Complaint Attachment D
Khani Declaration

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION,
1100 New York Avenue, N.W., Suite 725W
Washington, D.C. 20005

Plaintiff,

v.

ERIC D. HARGAN,
In His Official Capacity as Acting Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 1:17-cv-2645

DECLARATION OF JULIE KHANI

I, Julie Khani, declare the following to be true and correct to the best of my knowledge:

1. I am a resident of Fairfax County, Virginia. I am over the age of eighteen, and I am competent to provide this Declaration.

2. I am President of the American Clinical Laboratory Association ("ACLA"), where I have been employed for approximately 4 years. I joined ACLA in July 2013 as Senior Vice President, and was named as Executive Vice President in 2016. I have served as ACLA's President since January 2017.

3. ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. ACLA's members perform millions of tests each year for patients that are reimbursed under the Medicare program. Changes to the way that

laboratories are reimbursed under the Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, 128 Stat. 1040 (2014) ("PAMA") Section 216 are of significant importance to ACLA's membership.

4. My responsibilities at ACLA include leading ACLA's efforts to advance public policies that promote innovation and protect and enhance patient access to life-improving and life-saving diagnostics. I am also responsible for overseeing all aspects of ACLA's advocacy and interactions with Congress and executive branch agencies, including the Centers for Medicare & Medicaid Services ("CMS"). I manage ACLA's staff and budget, recruit and retain ACLA members, and serve on the ACLA Board of Directors.

5. I have been directly involved in ACLA's many efforts to work with government officials to implement PAMA Section 216, including officials and executive-level staff at the Department of Health and Human Services ("HHS"), CMS, and other federal agencies regarding the implementation of PAMA Section 216.

6. Congress designed Section 216 to bring about significant changes in the way that laboratories across the country are to be reimbursed under the Medicare program. Section 216 has two separate sets of provisions. The first imposes a mandatory obligation on laboratories that receive a majority of their Medicare revenues through Clinical Laboratory Fee Schedule or the Physician Fee Schedule payments to report private payor information to the HHS Secretary. Such laboratories are defined in the statute as "applicable laboratories." The second requires the Secretary to take that private payor information and use it to establish new Medicare reimbursement rates. These provisions are a matter of high priority for ACLA and its membership.

7. The initial purpose of ACLA's interactions with HHS, CMS, and executive-level staff at other federal agencies was to provide laboratory stakeholder insight on how the Secretary might effectively implement PAMA's data reporting requirements.

8. CMS proposed and then finalized a regulatory definition of "applicable laboratory" that is contrary to the statutory definition. Instead of requiring all "applicable laboratories" to report private payor information, as Congress directed, CMS's regulations carve out thousands of laboratories from the statutory requirements, effectively excluding hospital laboratories and many other laboratories from the obligation to report information.

9. Fewer than 2,000 laboratories out of more than 260,000 laboratories nationwide that have obtained a Medicare National Provider Identifier ("NPI") — just 0.7 percent — reported private payor information to the Secretary. *Compare* Office of Inspector General, Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data, OEI-09-16-0004, at 8 (Sept. 2016), *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf to "Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System," *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/vCY2018-CLFS-Payment-System-Summary-Data.pdf.

10. There are approximately 7,000 hospital laboratories in the country, but the Secretary defined "applicable laboratory" in such a way that only 21 of these laboratories reported private payor information to the Secretary. *Id.* That is, less than 1 percent of hospital laboratories are represented.

11. ACLA and its members repeatedly urged CMS to comply with the statutory requirements and explained why the agency's revised regulatory definition was unlawful,

unreasonable, and improper. ACLA and its members also identified alternative approaches that would allow the agency to comply with the statutory requirements.

12. Between 2014 and today, ACLA had at least 42 separate interactions with HHS, CMS, and federal executive-level staff related to the implementation of PAMA Section 216 and specifically the regulatory definition of "applicable laboratory." Those interactions included:

a. 22 in-person meetings;

b. 14 letters;

c. 1 presentation at a public meeting;

d. 3 teleconferences; and

e. 2 comments submitted to CMS proposed rulemaking/rates.

13. On May 19, 2014, laboratory stakeholders, including ACLA, met with Anne Tayloe Hauswald, Director, Division of Ambulatory Services, Hospital and Ambulatory Policy Group, Center for Medicare and other CMS career-level staff to discuss implementation of PAMA Section 216.

14. As a Director for the Division of Ambulatory Services at that time, Ms. Hauswald was a senior policy official with responsibility for implementing clinical diagnostic laboratory policy for the Medicare program, including the changes to the Clinical Laboratory Fee Schedule brought about by PAMA Section 216. A pre-meeting summary was submitted to Ms. Hauswald on May 16, 2014. Sean Cavanaugh, Deputy Administrator and Director, Center for Medicare and Marc Hartstein, Director, Hospital and Ambulatory Policy Group, Center for Medicare, were copied on the summary. At that time, Mr. Cavanaugh was the second in command at CMS and, as the Director for the Center for Medicare, the senior most individual with direct responsibility for establishing Medicare policy, including the implementation of PAMA Section 216. Mr.

Hartstein reported to Mr. Cavanaugh and was Ms. Hauswald's direct supervisor. As the Director of the Hospital Policy Group, Mr. Hartstein was the senior career official with final responsibility for establishing all Medicare reimbursement policy in the areas of hospital inpatient and outpatient services, physician services, other institutional services such as home health and hospice, and clinical diagnostic laboratory services.

15. The summary that ACLA provided to Ms. Hauswald, Mr. Cavanaugh, and Mr. Hartstein emphasized the concern of ACLA and other stakeholders that "the definition of 'applicable laboratory' should include hospital laboratories performing outreach testing . . . ." A true and correct copy of the summary sent to Ms. Hauswald prior to the meeting is attached as Exhibit 1.

16. On June 11, 2014, laboratory stakeholders, including ACLA, made a presentation to the White House Office of Management and Budget ("OMB") on the implementation of PAMA Section 216. The presentation highlighted stakeholders' top priorities in the Secretary's implementation of PAMA, including the definition of "applicable laboratory." Participants discussed the different segments of the laboratory market — independent laboratories, hospital laboratories, and physician office laboratories — and the role of each in serving Medicare beneficiaries. Meeting participants stressed the necessity of all types of laboratories participating in data collection and reporting, as Congress intended. A true and correct copy of the presentation is attached as Exhibit 2.

17. On June 23, 2014, laboratory stakeholders, including ACLA, submitted a follow-up letter to Ms. Hauswald, again copying Mr. Cavanaugh and Mr. Hartstein. The letter explored the range of types of clinical laboratories. ACLA was concerned that CMS might exclude hospital outreach laboratories from PAMA 216's reporting requirement on the erroneous

conclusion that the Medicare revenue standard should be applied to the entire hospital's revenue rather than the revenue for the hospital laboratory itself as the statute requires. To that end, the stakeholders' letter to Ms. Hauswald stated that "[i]t would not be appropriate to look at the sources of the entire hospital's Medicare revenue" in defining "applicable laboratory," asserting that "[i]f Congress intended for CMS to look at an entire hospital's revenues, then it presumably would have used a broader term in the law, such as 'entity,' rather than using the narrower term 'laboratory.'" Stakeholders also raised their objection that because Medicare rates derived from private payor data applies to laboratory tests furnished by hospital laboratories in certain situations, "it stands to reason that the same hospital laboratories should report their private payor data to CMS for those tests that are not bundled." A true and correct copy of the letter is attached as Exhibit 3.

