GAO Report on Implementation of PAMA Fails to Base Recommendations on Facts

Background

The Government Accountability Office (GAO) released a report on November 30, 2018, stating that the Centers for Medicare & Medicaid Services' (CMS's) implementation of the Protecting Access to Medicare Act (PAMA, P.L. 113-93) may lead to billions of dollars in excess payments. GAO claims that the agency's potential to overspend is due to two factors: 1) CMS used the national limitation amount of Medicare payment rates in 2017 as a baseline to start the phased in cuts to the clinical laboratory fee schedule instead of the 2016 actual rates that Medicare paid on average; 2) CMS stopped paying a bundled payment rate for certain panel tests. In its recommendations to the Administrator of CMS, GAO advises the following:

1. Collect complete private-payer data from all laboratories required to report or address the estimated effects of incomplete data;
2. Phase in payment-rate reductions that start from the actual payment rates rather than the maximum payment rates Medicare paid prior to 2018;
3. Use bundled rates for panel tests.

GAO's report is largely unfounded and speculative, at best. The GAO's recommendations either go against the PAMA statute or are not based on evidence. For the GAO to make unsupported, sweeping recommendations—even though it admits being unaware of the reality of practices in the laboratory field—regarding CMS losing billions of dollars is irresponsible and detrimental to independent clinical laboratories who provide critical services to Medicare beneficiaries. Congress should primarily be concerned with the fact that under the flawed implementation of PAMA, Medicare beneficiaries are losing access to laboratory services. Congress must act immediately to address this.

NILA's Response to GAO's Speculative and Incomplete Report

The National Independent Laboratory Association (NILA) vehemently disagrees with many of the findings of the GAO report and provides the following response to GAO's recommendations.

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GAO Recommendation #1: Collect complete private-payer data from all laboratories required to report.

- NILA takes issue with this recommendation because the GAO failed to point out that CMS excluded 99.3% of the laboratory market.[1] The deliberate omission of virtually all hospital-outreach private payer data, which comprises nearly one-third of the laboratory industry's total private payer data, and CMS's failure to collect sufficient private payer data from independent and physician office laboratories, resulted in skewed data. Therefore, a major fault in GAO's study is the reliance on incomplete data as defined and collected by CMS.

  NILA has consistently taken issue with CMS's definition of an applicable laboratory and believes that the agency unlawfully implemented PAMA by excluding large sectors of the laboratory market. The exclusion of hospital outreach laboratories from reporting Medicare revenue left nearly 30% of the laboratory market unaccounted for in the calculation of the weighted median used to establish the 2018 CLFS rates. In its report, GAO cites that **"[hospital-outreach laboratories] typically receive relatively higher private-payer rates."** Therefore, inclusion of this data would have had a significant impact on the weighted median of each test code. The purposefully deficient data collection process used to establish new clinical laboratory payment rates resulted in unreliable data and unsustainable rates that fell short of Congress' goal to establish a market-based system. GAO's recommendation does not go far enough, and simply stating that CMS should collect complete data does not address the need for CMS to ensure it is collecting data from all sectors of the laboratory market as outlined in the PAMA statute, which includes hospital outreach laboratories.

- NILA recommendation: CMS should lawfully implement PAMA as intended by Congress and collect complete private-payer data from all laboratories that have a majority of Medicare revenue, without the gross exclusion of large sectors of the laboratory market. GAO can amend its recommendation to read as follows: "collect complete private-payer data from all laboratories (including hospital outreach laboratories) required to report, as outlined in the PAMA statute, to ensure a full market analysis of reimbursement rates for laboratory services."

[1] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payer Rate-Based System available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf

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GAO Recommendation #2: Phase in payment rate reductions that start from actual payment rates rather than the 2017 National Limitation Amount.

- In its report, GAO suggests that CMS base reductions on "more relevant information [that is closer to] how much Medicare actually paid—such as the average allowable amounts in 2016" (pg. 26). Basing reductions on an average is in clear violation of the PAMA statute in two ways. First, the statute states that reductions in payments for the first six years must reference a percentage of the payment for the test for the preceding year. Thus, the suggestion by GAO to take an average of the 2016 allowable amounts is not from the preceding year and is inconsistent with the PAMA statute. Second, the PAMA statute outlines that reductions in payment amounts should not be greater than 10 percent in each of the first three years of PAMA, followed by 15 percent in the subsequent three years. The recommendation by GAO to base reductions on an average allowable amount would result in some laboratories being cut more than 10 percent in the first year.

  The example GAO used in Figure 5 using the Comprehensive Metabolic Panel (CMP) makes this point (pg. 25). The 2016 average Medicare allowable amount for the CMP is $11.45 and the national limitation amount in 2017 was $14.49. If, as the GAO suggests, CMS were to reduce the 2018 payment rates based on the average Medicare allowable in 2016, the 2018 payment rate would be $10.31 [$11.45 – 10% = $10.31]. However, any laboratory that was reimbursed at the 2017 national limitation amount would see a reduction of $4.18 [$14.49 - $10.31 = $4.18] which results in a 29 percent cut. This violates the PAMA statute.

