Summary of Clinical Laboratory Fee Schedule Reform Provisions in the Protecting Access to Medicare Act of 2014

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On April 1, the Protecting Access to Medicare Act of 2014 was enacted into law (Pub. L. 113-93).[i] Section 216, entitled Improving Medicare Policies for Clinical Diagnostic Laboratory Tests, modernizes the Medicare payment system for clinical laboratory tests with the establishment of a market-based payment system. This is the most significant modernization of the Clinical Laboratory Fee Schedule (CLFS) since the introduction of the CLFS in 1984.

Beginning in January 2017, Medicare payment for clinical diagnostic laboratory tests will be established by a market-based payment system. Under this new methodology the Centers for Medicare & Medicaid Services (CMS) will establish Medicare payment for each test based on the weighted median of the payment rates for private payors for the test. Applicable laboratories must begin reporting payment rates for covered tests in 2016.

The legislation creates a new class of Advanced Diagnostic Laboratory Tests defined as sole source multi-analyte tests with a unique algorithm yielding a single result or a test that is cleared or approved the Food and Drug Administration (FDA). Beginning in 2017, new Advanced Diagnostics introduced to the market will be paid at the actual list charge for three quarters before transitioning to the market-based payment system. Additionally, Advanced Diagnostics are eligible for temporary and unique permanent coding which will take effect prior to January 1, 2016.

For payment prior to 2017, the legislation creates a transitional period for both new and existing tests. The legislation rescinds CMS' statutory authority to make adjustments to future payments for tests based on "technological changes," which CMS had intended to apply to certain test codes on the CLFS beginning in calendar year 2015. New non-Advanced Diagnostic tests introduced to the market will be established through cross-walking or gapfilling, before transitioning to the market-based payment system. Beginning in July 2015, CMS is required to establish an expert advisory panel to provide recommendations for the cross-walking and gapfilling process. CMS is also required to provide a published rationale for its payment rate decisions for new non-Advanced Diagnostics.

The legislation also requires coverage policy for clinical diagnostics to be established through local contractor determinations (LCD). The legislation directs CMS to consider designating one or more Medicare Administrative Contractors (MACs) to establish coverage policies and process claims for clinical diagnostic laboratory tests.

The Congressional Budget Office (CBO) estimates that these reforms to CLFS will reduce Medicare spending by $1 billion between 2014 and 2019, and by $2.5 billion over the ten-year period between 2014 and 2024.

Key Dates for Implementation

The key provisions of the legislation pertaining to private data collection will need to be addressed by agency rulemaking, which will provide an opportunity for public comment. The agency may address other implementation issues through subregulatory guidance.

- After enactment CMS will establish the process for temporary codes and unique identifiers (no date required).
- January 1, 2015: beginning on this date, Medicare administrative contractors may only issue a coverage policy with respect to a test through a local coverage decision.
- January 1, 2015: CMS is precluded from making adjustments to payments for clinical tests based under regulations previously

promulgated under the "technological changes" adjustment authority.

- June 30, 2015: deadline for CMS to establish (through regulation) parameters for payment rate reporting.
- July 1, 2015: deadline for CMS to establish an expert outside advisory panel.
- January 1, 2016: applicable laboratories must begin reporting private payor payment rates.
- January 1, 2016: CMS must assign an unique HCPCS code to existing Advanced Diagnostics that are paid under a miscellaneous code.
- January 1, 2017: market-based payment system and initial payment period for Advance Diagnostics is effective.
- October 1, 2018: deadline for GAO report to Congress.

CMS' "Technological Changes" Review Authority Rescinded

CMS' Authority to Adjust Payment Based on "Technological Changes" Rescinded.— CMS will not have the statutory authority to implement adjustments to payments for clinical diagnostic laboratory tests based on "technological changes," as the agency finalized in the Calendar Year 2014 Physician Fee Schedule rule. Specifically, the statutory authority in section 1833(h)(2)(A)(i), upon which CMS' technological change review regulations are based (42 C.F.R. § 414.511), is amended to apply only to payment for tests furnished prior to the enactment of the new legislation.

New Market-Based Payment System Starting 2017

Use of Private Payor Rate Information to Determine Medicare Payment Rates.— Starting in 2017, payments under the CLFS will be established by CMS on a test-by-test basis at the weighted median of market rates submitted by laboratories. The established payment amounts will apply to tests furnished by a hospital laboratory if such test is paid for separately. All tests, new and existing, Advanced Diagnostic and non-Advanced Diagnostic, will be paid according to the market-based payment system.

Calculation of Weighted Median.— CMS will calculate the weighted median for each test by arraying the distribution of all payment rates weighted by volume for each payor for each laboratory.