18. On July 14, 2014, on behalf of ACLA, I presented comments at the Annual Clinical Laboratory Public Meeting regarding implementation of PAMA Section 216. The Annual Clinical Laboratory Public Meeting is called for under Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554, 114 Stat. 2763A-463, 547, and is also specifically required by PAMA Section 216(a), codified at 42 U.S.C. § 1395m-1(f)(3). In the prepared comments, I urged "CMS to work collaboratively with stakeholders in the coming months as the agency develops definitions, standards, processes and procedures to implement Section 216 of PAMA." The comments stated that "Congress's intent with respect to the private payor rate reporting requirements . . . was to ensure that Medicare rates for clinical laboratory services reflect private market rates and that all sectors of the laboratory market are represented in the calculation of the weighted median," including hospital outreach laboratories. A true and correct copy of my comments is attached as Exhibit 4.

19. On August 4, 2014, ACLA President Alan Mertz sent a letter to Glenn McGuirk, Division of Ambulatory Services, Hospital and Ambulatory Policy Group, Center for Medicare. This letter reiterates the points that were made in the June 23, 2014 letter previously sent to Ms. Hauswald, including describing the importance of including a range of laboratories, including hospital outreach laboratories, within the entities required to report private payor data. The letter also discussed ways in which the Secretary might capture a hospital laboratory's revenue. A true and correct copy of the letter is attached as Exhibit 5.

20. On August 26, 2014, laboratory stakeholders, including ACLA, met with Mr. Hartstein, the Director of Hospital and Ambulatory policy at CMS and Ms. Hauswald's supervisor, to discuss implementation of PAMA Section 216. At that meeting, ACLA discussed the importance of including hospital laboratories in the private payor data reporting, as well as the logistical difficulties anticipated for reporting entities.

21. On October 1, 2014, laboratory stakeholders, including ACLA, met with Mr. Cavanaugh, the Deputy Administrator and Director for the Center for Medicare, to discuss implementation of PAMA Section 216. ACLA's presentation to Mr. Cavanaugh stated that the definition of "applicable laboratory" "[s]hould include a hospital lab when a majority of the hospital lab's revenue comes from [the Clinical Laboratory Fee Schedule or Physician Fee Schedule]." A true and correct copy of the presentation used during that meeting is attached as Exhibit 6.

22. On January 13, 2015, ACLA President Alan Mertz sent a letter to Mr. Hartstein to "provide . . . further thoughts on the definition of 'applicable labs.'" In the letter, ACLA noted that "in many instances, laboratory services are furnished by hospitals, which provide outreach services, just as independent laboratories do, and in competition with them. Therefore, not only

is it appropriate from a policy standpoint to include hospitals in the reporting requirements, but the law itself envisions that hospital laboratories will be included." A true and correct copy of the letter is attached as Exhibit 7.

23. On March 3, 2015, ACLA and representatives of its membership met with Katie Martin, Counselor to the Secretary of HHS, to discuss the implementation of PAMA Section 216. Ms. Martin served within the Immediate Office of the Secretary, providing policy advice directly to then-Secretary Sylvia Mathews Burwell. The meeting focused on key issues in the implementation of PAMA, including the definition of "applicable laboratory" and the importance of all sectors of the laboratory industry, including hospital outreach laboratories, being included in the definition in order to meet the requirements of the statute.

24. On March 23, 2015, laboratory stakeholders, including ACLA, sent a letter to Mr. Cavanaugh, urging CMS to publish the proposed rule implementing PAMA Section 216 as soon as possible, given the statutory deadline to publish a final rule by June 30, 2015. The letter expressed concern about the ability of laboratories to "have ample time to create reporting systems based on the new data parameters, certify the data, and transmit it to CMS." The letter also stressed that the new payment model should "reflect[] the broad scope of the laboratory market." A true and correct copy of the letter is attached as Exhibit 8.

25. On March 30, 2015, stakeholders received a response from Mr. Hartstein on Mr. Cavanaugh's behalf, stating that CMS was "actively working on the numerous technical issues involved in implementing" PAMA Section 216. True and correct copies of those letters are attached as Exhibit 9.

26. On April 2, 2015, laboratory stakeholders, including ACLA, participated in a teleconference with HHS Office of Inspector General ("OIG") staff to discuss the

implementation and impact of PAMA Section 216. The stakeholders engaged with the OIG due to the statutory requirement that the OIG conduct annual analyses of the implementation and effect of the new laboratory payment system and reporting requirements under PAMA. *See* PAMA § 216(c)(2). Stakeholders discussed how hospital laboratories perform outreach services and serve non-hospital patients. Further, stakeholders discussed the importance of including in the definition of "applicable laboratories" regional laboratories, hospital outreach laboratories, specialty laboratories and physician office laboratories. Lastly, the meeting touched on challenges expected during the private payor data collection process.

27. On April 3, 2015, laboratory stakeholders, including ACLA, met with Mr. Cavanaugh to discuss the implementation of PAMA Section 216. The presentation urged CMS to conclude that "[a]pplicable labs include hospital laboratories," if billing "Medicare under <u>any</u> fee for service fee schedule." (emphasis original). A true and correct copy of the presentation used during that meeting is attached as Exhibit 10.

28. On June 24, 2015, I sent a letter to Mr. Hartstein in my capacity as ACLA Senior Vice President. The letter requested "[c]lear guidance from CMS [to] help to ensure that PAMA rates are reflective of the full market, as required by the statute and congressional intent, and [to] help laboratories to avoid the penalties associated with not reporting." The letter noted that "[i]n many instances, laboratory services are furnished by hospital laboratories, which provide outreach services, just as independent laboratories do[, such that] independent laboratories and hospital laboratories directly compete in the marketplace." Moreover, "[g]iven that hospital laboratories . . . performing outreach testing will be paid at the new prices established by PAMA, these hospital[] laboratories should be considered applicable laboratories subject to PAMA reporting requirements." A true and correct copy of the letter is attached as Exhibit 11.

29. On October 1, 2015, the HHS Secretary published her proposed rule related to PAMA Section 216. *See* 80 Fed. Reg. 59386 (Oct. 1, 2015) (CMS-1621-P). In the proposed rule, the Secretary proposed to define "applicable laboratory" as including any laboratory with a unique taxpayer identification number ("TIN"). The Secretary also requested comments on defining "applicable laboratory" as including any laboratory with a unique National Provider Identifier ("NPI").

30. On November 4, 2015, laboratory stakeholders, including ACLA, made a presentation to Mr. Cavanaugh regarding the implementation of PAMA Section 216 and the proposed rule. ACLA's presentation urged CMS to adopt a definition of "applicable laboratory" by Clinical Laboratory Improvement Amendments ("CLIA") number, which every laboratory is required to maintain to bill the Medicare program. ACLA noted that the Secretary's proposed rule would deprive the Secretary of the data she needs to ensure that rates are consistent with the private payor market, as Congress intended. A true and correct copy of the presentation is attached as Exhibit 12.

31. On November 17, 2015, ACLA and representatives of its membership met with Mr. Hartstein and other CMS career-level staff in person and by telephone regarding the proposed rule and the Secretary's implementation of PAMA Section 216. The presentation largely mirrored the presentation given to Mr. Cavanaugh on November 4, 2015, and again emphasized that the Secretary's proposed definition of "applicable laboratory" would exclude large portions of the clinical laboratory market, and called on the Secretary to define "applicable laboratory" consistent with Congress's directives. Stakeholders again urged CMS to consider adopting a definition of "applicable laboratory" based on CLIA certification number. A true and correct copy of the presentation used during that meeting is attached as Exhibit 13.

32. On November 23, 2015, ACLA submitted comments on CMS's proposed rule, CMS-1621-P via Regulations.gov. In its comments, ACLA discussed the definition of "applicable laboratory," pointing out that "[v]ery few hospital laboratories have laboratory-specific NPIs — even those with robust laboratory outreach programs — and they generally submit claims under the hospital's NPI." ACLA noted that "[d]etermining the source of a majority of a laboratory's Medicare revenue need not — and should not —- include an analysis of an entire entity's Medicare revenue, because Medicare revenue outside of the laboratory is not relevant to whether a laboratory is an 'applicable laboratory' under the statute." ACLA also proposed alternatives to identifying "applicable laboratory" by TIN or NPI number, including using laboratories' CLIA certification numbers. A true and correct copy of the comments is attached as Exhibit 14.

