



UnityPoint Health

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October 23, 2017

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

RE: Preliminary calendar year (CY) 2018 Medicare Clinical Laboratory Fee Schedule (CLFS) rates

*Submitted electronically via [CLFS\\_Annual\\_Public\\_Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov)*

Dear Ms. Verma:

UnityPoint Health (UPH) is pleased to provide input in response to the Centers for Medicare & Medicaid Services' (CMS) preliminary CY 2018 Medicare CLFS rates. UPH is one of the nation's most integrated healthcare systems – the 13th largest non-profit healthcare system and the fourth largest nondenominational healthcare system. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 32 hospitals in metropolitan and rural communities and home care services throughout our 9 regions, UPH provides care throughout Iowa, western Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provides a full range of coordinated care to patients and families through more than 6.2 million patient visits.

Serving as a critical diagnostic service for the system, UPH Laboratories provide comprehensive laboratory / pathology services to patients in our hospitals, clinics and home health settings. Laboratory services are also provided to nursing home residents, assisted living facilities, physician offices, and other hospitals in many regions. Our UPH Laboratories perform thousands of tests each day and over 8,000,000 tests per year. Testing is offered in all general laboratory disciplines and some specialty services for clinical and anatomical pathology. Our teams of dedicated individuals use their knowledge, expertise, skills, and abilities to provide a high quality, full service laboratory for our providers, patients and families.

We respectfully offer the following comments related to the CLFS preliminary rates.

### Preliminary CLFS Rates

Beginning on January 1, 2018, Medicare will use certain private payor rate information reported by “applicable laboratories” to calculate Medicare payment rates for most laboratory tests paid under the CLFS. Payment amounts will be determined based on the weighted median private payor rate for a given laboratory test, with certain exceptions for new tests. The preliminary private payor rate-based CLFS payment amounts are estimated to have an impact on Medicare Part B, including the Part B premium effects, of approximately -\$670 million for CY 2018.

*Comment:* **We urge CMS to suspend implementation of the proposed CLFS rates.** The actual length of the requested suspension is dependent upon CMS collecting more robust rates data and further engaging stakeholders in the rate-setting process. As proposed by CMS, CLFS rates are not based on the private market as Congress intended when it passed Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014, nor are the proposed rates protecting or promoting access to services, but rather will likely achieve the opposite, especially in our rural areas and in post-acute care settings.

Our specific concerns with the current rate-setting process are:

- **Access to care will decrease, particularly for the most vulnerable populations, and impact health outcomes.** It is estimated that up to seventy percent (70%) percent of all clinical decisions in America are guided by clinical lab testing. These preliminary CLFS rates will further constrain the tight operating margins for physician office and hospital laboratories. Ultimately, **it will result in tough operational decisions to restrict or eliminate our ability to offer clinical diagnostic laboratory tests in sparsely populated and remote physician clinics and nursing homes.** The impact on high-value and timely patient care cannot be understated and include trade-offs such as:
  - Outsourcing more tests resulting in higher cost, longer turnaround time of results, and potential increased length of stay;
  - Cutting / limiting hours of operation further preventing, not promoting, access; and
  - Delaying or avoiding updates to technology preventing the delivery of state of art services.

All of these trade-offs have a potential to **negatively impact patient outcomes by delaying test results and ultimately treatment.** If reimbursement drops to the point that our hospital and independent labs can’t afford to provide phlebotomy and courier services to our rural communities, then those patients will have to drive long distances for laboratory services and, in the end, may choose to skip having those tests done. Without lab tests, there will be undiagnosed conditions and illness, which could result in downstream hospitalizations, complications, and increased costs of care. Untimely and inconvenient service delivery also highly correlates with poor patient and caregiver experience ratings. As a system that provides service in a largely rural geography, we are concerned that these rates will force closure of rural and/or community laboratory services that would create a second-class healthcare delivery system in rural America.

- **Operational implications:** Along with primary access issues, **these rates have downstream implications that further exacerbate shortage for healthcare services in rural areas.** While

reducing clinical laboratory services was noted as having a negative impact on patient satisfaction, it also impacts physician and provider satisfaction, potentially harming retention and recruitment efforts in areas that already suffer from shortages.

In addition, our laboratories have sunk costs that do not proportionately decrease with reimbursement reductions. Among these costs are reagent and supply costs, benefit costs for staff, and costs of CLIA compliance. When reimbursement tightens, it is often staffing hours, locations, and transportation services that are impacted.

- **Financial impact overreaches that intended by Congress.** When PAMA passed, Congress estimated a \$3.9 billion savings over ten (10) years to Medicare – an annual reduction in reimbursement of approximately \$390 million. As proposed, the preliminary rates will cut reimbursement to clinical labs upwards of \$13 billion over ten (10) years, or triple the Congressional estimate. It is clear that **the rate-setting methodology does not comport with Congressional intent and inadvertently targets clinical labs for a disproportionate share of Medicare savings.**

In total, Medicare reimburses approximately \$7 billion per year for clinical diagnostic laboratory tests under the CLFS. This represents only 1.6% of Medicare spending – yet reimbursement reductions for these vital service providers will average nearly 18% annually over ten (10) years with heightened projections of 25% over the next three (3) years. The financial implications to two (2) of our UPH Laboratories for CY 2018, 2019 and 2020 are illustrated below:

