United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

January 23, 2019

VIA ELECTRONIC TRANSMISSION

The Honorable Alex Azar II
Secretary
Department of Health and Human Services

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid

Dear Secretary Azar and Administrator Verma:

According to a November 2018 report issued by the U.S. Government Accountability Office (GAO), recent changes to Medicare payment rates for laboratory services implemented by the Centers for Medicare and Medicaid Services (CMS) could result in billions of dollars in unnecessary costs.[1] The changes, made in response to requirements of the Protecting Access to Medicare Act of 2014 (PAMA), were intended to develop a national fee schedule for laboratory tests. The GAO report raises important questions about the implementation of the new fee schedule, specifically the methods used by CMS.

The GAO report notes that the new fee schedule was based on incomplete data, since not all laboratories who were required to report information to CMS actually did so. The GAO recommends that CMS undertake efforts to collect complete data from all laboratories who are required to report. I understand that the Department of Health and Human Services (HHS) is considering ways to increase reporting, such as conducting outreach to and auditing of laboratories who are expected to report data, but it is unclear whether or not these efforts are yet underway.

Furthermore, the GAO report raised concerns about the decision by CMS to use maximum rather than average Medicare payment rates as a baseline for calculating the new fee schedule. GAO notes that the decision to do so "resulted in excess payments for some laboratory tests and, in some cases, higher payment rates than those Medicare previously paid, on average."[2] The estimated cost to taxpayers as a result of that decision is staggering.

According to the GAO, "Medicare expenditures from 2018 through 2020 may be $733 million more than if CMS had phased in payment-rate reductions based on the average payment

[1] GAO Report to Congressional Committees "Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments" (November 2018). Available at: https://www.gao.gov/assets/700/695756.pdf
[2] *Id.*

rates in 2016."[3] As a solution, GAO recommends that CMS phase in payment-rate reductions based on actual rather than maximum rates. In a letter to GAO commenting on proposed recommendations, HHS explained that the method for calculating payment-rate reductions is established in a rule and must change through the rule-making process.[4] According to the report, higher expenditures resulting from the new way of calculating payment rates are now compounded by CMS' decision to stop paying a bundled rate for certain panel tests. Specifically, in cases where a current procedural terminology (CPT) panel code is not yet established and in cases where a panel code is established but a lab has not opted to use the code, Medicare has paid the individual rate for each component test in a panel rather than a bundled rate.[5] According to the GAO, it estimated that if the payment rate for each panel test were unbundled, "Medicare expenditures could increase by as much as $10.3 billion from 2018 through 2020 compared to estimated Medicare expenditures using lower bundled payment rates for panel tests."[6]

In the GAO report, HHS stated that the decision to stop paying a bundled rate for panels where a CPT code does not exist was made in an effort to comply with certain provisions of PAMA.[7] In a November 7, 2018, letter to the GAO, HHS indicated that it will "revisit this determination regarding [its] authority, and HHS is considering other approaches to payment for these tests consistent with section 1834A of the Social Security Act such as adding codes to the Clinical Laboratory Fee Schedule for this purpose."[8] Given the significant expense associated with paying individual rather than bundled rates for panel tests, it is unclear why HHS did not undertake this analysis sooner.

In its letter to the GAO, HHS also indicated that it is working on an update to its payment processing system that will allow it to detect claims where a CPT panel code should be used, regardless of whether or not the code has actually been used by a laboratory during its billing process.[9] Presumably, by detecting cases where a code should have been used by a laboratory but wasn't, and by paying the bundled rate for a panel test rather than the individual rates for each of the panel's component tests, the Medicare system will save money. According to HHS, the "update [to its payment system] is targeted to be operational no later than summer 2019."[10]

On December 14, 2018, CMS issued Transmittal 4182 which included a section titled, "Coding for Healthcare Common Procedure Coding System (HCPCS) Panel Codes." The Transmittal notes that prior to PAMA, CMS' claims processing system would not pay more than the associated CPT panel code for individually billed tests. The Transmittal asks for labs to bill for panel tests instead of individually while noting that a claims process edit is in the process of being reinstated.

---

[3] GAO Report to Congressional Committees "Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments" (November 2018). Available at: https://www.gao.gov/assets/700/695756.pdf
[4] *Id.* at 37-40.
[5] *Id.* at 8.
[6] *Id.* "GAO Highlights."
[7] *Id.* at 39.
[8] *Id.*
[9] *Id.*
[10] *Id.* at 40.

Accordingly, please answer the following questions no later than February 6, 2019.

1. What steps have been taken to ensure that all laboratories who are expected to report data to HHS actually do so?

2. Does HHS agree with the GAO recommendation that CMS phase in payment-rate reductions based on actual rather than maximum rates? Why or why not? If yes, what steps have been taken to amend relevant HHS rule(s) and implement the GAO recommendation?

3. Does HHS believe that it has the authority to create CPT codes for panel tests where they do not currently exist, or take other steps to ensure the completion of a bundled payment, while remaining compliant with the provisions of PAMA and other relevant federal laws? Please explain why or why not? If yes, why has HHS paid individual rather than bundled rates for these panel tests unnecessarily?

4. Did CMS make a systems edit to its claims processing system that prevented CMS from detecting whether individually billed tests should have been bundled? If so, why did CMS make that edit?

5. What is the status of efforts to detect panel tests where CPT codes do exist but have not been billed correctly by laboratories? When do you expect that CMS will be able to effectively detect and correct the billing problems?

6. During the time the claims processing system was unable to detect when a panel CPT code was appropriate, does CMS know how many laboratories billed individual tests and received a higher reimbursement rate when they should have billed as a panel code? Is CMS able to perform an audit to determine that number and the cost in excess reimbursement? If so, will CMS perform the audit?

Thank you in advance for your cooperation with this request. If you have any questions, please contact Josh Flynn-Brown of my Committee staff at (202) 224-4515.

Sincerely,

Charles E. Grassley
Chairman
Committee on Finance