33. On December 14, 2015, ACLA met again with Ms. Martin, Counselor to the HHS Secretary, regarding the proposed rule and the Secretary's obligations under PAMA Section 216. ACLA called on CMS to define "applicable laboratory" by CLIA number or some other alternative so as to allow a hospital to determine the laboratory's percentage of Medicare revenue, not the whole hospital's Medicare revenue. A true and correct copy of the presentation used during that meeting is attached as Exhibit 15.

34. On January 6, 2016, ACLA met with Dr. Adaeze Enekwechi, Associate Director for Health Programs, and career-level staff at the White House OMB regarding the proposed rule and the need for the Secretary to comply with PAMA Section 216. The meeting was an effort to ensure that OMB was focused on the implementation of PAMA, including the impact of the Secretary's definition of "applicable laboratory." The presentation largely mirrored the presentation given to Ms. Martin on December 14, 2015, and reiterated the need to ensure that

hospital laboratories could appropriately capture their laboratory revenue, including by defining "applicable laboratory" by CLIA number. A true and correct copy of the presentation used during that meeting is attached as Exhibit 16.

35. On March 2, 2016, ACLA met with staff of the HHS OIG, including Sarah Ambrose, China Tantameng, and Joe Chiarenzelli. Ms. Ambrose and Ms. Tantameng served as "Team Leaders" in preparation of the OIG reports related to the implementation of PAMA. Mr. Chiarenzelli served as program analyst. Like the presentations given to Ms. Martin on December 14, 2015 and OMB staff on January 6, 2016, this presentation discussed the flaws in the Secretary's re-definition of "applicable laboratory," including that only a small number of laboratories would be required to report payor data, effectively excluding all hospital laboratories. A true and correct copy of the presentation used during that meeting is attached as Exhibit 17.

36. On March 11, 2016, in my capacity as ACLA Executive Vice President, I sent a follow-up letter to Ms. Ambrose, Ms. Tantameng. and Mr. Chiarenzelli. In that letter, I re-iterated ACLA's concerns with the proposed definition of "applicable laboratory," and I suggested that "applicable laboratory" should be defined by CLIA number, with the "majority of Medicare revenues" test to be applied at the CLIA-level entity. A true and correct copy of that letter is attached as Exhibit 18.

37. On April 13, 2016, laboratory stakeholders, including ACLA, sent a letter to Andy Slavitt, Acting CMS Administrator. In that letter, stakeholders noted that "Congress enacted Section 216 of PAMA with the goal of establishing Medicare Clinical Laboratory Fee Schedule . . . reimbursement rates that reflect market rates," and that, despite the makeup of the laboratory market, CMS's proposed definition of "applicable laboratory" effectively excludes

hospital-affiliated laboratories from reporting. Stakeholders recommended that CMS define the term by CLIA number to ensure that "a hospital laboratory's statute as an 'applicable laboratory' is based on whether the part of a hospital furnishing laboratory services receives a majority of Medicare revenue from the [Clinical Laboratory Fee Schedule or Physician Fee Schedule], rather than applying the test to an entire hospital, even those parts of the hospital furnishing services that are reimbursed under the inpatient and outpatient prospective payment systems." (emphasis original). A true and correct copy of that letter is attached as Exhibit 19.

38. On June 23, 2016, the Secretary issued her final rule. *See* 81 Fed. Reg. 41035 (June 23, 2016). In the final rule, the Secretary continued to violate the statute, defining "applicable laboratory" based on laboratory's unique NPI number and, as a result, excluding a large portion of clinical laboratories from the definition and reporting requirements.

39. On August 30, 2016, in my capacity as ACLA Executive Vice President, I sent a letter to Carol Blackford, the new Director for the Hospital and Ambulatory Policy Group, Center for Medicare. Ms. Blackford replaced Mr. Hartstein in this position after Mr. Hartstein left the agency. The letter highlighted inconsistences between the final rule and other sub-regulatory guidance issued by CMS relating to reporting of private payor rates and how "applicable laboratories" are defined. It also requested additional guidance on what information should be reported by "applicable laboratories" and how that information was to be reported. A true and correct copy of the letter is attached as Exhibit 20.

40. On March 23, 2017, ACLA and members of its Board of Directors met with Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director of the Center for Medicare. Mr. Kouzuokas replaced Mr. Cavanaugh in this position as a result of the change in presidential administrations. The meeting focused on problems with the implementation of

PAMA, including the Secretary's definition of "applicable laboratory," and called on the Secretary to extend the deadline for laboratories to report private payor data to CMS due to problems with the agency's reporting portal and the difficulties that reporting laboratories were facing in collecting and submitting data.

41. On March 24, 2017, laboratory stakeholders, including ACLA, sent a letter to Department of Health and Human Services Secretary Thomas Price. Seema Verma, CMS Administrator, Senator Orrin Hatch, Senator Ron Wyden, Representative Kevin Brady, Representative Richard Neal, Representative Greg Walden and Representative Frank Pallone were copied on the letter. The letter called for the regulatory definition of "applicable laboratory" to be "reassessed and redefined," given that the most recent OIG analysis showed that only 5 percent of clinical laboratories would report data, with no hospitals participating. The stakeholder letter stated: "The exclusion of an entire laboratory sector, particularly hospitals operating large outreach laboratories, negatively affects the integrity of rate calculations under PAMA. The implications are immense and would ultimately threaten to reduce laboratory infrastructure across the country, and therefore, limit beneficiary access to laboratory test services that support patient clinical care management." A true and correct copy of the letter is attached as Exhibit 21.

42. On April 27, 2017, ACLA and representatives of its membership met with Administrator Verma. ACLA noted that a mere 5 percent reporting rate by laboratories, including total exclusion of hospital laboratories "does not reflect the private market" and called on CMS to revise the regulatory definition of "applicable laboratory." ACLA also noted that hospital and rural laboratories serve distinct patient populations, making inclusion of their private payor data important to truly reflect the market. True and correct copies of background

material provided to Ms. Verma and the presentation used during the meeting are attached as Exhibits 22 and 23, respectively.

43. On June 7, 2017, in my capacity as ACLA President, I sent a follow-up letter to Administrator Verma at her request to provide additional information on topics discussed at the April 27, 2017 meeting, including the treatment of hospital outreach laboratories. Therein, ACLA reiterated that "the data that CMS will use to calculate [Clinical Laboratory Fee Schedule] rates is incomplete and not reflective of the entire laboratory market." ACLA also provided recommendations to Administrator Verma to address the discussed issues, including postponing the calculation and publication of payment rates, amending the definition of "applicable laboratory" to include all hospital outreach laboratories that exceed the minimum revenue threshold, and establishing later dates to allow such hospital outreach laboratories to report data. Specifically, ACLA called for the regulatory definition of "applicable laboratory" to change in such a way that hospital outreach laboratories would qualify for the minimum revenue threshold by consideration of their Medicare claim forms. A true and correct copy of that letter is attached as Exhibit 24.

44. On June 26, 2017, laboratory stakeholders, including ACLA, sent a letter to Secretary Price, requesting a meeting on the implementation of PAMA Section 216 and expressing concern with the exclusion of hospital outreach and physician office laboratories under the final rule's data reporting requirements. A true and correct copy of that letter is attached as Exhibit 25.

45. On June 28, 2017, ACLA participated in a teleconference with the HHS OIG to discuss the OIG's analysis showing that CMS's regulatory definition of "applicable laboratory" leaves out the majority of laboratory sectors from reporting private payor data. ACLA offered an

alternative, whereby Medicare revenues would be captured for hospital outreach laboratories via their Medicare claim forms. A true and correct copy of the presentation used during that meeting is attached as Exhibit 26.

