IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ERIC D. HARGAN, *In His Official Capacity as Acting Secretary of Health and Human Services*, Defendant.	Civil Action No. 1:17-cv-2645 (EGS)

BRIEF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTEREST OF AMICUS CURIAE[1]

The Advanced Medical Technology Association ("AdvaMed") is the world's largest medical technology association, with approximately 300 member companies that develop medical devices, diagnostic tools, and health information systems. Its members span every field of medical science and range from cutting-edge startups to multinational manufacturers, all dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards. The innovations created by AdvaMed's members advance efficiency in health care through earlier disease detection and more effective treatments which, in turn, reduce the economic burden of disease and allow people to live longer, healthier, and more productive lives.

AdvaMedDx is an association within AdvaMed, whose member companies produce advanced in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease, and often reduce overall health care costs. AdvaMedDx members are engaged in the development of innovative diagnostics that support the advancement of the public health, including next generation sequencing-based technologies.

As suppliers to the diagnostic laboratory market, AdvaMed and AdvaMedDx have a keen interest in preventing market upheavals triggered by skewed data collection leading to reimbursement rates that are not reflective of actual market conditions. Basing reimbursement rates on data that greatly over-represents large independent laboratories in well-served areas that enjoy significant economies of scale will lead to the remainder of the market for diagnostic tests being underserved, or abandoned as economically infeasible, as a consequence of such skewed rates.

[1] No person or entity other than amicus curiae and its counsel assisted in or made a monetary contribution to the preparation or submission of this brief.

INTRODUCTION

Since 1984, the Centers for Medicare & Medicaid Services ("CMS") have paid for outpatient clinical diagnostic laboratory tests covered by Medicare Part B pursuant to the Clinical Laboratory Fee Schedule ("CLFS"). *See* 42 U.S.C. §1395l(h). Despite significant advancements in medical technologies and personalized medicine over the last 30 years, payment methodologies for the CLFS remained largely unchanged. CLFS lagging behind the evolving health care market resulted in arbitrary rates that ignored market forces and "hampered the ability of labs across the country to continue to innovate and improve the diagnosis and treatment of disease." 160 Cong. Rec. S2860 (daily ed. May 8, 2014) (statement of Senator Richard Burr, affirmed by Senator Orrin Hatch). To reorient reimbursement practices towards actual market conditions, in 2014, Congress enacted the Protecting Access to Medicare Act ("PAMA"), Pub. L. No. 113-93, 128 Stat. 1040. PAMA seeks to modernize the way in which CMS reimburses laboratories and to "ensure that Medicare rates reflect true market rates for laboratory services." 160 Cong. Rec. S2860.

As the first step in establishing market-driven Medicare reimbursement rates, Section 216 of PAMA requires CMS to collect information about actual private payor rates for clinical diagnostic laboratory tests. Specifically, Section 216 provides that "an applicable laboratory (as defined in paragraph (2)) shall report" the "payment rate" paid by each private payor for clinical diagnostic laboratory tests and the volume of each test performed, within a defined data collection period. See 42 U.S.C. §1395m-1(a)(1), (3). Congress defines an "applicable laboratory" to mean a laboratory that receives a majority of its Medicare revenue pursuant to the CLFS or the Medicare Physician Fee Schedule ("MPFS"), and allows CMS to establish a low volume/low expenditure threshold for excluding a laboratory from the definition of applicable laboratory. See 42 U.S.C. §1395m-1(a)(2).

CMS's final rule implementing PAMA defines an "applicable laboratory," in relevant part, as a laboratory that "[b]ills Medicare Part B under its own National Provider Identification (NPI)" and "[r]eceives at least $12,500 of its Medicare revenues from [the CLFS]. 42 C.F.R. §414.502; 81 Fed. Reg. 41036 (June 23, 2016) (hereinafter, the "Final Rule"). Unfortunately, this interpretation results in the exclusion of two major segments of the laboratory market, hospital outreach laboratories and physician office laboratories. Hospital outreach laboratories and physician office laboratory are excluded because they generally lack separate NPIs. Additionally, physician office laboratories are excluded because the great majority of them do not receive at least $12,500 of their Medicare revenue from the CLFS. Thus, a significant portion of the relevant laboratory market does not contribute any data pursuant to the Final Rule, skewing the results contrary to the express intent of Congress. Further, the rule-making and publication of the preliminary reimbursement rates under the CLFS did not afford stakeholders sufficient means by which to ensure and evaluate the accuracy of the data.

