Access to Clinical Laboratory Services in Jeopardy
Due to CMS Implementation of PAMA

Talking Points

The Ask: Congressional Support for Administrative Delay of Implementation of Sec.126 of PAMA until January 2018.

Sec. 126 of PAMA – Protecting Access to Medicare Act – requires CMS to calculate and establish a new Medicare Clinical Lab Fee Schedule (CLFS) based on private payer payment data submitted by "applicable labs". The intent was to revise the CLFS based on true market based pricing. The project as laid out by CMS is flawed and does reflect true marked based reimbursement rates as intended by Congress.

Concerns:

1. New reimbursement rates will be set based on incomplete and inaccurate data
    a. CMS's current definition of "applicable lab" excludes virtually all hospital labs and physician office labs and about half of independent labs.
    b. Per the OIG, Medicare spend is $7B. Because of how CMS defined "applicable lab", only $2B of payment data is being reported and will be used to set new payment rates leaving out 72% of payment data.
    c. New CLFS will apply to all labs, not just those who reported data
    d. As recently as March 13, 2017 CMS was still providing conflicting information to labs as to whether they were an applicable lab and should report their data. The deadline to report is March 31, 2017.
2. The new CLFS will not just affect Medicare and Medicaid. Almost all private payors base their contracted fees for lab services on the Medicare CLFS. If the Medicare CLFS is decreased by 10%-15%, the private payor rates will also be lowered, cutting ALL reimbursements.
3. The OIG in September 2017 voiced significant concerns regarding PAMA
    a. Only 5% of labs would be reporting data, skewing the data used to calculate the new fee schedule
    b. CMS has no plans to conduct audits to:
        i. identify applicable labs
        ii. identify whether all labs reported
        iii. verify completeness or accuracy of data
4. CMS promised the lab community transparency in their calculation of new payment rates, but has yet to specify how they would provide this
5. The Medicare CLFS is the oldest fee schedule and has not been seriously reviewed and revised since it was implemented in 1986! Using the flawed data collection process set under PAMA is not the way to rationalize and modernize the CLFS.
6. Under PAMA, CMS can lower current reimbursement rates up to 10% in 2018, 2019 and 2020 and up to 15% in 2021, 2022 and 2013. If PAMA is allowed to move forward, it has

the potential to be the single most financially disruptive event for clinical labs, already subjected to repeated and severe reimbursement cuts for the last three decades!

7. The financial impact on clinical laboratories if PAMA is implemented is significant, especially for community based hospitals, rural hospitals and nursing homes. With typical profit margins of 3% to 5%, a 10% to 15% cut in reimbursement will mean:
    a. No money for raises, inability to be competitive and recruit staff
    b. No money for new equipment and new technology
    c. Less testing done in-house and more sent to outside reference labs – possible layoffs if less testing
    d. Increased delay in getting results if sent out causing delay in diagnose and in inpatient, increased length of stay
    e. Labs no longer financially viable - possible lab closings and bankruptcy
    f. Selling off the lab business to a national reference lab – already seen in the industry with PAMAL and others. This results in a loss of hundreds of high paying, technical jobs as well as significant local economic impact and loss of locally available lab services.
8. Access to care for both the community and nursing home patients served by the community hospital lab will be compromised – less access to quality lab services – exactly the opposite of PROTECTING Access to Medicare – the name of the regulation.

For all these reasons, setting a new Medicare CLFS based on the flawed data collection process under PAMA <u>must</u> be delayed.