46. On July 13, 2017, ACLA and representatives of its membership met with Executive Office of the President staff. In that meeting, ACLA asserted that because "[a]ll sectors of the market will be reimbursed by PAMA rates, all should be part of data reporting." If PAMA is implemented successfully, ACLA noted, it will maintain beneficiary access to laboratory services, save the Medicare program money, and lead to stable, market-based rates for laboratories. ACLA also noted that, if CMS continues with its final rule, the "[r]esulting reimbursement rates will be flawed, [with] hospital, nursing home, rural labs, [and] labs with high Medicare volume" feeling the greatest impact. A true and correct copy of the presentation used during that meeting is attached as Exhibit 27.

47. On July 13, 2017, ACLA and representatives of its membership also met with White House OMB staff regarding the implementation of PAMA Section 216 and the final rule. ACLA expressed concern about the regulatory definition of "applicable laboratory" and how it effectively excludes large portions of the clinical laboratory market from reporting private payor data. On information and belief, the presentation utilized during that meeting is substantially similar to that found at Exhibit 27.

48. On August 18, 2017, in my capacity as ACLA President, I sent a letter to Administrator Verma related to the laboratory billing codes for which CMS had received no reported data. In the letter, ACLA noted that one reason for the lack of data might be because a test might be offered primarily by laboratories not meeting the regulatory definition of "applicable laboratory." A true and correct copy of that letter is attached as Exhibit 28.

49. On August 22, 2017, laboratory stakeholders, including ACLA, participated in a meeting with HHS staff. Stakeholders again called for CMS to delay its planned implementation of PAMA based on flaws in the collected data and the lack of its representativeness of the market. Stakeholders focused on the role of hospital outreach laboratories, including their range in payor and client mix. One non-profit health system from Georgia in attendance estimated that its hospital outreach laboratories account for from 17 to 20 percent of its Medicare test volume. The health system's representative also described to HHS staff the inability for its hospital laboratory to report under the Secretary's definition of "applicable laboratory." A true and correct copy of the presentation used during that meeting is attached as Exhibit 29.

50. On August 30, 2017, laboratory stakeholders, including ACLA, met with Mr. Kouzoukas to discuss the implementation of PAMA Section 216. The presentation was similar to the presentation made to HHS staff on August 22, 2017, and again highlighted the importance of including hospital outreach laboratories in the data collection process. Again, a representative from the non-profit health system in Georgia highlighted the volume of hospital outreach services it provides and the inability to report any private payor data under the Secretary's definition of "applicable laboratory." A true and correct copy of the presentation used during that meeting is attached as Exhibit 30.

51. On September 11, 2017, ACLA met again with Mr. Kouzoukas to discuss the implementation of PAMA Section 216 as follow-up to the August 30, 2017 meeting. Additional laboratory stakeholders joined this meeting, including an independent laboratory, as did other CMS staff, including Carla DiBlasio and Ing Jye Cheng, who is Ms. Blackford's deputy. The independent laboratory shared a proprietary data analysis showing that physician office and hospital laboratory private payor rates were approximately 150 percent and 250 percent,

respectively, above its own rates. The independent laboratory also shared projected data demonstrating how the exclusion of approximately half of physician offices and nearly all hospital laboratories from data reporting skewed the weighted median of private payor data.

52. On September 12, 2017, ACLA participated in a conference call with CMS career-level staff (including Ms. Blackford and Ms. Cheng) at the request of Mr. Kouzoukas to further discuss the data analysis shared on September 11, 2017, which showed the disparity between the large, independent laboratory's private payors rates, as compared to physician office and hospital laboratory rates.

53. On September 18, 2017, ACLA met with HHS and CMS staff to discuss the implementation of PAMA Section 216. The presentation was similar to the presentation given to HHS staff on August 22, 2017, and to Mr. Kouzoukas on August 30, 2017. Again, ACLA spent a considerable amount of time discussing the role of hospital outreach laboratories and how their exclusion in the reported data results in a flawed restructuring of the Clinical Laboratory Fee Schedule. A true and correct copy of the presentation used during that meeting is attached as Exhibit 31.

54. On September 22, 2017, CMS published proposed Clinical Laboratory Fee Schedule rates for calendar year 2018 based on the private payor data it collected.

55. On October 6, 2017, laboratory stakeholders, including ACLA, sent a letter to Administrator Verma. In the letter, stakeholders expressed concern that the proposed rates would result in significant harm to the laboratories and reduce access to clinical laboratory testing for Medicare beneficiaries. Stakeholders called on CMS to "[e]nsure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market (national independent, community and rural independent, hospital outreach, and physician office

laboratories)." Stakeholders also requested that CMS delay implementing the proposed rates. A true and correct copy of the letter is attached as Exhibit 32.

56. On October 16, 2017, ACLA participated in a meeting with CMS staff. In that presentation, ACLA stated that in order for new laboratory payment rates to go into effect, the "[l]aboratory market has to be represented in the data" and a "[s]ubstantial proportion of applicable labs must report data." ACLA also highlighted concerns with the data CMS received on which it was basing rates. A true and correct copy of the presentation used during that meeting is attached as Exhibit 33.

57. On October 23, 2017, in my capacity as ACLA President, I sent a letter to Administrator Verma. This letter is a response to the proposed Clinical Laboratory Fee Schedule rates for calendar year 2018 based on CMS-collected data. At the outset, ACLA reiterated that the Secretary's definition of "applicable laboratory" is contrary to statute. Having failed to establish laboratory data reporting obligations consistent with PAMA, ACLA objected that the Secretary cannot proceed with then establishing new payment rates based on flawed data. A true and correct copy of that letter is attached as Exhibit 34.

58. On November 8, 2017, ACLA met with the Government Accountability Organization ("GAO") officials. GAO officials initiated the meeting with ACLA due to ACLA's visibility and engagement related to PAMA Section 216. GAO officials had read ACLA's comments to the proposed rule related to PAMA Section 216 and other related communications with CMS. The GAO has a statutory requirement to issue a report to Congress by October 1, 2018 related to the implementation of PAMA Section 216, covering topics like reported private payor rates, the conversion to new Clinical Laboratory Fee Schedule amounts, the impact on beneficiary access, the impact on small, low-volume laboratories, Medicare

spending trends for laboratory tests, and how well reported private-payor data reflected market prices. *See* PAMA § 216(c)(1). The focus of the discussion with GAO was industry perspectives regarding PAMA's implementation and how CMS has responded to challenges faced by laboratories.

59. On November 16, 2017, ACLA and other laboratory stakeholders met with Mr. Kouzoukas in response to the stakeholder letter submitted to Administrator Verma on October 6, 2017. Ms. Blackford, Valerie Miller, Director, Hospital and Ambulatory Policy Group, Center for Medicare and Sarah Shirey-Losso, Deputy Director, Hospital and Ambulatory Policy Group, Center for Medicare, joined by teleconference. ACLA again highlighted the ramifications of the exclusion of hospital laboratories, particularly on laboratories in rural areas and those serving nursing homes. ACLA called on CMS to suspend implementation of the new Clinical Laboratory Fee Schedule rates until such time as the collected private payor data "accurately represents all segments of the clinical laboratory market." ACLA also discussed the flaws in the "simulations" used by CMS in its proposed rates to justify its exclusion of hospital laboratories. Based on a data analysis of publicly available Medicare data done by Braid-Forbes Health Research on behalf of ACLA, over 3,000 hospital laboratories were paid more than $12,500 on the Clinical Laboratory Fee Schedule in the first two quarters of calendar year 2016, the designated reporting period. However, only 21 hospital NPIs reported private payor data. ACLA also provided dozens of specific examples of hospital laboratories excluded from reporting—some with multi-millions of dollars paid on the Clinical Laboratory Fee Schedule. Lastly, both a hospital and large independent laboratory provided specific information on their service models and the differences between the markets that they serve. A true and correct copy of the presentation is attached as Exhibit 35.

