gram, with the Comptroller General to submit not later than Apr. 1, 1991, a report to Committees on Ways and Means and Energy and Commerce of House of Representatives and Committee on Finance of Senate on the study including recommendations.

REPORTS ON MEDICARE BENEFICIARY DRUG EXPENSES

Pub. L. 100–360, title II, § 202(i), July 1, 1988, 102 Stat. 718, directed Secretary of Health and Human Services, by not later than Apr. 1, 1989, to report to Congress on expenses incurred by medicare beneficiaries for outpatient prescription drugs, and to provide Director of Congressional Budget Office with such data from that Survey as Director might request to make required estimates, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

ADDITIONAL STUDIES BY SECRETARY OR COMPTROLLER GENERAL

Pub. L. 100–360, title II, § 202(k), July 1, 1988, 102 Stat. 719, directed Secretary of Health and Human Services to conduct a study, and make a report to Congress by Jan. 1, 1990, on possibility of including drugs which have not yet been approved under section 355 or 357 of Title 21, Food and Drugs, and biological products which have not been licensed under section 262 of this title but which are commonly used in the treatment of cancer or in immunosuppressive therapy and other experimental drugs and biological products as covered outpatient drugs under medicare program, to conduct a study, and report to Congress by Jan. 1, 1990, evaluating potential to use mail service pharmacies to reduce costs to medicare program and to medicare beneficiaries, to conduct a study, and report to Congress by Jan. 1, 1993, on methods to improve utilization review of covered outpatient drugs, and to conduct a longitudinal study, and report to Congress by Jan. 1, 1993, on use of outpatient prescription drugs by medicare beneficiaries with respect to medical necessity, potential for adverse drug interactions, cost (including whether lower cost drugs could have been used), and patient stockpiling or wastage, and which further directed Comptroller General to conduct studies, and report to Congress by not later than May 1, 1991, on comparing average wholesale prices with actual pharmacy acquisition costs by type of pharmacy, on determining the overhead costs of retail pharmacies, and on discounts given by pharmacies to other third-party insurers, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

DEVELOPMENT OF STANDARD MEDICARE CLAIMS FORMS

Pub. L. 100–360, title II, § 202(*l*), July 1, 1988, 102 Stat. 720, directed Secretary of Health and Human Services to develop, in consultation with representatives of pharmacies and other interested individuals, a standard claims form (and a standard electronic claims format) to be used in requests for payment for covered outpatient drugs under medicare program and other third-party payors, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

STUDIES AND REPORTS ON SCREENING MAMMOGRAPHY

Pub. L. 100–360, title II, § 204(f), July 1, 1988, 102 Stat. 729, directed Physician Payment Review Commission to study and report, by July 1, 1989, to Committees on Ways and Means and Energy and Commerce of the House of Representatives and Committee on Finance of the Senate concerning the cost of providing screening mammography in a variety of settings and at different volume levels, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

DEADLINE FOR ESTABLISHMENT OF FEE SCHEDULES FOR RADIOLOGIST SERVICES; REPORT TO CONGRESS

Pub. L. 100–203, title IV, § 4049(b)(1), Dec. 22, 1987, 101 Stat. 1330–92, as amended by Pub. L. 100–360, title IV, § 411(f)(8)(E), July 1, 1988, 102 Stat. 780; Pub. L. 101–508, title IV, § 4118(g)(3), Nov. 5, 1990, 104 Stat. 1388–70, directed Secretary of Health and Human Services to propose the relative value scale and fee schedules for radiologist services (under subsec. (b) of this section) by not later than Aug. 1, 1988.

