# Government Agency Defends Analysis of PAMA Implementation, Future Impact on Medicare Spending

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NEW YORK (GenomeWeb) – The Government Accountability Office is defending itself against lab and diagnostics industry groups that have challenged its recent report projecting how Medicare spending on lab tests could increase in coming years and accused it of mischaracterizing their billing practices.

In an interview with 360Dx this week, James Cosgrove, director of healthcare at the GAO, stood by the report, released last November, which he clarified was aimed at identifying the ways in which Medicare expenditures could increase under the Protecting Access to Medicare Act of 2014 (PAMA) and draws no conclusions about the lab industry's billing practices. "We weren't analyzing what labs are or aren't doing," Cosgrove said. "We were analyzing what the exposure to Medicare would be."

In the report, the GAO assessed the future financial impact of the implementation of PAMA, which aims to establish a market-based payment system for lab tests, on the Centers for Medicare & Medicaid Services. The agency identified a number of choices CMS made in implementing the new pricing law that could result in the government payor spending more than it has to.

Based on the overpayment risks it identified, the GAO recommended that CMS should make sure that all labs required to report private payor rates are doing so; phase in payment reductions based on average Medicare payments for a test rather than maximum payments; and pay bundled rates when tests are performed together instead of paying for them separately. This last recommendation, the GAO said, is intended to caution CMS that Medicare costs could increase by $10.1 billion from 2018 to 2020 — a worst-case scenario based on the government payor stopping bundling payments for all commonly performed organ- and disease-specific panel tests.

The report has caught the attention of Senator Charles Grassley, R-Iowa, chair of the Senate Finance Committee, which deals with matters related to Medicare expenditures. Grassley recently wrote to CMS expressing concern about the GAO's findings and asked the agency to explain how it plans to avoid these pitfalls and "ensure fiscal responsibility prevails when it comes to Medicare payments."

The congressional attention the report received didn't sit well with the lab and diagnostics industry, which is particularly sensitive to any suggestion of further payment cuts given it shouldered the first round of reductions last year from the implementation of PAMA. CMS is estimated to have saved $670 million last year, a 10 percent discount to the $7 billion the agency spends annually on lab tests. PAMA allows Medicare to cut pricing by a maximum of 10 percent in 2019 and in 2020.

In a letter this week, industry groups AdvaMedDx, the American Clinical Laboratory Association, the College of American Pathologists, the National Independent Laboratory Association, and the Point of Care

Testing Association told the GAO that they disagreed with its suggestions that Medicare could be paying too much for lab tests in certain circumstances.

These groups were most offended by the GAO's analysis of the impact that unbundling payments for panel tests could have on Medicare spending. "The discussion on panel test billing demonstrates a fundamental misunderstanding by GAO of actual, real-world billing practices of clinical laboratories," they wrote in a letter to GAO's Cosgrove. "This misunderstanding leads to an inflammatory and false claim that Medicare is overpaying clinical laboratories for panel tests on the magnitude of billions of dollars."

**Impact of choices**

The GAO identifies two ways in which Medicare may overspend on lab tests. One involves CMS' decision to use the national limitation amount (representing maximum Medicare payment rates) as the baseline from which to cut test pricing by 10 percent, instead of using average payment rates. Another involves CMS' decision to stop paying bundled rates for certain panel tests with codes, and for tests commonly performed together without panel codes.

In the first case, CMS' decision to rely on maximum payment amounts resulted in excess payment for certain tests, the GAO wrote, and in some cases, Medicare ended up paying more for tests than it previously had on average. One example in the report was for comprehensive metabolic panel tests, which had a national limitation amount of $14.49, but the average amount Medicare paid in 2016 was $11.45 and the median payment labs reported getting from private payors was $9.08 per test.

The agency estimated that from 2018 to 2020, Medicare spending could be $733 million more than if CMS had calculated payment reductions based on the average prices it paid in 2016.

AdmaMedDx and the other groups noted in their letter that basing cuts on average payments would mean that some tests would see prices reduced by more than 10 percent. "This proposed outcome is in direct conflict with the PAMA statute, and would have resulted in disproportionate hardship across the industry, primarily based on nothing other than the geographic location of the laboratory," they wrote.

The GAO pointed out in the report, however, that CMS often pays less than the national limitation amount for a test, particularly when paying bundled rates for tests performed together. "CMS had a choice" when implementing PAMA whether to use average or maximum rates as the starting point for cuts, said Marty Gahart, assistant director of healthcare at the GAO. "And we're pointing out the choice they made gave them additional costs they didn't have to have."

**Worst case scenario**

The GAO report also flagged CMS' decision to stop bundled payments for certain panel tests as a big risk for Medicare overpayment.

PAMA stipulated that labs must report private payor rates for individual tests, which raised questions about CMS' statutory authority to bundle payments when tests were performed together. Because of this uncertainty, after PAMA went into effect, CMS eliminated bundled payments when there wasn't a specific panel code for a group of tests performed together and paid for the individual assays instead.