60. On November 17, 2017, the Secretary finalized Clinical Laboratory Fee Schedule rates for 2018, relying on his definition of "applicable laboratory" that runs counter to the statutory language and excludes nearly all hospital laboratories. Although the Secretary made small revisions based on stakeholder feedback to the proposed rates, he made no adjustment to the definition of "applicable laboratory." Instead, he dismissed concerns, noting that the definition was finalized through notice and comment rulemaking and that "a hospital outreach laboratory, that is, a hospital based laboratory that furnishes laboratory tests to patients other than inpatients and outpatients of the hospital, could be an applicable laboratory if it meets the definition of applicable laboratory in 42 CFR 414.502." *See* Information Regarding the Final CY 2018 Private Payor Rate-Based Clinical Laboratory Fee Schedule (CLFS) Payment Rates, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-HCPCS-Median-Calculations.pdf. A three-sentence discussion of the exclusion of hospital laboratories from reporting private payor data completely ignores the years of feedback the Secretary has received regarding the impact of such exclusion.

61. In addition to the above engagement specifically related to the regulatory definition of "applicable laboratory," ACLA and its members have also engaged with CMS on other matters of importance related to the implementation of PAMA Section 216 and changes to the Clinical Laboratory Fee Schedule. Those interactions included additional in-person meetings, as well as several presentations and comments at public meetings. For example, ACLA requested that CMS clarify certain reporting requirements included in the final rule and under the Secretary's subregulatory guidance. ACLA also pointed out laboratory tests with unique billing requirements that would make reporting difficult.

62. In conclusion, having engaged with officials and executive-level staff at HHS, CMS and other federal agencies several dozen times in the past 3.5 years, I believe ACLA and its membership have exhausted all potential avenues for further dialogue. CMS has made clear that it will not revisit its final rule and that it intends to move forward with a definition of "applicable laboratory" that does not comply with PAMA.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Julie Khani
President
ACLA

12/8/17
Date

Khani Declaration Exhibit 1

May 16, 2014

Ms. Anne Tayloe Hauswald, Director
Division of Ambulatory Services
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Hauswald:

Thank you for your willingness to meet with representatives of the clinical laboratory community on May 19, 2014 to discuss the Clinical Laboratory Fee Schedule ("CLFS") reform provisions included in Section 216 of the recently-enacted Protecting Access to Medicare Act of 2014 ("PAMA").[1] Our organizations – the American Clinical Laboratory Association ("ACLA"), AdvaMedDx, and the Coalition for 21st Century Medicine – together represent members of the laboratory industry that furnish millions of tests to Medicare beneficiaries each year. Having supported the inclusion of the CLFS reform provision in PAMA, we are supportive of CMS's efforts to implement the law, and we hope to work with you throughout the process to ensure the success of the program.

This is the first major reform of reimbursement methodology under the CLFS since its inception in 1984, and we are certain that you have an appreciation for how complex this undertaking will be for CMS and for the clinical laboratories and other healthcare providers that will be required to collect, aggregate, and report private payor data to CMS as part of that rate-setting. Our organizations and members intend to work very diligently with CMS and with other stakeholders on the front end of the implementation process so that the information technology infrastructure development, data collection and aggregation, private payor rate reporting, Medicare payment amount calculations, coding, and other activities proceed as smoothly as possible.

We are writing in advance of our May 19th meeting to provide you with an overview of the broad topics we would like to discuss with you. Below are our preliminary recommendations, which we hope you will consider as you implement the new program. We look forward to talking about these preliminary recommendations with you in further detail at our meeting.

Rate Reporting and Rate Setting

1. In addition to including independent clinical laboratories, the definition of "applicable laboratory" should include hospital laboratories performing outreach testing and certain physician office laboratories. Like independent clinical laboratories, hospitals and physician office laboratories should report their private payor rates for clinical laboratory tests that are not part of a bundled payment.

[1] Pub. L. 113-93 (codified at 42 U.S.C. § 1395m-1 (2014)).

2. To ensure consistency among reported rates, laboratories should report the final total approved payment rates for covered services during the reporting period, excluding those for which appeals are not fully exhausted and for which final rates are not yet determined. The approved payment rate is the total "Allowable Amount" paid by a private plan, including any copayments, coinsurance, deductible amounts, and other patient cost-sharing.

3. A six month period should be the length of the first data collection period, and this initial data collection period should cover the first six months of 2015.

4. There should be at least six months between the end of the initial data collection period and the date by which applicable laboratories must report data so that laboratories have adequate time to collect, organize, review and verify the data so that they may submit accurate payment rates and volumes to CMS. This also would allow a lab to factor into its reported rates any volume-based discounts, rebates, and price concessions.

5. An electronic reporting mechanism, such as an internet-based portal, should be established for laboratories to test their rate-reporting capabilities and for CMS to test its information technology infrastructure prior to the actual reporting date. The agency also should consider establishing a reporting test period, limited to a small number of codes, and calculate "draft" weighted median Medicare rates so that CMS and applicable laboratories can review the rates that the agency calculates, before the reporting system is used for all clinical laboratory test rates.

6. We urge CMS to ensure that there is sufficient transparency in the rate-calculation and rate-setting processes so that interested stakeholders can validate the payment rates for individual tests.

Advanced Diagnostic Laboratory Tests and Coding

7. For advanced diagnostic laboratory tests ("ADLTs"), the "initial period of three quarters" for rate reporting that is referenced in the statute should begin once a Medicare administrative contractor ("MAC") determines that an ADLT is covered by Medicare and a unique Healthcare Common Procedure Coding System ("HCPCS") code has been issued to identify the test.

8. A process should be developed as soon as possible through subregulatory guidance to issue unique HCPCS codes and publish the payment rates for existing ADLTs and existing clinical laboratory tests that were cleared or approved by the Food and Drug Administration ("FDA") and paid by Medicare as of the date of enactment under a miscellaneous code or otherwise not reported under a uniquely-assigned code.

9. Congress gave CMS the authority, codified in Section 1834A(d)(5)(C) of the Social Security Act, to establish criteria under which tests that do not fit the statutory definition of an ADLT but that are similar to ADLTs may be considered ADLTs. CMS should use that authority to establish a process in rulemaking that allows a laboratory to request that such a test be classified as an ADLT, at the time of submission of clinical evidence for Medicare coverage. Based on the process that CMS establishes in rulemaking and based on criteria that CMS sets forth in guidance, the relevant MAC or MACs may determine whether a requesting lab's test warrants classification as an ADLT.

Clinical Laboratory Expert Advisory Panel

10. A public announcement should be issued regarding the clinical laboratory expert advisory panel, which discusses the types of individuals the agency would expect to serve on the advisory panel and that solicits nominations from the public. CMS should ensure that at least some panel members have recent industry experience with clinical laboratory operations, commercial test development, and diagnostics reimbursement, and it also should account for patient and clinician perspectives. Stakeholders should be afforded an opportunity to provide input on the advisory panel's charter, role, processes, and meetings.

Rulemaking

11. Given how soon laboratories will have to collect data to report to CMS early in 2016, it is important for the agency to proceed with the regulatory implementation process as soon as possible. Therefore, CMS should include information about its proposed process and timeline for PAMA implementation in the CY 2015 Physician Fee Schedule proposed rule and solicit input from interested stakeholders on discrete questions. Also, as part of that rule, CMS should formally withdraw the regulation that appears at 42 C.F.R. § 414.511 regarding adjusting prices on the CLFS based on technological changes, which is based on a statutory provision that Congress eliminated in PAMA.

