Protecting Laboratory Access for Medicare Beneficiaries

Findings, Recommendations from GAO Would Undermine Patient Care

Background

Clinical laboratories are at the forefront of diagnosing our most complex diseases, supporting early intervention and preventive care while helping to manage chronic conditions for millions of Americans. Roughly 250,000 laboratories across the country perform lifesaving diagnostic services each day, ranging from routine blood tests to groundbreaking genetic tests.

Currently, the Medicare program is the single largest purchaser of clinical diagnostic laboratory tests. In 2017, Medicare beneficiaries received an average of three tests a day to assess or diagnose various health conditions. In total, the Medicare program was billed for 433 million tests at a total cost of $7.1 billion that year. Medicare expenditures on laboratory spending has remained relatively unchanged over the last four years according to federal government reporting.

In an effort to modernize and support a competitive market for clinical laboratory services, Congress passed the Protecting Access to Medicare Act (PAMA) with the intent of transitioning to a sustainable, national market-based reimbursement model. As part of PAMA, Congress directed the Centers for Medicare and Medicaid Services (CMS) to establish new Medicare rates for clinical lab services based on the commercial market rates of all types of laboratories – independent labs, hospital labs and physician office labs. The new payment model established a single, national fee schedule for laboratory tests. As part of PAMA's requirements, CMS collected laboratory reported payment data at the billing code (which is called "CPT code") level and determined a weighted median to establish new Medicare payment rates that went into effect January 1, 2018.

However, in the process of collecting private payor data to establish market-based rates, CMS only gathered rate information from less than one percent of laboratories nationwide. By ignoring the data from more than 99 percent of the nation's laboratories, CMS's actions have skewed payment rates and culminated in year-over-year cuts to seniors' access to Medicare lab tests.

By drastically cutting rates, particularly for the top-25 most performed lab tests, CMS is targeting beneficiaries managing diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections and opioid dependency. If this haphazard approach to data collection continues, it could establish a harmful precedent for the agency's review and approval of payment rates across all health services covered by Medicare and Medicaid and will have a chilling effect on patient care and delivery system reforms moving forward.

Overview of GAO Report on Laboratory Billing in the Medicare Program

In November 2018, the Government Accountability Office (GAO) released a report on CMS's implementation of new laboratory payment rates under PAMA. As part of its report, GAO analyzed 2016 Medicare claims data, and in particular, organ and disease panel tests. Millions of Americans who are managing diabetes, heart disease, liver disease, kidney disease, cancer, anemia and countless other common diseases and conditions rely heavily on access to these routine lab tests to monitor their health and prevent costly interventions.

There are seven organ and disease panels (i.e. comprehensive metabolic panel, lipid panel), which are comprised of routine tests that are commonly performed together. The routine tests (i.e., glucose, potassium, cholesterol, etc.) that are included as part of organ and disease panels are known as automated multichannel chemistry (AMCC) tests. Each of the 23 AMCC tests also has its own CPT code.

Clinical laboratories are required to bill Medicare according to the American Medical Association (AMA) CPT guidelines, which provide clear direction on the billing of organ and disease panels. These guidelines direct laboratories to bill the panel CPT code when all of its component-level tests are performed. If there are any remaining tests that are not part of the panel, or any other organ and disease panel, a lab is directed to bill using individual CPT codes for those additional tests, as per the AMA CPT guidelines.

Before PAMA, CMS contractors applied claims system controls to ensure the Medicare program did not overpay for organ and disease tests and panels. Even if a laboratory billed for each component test individually, rather than billing the requisite panel CPT code, Medicare contractors relied on a technical edit that “rolled up” the individual tests into the proper panel and reimbursed the lab at the panel rate. Inexplicably, CMS removed this technical edit prior to PAMA implementation, and later reinstated it. Despite this bureaucratic error, laboratories continued to appropriately bill at the panel rate per AMA CPT billing guidelines.

However, in its findings and conclusions, GAO ignored these standard industry practices and suggested that laboratories were receiving “excess payments” by unbundling these lab tests. Based on industry surveys and standard billing practices in the Medicare program, GAO’s findings reflect fatally flawed assumptions and miscalculations on laboratory payments in the Medicare program.

Fact Check on GAO’s Findings and Recommendations

Pure Fiction: GAO’s assertion of $10.3 billion in potential additional costs from lab services

- In order to come up with its assumption of an additional $10.3 billion in costs from laboratory services, GAO presents a false representation of how labs bill and are reimbursed for panel testing under the Medicare program and wrongly suggests that labs are receiving “excess payments” for these services.

- Clinical laboratories are required to bill Medicare for these tests according to the guidelines outlined by the American Medical Association (AMA).

- Rather than acknowledging these current standards, GAO concocts a hypothetical scenario that suggests labs are unbundling certain panel tests and receiving higher reimbursement. This is grossly inaccurate and runs counter to standard industry practice.

- In a recent interview, GAO director of healthcare, James Cosgrove admitted the report draws no conclusions about the actual billing practices of the lab industry, stating "We weren't analyzing what labs are or aren't doing. We were analyzing what the exposure to Medicare would be."