Lab Name	2017 Test Volume	2018 Impact	2019 Impact	2020 Impact	3-year Total
Pathology Laboratory	94,607 <sup>1</sup>	\$(255,128)	\$(278,147)	\$(241,405)	<b>\$(774,681)</b>
Sioux City Laboratory	31,171 <sup>2</sup>	\$(61,750)	\$(101,756)	\$(136,229)	<b>\$(299,735)</b>

<sup>1</sup>Impact calculated for all tests, annualized on tests performed from January through June 2017

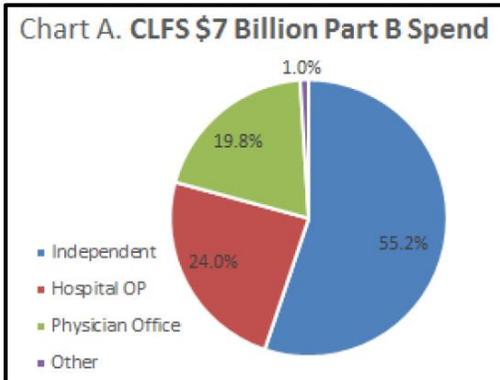
<sup>2</sup>Impact calculated for top 29 tests only from September 2016 to August 2017

Pathology Laboratory is an independent laboratory. Sioux City Laboratory is hospital based. Note that the estimates above reflect reductions in Medicare reimbursement only, contains data from two (2) of the nine (9) UPH service area regions, and, in one case, reflect reductions for the top 29 tests only versus all CPT codes. It is not difficult to recognize, based upon this subset of data, that overall impact to UPH will be significant and will impact our ability to continue to provide laboratory services across our system.

- **“Applicable lab” definition is not representative of services and skews rate setting.** This definition excluded 95% of laboratories from the CMS reporting process and makes it impossible for the data collected to reflect true market value. In fact, CMS reported that only 1,942 (0.07%) of the nation’s total number of labs submitted data. For UPH, only four (4) of our system laboratories were eligible to participate – one (1) system Physician Office Laboratory (POL) and three (3) Independent Laboratories. Significantly, UPH hospitals and rural POLs were not eligible. As a result, preliminary prices over-represent volume from large independent laboratories, under-represent volume from physician office laboratories, and virtually exclude test volume from hospital and post acute care laboratories. **In general, the proposed methodology significantly**

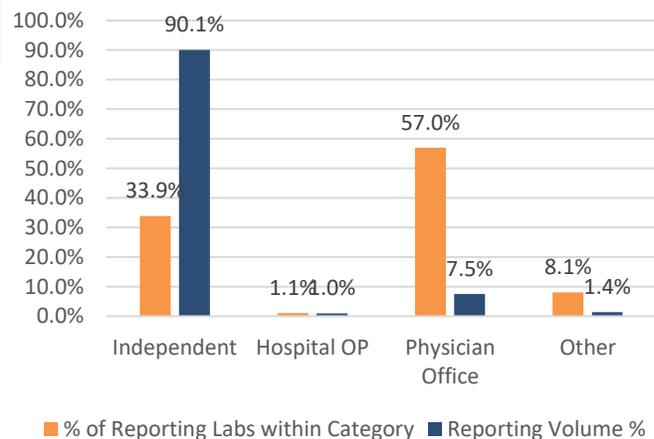
under-represents costs. Top-of-mind concerns with this reporting distribution include the percentage of tests from large laboratories, which tend to represent depressed pricing as a result of economies of scale and negotiation power not available to smaller laboratories, as well as the practical exclusion of certain laboratory categories altogether.

We suggest that CMS ensures that the private payer data they collect accurately represents all segments of the clinical laboratory market (national independent, hospital outreach, physician



office laboratories, and other). Chart A represents the percentage of laboratory categories comprising the Clinical Laboratory Part B reimbursement. As shown in Table 1, the number of reporting laboratories and their respective test volumes are

**Table 1. CLFS Rate Setting Lab Reporting**



not proportional to reimbursement levels – i.e. independent laboratories are overly emphasized. In addition to more than 90% of the tests being reported by independent laboratories, two of the nation’s largest independent laboratories provided about 80% of the volume that CMS used to calculate the rates. We believe that CMS should collect reporting data proportional to

revenue share; for instance, since hospital outreach laboratories comprise roughly 24% of the revenue, pricing data should be collected and entered into the cost calculation in that proportion. We also suggest that CMS include more transparency regarding geographic distribution. CMS has stated that reporting included applicable laboratories from all states. That said, it is extremely problematic for UPH’s largely rural geography that only 1.85% of rural laboratories met the applicable laboratory definition. This flaw to the pricing calculation discards the needs of rural residents and any pricing factors related to distance and small economies of scale. Without a tie to revenue and greater transparency, this pricing process will continue to distort the true market value.

- Medicare rates influence and are often embedded in commercial payer rates.** Third-party payers often follow the lead of Medicare in setting rates, and **many third-party contracts are based on a percentage of Medicare rates.** This underscores the importance of rate-setting accuracy and transparency. UPH is estimating that the financial impact from these proposed rates will result in a similar impact across all payers. This degree of reduction is not sustainable and will force significant changes in our delivery of clinical laboratory services.

Again, we urge CMS to suspend the rate-setting process so that a more robust dataset can be established and the rates be calculated in a more thoughtful fashion with the involvement of stakeholders. On behalf of our patients and their families and caregivers, UnityPoint Health appreciates the opportunity to provide input on CLFS rates and policies. To discuss UPH comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Public Policy and External Affairs at [Sabra.Rosener@unitypoint.org](mailto:Sabra.Rosener@unitypoint.org) or 515-205-1206.

Sincerely,



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