To demonstrate the way this could impact Medicare spending, the GAO offered the example of two common assays that CMS previously bundled. In 2016, Medicare paid 435,000 claims for panel tests that included a creatinine assay (code 82565) and a urea nitrogen assay (code 84520) at an average bundled rate of $6.82. In 2018, CMS paid $6.33 for creatinine and $4.88 for urea nitrogen testing, or $11.21 in total, when they were billed separately, marking a 63 percent increase from the 2016 bundled rate.

Even when there are panel codes, CMS implemented PAMA in a way that "could lead to unbundling payment rates," the GAO reported. In 2018, because of the uncertainty around its statutory authority under PAMA, CMS asked its Medicare Administrative Contractors to stop paying bundled rates for commonly performed tests when labs billed for the individual components instead of the existing panel code.

"This change could potentially have a large effect on Medicare spending," the GAO warned in the report. There are 14 test components of a comprehensive metabolic panel, for example, which if labs claimed them individually would garner $81.91. This, according to the GAO, would be a 528 percent increase in the Medicare payment rate, compared to the 2018 bundled rate of $13.04 for the panel.

If CMS continues this practice, the GAO estimated that in the most extreme case, unbundling payment rates for all panel tests could increase Medicare expenditures from 2018 to 2020 by $218 million for tests without panel codes and by $10.1 billion for panel tests with billing codes, compared to if CMS continued to bundle payments.

"These estimates represent an upper limit on the increased expenditures that could occur if every laboratory stopped using panel test billing codes and instead used the billing codes for individual component tests," the GAO wrote. "We do not know the extent to which laboratories will stop filing claims using panel test billing codes."

By providing these estimates, the GAO is illustrating the worst-case scenario in terms of Medicare spending, explained Gahart, who added that the agency makes clear in the report that it doesn't know the extent to which labs are unbundling payments. "CMS told us it is monitoring that and expects it happens some," he said. In the report, the GAO noted that CMS has also indicated that unbundling payments in 2018 resulted in higher payments compared to past years for some tests, and is verifying this with more complete data.

To arrive at the $10.1 billion figure, the GAO focused on panels comprising automated multi-channel chemistry tests, and then calculated the maximum cost exposure to Medicare for those specific tests by applying 2018, 2019, and 2020 unbundled payment rates, assuming 2016 test utilization levels.

"That is, we calculated what the maximum increase in Medicare spending over the three-year period would be for the panel tests we examined if all labs billed the component tests separately," Cosgrove explained. "Our review focused on these panels because CMS changed its policy for paying for them and because they are among the most common tests that Medicare reimburses for."

**Let's talk**

AdvaMedDx and the other groups that have written to the GAO maintain the agency's analysis is flawed and mischaracterizes the lab industry's billing practices. They have accused the GAO of claiming falsely that the lab industry is inappropriately billing for individual tests when they should be billing panel codes.

"The GAO report asserts that 'if every laboratory stopped using panel test billing codes,' then Medicare could overpay by over $10 billion," a spokesperson for AdvaMedDx said. "The GAO reaches its conclusion based on an assumption that laboratories would change their billing behavior, and bill inappropriately for test panels that have CPT codes. We do not believe this is the case."

The groups cited a survey of labs done between 2017 and 2018, before and after the implementation of PAMA, which found that it was extremely rare that a lab would bill individual test codes in a panel when a panel code existed — less than one tenth of one percent of some 20 million claims. The specific parameters of this lab industry survey, which was done under attorney client privilege, have not been made public, though.

"In light of these findings, we are concerned that the GAO report made such broad claims, not only due to the report's lack of supporting data, but also because the GAO failed to utilize open channels of communication with the undersigned organizations to truly understand actual billing practices," AdvaMedDx and other groups wrote. They have requested a meeting with the GAO to talk through their concerns in greater detail.

In response these accusations, Cosgrove said industry groups are "mischaracterizing the report" as stating that Medicare spending will definitely go up by $10.1 billion, when in fact that's not the language the GAO uses. "The report talks about if all the tests were unbundled what the maximum exposure would be to Medicare," he said. "Our recommendations are made to CMS in order to put controls back in place so the worst-case scenario doesn't happen."

CMS has taken a number of steps to guard against this risk since the GAO released its report. The government payor has indicated it will update its claims processing system so it can flag when labs aren't using a CPT code for a panel but should be. The agency has also instructed labs to bill existing CPT codes that group tests into organ- and disease-specific panels instead of billing the components of the panel separately. CMS also updated its National Correct Coding Initiative Policy Manual to specify that when there are specific codes for multi-gene next-generation sequencing panels, labs should bill them, and when there aren't, labs should bill CPT 81479 describing "an unlisted molecular procedure."

"It's not about what the lab industry was or wasn't doing," Cosgrove said. "It's about the need to have controls in place."

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