DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

MAR 19 2019

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Grassley:

Thank you for your letter regarding the November 2018 U.S. Government Accountability Office (GAO) report on recent changes to Medicare payment rates for laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). Secretary Azar asked me to respond on his behalf.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) added section 1834A to the Social Security Act (the Act) and required significant changes to the way that clinical diagnostic laboratory tests are paid under the CLFS by basing Medicare payment rates on certain payment rates paid by the private sector. In doing so, the Centers for Medicare & Medicaid Services (CMS) is helping to ensure patient access to the laboratory tests and services they need, while protecting taxpayer dollars.

Prior to implementing these new Medicare rates, CMS was required to collect certain private payor rate data from applicable laboratories to inform the rate setting process. Through notice and comment rulemaking, CMS considered stakeholder input in establishing parameters for the collection of the applicable information. In addition to rulemaking, we posted press releases and fact sheets on the CMS website describing the changes required by section 216(a) of PAMA and our progress in implementing the law, and we held three national provider calls focused on data reporting and the data collection system.

As a result of these efforts, the data reported to CMS during the initial data reporting period captured more than 96 percent of laboratory tests on the CLFS, representing over 96 percent of Medicare's spending on CLFS tests in calendar year 2016. Laboratories from every state, the District of Columbia, and Puerto Rico reported applicable information. To determine if we could improve the 96 percent reporting rate without creating significant further burden for laboratories, particularly small laboratories, we modeled three additional reporting scenarios to estimate the impact of increasing data reporting. Based on this analysis,[1] we determined that additional

[1] Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf

reporting requirements were not likely to result in a significant change to payment amounts, irrespective of how many additional laboratories reported. However, we noted that we would continue to analyze the effect of additional data when setting Medicare payment rates in the future.

In preparation for the next data collection period for most tests that runs from January 1, 2019, through June 30, 2019, we made two changes to the definition of applicable laboratory in the Medicare Physician Fee Schedule Calendar Year 2019 final rule (83 FR 59671, 60033 and 60074), which we believe will lead to an even more robust data collection from which to calculate payment rates for the next CLFS update, as more laboratories may be required to report data. First, the final rule excludes Medicare Advantage plan payments from the total Medicare revenues, the denominator of the Medicare revenues threshold, which we believe will result in more types of laboratories qualifying as an applicable laboratory. We believe that our previous interpretation of total Medicare revenues, which included Medicare Advantage revenues, may have had the effect of excluding certain laboratories from meeting the majority of Medicare revenues threshold criterion and, therefore, from qualifying as applicable laboratories. In addition, we amended the definition to include hospital outreach laboratories that bill Medicare Part B using the CMS-1450 14x Type of Bill.

We are continuing to evaluate ways to increase data reporting, including targeted outreach and auditing of laboratories that may meet the definition of an applicable laboratory. CMS had a National Provider Call (NPC) on January 22, 2019, to educate laboratories on the new CLFS requirements. An audio recording and transcript of the call are available online.[2] A Medicare Learning Network Matters article with helpful information for laboratories is also available,[3] and we continue to update Frequently Asked Questions on our website with information that we believe is of value to laboratories. Laboratories, or other stakeholders, that have questions or concerns regarding their status as an applicable laboratory or the status of a data submission are encouraged to contact CMS, and we will continue to provide additional information through NPCs and other informational materials.

As you noted, the GAO recommended that CMS phase in payment-rate reductions that start from the actual payment rate rather than the national limitation amounts that Medicare paid prior to calendar year 2018. The requirements to phase-in payment rate reductions from the national limitation amounts were finalized after notice and comment rulemaking in the Medicare Clinical Diagnostic Laboratory Tests Payment System final rule (81 FR 41036) and codified in regulation at 42 C.F.R. §414.507(d).

Prior to the implementation of PAMA, test panels without a Current Procedural Terminology (CPT) code were paid at a bundled rate using a payment algorithm developed by CMS. However, under section 1834A of the Act, Medicare payment rates for each clinical diagnostic

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[2] Available at https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2019-01-22-CLFS.html

[3] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019-Transmittals-Items/SE19006.html

laboratory test under the CLFS generally must be a separate amount that is equal to the weighted median of the private payor rates for each test based on the applicable information reported by applicable laboratories. Thus, in a transmittal to Medicare contractors issued in November 2016, CMS implemented a change to claims processing procedures intended to accord with this provision.

CMS is working to analyze claims data to determine whether any panel tests with their own CPT codes were instead billed by laboratories using separate CPT codes. We also specified again on January 1, 2019, in the National Correct Coding Initiative Policy Manual for Medicare Services, that section 1834A of the Act requires separate rates for each test, including panel tests, and thus, such panel tests cannot be billed as individual tests.[4] This manual specification serves to remind laboratories that they must report the panel code and not the codes for individual components of the tests when applicable. Finally, CMS is working to automatically detect claims that have inappropriately unbundled the panel tests.

Thank you again for your letter. PAMA made significant market-based reforms to the way that payment is made under the CLFS, and we continue to work with laboratories and others to ensure the correct reporting and payment of laboratory tests under the CLFS for the benefit of taxpayers and patients.

Sincerely,

Seema Verma

[4] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019-Transmittals-Items/R4208CP.html