Phase-in of Reductions from Private Payor Rate Implementation.— For each year during 2017 through 2022, payment amount for existing test shall not be reduced by more than 10 percent (2017-2019) or 15 percent (2020-2022) compared to payment for the test in the preceding year. However, new tests are not subject to this phase-in provision.

Application of Market Rates.— The payment amounts established will continue to apply until the year following the next data collection period, and may not be subject to any adjustment (such as geographic, budget neutrality, annual update).

Sample Collection Fee.— For samples collected in a skilled nursing facility or by a laboratory on behalf of a home health agency, the specimen handling fee will be increased by $2.

Reporting of Private Sector Payment Rates for Establishment of Medicare Payment Rates

In General.— Beginning in January 1, 2016, applicable laboratories must report for each test the payment rate that was paid by each payor and the volume of such tests for the period for which payment is made. Private payer data for existing clinical diagnostic laboratory tests must be reported every three years. (As discussed below, data for Advanced Diagnostic laboratory tests must be reported annually).

Data to be Collected.— The Secretary must establish the parameters for data collection through rulemaking by June 30, 2015. The legislation does not specifically define what private payor rates must be reported or how laboratories must report the data. The legislation excludes from reporting tests that are paid on a capitated basis. The private payor rates to be reported are required to reflect all discounts, rebates and other price concessions. The legislation gives the agency the authority to define the data collection period,

providing "previous 12 months" as an example.

Definition of Applicable Laboratory.— The term "applicable laboratory" means a laboratory that, with respect to its revenues under Medicare, a majority of such revenues are from this section, section 1833(h) (CLFS), or section 1848 ("Payment for Physicians' Services"). Thus, although the legislation only affects the pricing of CLFS tests, both clinical laboratory and physician pathology tests will be used for the applicable laboratory rule.

Definition of Private Payor.— The term 'private payor' includes a health insurances issuer and a group health plan, a Medicare Advantage plan, and a Medicaid managed care organization.

Several Payment Rates for Same Test for Same Payor.— If a 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, all rates must be reported. CMS may establish rules on aggregate reporting beginning in 2019.

Compliance.— An officer in a laboratory must certify the accuracy and completeness of information submitted to CMS. Failure to report or a misrepresentation in reporting is subject to civil money penalty of up to $10,000 per day.

Confidentiality of Information.— The information submitted to CMS may not be disclosed as to disclose the identity of a specific payor or laboratory or prices charged, except (1) as CMS determines to be necessary to carry out this section, and (2) to permit the Comptroller General, CBO, or MedPAC to review the information provided.

Advanced Diagnostic Laboratory Tests

The legislation establishes special payment and coding rules for clinical laboratory diagnostic tests that meet the statutory definition of an Advanced Diagnostic Laboratory Test.

Advanced Diagnostic Laboratory Test Defined.— "Advanced Diagnostic Laboratory Test" is defined as a clinical diagnostic laboratory test that is offered and furnished by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner). In addition, the test must meet at least one of the following three criteria:

(1) 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;

(2) the test is cleared or approved by the FDA; or

(3) the test meets other similar criteria established by CMS.

Payment During Transitional Period.— With respect to Advanced Diagnostic Laboratory Tests, CMS will continue to use the current methodologies for pricing, coding, and coverage through December 31, 2016.

Initial Payment for New Advanced Diagnostics After 2017

Payment at List Charge For Three Calendar Quarters.— Beginning in 2017, for a new Advanced Diagnostic Laboratory Test (i.e. for which payment has not been made under CLFS prior to the date of enactment), the initial payment amount for the test during the first three calendar quarters will be the actual list charge (publicly available rate on the first day available) for the test. By end of second quarter, the laboratory must begin reporting the private payor data.

Application of Market Rates After Initial Period.— Following the three quarters of payment at list price, payment for Advanced Diagnostic laboratory tests will be made based on private payor rates reported and calculated as for existing CLFS tests. Private payor data for Advanced Diagnostic Laboratory Tests must be reported annually, and Medicare payment will be adjusted on an annual basis.

Recoupment if Actual List Charge Exceeds Market Rate.— If after the initial period CMS determines that, during the initial period, the payment amount for an Advanced Diagnostic Laboratory Test was greater than 130 percent of payment amount that is applicable under the private payor payment, CMS will recoup the difference between such payment amounts for tests furnished during the initial period.

Unique Coding for Existing Tests.— By January 1, 2016, CMS must assign a unique HCPCS code and publicly report the test payment rate for each existing Advanced Diagnostic Laboratory Test and existing tests that are FDA cleared or approved by the FDA that receives Medicare payment with a miscellaneous code as of the date of enactment.

Temporary Codes for Certain New Tests.— CMS will adopt temporary HCPCS codes (for up to two years) to identify new Advanced Diagnostic Laboratory Tests and new laboratory tests that are cleared or approved by the FDA. CMS may extend the temporary code beyond two years or establish a permanent HCPCS code.

