Mandated report: The Protecting Access to Medicare Act of 2014’s changes to the Medicare clinical laboratory fee schedule

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September 3, 2020
Further Consolidated Appropriations Act, 2020, mandated MedPAC to investigate PAMA changes.

Congressional mandate requires the Commission to:

- Review the methodology CMS has implemented for the private payer-based CLFS rates.
- Report on the least burdensome data collection process that results in a representative sample of all laboratory market segments.

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Medicare’s clinical laboratory fee schedule

- Clinical laboratory tests analyze specimens from the body
- Medicare covers separately payable clinical laboratory tests under the CLFS
- The CLFS includes over 1,400 HCPCS codes
  - e.g., simple chemistry tests, complex molecular pathology tests
- In 2019, Medicare spent about $7.5 billion on 428 million CLFS tests
  - Almost entirely furnished by three types of laboratories: Independent, hospital, and physician office
Historical background on the CLFS

Prior to 2018

CLFS payment rates were set based on local laboratory charges, updated for inflation, and capped at certain amounts.

Payment rates were not adjusted for efficiency, technology, or market conditions.

In 2013, OIG found that Medicare paid between 18% and 30% more than other insurers for 20 high-volume or high-expenditure laboratory tests.

Clinical laboratory fee schedule (CLFS). Office of Inspector General (OIG). Results preliminary; subject to change.
Roadmap for today’s presentation

1. CLFS historical background
2. Changes to the CLFS under PAMA
3. Trends in utilization and Medicare spending
4. Next steps and Commission feedback

PAMA required Medicare CLFS payment rates to be based on private-payer rates

- PAMA shifted the basis for CLFS payment rates from laboratory charges to private-payer rates
- CLFS payment rates set based on the weighted median of private-payer rates
- Among other requirements, laboratories must report if they exceed two thresholds:
  - “Majority of Medicare revenues” threshold
  - “Low expenditure” threshold
- Laboratories report their private-payer rates every three years
CMS projected large savings because private-payer rates were lower than Medicare rates in 2017

- CMS estimated that private payer-based CLFS rates would reduce Medicare spending by about $670 million in 2018
- GAO found that private payer-based rates were lower than Medicare’s 2017 payment rates for about 88 percent of laboratory tests
- PAMA established a long phase-in of payment reductions to mitigate impact on laboratories


Results preliminary; subject to change.
Independent laboratories were overrepresented in first round of data reporting

- 1,942 laboratories reported private-payer rates for 248 million tests
- Independent laboratories were overrepresented; hospital and physician laboratories were underrepresented

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<tr>
<th>Type of laboratory</th>
<th>Percent of Medicare CLFS tests in 2016</th>
<th>Percent of private payer test volume reported</th>
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<tr>
<td>Independent</td>
<td>48%</td>
<td>90%</td>
</tr>
<tr>
<td>Physician office</td>
<td>22</td>
<td>8</td>
</tr>
<tr>
<td>Hospital</td>
<td>29</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: CMS and Acumen LLC analysis of Medicare CLFS claims for MedPAC.

Clinical laboratory fee schedule (CLFS). Results preliminary; subject to change.
CMS found that greater hospital and physician office laboratory reporting would only change rates modestly

- Stakeholders contend:
  - Hospital and physician office laboratories receive higher private-payer rates than independent laboratories
  - Hospital and physician office laboratory underrepresentation could lead to artificially low Medicare payment rates
- CMS’s analyses suggested payment rates would have increased only modestly with greater hospital and physician office laboratory reporting

Results preliminary; subject to change.
CMS made changes to increase the number and variety of laboratories reporting private-payer data in the future.

- Removed Medicare Advantage revenue from the denominator of the majority of Medicare revenues threshold.
- Separated certain hospital outreach laboratories from their parent hospital for the majority of Medicare revenues threshold.

Second round of data reporting delayed until 2022.

Note: Hospital outreach laboratories are hospital-based laboratories that furnish tests to patients other than admitted inpatients or registered outpatients of a hospital.
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From 2017 to 2019, CLFS utilization was stable, but spending increased

- Utilization went from 12.8 to 12.9 tests per beneficiary
- Spending increased from $7.1 billion to $7.5 billion, driven by technical changes under PAMA and new, high-cost tests (e.g., molecular pathology tests)

CLFS utilization and spending trends varied by type of laboratory from 2017 to 2019

- Utilization: Small increase for independent laboratories (2.4%) and small decreases for hospital and physician office laboratories (-1.0%)
- Spending: Increase for independent laboratories and decreases for hospital and physician office laboratories

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<th>Type of laboratory</th>
<th>Medicare spending (in millions)</th>
<th>Percent change</th>
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<tr>
<td>Independent</td>
<td>$0 - $4,000</td>
<td>16%</td>
</tr>
<tr>
<td>Hospital</td>
<td>$1,000 - $3,000</td>
<td>-9%</td>
</tr>
<tr>
<td>Physician office</td>
<td>$2,000 - $4,000</td>
<td>-6%</td>
</tr>
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Source: Acumen LLC analysis of Medicare CLFS claims for MedPAC. Clinical laboratory fee schedule (CLFS). Results preliminary; subject to change.
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Next steps: Review of CMS methodology

- Refine CLFS spending and utilization analysis from 2017 to 2019 (e.g., urban vs. rural analysis)
- Analyze private-payer rate data from the first round of data reporting
- Analyze revised data reporting requirements for the second round of reporting, which is scheduled to occur in 2022
Next steps: Report on least burdensome data collection process resulting in representative sample

- Stakeholders are concerned that currently collected data are not representative
- Increasing the number of laboratories reporting increases administrative burden
- One alternative is to collect representative data through a survey
- We plan to study how private-payer rates could be collected through a survey (e.g., sampling techniques, required sample sizes, etc.)
Summary and feedback

- As of 2018, Medicare relies on private-payer data to set CLFS rates; payment rates for many tests declined substantially.
- Stakeholders are concerned that reported rates are not representative and are too low.
- From 2017 to 2019, there is no evidence of substantial utilization changes, but spending increased largely due to new, high-cost tests.
- CMS changed reporting requirements to include more laboratories, but effects won’t be known until 2022.

Staff seeks feedback from the Commission on the plans outlined above.