ARGUMENT

For reimbursement rates under the CLFS to reflect actual market conditions, as Congress intended, complete and accurate data must be collected. Complete data requires that a significant representative sample is included for all segments of the market, including hospital outreach laboratories and physician offices.

By imposing an additional qualification on the definition of "applicable laboratory" – that an "applicable laboratory" must "[b]ill[] Medicare Part B under ***its own*** National Provider Identifier (NPI)" – the Final Rule excludes nearly all hospital outreach laboratories and many physician office laboratories from contributing payment rate data intended to inform the CLFS. In most cases, hospital outreach laboratories and physician office laboratories bill Medicare under their hospitals' or physicians' NPIs and do not use a separate NPI specific to the

laboratory.[2] Hospital outreach laboratories represent about 26 percent (26%) of CLFS payments.[3] Separately, CMS set the low volume/low expenditure threshold for excluding laboratories from the definition of applicable laboratory – $12,500 – at an amount that is too high because it eliminates the vast majority of those physician office laboratories not otherwise excluded by the NPI requirement. 42 U.S.C. §1395m-1(a)(2); 42 C.F.R. §414.502. In 2016, physician office laboratories received approximately 18 percent of CLFS payments.[4]

Taken together, these exclusions render the data significantly incomplete and potentially not representative. CMS admitted in its executive summary that payment rates were established using data from only 1,942 laboratories.[5] This figure is appreciably lower than the approximate 12,000 laboratories that the Office of the Inspector General ("OIG") estimated in 2016 would be the basis for new payment rates.[6] It is but a tiny percentage – less than one percent (1%) – of the 235,928 laboratories in the nation.[7] This minuscule portion of laboratories from which CMS

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[2] *See* CMS, Medicare Program Integrity Manual, Chp. 15 Medicare Enrollment, Section 15.7.8.1 CLIA Labs, at 243, *available at* https://www.cms.gov/Regulations-and Guidance/Guidance/Manuals/Downloads/pim83c15.pdf ("***Labs that are 'integrated' into an existing provider or supplier do not require a separate Form CMS-855B enrollment***. 'Integrated' labs typically are those that have exactly the same ownership and physical location as another enrolled supplier or provider. (Common examples include: (1) ***hospital labs*** and (2) a lab at a ***physician's office***.") (emphasis added).

[3] *See* U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") Data Brief, Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data, OEI-09-16-0004 (Sept. 2017) at 2, *available at* https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf ("OIG 2016 Data Brief").

[4] *Id.*

[5] Summary of Data Reporting for Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System (September 2017) at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf ("CMS Summary of Data").

[6] HHS OIG Data Brief, Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data, (September 2016) at 7, *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf.

[7] *Id.*

collected private payer data does not accurately represent the U.S. market, contrary to the original intent of the law. Indeed, despite hospital outreach laboratories receiving 26 percent (26%) of the CLFS payments in 2016, only 21 hospital laboratories, representing one percent (1%) of the total reported test volume, reported payment rate data in 2017.[8]

Further, the exclusion of certain hospital outreach laboratories and physician office laboratories skews the data itself because hospitals and physicians, particularly those in rural and other underserved areas, lack the economies of scale of large independent laboratories. Laboratories located in physicians' office perform point-of-care tests for patients, and also tests for other physicians, particularly in underserved areas where access to other laboratory testing services is limited. Physician offices contract with private payers for many of these tests, which are performed in the physician office laboratory using special point-of-care technologies. Physician office laboratories are often low volume, and thereby lacking economies of scale, relatively high cost. Predictably, with the overwhelming bulk of submitted data generated by the lowest-cost segment of the market, the reporting exercise implemented by the Final Rule fails the essential purpose of PAMA, which was to ensure that the resultant reimbursement rates reflect actual market conditions.

