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Summary of Clinical Laboratory Provisions in the "Protecting Access to Medicare Act of 2014"

For the first time in 30 years, Congress has implemented a number of reforms to modernize the Medicare Clinical Laboratory Fee Schedule (CLFS). Many of the provisions in Section 216 of the "Protecting Access to Medicare Act of 2014," which are detailed below, were included in legislation introduced in 2013 (HR 2085) and were also contained in the joint stakeholder proposal for CLFS reform. Section 216 of the law requires that certain laboratories begin reporting payments made by private payers in 2016. Beginning in 2017, Medicare payment rates for established tests on the CLFS will reflect those private market rates. The law requires the Secretary to establish an advisory panel to make recommendations for gapfilling or crosswalking of new tests. CMS will be required to establish mechanisms for granular coding and unique test identification, including the assignment of temporary billing codes for certain new tests. Finally, the law requires a GAO study and report on the new payment system for lab tests, including a review of downstream cost impact and health care decision-making based on lab tests.

Payment Adjustments for Existing Tests: Requires "applicable laboratories" to report payment rates for diagnostic tests furnished by the laboratory, beginning in 2016. Beginning in 2017, payment rates for tests will reflect the weighted median of reported rates. The language phases-in the reductions based on the implementation of the private payer rate process, by limiting any adjustments to 10 percent for each of 2017 through 2019, and to 15 percent for each of 2020 through 2022. "Applicable laboratory" is defined as a laboratory that received a majority of its Medicare revenue from billing the Clinical Laboratory Fee Schedule or the Physician Fee Schedule for tests.

Payment for New Advanced Diagnostic Laboratory Tests: Defines a new category of tests for which payment has not been made under the CLFS that are offered and furnished only by a single lab and not sold for use by the laboratory; and the test is a MAAA, or is cleared or approved by the FDA, or meets other criteria set by the Secretary. During an initial payment period of three quarters, payment amounts for such tests will be based on the actual list charge for the test. Payment rates will then be based on the market rate after the initial period, based on data reported by the laboratory. The bill mandates recoupment of payments in excess of 130% of the market rate.

Advisory Panel: Requires the Secretary to establish by July 1, 2015, an expert panel to provide input on issues relating to clinical laboratory tests, including the development, validation, performance, and application of such tests. The panel will provide input on whether to gapfill or crosswalk new tests, and input on the factors used in determining coverage and payment processes for new tests. The panel shall be composed of a selection of individuals with appropriate expertise, including molecular pathologists, researchers, and individuals with

expertise in laboratory science or health economics. Advisory panel meetings must comply with the Federal Advisory Committee Act and be open to the public with advance notice in the Federal Register prior to the meeting.

Gapfill Requirements: The process for gapfilling shall take into account the following: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; charges, payment amounts, and resources required for other tests that may be comparable; and other criteria the Secretary determines appropriate. Payment amounts under crosswalk or gapfill shall also include recommendations from the advisory panel.

Payment for New Tests: The process for establishing payment amounts for new tests that are not advanced diagnostic laboratory tests shall comply with the gapfilling process and the requirements for the advisory panel.

Transparency: The Secretary is required to make publicly available an explanation of the payment rate for the test including an explanation of how criteria relating to the gapfill assessments and input from the panel are applied.

Temporary Codes: CMS is required to provide temporary codes for advanced diagnostic tests and new FDA-approved or cleared tests. Temporary codes remain in effect until a permanent HCPCS codes is established, but may not exceed 2 years, although the Secretary may allow for an extension, as appropriate.

Coding Granularity: For existing tests (advanced diagnostic tests and existing lab test cleared or approved by the FDA), the Secretary is required to assign a unique HCPCS code for the test and publicly report payment rate for the tests. CMS must establish a mechanism for providing unique identifiers upon request by a manufacturer or lab for advanced diagnostic tests or tests cleared or approved by the FDA, for purposes of tracking or monitoring specific tests.

Coverage and Payment MACs: The proposal allows the Secretary to establish up to four Medicare Administrative Contractors to establish coverage policies and process claims for payment for lab tests.

CMS Rate Reassessment Process: The authority for CMS to reassess payment rates of tests on the CLFS, as announced in CY2013, is struck and replaced by the process detailed above for existing tests.

GAO Study: GAO study on the implementation of new payment rates for clinical diagnostic tests including, health care economic information on downstream cost impacts of tests, and the impact of the new payment rates on beneficiary access. This report is due no later than October 1, 2018.