GAO LAB REPORT – SOUND ANALYSIS? CRITICISM FROM SENATOR GRASSLEY AND OTHERS AND CMS'S RESPONSE

In November 2018, the Government Accountability Office ("GAO") released a report ("Report") on new laboratory payment rates established by CMS under the Protecting Access to Medicare Act ("PAMA"). In the Report, the GAO analyzed Medicare claims data to assess how CMS's implementation of these new rates will impact Medicare expenditures and recommended CMS take certain actions to address issues it found. In response to the Report, Senator Grassley sent a letter to HHS Secretary Alex Azar and CMS Administrator Seema Verma asking for answers to several questions related to the Report. Below we provide an overview of the Report, Grassley's letter to CMS and CMS's response.

BACKGROUND

PAMA required CMS to develop a new national laboratory fee schedule based on data on payments from private payers. In addition, PAMA included a provision for GAO to assess CMS's implementation of new payment rates for these tests, which resulted in the Report and the GAO's recommendations as discussed below. Interestingly, industry groups opposed the PAMA revisions, but the Report claims that the changes could cost CMS billions in increased payments.

Specifically, in the Report, the GAO stated that CMS's changes could lead to billions of dollars in excess payments due to two factors:

1. CMS used maximum Medicare payment rates instead of actual Medicare rates as a baseline to phase in payment reductions; and
2. CMS stopped paying a bundled payment rate for certain panel tests.

Specifically, the GAO stated that by paying for unbundled tests, 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. Further, GAO recommended that CMS:

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; and
3. Use bundled rates for panel tests.

The Report and the recommendations obviously raised concerns on both sides of the issue. In response to the Report, Senator Grassley raised concerns with the GAO's findings in a letter to CMS, and Grassley asked for responses to several questions, which included information on how CMS would ensure laboratories report data, how CMS would prevent laboratories from unbundling panel tests and whether CMS would use actual Medicare rates to establish payment reductions.

However, the Report was also met with pushback from some industry stakeholders. For example, the American Clinical Laboratory Association ("ACLA") stated that the Report's findings were based on a "fundamental misunderstanding by GAO of actual, real-world billing practices of clinical laboratories." The ACLA specifically took issue with GAO's assertion that laboratories were not following CPT billing guidance by separately billing individual components of panel tests instead of the panel test codes themselves. Some will remember that lab unbundling project was a national initiative in the late 1990's.

In a letter dated March 19, 2019, CMS Administrator Seema Verma responded to Senator Grassley's request for information. Verma acknowledged that CMS phased in payment reductions under PAMA based on the average Medicare payment rate for a test, instead relying on the maximum rates, which was established through notice and comment rulemaking.

In addition, Verma stated that CMS would review claims data to determine whether any panel tests were unbundled, but Medicare policy requires laboratories to report the panel code and not the codes for individual components of the tests when applicable. Finally, Verma

stated that CMS will continue to evaluate ways to increase data reporting participation by laboratories, including targeted outreach and auditing of laboratories that may meet the definition of an applicable laboratory.

PRACTICAL TAKEAWAYS

- CMS will continue evaluate ways to increase data reporting participation by laboratories, including targeted outreach and auditing of laboratories that may meet the definition of an applicable laboratory.
- CMS may look to implement safeguards to prevent against unbundling and will review claims data to determine whether any panel tests were unbundled.
- Laboratories should bill Medicare for panel tests rather than individual components of the tests when applicable.
- Laboratories should monitor Congressional and CMS revisions to PAMA data reporting requirements.

If you have any questions or would like additional information about this topic, please contact:

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