Unique Identifiers.— If a laboratory or a manufacturer requests a unique identifier for an Advanced Diagnostic Laboratory Test or a test that is approved or cleared by the FDA, CMS must provide a means to track or monitor the test through a mechanism such as a HCPCS code or modifier. The phrase "such as" indicates CMS has flexibility to adopt an alternative coding system from HCPCS codes. While the term "modifier" typically describes a two-place alphanumeric code, it might also refer to a five-place code placed on a separate claim line.

Initial Payment for New Non Advanced Diagnostic Tests Prior to Market-Based Rates

Payment by Gapfill/Cross-walk During Initial Period.— For a new clinical diagnostic laboratory test (i.e. that is assigned a new or substantially revised HCPCS code on or after the date of enactment, and which is not an Advanced Diagnostic Laboratory Test), the initial payment rates, until private payment rates are reported, will be determined using cross-walking to the most appropriate existing test under the fee schedule. If no existing comparable test exists, then the initial payment will be made according to a "gapfiling" process, which takes into account (1) charges for the test and routine discounts to charges, (2) resources required to perform the test, (3) payment amounts determined by other payors, and (4) charges, payment amounts, and resources required for other tests that are comparable or otherwise relevant.

Additional Consideration and Explanation of Payment Rates.— CMS must consider recommendations by the expert outside advisory panel (described below) in determining the payment amount under cross-walking or gapfilling. Further, CMS also must publish the rationale for the payment rate, including the explanation of how the gapfilling criteria and expert panel recommendations are applied.

Timing.— The initial payment method applies to all non-Advanced diagnostic tests introduced after the date of enactment (including before the market-based system is effective in 2017). As noted, the method generally mirrors the existing gapfill/cross-walk method. The payment for these tests will be transitioned to the market-based system after sufficient private payor data has been reported in the next reporting period, which occur every three years from 2016.

Expert Outside Advisory Panel

In General.— CMS must establish an expert outside advisory panel no later than July 1, 2015, composed of individuals with expertise (e.g. pathologists, researchers, others with experience in economics or laboratory science) to provide (1) recommendations to CMS in determining the payment amount under cross-walking and gapfilling processes, (2) input on the establishment of payment rates for new clinical diagnostic laboratory tests, and (3) input on the factors used in determining coverage and payment processes for new tests.

Compliance with FACA.— The panel will be subject to the Federal Advisory Committee Act.

Continuation of Annual Meetings.— CMS will continue to convene meetings with the panel annually.

Contractor and Local Coverage Decisions Reforms

Issuance of Coverage Policies.— Beginning in 2015, a Medicare Administrative Contractor may not issue a coverage policy for a clinical diagnostic laboratory test through any process except a local coverage determination, including the appeals and review process for local coverage determinations.

Designation of One or More Medicare Administrative Contractors for Clinical Diagnostic Laboratory Tests.— CMS may designate up to four Medicare Administrative Contractors to either establish coverage policies or coverage policies and process claims for payment for

clinical diagnostic laboratory tests. A similar provision was enacted as part of the Balanced Budget Agreement Act of 1997 but was never implemented by CMS.

GAO Study, OIG Report, and Implementation

GAO Study and Report on Implementation of New Payment Rates for Clinical Diagnostic Laboratory Tests.— The Government Accountability Office (GAO) will conduct a study on the implementation of the new payment for tests, for submission to Congress by October 1, 2018. The report will include an analysis of—

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

(2) the conversion to the new payment rate for laboratory tests,

(3) the impact of implementation on beneficiary access under Medicare,

(4) the impact of the new payment system on laboratories that specialize in a small number of tests and laboratories that furnish a low volume of services,

(5) the number of new HCPCS codes issued for tests,

(6) the spending trend for tests,

(7) whether the information reported by the laboratories and the new payment rates accurately reflect market prices,

(8) the initial list price for new tests and the subsequent reported rates,

(9) changes in the number of Advanced Diagnostic laboratory tests and tests cleared or approved by the FDA, and

(10) healthcare economic information on downstream cost impacts for such tests and decision making based on accepted methodologies.

OIG Monitoring of Medicare Expenditures and Implementation of New Payment System for Laboratory Tests.— The Office of Inspector General (OIG) will release an annual analysis of the top 25 tests by expenditures under Medicare, and conduct appropriate analyses with respect to the implementation and effect of the new payment system for tests.

No Judicial Review.— There will not be judicial review of the establishment of payment amounts under this law.

Funding.— The Secretary must provide funding for the implementation of this law in the amount of $4 million for each year during 2014-2018, and $3 million for each year during 2019-2023.

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i. The Protecting Access to Medicare Act of 2014 (H.R. 4302) passed the House of Representatives on March 27 by a voice vote, and the Senate on March 31 by a vote of 64-35. It was signed into law by President Obama on April 1.↩

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