



GLOBAL LIFE SCIENCES: U.S. HEALTHCARE UPDATE

CMS Releases Proposed Medicare Prices for New Genetic/Genomic Test Codes

The Centers for Medicare and Medicaid Services (CMS) recently released proposed Medicare payment rates for certain new Current Procedural Terminology (CPT) codes created to provide more targeted reimbursement for genetic and genomic tests. In accord with the “gapfill” process used by CMS to price new clinical laboratory tests, CMS posted prices received from its Medicare Administrative Contractors (MACs) for 10 of the 29 new CPT codes that cover molecular diagnostic tests. Stakeholders may submit comments to CMS regarding these prices until mid-July 2015. CMS then is expected to release “final” median pricing and the national limitation amount (NLA) used for future reimbursement purposes for these codes in September 2015, with the final pricing effective in January 2016.

With respect to the 10 codes for which prices were posted, none of the codes were priced by all of the MACs, and for certain codes very few MACs actually submitted prices. MACs may refrain from pricing a test if it is not performed in their jurisdiction; or if the test lacks a benefit category, medical necessity, or high quality, peer-reviewed evidence of clinical utility for Medicare patients; or if no qualifying technical assessment under the MolDx Program has been submitted to the MAC for the test. (The MolDx Program, administered by the MAC Palmetto GBA, is CMS’ current method used to determine coverage and payment for molecular pathology tests.)

The prices for these new CPT codes were generally lower, and often far below, the amount laboratories previously obtained under the former “code-stacking” method used to reimburse such tests prior to CMS’ imposition of the MolDx Program in 2013. Applicable MACs priced a CPT code describing a Multianalyte Assays with Algorithmic Analysis (MAAA) test for breast cancer in the US\$2,062.40 – US\$3,416 range, and priced CPT codes describing cancer panels of five to 50 genes at US\$90. Codes for whole genome sequencing, or for panels of more than 50 genes, were not priced at this time.

Notably, CMS is also supposed to begin collecting data on private sector clinical laboratory test prices in January 2016 under provisions of the Protecting Access to Medicare Act of 2014 (PAMA) that will shift clinical laboratory services payment to a market-based system. Regulations describing this process are due to be finalized by June 30, 2015 under the statute, but CMS has yet to release proposed regulations or to announce a revised timeframe for their issuance. Accordingly, it is unclear when PAMA will be implemented and what impact it may have on genetic and genomic tests, some of which may be subject to more favorable pricing under PAMA provisions governing advanced diagnostic laboratory tests.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

Barbara Cammarata
Counsel
+1.202.736.8785
bcammarata@sidley.com

Richard D. Raskin
Partner
+1.312.853.2170
rraskin@sidley.com

Sidley Global Life Sciences Practice

On three continents, Sidley's Global Life Sciences Practice team offers coordinated cross-border and national advice on Food, Drug and Medical Device Regulatory, Life Sciences Enforcement, Litigation and Compliance, Healthcare Regulatory, Products Liability, Intellectual Property, Corporate and Technology Transactions, Securities and Corporate Finance, International Trade and Arbitration, FCPA/Anti-Corruption, Antitrust/Competition, Environmental/Nanotechnology.

Globally rated as one of the top life sciences practices, our team includes former senior government officials, medical doctors and leaders in various life sciences fields.

For further information on the Global Life Sciences Practice, please contact:

Scott Bass +1.202.736.8684 +1.212.839.5613 sbass@sidley.com	James C. Stansel +1.202.736.8092 jstansel@sidley.com	Maja C. Eaton +1.312.853.7123 meaton@sidley.com
Paul E. Kalb, M.D. +1.202.736.8050 pkalb@sidley.com	M. Patricia Thayer +1.415.772.7469 +1.650.565.7569 pthayer@sidley.com	David J. Zampa +1.312.853.4573 dzampa@sidley.com

Sidley Healthcare Practice

Our Healthcare Practice represents participants in all facets of the healthcare industry, including pharmaceutical, biotech and device companies, DME suppliers, hospitals, skilled nursing facilities, physician-owned companies, professional associations and research institutions. Our lawyers combine a strong background in the complexities of healthcare financing and delivery, including coding, reimbursement, and coverage issues, privacy and security, trade regulation, and competition. We have extensive experience representing clients on enforcement and regulatory matters before federal and state enforcement agencies.

For further information on the Healthcare Practice, please contact:

Paul E. Kalb, M.D. +1.202.736.8050 pkalb@sidley.com	Richard D. Raskin +1.312.853.2170 rraskin@sidley.com
---	--

To receive Sidley Updates, please subscribe at www.sidley.com/subscribe.



BEIJING · BOSTON · BRUSSELS · CHICAGO · DALLAS · GENEVA · HONG KONG · HOUSTON · LONDON · LOS ANGELES · NEW YORK · PALO ALTO · SAN FRANCISCO · SHANGHAI · SINGAPORE · SYDNEY · TOKYO · WASHINGTON, D.C.