We are looking forward to a productive meeting with you and with your colleagues on May 19th, and we sincerely hope that it will be the first in a series of opportunities for us to ask questions and raise issues and for the agency to solicit input and hear about how different policy options might affect different sectors of the laboratory industry. Thank you again for the opportunity to meet with you to discuss these issues of critical importance to us.

Sincerely,

Alan Mertz, President
ACLA

Don May, Executive Vice President
Payment & Health Care Delivery Policy
AdvaMed

John Hanna, Chair, Reimbursement & Policy Workgroup
Coalition for 21st Century Medicine

cc: Sean Cavanaugh
Marc Hartstein

Khani Declaration Exhibit 2

Protecting Access to Medicare Act of 2014

Section 216 – SSA §1834A
Improving Policies for Clinical Diagnostic Laboratory Tests

Office of Management and Budget

June 11, 2014

AGENDA

- Welcome & Introductions
- Review of Key Stakeholder Concerns
  - Implementation Process & Timeline
  - Key Procedural Definitions
  - Critical Reporting Issues
  - Issues affecting Advanced Diagnostic Lab Tests
  - Expert Advisory Panel
  - Test Period for Reporting Process
- Comments & Questions
- Adjourn

Implementation Process and Timelines

- First major reform to CLFS since 1984
- Dissimilar from other payment systems
- Need for significant & substantive guidance
- Very short timeframe to implement
- Very high risk of “getting it wrong”
- Strong incentive to pressure test systems and capabilities

Implementation Process and Timelines

- July 2014: PAMA discussion at CMS public meeting
- December 2014: Proposed rule on lab reporting and data collection (estimate)
- 2015: CMS to assign HCSPCS codes to ADLTs and FDA-approved or cleared tests that do not already have unique codes
- June 2015: Final rule on lab reporting and data collection
- July 2015: Expert Advisory Panel established
- January 2016: Lab reporting begins
- January 2017: New Medicare rates based on the weighted median of reported private payor rates goes into effect

KEY ISSUES

- Applicable Laboratories
- Lab Reporting
- ADLTs
- Expert Advisory Panel
- Test Period for Reporting Process

Questions?

Khani Declaration Exhibit 3

June 23, 2014

VIA E-MAIL AND FIRST CLASS MAIL

Ms. Anne E. Tayloe Hauswald, Director
Division of Ambulatory Services
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Hauswald,

Thank you for meeting with us on May 19, 2014 to discuss implementation of Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which adds Section 1834A to the Social Security Act to reform reimbursement rate setting under Medicare's Clinical Laboratory Fee Schedule ("CLFS").[1] We found it to be a productive meeting, and we appreciated the opportunity to share with you our preliminary thoughts on implementation of the law and to hear from you about the agency's current thinking.

This memo provides background and recommendations on the legal, policy, and implementation issues raised by specific provisions included in Section 216 of PAMA, which modifies the reimbursement rate methodology under the CLFS for the first time in three decades. We have organized our discussion around five general categories of issues, questions, and suggestions related to the CLFS reform provisions contained in Section 216: (1) reporting of private payor rates and volumes; (2) Medicare payment rate development; (3) coding; (4) coverage; and (5) steps involved in the overall implementation of the new law.

As we review the complex new reporting requirements of the law, we see an urgent need for CMS to provide clear and consistent direction to the laboratories affected by these requirements as soon as possible to ensure that implementation proceeds smoothly. There are many technical factors that will impact laboratory compliance, and we urge CMS to solicit laboratory input on these matters. We believe that the creation of a new expert advisory panel could provide CMS with assistance as it moves forward in this area.

I. REPORTING

Reporting of payment rates and volumes for clinical diagnostic laboratory tests and advanced diagnostic laboratory tests ("ADLTs") is perhaps the most critical area for discussion

[1] Pub. L. 113-93 (codified at 42 U.S.C. § 1395m-1 (2014)).

and consideration. Reporting could begin as early as January 1, 2016, and the statute requires regulations to be issued not later than June 30, 2015. There are a remarkable number of details to be worked out before laboratories can begin to prepare to report data to CMS. The way in which CMS defines the parameters, participants, methods, and time frames for reporting can have a substantial impact on the rates that the Medicare program pays for clinical laboratory tests. It will be an enormous undertaking for CMS to prepare to receive millions of pieces of information from thousands of laboratories and for each one of those laboratories to collect, organize, and transmit the data. While we recognize that CMS must address many facets of implementation concurrently, reporting is one area that we believe should be a primary focus for the agency in the near term.

A. The Law

Beginning January 1, 2016 and generally every three years thereafter, an applicable laboratory is to report certain information to the Secretary about private payor data for laboratory tests. An "applicable laboratory" is a laboratory that receives a majority of its Medicare revenue under the CLFS, the Physician Fee Schedule ("PFS"), or the new Section 1834A of the Social Security Act, as added by PAMA. For most clinical diagnostic laboratory tests furnished during a specified data collection period, an applicable laboratory must report both the payment rates paid by each private payor for the tests during the period and the volume of such tests for each private payor for the period (except for tests paid on a capitated basis). When an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the lab is to report each of those rates and the corresponding volumes (the Secretary may allow aggregate reporting of this data starting January 1, 2019). A "private payor" is "a health insurance issuer and a group health plan," a Medicare Advantage plan, or a Medicaid managed care organization.

The timetable for reporting is different for ADLTs.[2] During the initial reporting period, an applicable laboratory is to report private payor rates and volumes for ADLTs no later than the "last day of the second quarter" of such initial period, and afterward, reporting is to be annual for these tests (rather than every three years).

Information reported by an applicable laboratory is confidential and is not to be disclosed by CMS or any Medicare contractor in a form that reveals the identity of a payor or laboratory, except "as the Secretary determines to be necessary to carry out this section," or to the Comptroller General of the United States, the Congressional Budget Office, or MedPAC.[3]

[2] An ADLT is a laboratory test covered under Medicare that is offered and sold only by the developing lab (or its successor) and that meets one of the following criteria: (a) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (b) the test is approved or cleared by the Federal Food and Drug Administration ("FDA"); or (c) the test meets other similar criteria established by the Secretary. Social Security Act § 1834A(d)(5) (42 U.S.C. § 1395m-1(d)(5)).

[3] Social Security Act § 1834A(a)(10) (42 U.S.C. § 1395m-1(a)(10)).

B. Issues, Questions, and Suggestions

1. "Applicable laboratories". The law defines an "applicable laboratory" as a "laboratory" that receives the majority of its Medicare revenues under the CLFS, the PFS, or the new section 1834A of the Social Security Act, yet neither the term "laboratory" nor the term "revenues" is defined in PAMA or elsewhere in the Social Security Act. The law also permits CMS to exclude certain laboratories from the definition of "applicable laboratory" by establishing low volume or low expenditure thresholds. Laboratory services can be furnished by a variety of entities, and CMS will have to determine what types of laboratories are encompassed by the term "applicable laboratories." The range of laboratories includes:

- Independent clinical laboratories: national, regional, and local laboratories that are not affiliated with hospitals or physician offices. Some independent clinical laboratories perform a full range of laboratory testing, while others offer a handful of specialized tests. Specimens may be collected in the community by the laboratory or collected and referred by physicians, health care facilities, and other laboratories and sent to independent laboratories.

- Hospital laboratories: perform laboratory testing for the benefit of hospital inpatients and outpatients. Many hospitals also have laboratory outreach programs through which they serve members of the community, much in the same way that many independent clinical laboratories do.

- Physician office laboratories: Many physician offices have in-office laboratories and perform point-of-care testing for their own patients. They also may perform moderate- and high-complexity laboratory tests and tests for other physicians, as well.