- In fact, public data refutes the GAO's claim. In order for GAO's "unbundling" assumption to be true, the volume of panel tests should have decreased and the volume for individual panel codes should have skyrocketed. Instead, volume for *both* the panel and component tests have fallen on average. Comparing the first two quarters from both 2017 (pre-PAMA) and 2018 (under PAMA), the component tests for the Comprehensive Metabolic Panel (CMP) *decreased* in volume year-over-year by an average of 5%, and the panel test volume decreased by 2% – demonstrating that labs are NOT driving up Medicare spending through inappropriate and dramatic over-billing of the component tests, disproving GAO's claim of overpayments.

Table: Comparison of volume changes pre- and post-PAMA for the Comprehensive Metabolic Panel and the panel's individual components, demonstrating labs are not overbilling component codes

HCPCS Code	Descriptor	Q1 & Q2 2017 Total Volume	Q1 & Q2 2018 Total Volume	Absolute Total Volume Change	Total Volume % Change
80053	Comprehen metabolic panel	21,079,281	20,722,695	(356,586)	-2%
Comprehensive Metabolic Panel Components:					
82040	Assay of serum albumin	378,659	370,886	(7,773)	-2%
82247	Bilirubin total	287,830	282,652	(5,178)	-2%
82310	Assay of calcium	407,256	416,847	9,591	2%
82374	Assay blood carbon dioxide	53,044	53,162	118	0%
82435	Assay of blood chloride	112,783	108,096	(4,687)	-4%
82565	Assay of creatinine	1,378,986	1,284,242	(94,744)	-7%
82947	Assay glucose blood quant	1,513,443	1,332,975	(180,468)	-12%
84075	Assay alkaline phosphatase	313,851	303,652	(10,199)	-3%
84132	Assay of serum potassium	428,939	402,091	(26,848)	-6%
84155	Assay of protein serum	359,746	343,637	(16,109)	-4%
84295	Assay of serum sodium	222,094	185,335	(36,759)	-17%
84460	Alanine amino (alt) (sgpt)	1,213,239	1,349,495	136,256	11%
84450	Transferase (ast) (sgot)	870,985	771,805	(99,180)	-11%
84520	Assay of urea nitrogen	773,433	672,473	(100,960)	-13%
	Total Component Volume	**8,314,288**	**7,877,348**	**(436,940)**	**-5%**

Data analysis informing sound policy

Braid-Forbes Health Research, LLC

Prepared for the American Clinical Laboratory Association

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Sources: *2017 and 2018 Q1, Q2 100% Outpatient Standard Analytic Files, 5% Carrier Standard Analytic Files,*

** Volume is representative of the first two calendar quarters of each year specified. Carrier SAF 5% file code-level volume has been multiplied by a factor of 20 to estimate a 100% national figure. Outpatient SAF 100% file code-level volume is already a 100%*

Worse, GAO's analysis ignores the impact of unprecedented, year-over-year cuts to laboratory services that pose direct harm to beneficiaries' access to care.

- As a result of CMS continuing with a flawed data collection process, the blatant omission of payment data from more than 99 percent of the nation's laboratories has resulted in reimbursement rates that fail to represent the true market for clinical laboratories and has ultimately led to drastic cuts to vital lab services.

- In 2018 alone, seniors saw their Medicare lab benefits cut by millions of dollars – a direct hit to beneficiaries managing diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections and opioid dependency.

- These cuts are scheduled to continue over the next two years, further exacerbating the issue.

ACLA strongly supports a reimbursement model that fosters competition and improves patient access, and GAO's assessment that CMS has failed to implement PAMA in the way Congress intended is correct. However, several of GAO's core recommendations would result in far greater disruption to seniors' access to essential lab tests.

- GAO's suggestion that additional savings could have been achieved by using an alternative "average rate" benchmark to phase-in rate reductions under PAMA is wrong on multiple fronts.

- Under PAMA, an individual test can be cut by no more than 10 percent in each of the first three years of implementation – 2018, 2019, 2020. GAO ignores these statutory limits in its recommendation, and instead proposes steeper, discriminatory cuts based on antiquated fee schedules.

- Seniors' laboratory benefits are already facing a nearly 30 percent reduction over the next three years. Implementing GAO's recommendation could decimate access for the most vulnerable Medicare beneficiaries, including homebound seniors and those in rural communities.

Bottom Line: The best solution for protecting patients and maintaining a competitive laboratory market starts by reforming PAMA's flawed implementation.

- More than 30 organizations from across the health system urged Congress to take immediate action to protect seniors from pending cuts over the next two years.

- ACLA has also filed a legal challenge against CMS (*ACLA v. Azar*) arguing that the agency has overstepped its authority in implementing PAMA, undermining Congressional intent in protecting access to Medicare services.

- Other leading laboratory and health organizations continue to raise concerns about PAMA's devastating impact on our most vulnerable seniors. Several have issued amicus briefs in support of ACLA's position, including the College of American Pathologists, along with AdvaMed and the National Association for the Support of Long Term Care and the American Association of Bioanalysts / National Independent Laboratory Association.