In addition to complete data, the market-based reimbursement system intended by Congress also requires accurate data. Several factors impact the accuracy of the data submitted by laboratories pursuant to the Final Rule.

First, PAMA required CMS to establish no later than June 30, 2015, through notice and comments rulemaking, parameters for data collection for the time period beginning January 1, 2016. 42 U.S.C. §1395m-1(a)(12). However, the Final Rule was not issued until June 23, 2016.

[8] *Compare* OIG 2016 Data Brief at 2, *with* CMS Summary of Data at 3.

Notwithstanding this year delay, laboratories were still required to report payment data retroactive to January 1, 2016. Laboratories first learned about the retroactive data collection period when the Final Rule was issued, and thus were forced to attempt to reconstruct data they had not expected to report. Because the Final Rule was retroactively applied, as of January 1, 2016, most laboratories did not have existing information technology systems that were designed or equipped to retrieve the data in the manner in which CMS ultimately required it to be reported. As a result, laboratories encountered challenges compiling and submitting appropriate data to CMS, and technical issues with the web portal further complicated those efforts.

Second, the data collection and reporting system lacks sufficient transparency into the rate-setting process. On September 22, 2017, CMS published the CLFS payment rates and method determinations for calendar year 2018. CMS accepted public feedback on the accuracy of the preliminary determinations until October 23, 2017.[9] CMS did not provide for review during this process of the actual, or even some of the underlying raw data received; instead, stakeholders could only review weighted medians for each laboratory test.[10] This limited data release prohibits a meaningful review of the accuracy and validity of the preliminary payment rates. Indeed, even CMS noted in its analysis of the data reporting that it could not validate certain data.[11] The amount of data released under the CLFS is significantly less than the data

[9] Information Regarding the Final CY 2018 Private Payor Rate-Based Clinical Laboratory Fee Schedule (CLFS) Payment Rates (November 2017), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-HCPCS-Median-Calculations.pdf.

[10] PAMA provides that the information disclosed by laboratories is confidential and shall not be disclosed in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except in certain circumstances, including if the Secretary determines it is necessary to carry out the law. 42 U.S.C. §1395m–1(a)(10).

[11] CMS Summary of Data at 5-6.

made available for other Medicare payment systems.[12] The complete data files available under these other payment systems allow stakeholders to perform a thorough review of the preliminary payment rates prior to their effective date or to request that CMS re-examine and correct rates that are potentially inaccurate.

Incomplete and inaccurate data lead to reimbursement rates that are significantly lower than what is actually dictated by the market. In fact, the reimbursement rates for calendar year 2018 were substantially lower than expected. CMS originally estimated that reimbursement to laboratories under the CLFS would decreased by $390 million. In fact, the reimbursement decreased by $670 million. 81 Fed. Reg. 41092.

Reimbursement rates that are not market-driven as intended are likely to negatively impact patient access to necessary laboratory tests that support clinical care management. For example, dramatic reductions in payment amounts for many tests that are currently furnished at the point of care in the physicians' office could have a negative impact on patient access if financial constraints preclude physicians from furnishing them at the point of care. Inappropriate reimbursement rates may also reduce the ability of laboratories to invest in new medical technologies offered by diagnostic test manufacturers and suppliers.

CONCLUSION

To create a market-based reimbursement system, as Congress intended, revised Medicare reimbursement rates under the CLFS must reflect market rates. For that to have any chance of happening, an accurate representative sampling and cross-section of actual market participants

[12] CMS releases voluminous data files for the MPSF and the Hospital Outpatient Prospective Payment System. *See, e.g.,* CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B and Supporting Documentation, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1676-P.html. In addition to the MPFS data available on CMS's website, additional data is also available for purchase.

must report payment data and such data must be reasonably accurate. The Final Rule, however, incorrectly and unreasonably interprets the statutory definition of "applicable laboratory" virtually to exclude an entire segment of the laboratory market, contrary to the express intent of Congress, and CMS's implementation of the Final Rule has led to the submission of inaccurate data.

Respectfully submitted,

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