For hospitals, CMS first must determine whether an "applicable laboratory" includes a hospital laboratory, where a majority of the laboratory's Medicare revenue comes from the CLFS, the PFS, or the new Section 1834A of the Social Security Act. It would not be appropriate to look at the sources of the entire hospital's Medicare revenue. If Congress intended for CMS to look at an entire hospital's revenues, then it presumably would have used a broader term in the law, such as "entity," rather than using the narrower term "laboratory."[4] The law is clear that the appropriate inquiry is from what sources a ***laboratory's*** Medicare revenues are derived. To answer that, it is appropriate to look at the laboratory within the hospital, which is a distinct and identifiable cost center.

The second question is what is meant by "revenues." A hospital may provide laboratory services in three different ways, but in most situations, it will not receive what would be considered laboratory "revenues." First, it can provide laboratory services to hospital inpatients, in which case the hospital is paid a bundled rate (a global DRG payment) that includes the

[4] *See* Social Security Act § 1834A(a)(2) (42 U.S.C. § 1395m-1(a)(2)) ("the term 'applicable laboratory' means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848.").

laboratory services. The laboratory receives no separate "revenues" attributable to the laboratory services in this case. Second, a hospital laboratory can provide services to hospital outpatients. As results of the new bundling requirement that CMS established in the CY 2014 Hospital Outpatient Prospective Payment System ("OPPS") rule, hospitals are not paid separately for most laboratory services furnished to outpatients.[5] The payment for the laboratory service is included in the Ambulatory Payment Classification ("APC") payment; therefore, the hospital laboratory does not receive any separate laboratory "revenues" in this situation either. Finally, a hospital can provide "outreach" services, *i.e.*, where a hospital obtains specimens from physicians who see patients in their own offices, just like independent clinical laboratories do. In that case, a hospital is paid separate laboratory "revenue" for those services under the CLFS.[6]

In sum, a hospital laboratory has separately-identifiable "revenues" when it is paid separately for its outreach testing services furnished to non-patients.[7] CMS has noted on several occasions that when a hospital furnishes testing services for non-hospital patients, it is "functioning as an independent clinical laboratory."[8] Thus, it seems reasonable, and justified by the terms of the statute, to determine that a hospital laboratory performing outreach testing is an "applicable laboratory."

Moreover, it is reasonable as a matter of policy to require hospitals to be included in rate reporting for purposes of Section 216 of PAMA. In drafting this law, Congress clearly contemplated that the Medicare rates that CMS derives from private payor data would apply to laboratory tests furnished by hospital laboratories when such tests are not part of a bundled payment (*i.e.*, when provided on an outreach basis).[9] Therefore, it stands to reason that the same hospital laboratories should report their private payor data to CMS for those tests that are not bundled. Because Congress's intent is for Medicare rates to approximate private market rates for clinical laboratory tests, data reflecting the entire market must be included to set rates accurately.[10]

[5] *See* 78 Fed. Reg. 74229, 74939 (Dec. 12, 2013).

[6] CMS itself has recognized these distinctions, and it recently has given instructions to hospitals on how to distinguish separately-billable outreach services from outpatient services that are bundled under an APC. *See* CMS Transmittal 2845, Change Req. 8572 (Dec. 27, 2013); *see also* CMS Transmittal 2971, Change Req. 8776 (May 23, 2014).

[7] As noted, hospitals also are permitted to be paid separately for laboratory services furnished to outpatients if those services are for molecular pathology services. However, if those payments are included as revenues, it would not affect the outcome, as they still would constitute revenues from 1833(h) of the Social Security Act, which is one of the applicable sections included in Section 216 of PAMA.

[8] *See, e.g.*, Medicare Claims Processing Manual, Chapter 16, § 10 ("When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory…").

[9] *See* Social Security Act § 1834A(b)(1)(B) (42 U.S.C. § 1395m-1(b)(1)(B)).

[10] Congress's intent was made explicit in a colloquy between Sen. Richard Burr (R-NC), a member of the Senate Finance Committee, and Sen. Orrin Hatch (R-UT), Ranking Member of that committee. *See* 160 Cong. Rec. S2860 (daily ed. May 8, 2014). Sen. Burr noted that it was his understanding that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach

- ***Recommendation: Hospital laboratories performing outreach testing should be included in the definition of "applicable laboratory" and should report their private payor data for clinical laboratory tests that are not part of a bundled payment.***

Similarly, it seems appropriate that certain physician office laboratories for which the majority of Medicare revenues come from the CLFS, the PFS, or Section 1834A also should be included in the definition of "applicable laboratory" and report their private payor data. Certain physician office laboratories perform a significant number of point-of-care tests, so data from physician office laboratories may be particularly important for setting accurate rates for such tests, and physician office laboratories may perform more complex tests, as well. As noted above, if the intent is for Medicare rates to reflect market rates, then the full range of pricing data should be included. At the same time, we acknowledge that CMS must balance the importance of complete information about private payor data against the burden on physician office laboratories that may have limited resources to submit complete and accurate rate information.

- ***Recommendation: CMS should solicit public comments on the inclusion of physician office laboratories in the definition of "applicable laboratory," and it also should seek input on how to strike the appropriate balance between complete private payor market data and the burden that a reporting obligation would impose on physician office laboratories.***

2. Private payor rates and volumes. As we have discussed issues related to implementation of the law over the past several weeks, we have been reminded of the vast number of individual private payor rates paid to just a single major laboratory and the significant task of collecting and reporting each individual rate and associated volume. One laboratory may have contracts with more than a thousand private payors, as that term is defined in the law, with separate payment rates for many or all of the individual plan offerings by each of the payors, and separate payment rates for each one of the more than one thousand codes on the CLFS. The individual plans may pay different payment rates for each of the codes, depending on a number of factors. Rates also may differ for services offered in different states. These thousands of individual rates then will be multiplied by the number of applicable laboratories participating in the Medicare program and reporting their own rates. CMS's information technology challenge in accepting and organizing this much data and using it properly to calculate accurate payment rates is equaled by the information technology challenges that will be faced by each laboratory that must collect, organize, de-duplicate, and transmit data to CMS.

Recent events in California demonstrate how difficult and complex this exercise is bound to be. In 2012, the California legislature enacted similar reporting requirements to establish new payment levels for clinical laboratory tests paid for by the California Medicaid program ("Medi-

laboratories that receive payment on a fee-for-service basis under the fee schedule." Sen. Hatch agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."

Cal"). The law requires laboratories to report their pricing information for more than 400 separate tests to the California Department of Health Care Services ("DHCS"). Affected laboratories are required to submit rates for at least their top five payors for California, not including Medicare and Medi-Cal. Many laboratories that participate in Medi-Cal had difficulty assembling the required information by the first deadline on May 31, 2013, and DHCS was forced to extend the deadline for data submission by three months in order for laboratories to complete the process. The amount of information that each applicable laboratory must report under Section 216 of PAMA dwarfs the amount that had to be reported in California. CMS should be prepared to receive an overwhelming amount of data and to give laboratories flexibility in how they are required to report such data.

"Private payor" is a term that is defined in the law, yet laboratories will need additional guidance from CMS about how to distinguish payors when reporting. The definition of a "private payor" includes "a health insurance issuer" and a "group health plan," as those terms are defined in the Public Health Service Act. A "health insurance issuer" is "an insurance company, insurance service, or insurance organization (including an [HMO]) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance…". A "group health plan" is an employee welfare benefit plan, to the extent that the plan provides medical care to employees and their dependents directly or through insurance, reimbursement, or otherwise.[11] A "health insurance issuer" often is an enormous corporation that is licensed in many or all states to sell health insurance coverage through a variety of products.

