 2017)”;

(iii) by striking “or (ii)” and inserting “or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii)”;

and
(iv) in clause (ii), by striking “on the basis” and inserting “for tests furnished before January 1, 2017, on the basis”;

(B) in paragraph (2)(D)—

(i) by striking “(i) on the basis” and inserting “(i)(I) on the basis”;

(ii) in subclause (I), as added by clause (i), by striking “subsection (h)(1)” and inserting “subsection (h)(1) (for tests furnished before January 1, 2017)”;

(iii) by striking “or (ii)” and inserting “or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such

section or the amount of the charges billed for the tests, or (ii)”;
and
(iv) in clause (ii), by striking “on the basis” and inserting “for tests furnished before January 1, 2017, on the basis”;

(C) in subsection (b)(3)(B), by striking “on the basis” and inserting “for tests furnished before January 1, 2017, on the basis”;

(D) in subsection (h)(2)(A)(i), by striking “and subject to” and inserting “and, for tests furnished before the date of enactment of section 1834A, subject to”;

(E) in subsection (h)(3), in the matter preceding subparagraph (A), by striking “fee schedules” and inserting “fee schedules (for tests furnished before January 1, 2017) or under section 1834A (for tests furnished on or after January 1, 2017), subject to subsection (b)(5) of such section”;

(F) in subsection (h)(6), by striking “In the case” and inserting “For tests furnished before January 1, 2017, in the case”; and

(G) in subsection (h)(7), in the first sentence—

(i) by striking “and (4)” and inserting “and (4) and section 1834A”; and

(ii) by striking “under this subsection” and inserting “under this part”.

(2) Section 1869(f)(2) of the Social Security Act (42 U.S.C. 1395ff(f)(2)) is amended by adding at the end the following new subparagraph:

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

(c) GAO STUDY AND REPORT; MONITORING OF MEDICARE EXPENDITURES AND IMPLEMENTATION OF NEW PAYMENT SYSTEM FOR LABORATORY TESTS.—

(1) GAO STUDY AND REPORT ON IMPLEMENTATION OF NEW PAYMENT RATES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.—

(A) STUDY.—The Comptroller General of the United States (in this subsection referred to as the “Comptroller General”) shall conduct a study on the implementation of section 1834A of the Social Security Act, as added by subsection (a). The study shall include an analysis of—

(i) payment rates paid by private payors for laboratory tests furnished in various settings, including—

(I) how such payment rates compare across settings;

(II) the trend in payment rates over time; and

(III) trends by private payors to move to alternative payment methodologies for laboratory tests;

(ii) the conversion to the new payment rate for laboratory tests under such section;

(iii) the impact of such implementation on beneficiary access under title XVIII of the Social Security Act;

- (iv) the impact of the new payment system on laboratories that furnish a low volume of services and laboratories that specialize in a small number of tests;
- (v) the number of new Healthcare Common Procedure Coding System (HCPCS) codes issued for laboratory tests;
- (vi) the spending trend for laboratory tests under such title;
- (vii) whether the information reported by laboratories and the new payment rates for laboratory tests under such section accurately reflect market prices;
- (viii) the initial list price for new laboratory tests and the subsequent reported rates for such tests under such section;
- (ix) changes in the number of advanced diagnostic laboratory tests and laboratory tests cleared or approved by the Food and Drug Administration for which payment is made under such section; and
- (x) healthcare economic information on downstream cost impacts for such tests and decision making based on accepted methodologies.

(B) REPORT.—Not later than October 1, 2018, the Comptroller General shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the study under subparagraph (A), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(2) MONITORING OF MEDICARE EXPENDITURES AND IMPLEMENTATION OF NEW PAYMENT SYSTEM FOR LABORATORY TESTS.—The Inspector General of the Department of Health and Human Services shall—

Analysis.
42 USC 1395m-1
note.

(A) publicly release an annual analysis of the top 25 laboratory tests by expenditures under title XVIII of the Social Security Act; and

Public
information.
Deadline.

(B) conduct analyses the Inspector General determines appropriate with respect to the implementation and effect of the new payment system for laboratory tests under section 1834A of the Social Security Act, as added by subsection (a).