  Additionally, it is important to point out that CMS deliberated on the point of basing the reductions off of actual payment rates instead of the national limitation rates during rulemaking. Ultimately, CMS made an informed decision to use the national limitation rates as a baseline.

- NILA recommendation: Collect complete data from all sectors of the laboratory market as intended in PAMA, calculate a weighted median, and base reductions using the 2017 national limitation amounts as the baseline.

GAO Recommendation #3: Use bundled rates for panel tests.

- GAO claims that CMS will overpay as much as $10.3 billion from 2018 to 2020 compared to estimated Medicare expenditures using only bundled payment rates for panel tests. NILA refutes this point based on a lack of data, and admonishes GAO for wild speculation without the data to support such claims. GAO's estimates are based on an incorrect assumption that each panel test is being unbundled and billed as individual codes. GAO

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even states that "these *estimates* represent an *upper limit* on the increase expenditures that *could* occur if *every* laboratory stopped using panel testing billing codes…*We do not know* the extent to which laboratories will stop filing claims using panel test billing codes" (pg. 30, *emphasis added*).

Additionally, on December 12, 2018, CMS released the revised version of the National Correct Coding Initiative Policy Manual for Medicare Services which is updated annually to promote national correct coding methodologies and control improper coding leading to inappropriate payment in Part B claims. Revisions related to test panels are effective January 1, 2019 and include changes to the General Coding Policies in Chapter 1 and the Pathology/Laboratory Services CPT Codes 80000-89999 in Chapter 10. Changes in both chapters state that laboratories shall bill panel codes, and not individual test codes as was previously allowed. The changes made by CMS makes GAO's speculative claims of excess payments unfounded. Below is a side by side comparison showing the amendments made by CMS from 2018 to 2019.

	2018	**2019**
Chapter 1	*Section N. Laboratory Panel* If a laboratory performs all tests included in one of these [organ and disease specific] panels, the laboratory may report the CPT code for the panel or the CPT codes for the individual tests[2]	*Section N. Laboratory Panel* If a laboratory performs all tests included in one of these [organ and disease specific] panels, the laboratory *shall* report the CPT code for the panel.[3]
Chapter 10	*Section C. Organ or Disease Oriented Panels* If all tests of a CPT defined panel are performed, the provider may bill the panel code or the individual component test codes.[4]	*Section C. Organ or Disease Oriented Panels* If all tests of a CPT defined panel are performed, the provider *shall* bill the panel code.[5]

[2] Centers for Medicare & Medicaid Services. *The National Correct Coding Initiative Policy Manual for Medicare Services*. (2018). Chapter 1: Section N: Laboratory Panel. Page I-32.
[3] *Ibid*. (2019). Page I-32.
[4] *Ibid*. 2018). Chapter 10: Section C: Organ or Disease Oriented Panels. Page X-6.
[5] *Ibid*. (2019). Page X-6

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Finally, while making these unsubstantiated claims, GAO made no effort to ask NILA about the practice of bundling as it occurs in independent clinical laboratories. GAO interviewed NILA for its report in December 2017, and the list of questions given to NILA did not ask anything about bundling or unbundling of test panels. GAO also chose not to reach out to NILA as it wrote its recommendation about bundled panels and could have easily requested information about laboratory practices. Instead, GAO chose to make sweeping recommendations and statements based on speculation, not empirical data.

- NILA recommendation: The GAO report states that as of July 2018, CMS had preliminary data on unbundling from 2018 and that the agency is monitoring activities (pg. 27). Therefore, Congress should request any data CMS has from the start of 2018 regarding the reality of laboratories unbundling test panels in 2018. In the meantime, GAO's claim that CMS could be paying billions in excess between 2018-2020 is unsubstantiated based on the amendments to require laboratories to bundle test panels as outlined in the National Correct Coding Initiative Policy Manual for Medicare Services for 2019. GAO should amend its recommendation in light of this new policy, and Congress should make every effort to understand the reality of bundling billing practices as it occurs in clinical laboratories.

Conclusion

GAO's report fails in many respects. GAO fails to address many of the specific questions laid out in the PAMA statute and chooses to ignore the feedback NILA provided. For example, by ignoring CMS's exclusion of virtually all hospital outreach private payer data, the GAO fails to analyze, as required by PAMA, payer rates "furnished in various settings, including – (I) how such payment rates compare across settings." GAO fails to understand laboratory billing practices for bundled panel tests in independent clinical laboratories. GAO fails to base its sweeping recommendations on empirical data, and instead speculates and admits that it does not understand the reality of laboratory billing practices surrounding panel test billing codes (pg. 30). Most importantly, GAO fails Medicare beneficiaries by ignoring the severe reductions to laboratory reimbursement already occurring as a result of PAMA.

GAO presents many variables that could increase payments to Medicare, but does not provide any conclusions based on facts and data. The GAO report only emphasizes the flawed implementation of PAMA by CMS. CMS and Congress must work towards a comprehensive fix for PAMA, and not fall short with a shortsighted, patchwork stopgap that fails to address the larger problems.

NILA and its members remain available to members of Congress to discuss the reality of billing practices in their clinical laboratories.

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