



Sarah Harding Joins NVHPF to Discuss Medicare Payment Policy for Diagnostics

On October 7, 2026, the Northern Virginia Health Policy Forum hosted a discussion on Medicare payment policy for diagnostic tests, focusing on the Clinical Laboratory Fee Schedule ([CLFS](#)) and implementation of the Protecting Access to Medicare Act of 2014 ([PAMA](#)). Moderated by Jim Scott, President and CEO of Applied Policy, the conversation featured Sarah Harding of the Division of Ambulatory Services at the Centers for Medicare & Medicaid Services (CMS), who has worked on clinical laboratory payment policy for more than 15 years.

HOW CMS SETS RATES FOR NEW TESTS

Harding explained that new codes generally originate in the American Medical Association's (AMA) Current Procedural Terminology (CPT) process, and her division sets a rate for each generally once a year. This may entail crosswalking, in which a new code is assigned the rate of a similar test already on the CLFS. When no comparable test exists on the CLFS, the agency uses gapfilling, which relies on pricing data from Medicare Administrative Contractors and can add a year to the process.

She described an annual cycle in which CMS publishes a *Federal Register* notice listing the codes under review in April or May, holds a public meeting in June at which labs present their tests, and convenes an advisory panel in July. Preliminary determinations are announced in August or September and are followed by a 30-day comment period. Final rates, which are typically announced around Thanksgiving, take effect in January. Labs that disagree with a decision can request reconsideration.

DESCRIPTORS DRIVE THE RATE

Scott asked whether the process differed for tests with Proprietary Laboratory Analyses ([PLA](#)) codes versus CPT Category I codes. Harding replied that it did not, but observed that CMS often has less information when it comes to proprietary tests. She noted that the code descriptor is “the most important aspect of your test when it comes to setting your payment rate.” CMS starts with the primary methodology the descriptor names, such as reverse transcription-polymerase chain reaction (RT-PCR) or an immunoassay. If a descriptor omits a feature, such as an algorithm for example, CMS has difficulty considering it. This is because each priced test becomes a potential crosswalk for future tests.

Scott suggested that it would be in a developer’s interest to weigh its desired crosswalk and payment before working with the AMA on a descriptor. Harding agreed, noting that the AMA can be persuaded to revise a descriptor if an important component of the test is omitted and that a



substantial revision restarts the payment process. She encouraged developers to review CMS's past determinations, which are online going back at least a decade, to see where tests using a given technology have been priced.

WHAT CMS CAN AND CANNOT CONSIDER

CMS prices tests following statutory instructions rather than through largely subjective factors. Because statute and regulations do not list improved sensitivity or specificity of a test as factors to be considered in the rate-setting process, CMS does not consider them in selecting crosswalks. Harding acknowledged concerns that better-performing tests receive no recognition in their initial rate, but noted that there is an assumption that the market will reward them: "If it works the best, then it'll be ordered the most, and the company will reap all of those benefits."

Resources associated with the test, such as Food and Drug Administration (FDA) approval, can be considered. Harding said CMS recognizes that FDA review can be costly and lengthy. CMS has previously matched FDA-approved tests to similar tests that also have FDA approval. A lab can make that consideration easier by sharing a breakdown of its test-development and FDA-related costs. Because FDA status does not appear in descriptors, however, CMS must document these decisions so that future tests without FDA approval are not crosswalked to the higher rates, which would build "a house of cards."

ENGAGING WITH CMS

Harding described engagement as "incredibly important" and said CMS collects information as soon as the *Federal Register* notice is published. She described labs that lacked guidance through the process, were crosswalked on the descriptor alone, and were surprised by their rate a year later, when it can be hard to make changes. "It is complicated," she said. She added that her office has never turned down a meeting request because "the more information we have, the better we can get labs where they need to be."

Harding noted that labs can expect pushback if it appears that a proposed crosswalk is based on a target price. She urged presenters to focus meetings on methodology and crosswalk candidates, information that CMS is allowed to act upon given statutory and regulatory requirements, and to submit broader context on a test's value in writing. Scott added that developers should begin thinking about reimbursement before submitting anything to the FDA.

PAMA OUTLOOK

CMS completed its second PAMA data reporting period this year, the first since 2017. For tests with reported data, the new rate is the volume-weighted median of private payer rates, with reductions capped at 15 percent annually for three years. Comments and feedback from stakeholders are requested on the [published preliminary median rates](#) and must be received prior to October 21.

Codes without reported data will be crosswalked or gapfilled as new tests. Harding acknowledged that the governing regulations predate PLA codes and did not anticipate the many single-lab tests now in that group. She said preliminary determinations are coming soon and every test will have a rate on January 1.

Harding referenced a [video](#) in which CMS Administrator Dr. Mehmet Oz framed the new rates as reducing waste and projected that, once fully phased in, they will prevent more than \$1 billion in waste annually.

LOOKING AHEAD

Harding's message was consistent: rates are built from the descriptor and methodology within statutory limits, and developers who plan ahead and engage CMS early are best positioned.

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This Applied Policy® Summary was prepared by Annie Tuttle with support from the Applied Policy team of health policy experts. If you have any questions or need more information, please contact her at atuttle@appliedpolicy.com or at (202) 558-5272.