

Protecting Access to Medicare Act of 2014 (P.L. 113-93)
Enacted April 1, 2014
Diagnostic Test Reimbursement Provisions

Expert Advisory Panel: Requires the Secretary of Health and Human Services (HHS) 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 shall be open to the public.

Gap-filling requirements: The process for gap-filling must 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 must also include recommendations from the advisory panel.

Transparency: Requires the Secretary 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: Directs the Secretary to establish a process for the assignment of a temporary national HCPCS (Healthcare Common Procedure Coding System) code to uniquely identify a diagnostic test until a permanent national HCPCS code is available for assignment to that test.

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.

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.

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.

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.