STUDY AND EVALUATION

Pub. L. 100–203, title IV, § 4062(c), Dec. 22, 1987, 101 Stat. 1330–107, as amended by Pub. L. 100–360, title IV, § 411(g)(1)(C), July 1, 1988, 102 Stat. 782, provided that:

''(1) The Secretary of Health and Human Services shall monitor the impact of the amendments made by this section [enacting this section, amending sections 1395f, 1395k, 1395*l*, and 1395cc of this title, and repealing section 1395zz of this title] on the availability of covered items and shall evaluate the appropriateness of the volume adjustment for oxygen and oxygen equipment under section 1834(a)(5)(C) of the Social Security Act [42 U.S.C. 1395m(a)(5)(C)] (as amended by subsection (b) of this section). The Secretary shall report to Congress, by not later than January 1, 1991, on such impact and on the evaluation and shall include in such report recommendations for changes in payment methodology for covered items under section 1834(a) of such Act.

''(2) Before January 1, 1991, the Secretary may not conduct any demonstration project respecting alternative methods of payment for covered items under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

''(3) In this subsection, the term 'covered item' has the meaning given such term in section 1834(a)(13) of the Social Security Act [42 U.S.C. 1395m(a)(13)] (as amended by subsection (b) of this section).

''(4) The Secretary shall, upon written request and payment of a reasonable copying fee which the Secretary may establish, provide the data and information used in determining the payment amounts for covered items under section 1834(a) of the Social Security Act [42 U.S.C. 1395m(a)], but only in a form which does not permit identification of individual suppliers.

''(5) The Comptroller General shall conduct a study on the appropriateness of the level of payments allowed for covered items under the medicare program, and shall report to Congress on the results of such study (including recommendations on the transition to regional or national rates) by not later than January 1, 1991. Entities furnishing such items which fail to provide the Comptroller General with reasonable access to necessary records to carry out the study under this paragraph are subject to exclusion from the medicare program under section 1128(a) of the Social Security Act [42 U.S.C. 1320a–7(a)].''

§ 1395m–1. 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 subchapter, a majority of such revenues are from this section, section

1395*l*(h) of this title, or section 1395w–4 of this title. 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 1395w–3a(c)(3) of this title.

(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 300gg–91 of this title).

(B) A Medicare Advantage plan under part C.

(C) A medicaid managed care organization (as defined in section 1396b(m) of this title).

(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 1320a–7a of this title (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 1320a–7a(a) of this title.

(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.

(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), 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 1395*l*(t) of this title.

(2) Calculation of weighted median

For each laboratory test with respect to which information is reported under sub-

section (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[1] (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 1395*l*(h)(3)(A) of this title 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 April 1, 2014, 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 1395*l*(h) of this title prior to April 1, 2014, 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.

[1] So in original. Probably should be preceded by ''laboratory''.

(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 April 1, 2014, 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 1395*l*(h)(8)(B)(iii) of this title 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 1395ff(f)(2)(B) of this title), 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 1395ff(f)(1)(B) of this title).

(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 1395ff of this title, section 1395*oo* of this title, or otherwise, of the establishment of payment amounts under this section.

(2) Administration

Chapter 35 of title 44 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 1395t of this title, 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 April 1, 2014, 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 April 1, 2014, which may include cross-walking or gapfilling methods.

(Aug. 14, 1935, ch. 531, title XVIII, § 1834A, as added Pub. L. 113–93, title II, § 216(a), Apr. 1, 2014, 128 Stat. 1053.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (f)(2), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

MONITORING OF MEDICARE EXPENDITURES AND IMPLEMENTATION OF NEW PAYMENT SYSTEM FOR LABORATORY TESTS

Pub. L. 113–93, title II, § 216(c)(2), Apr. 1, 2014, 128 Stat. 1061, provided that: ''The Inspector General of the Department of Health and Human Services shall—

''(A) publicly release an annual analysis of the top 25 laboratory tests by expenditures under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]; and

''(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 [42 U.S.C. 1395m–1], as added by subsection (a).''

§ 1395n. Procedure for payment of claims of providers of services

(a) Conditions for payment for services described in section 1395k(a)(2) of this title

Except as provided in subsections (b), (c), and (e), payment for services described in section 1395k(a)(2) of this title furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc(a) of this title, and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service; and

(2) a physician, or, in the case of services described in subparagraph (A), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that—

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, (iii) such services are or were furnished while the individual is or was under the care of a physician, and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth and other than with respect to en-