Flawed Attempt to Set Market-Based Fee Schedule Will Jeopardize Access to Quality Care

Position

The clinical laboratory community urges Congress and the Administration to ensure access to quality clinical laboratory services within the Medicare program will not be impeded by fee schedule cuts authorized within the Protecting Access to Medicare Act (PAMA) of 2014. Final regulations promulgated by the Obama Administration should be reviewed by the Trump Administration to ensure they do not destabilize the clinical laboratory testing market and impede access to care. We urge the Trump Administration to:

- ✓ Extend the deadline for data collection and reporting periods for the clinical laboratory fee schedule (CLFS) under Medicare by **twelve (12) months to March 31, 2018**
- ✓ Delay enforcement of the updated CLFS until **January 1, 2019**
- ✓ Revise the definition of "applicable laboratory" to mean a facility identified by a Clinical Laboratory Improvement Act (CLIA) number, so that true market-based reimbursement rates can be calculated

Rationale

PAMA requires "applicable laboratories" to report private payor payment rates and the associated test volume for those laboratory services defined by CMS. This data will be used by CMS to calculate the new Clinical Lab Fee Schedule (CLFS). The intent of the PAMA was to ensure true market-based pricing by setting the fee schedule to a weighted median of the collected data. To determine a true, market price, laboratories reporting data should be representative of the broad scope of the laboratory market, including hospital and physician office laboratories.

PAMA directed CMS to establish parameters for payment rate reporting by June 30, 2015, and required the market-based payment system to start on January 1, 2017. However, in the Final Rule, CMS delayed the data collection and reporting requirement pushing back the effective implementation date to January 1, 2018. CMS originally estimated $390 million in savings in 2018, $1.7 billion over five years, and $3.9 billion over ten years, but **recent industry estimates indicates that cuts will go well beyond these figures.**

As recently as March 13, 2017, CMS gave conflicting definitions "applicable laboratories," leaving many laboratories still in doubt as to their status. **The current definition ignores the intent of Congress by excluding virtually all hospital laboratories, physician office laboratories, and over 50 percent of independent laboratories.** This results in unnecessarily limited payment data captured from laboratories performing just $2 billion of the total $7 billion Medicare spends on laboratory services each year.

Excluding pricing data from a broad representation of the laboratory community forces CMS to base payment rates on data drawn almost exclusively from large reference laboratories.. These laboratories provide narrower menus of services with less urgent time constraints to deliver results. In contrast, hospital and physician office laboratory service deliver services in urgent, acute, and long term care settings not served by commercial laboratories, which naturally leads to higher costs in those settings. CMS is missing necessary data to address this difference.

In September of 2016, the Department of Health and Human Services (HHS) and the Office of Inspector General (OIG) released reports updating stakeholders on the Centers for Medicare & Medicaid Services' (CMS) implementation of Medicare's new system. The OIG's report noted the potential for skewing of median payment information based on the collection plan. The OIG also raised concern that once laboratories reported, CMS did not plan to verify the data's completeness or accuracy. **Without these safeguards, CMS is unable to determine whether labs complied with reporting requirements or whether the data on which new Medicare lab payment rates will be complete and/or accurate.**

Impact

The accuracy of an updated CLFS is now in doubt if existing regulations on data collection and reporting are not revised. The estimated impact to the clinical laboratory market could go well beyond what Congress had envisioned when it enacted PAMA and may impact access to laboratory services not just for Medicare beneficiaries, but for all patients as the vast majority of private payors peg their reimbursements to the CLFS.

Indiscriminate cuts in the CLFS will ripple through the entire laboratory system.

Without immediate action, the administration will implement a brand new payment system, based on potentially flawed and incomplete data that is likely to impact the availability of critical laboratory services in communities all over the country.

The anticipated cuts are already causing consolidation. In recent weeks, PeaceHealth Outreach Laboratory was sold to Quest Diagnostics, and Pathology Associated Medical Laboratories was purchased by LabCorp. The result will be the loss of hundreds of jobs, significant local economic displacement, and compromise locally available laboratory services.

Community laboratories are typically very small operations and will be extremely vulnerable to Medicare cuts to the CLFS. Medicare fee decreases of 10 percent for a community laboratory that has 60% Medicare patients will result in closures or bankruptcies. Even laboratories with a lower percentage of Medicare patients will be affected by private payor links to the CLFS.

Laboratories will respond by reducing staff and cutting back on capital investment, leaving clinicians without important tools to quickly diagnose and treat patients. Access to care for both the community and nursing homes served by the community-based, hospital laboratory outreach programs will be compromised.

Setting the new CLFS based on the flawed and incomplete data has the potential to be the single most financially disruptive event for clinical laboratories, which have already been subjected to repeated and severe reimbursement cuts for three decades.

Background

Under PAMA, CMS can lower the price of individual tests up 10% in 2018, 2019 and 2020. PAMA then allows price cuts up to 15% in 2021, 2022 and 2023.

PAMA requires "applicable laboratories" to report to CMS, and defines an "applicable laboratory" as a laboratory that receives a majority of its Medicare revenue during the data collection period from the CLFS or the Physician Fee Schedule. In the proposed rule, CMS defined applicable laboratories based on an entity's IRS Taxpayer Identification Number (TIN). In the Final Rule, in response to comments, CMS modified the definition of an applicable laboratory to be at the National Provider Identifier (NPI) level, not the TIN level. CMS stated that this would allow the inclusion of hospital outreach laboratories in the definition of "applicable laboratories." However, that interpretation does not consider that most of those laboratories do not have separate NPI numbers.

In the Final Rule, CMS elected to shorten the data collection period to six months to give laboratories a six-month window to ensure the completeness and accuracy of data. The data collection period is now from January 1 through June 30 for CDLTs with specific HCPCS codes. CMS stated in the Final Rule that it would re-evaluate the length of the data collection period in future rulemakings, including whether the six-month review period before the reporting period is necessary. Laboratories must report the data to CMS by March 31, 2017. CMS will provide sub-regulatory guidance to specify the manner and form for reporting applicable information before the first reporting period. Although CMS will use NPI to determine an applicable laboratory, reporting will still be done by the TIN level entity.

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