Payment for Genetic and Genomic Tests: Two Related Regulatory Issues

ISSUE #1

CY2013 Physician Fee Schedule (PFS) Proposed Rulemaking: Assignment of New Codes for Genetic and Genomic Tests

ISSUE #2

Payment Status for Multianalyte Assays with Algorithmic Analyses (MAAAs)

The CY2013 PFS Proposed Rule

- The CY2013 Proposed Rule seeks comment on whether 101 new codes for genetic and genomic laboratory tests meet the narrow regulatory exceptions for being paid on the PFS instead of the CLFS.

- The Proposed Rule also contemplates modifying the existing regulation to change the definition of what services are covered under the PFS.

- If so modified, CMS implies that it will immediately move existing tests from the CLFS to the PFS without further notice and comment.

CLFS vs. PFS

- The AMA has created 101 new codes for greater specificity in the billing of over 370 molecular tests. These are new codes, not new tests.
- These tests have been reimbursed on the CLFS for well over 10 years. CMS now has nevertheless proposed placing all 101 codes on the PFS.
- The vast majority of these tests are performed by PhD scientists and do not ordinarily require performance by a physician — the key legal element.
- Moving these tests to the PFS is inappropriate and could have a devastating affect on clinical lab reimbursement and patient access to advanced diagnostics.
- CMS's proposal to amend the underlying regulation to enable this new policy — without adequate notice and comment — is impermissible.

Two Narrow Exceptions for PFS Payment of Clinical Laboratory Tests

- Since 1983, CMS has narrowly defined the rare instances in which a clinical laboratory test constitutes a "physician pathology service" payable on the PFS.

- Two regulatory thresholds govern when a clinical laboratory test can be paid on the PFS rather than the CLFS. Both thresholds must be met.

  (1) The test must "ordinarily require performance by physician"
  42 C.F.R. § 415.102(a)

  (2) The test must be in one of four specific categories of pathology service.
  42 C.F.R. § 415.130(b)

Legal Scope of PFS Proposed Rulemaking

- In the CY2013 PFS Proposed Rule, CMS "requests comment on whether these molecular pathology codes . . . ordinarily require physician work."

- This is a fact-based inquiry, not a policy-based inquiry.

- The Proposed Rule does not solicit comments on new regulatory text or on a specific expansion of § 415.130.

- CMS acknowledges that the current regulation may need to be modified to permit payment of molecular pathology tests on the PFS:

> "If we decide to finalize payment for these new codes under the PFS, we would consider modifying § 415.130 as appropriate to provide for payment to a pathologist for molecular pathology services."

CMS Cannot Amend § 415.130 Via the Final Rule Without Proper Notice

- CMS has given 42 C.F.R. § 415.130 a definitive interpretation for years: Tests that do not "ordinarily require" performance by a physician are not to be placed on the PFS.

- 5 U.S.C. § 553(b) requires that notice of a proposed rulemaking include "either the terms of substance of the proposed rule or a description of the subjects and issues involved."

- The Proposed Rule offers no "terms of substance" of potential revision to § 415.130. Contrast to the 1982 Proposed Rule, which expressly provided regulatory text for this provision (47 Fed. Reg. 43,595-97 (Oct. 1, 1982)).

- "Once an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking." Paralyzed Veterans of America v. D.C. Arena, 117 F.3d 579, 586 (D.C. Cir. 1997).

What is a Multi-analyte Assay with Algorithmic Analyses (MAAA)?

- A "MAAA" is a new CPT code category created by AMA to describe advanced diagnostic tests. The AMA describes MAAAs as:

  [P]rocedures that utilize multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid based assays (e.g., proteins, polypeptides, lipids, carbohydrates). Algorithmic analysis, using the results of these assays as well as other patient information (if used), is then performed and reported typically as a numeric score(s) or as a probability.

- The MAAA risk score or probability is the test result ordered by the treating physician for use in patient management — <u>not</u> the biomarker results that underlie the MAAA.

- The MAAA risk score or probability is the measure the laboratory validates before lawfully marketing the test under CLIA and state regulation.

- Many MAAAs involve R&D investments in the tens of millions of dollars to develop and validate the tests prior to obtaining Medicare coverage.

MAAA Code Reimbursement

- In the 2013 CLFS Preliminary Notice, CMS stated that MAAAs are "numeric scores" and "non-covered" services because codes already exist to pay for the underlying measures of the test.
  - "**CMS uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done and does not recommend separately pricing the MAAAs codes**"
- This statement reflects a fundamental misunderstanding of what MAAAs are. MAAAs <u>are</u> the clinical diagnostic laboratory tests that are ordered by and reported to the treating physician. There are no "underlying tests."
- MAAAs are <u>not</u> analogous to the unbilled simple calculations that clinical laboratories often report for the convenience of physicians who are interpreting a distinct "underlying test."

The MAAA Proposal is Inconsistent with Current Policy

- CMS currently pays for many lab tests that utilize algorithms to produce a result.

- Many tests that would fall in the MAAA category have been covered and reimbursed by CMS contractors for years.
  - Afirma
  - Allomap
  - HIV Genotyping
  - OncotypeDX

- Refusing to pay for MAAAs and recommending that clinical laboratories report and bill for multiple biomarker assays would violate:
  - CLIA regulations (reporting on tests not ordered by an authorized person)
  - Medicare billing rules (billing only for tests ordered by the treating physician).

CMS Should Recognize the MAAA Codes and Pay Them Under the CLFS

- If finalized, the Preliminary Determination on the MAAAs will have broad-reaching implications on the ability of advanced diagnostic labs to offer these tests and to continue investing in their development.

- CMS must not adopt the Preliminary Determination.

- Instead, in the CY2013 CLFS Final Determination, CMS should:

  (1) recognize the MAAA codes for Medicare payment purposes;

  (2) defer to the local contractors to establish payment rates under gap-filling; and

  (3) pay for these tests under the CLFS.