Notwithstanding the statutory definition noted above, CMS will need to define exactly how "private payor" is to be understood in this context to provide clear instruction to applicable laboratories about how to assemble and report data. For example, laboratories do not have a "United Healthcare" rate for a given laboratory test – United Healthcare pays thousands of different rates for a test, based on the plan, location, place of service, and health care provider. Similar complexity will arise with Medicare Advantage and Medicaid managed care organization plans. Adding to the complexity of the task of determining which rates applicable laboratories will report to CMS is the fact that laboratories that are out-of-network are paid varying rates, sometimes by the same payor in the same year.[12]

CMS also will need to be clear about what constitutes a payment rate. In most cases, the rates that private payors set for laboratory tests account not only for the amount that the health insurer will pay, but also the copayment that a patient will pay to the laboratory. For example, when a private payor rate for a laboratory test is $100 and there is a 20 percent coinsurance

[11] Public Health Service Act § 2719 (42 U.S.C. § 300gg-91). *See* Social Security Act § 1834A(a)(8)(A) (42 U.S.C. § 1395m-1(a)(8)(A)).

[12] When a laboratory is out-of-network, it may bill a payor the charge for a test and be paid just a fraction of that amount by the payor, based on the payor's policy for determining its liability for out-of-network services without regard for any negotiation with the laboratory about the rate for a specific test. Under such circumstances, the payor may allow the laboratory to collect the remainder of its charge from the patient as the patient's cost-sharing for the out-of-network test. The total amount allowed by the payor and due to the laboratory, and not just the amount paid by the payor, is what is relevant and should be reported.

liability, a laboratory counts on a private payor to pay $80 and on the patient to pay $20. Patients also sometimes have deductibles to meet, meaning that a private payor may be involved in the rate-setting for a particular service but not involved in payment if the deductible exceeds the rate set by the payor for the test. In addition, some patients may have multiple payors on a claim (including a primary and a secondary payor) that may have different rates allowed for the same claim.

CMS's definitions of "private payor rates" and volumes should lead to a reporting system that yields the most complete information for the agency about how laboratories are compensated for their services to support calculation of accurate Medicare rates and that places the least burden possible on the reporting laboratories.

- ***Recommendation: To ensure consistency among reported rates, laboratories should report the final total approved payment rates for covered services during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. The approved payment rate should be the total "Allowed Amount" paid by a private plan, as that term is understood in the context of HIPAA 5010 transactions, including any copayments, coinsurance, deductible amounts, and other patient cost-sharing.***

3. Length of the data collection period. CMS should require laboratories to report as much data as the agency needs to calculate accurate market-based Medicare payment rates, but it should not require laboratories to report any more data than is necessary. For example, one calendar quarter's worth of private payor data may be sufficient for the agency to derive a Medicare rate reflecting the private payor market rate for a high-volume, broadly-distributed laboratory test such as a complete blood count ("CBC"). This is one of the most commonly performed laboratory tests, so one quarter's worth of data would yield a sufficient volume and cross-section of claims to develop an accurate Medicare payment rate, as contemplated by the law. For other tests that are performed more rarely, the volume in a given quarter may be lower, and data from one quarter may not be sufficient to reflect private market rates accurately. When members of the undersigned organizations of this letter evaluated their payment experience for six months of test claims, compared with 12 months of test claims, the resulting median payment amounts generally were consistent with each other. Therefore, we believe CMS can strike the right balance for all tests, regardless of volume or frequency, by requiring laboratories to report data for tests furnished in a six-month period.

- ***Recommendation: The first data collection period should be six months, and it should cover the first six months of 2015. We believe future data collection periods also should span six months, although the initial experience may indicate the desirability of some change. CMS should establish reporting periods via notice-and-comment rulemaking.***

4. Time period for reporting. The text of the statute says that an applicable laboratory shall report the rate and test volume at each rate "for each clinical diagnostic

laboratory test that the laboratory furnishes during [the data collection] period".[13] While the data collection period will have a defined beginning and end during which tests are furnished (*i.e.*, the date of service of the laboratory test), it can take months for payors to adjudicate a claim fully and to determine the rate that ultimately is allowed for a given test. Thus, the date of the service of the laboratory test may be within the data reporting period, but final adjudication of the allowed rate may fall on a date well after the end of the reporting period. The lag in payment is particularly pronounced for out-of-network laboratories that do not have contracts with a given payor to which they submit claims.

In order to report accurate rates and test volumes to CMS, laboratories will need time to collect fully adjudicated payments between the end of a data reporting period and the date on which payment arrays must be reported to the agency. Laboratories also will require some time after payments are made to gather all relevant data and prepare an array for reporting.

- ***Recommendation: Applicable laboratories should report private payor payment rates for tests with a date of service that falls within the six month data reporting period and that have been fully adjudicated within six months after the end of the reporting period. Thus, CMS should leave at least six months between the end of the data reporting period and the end of a follow-up period that allows laboratories adequate time to collect payment data so that they may submit accurate payment rates and volumes to CMS. This also would allow a lab to factor into its reported rates any volume-based discounts, rebates, and price concessions. Laboratories should have an additional sixty days following the conclusion of the follow-up period to organize, review, verify, and report their data array.***

A schematic of this recommended timeline is included as an attachment to this letter.

5. Mechanism for reporting data. Laboratories will be required in some cases to report thousands of private payor rates to CMS, and CMS will need to accept a huge amount of data from hundreds or even thousands of laboratories. CMS must develop a reporting mechanism that is workable for many different kinds of laboratories (that may have very different information technology capabilities and resources), that is secure, that is user-friendly, and that allows CMS to organize the data to derive accurate Medicare payment rates. Ideally, this should be through an Internet reporting portal. (CMS has experience with this for reporting drug payment rates under the Medicaid drug rebate law. The volume of data required to be reported in this instance is substantially greater than that reported for Medicaid rebates.) CMS should consider convening a meeting of its information technology experts with those working in the laboratory industry to develop plans for an easy-to-use and reliable reporting mechanism that will be effective for the agency and for reporting laboratories alike.

- ***Recommendation: An electronic reporting mechanism, such as an internet-based portal, should be established for laboratories to report their private payor***

[13] Social Security Act § 1834A(a)(1) (42 U.S.C. § 1395m-1(a)(1)).

data. CMS should provide opportunities for laboratories to test their rate-reporting capabilities in an "end-to-end" fashion and for CMS to test its information technology infrastructure prior to the actual reporting date.

6. Confidentiality of data. Congress clearly intended for CMS to guard the confidentiality of data reported by applicable laboratories and for such data to be disclosed in a manner that may identify a laboratory or a payor only in very limited situations. The laboratory industry seeks assurance from CMS that disclosures made "as the Secretary determines to be necessary to carry out" the law will be arrived at judiciously and that no more identifiable data will be revealed than is truly required.

- ***Recommendation: To maintain the integrity and legitimacy of the reporting process, CMS should apprise the public of the situations in which the Secretary would find such disclosures to be necessary and to set a high bar for disclosing information that might reveal the identity of a laboratory and/or a private payor.***

II. MEDICARE PAYMENT RATE DEVELOPMENT

Just as important as how CMS collects data on private payor data from applicable laboratories is how it uses the data to arrive at Medicare rates that will apply until the next data collection cycle. It is crucial that the Medicare payment rates are developed accurately and transparently to ensure appropriate Medicare payments and because many other payors (including many Medicaid programs) base their rates on Medicare rates.

A. The Law

For a clinical laboratory test furnished on or after January 1, 2017 (that is not a new test or an ADLT), the Medicare payment amount is to be the "weighted median" for the most recent data collection period. The "weighted median" payment for a laboratory test is to be calculated by "arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory."[14] Once a rate is established, it is to remain in effect until the year following the next data collection period, and it "shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)".[15] Also, for the years 2017 through 2019, the amount of a reduction in the Medicare rate (if any) shall not exceed 10 percent from the prior year's rate, and for 2020 through 2022, any reduction shall not exceed 15 percent from the prior year's rate.

An ADLT will be paid "during an initial period of three quarters" at the "actual list charge," which is the publicly-available rate on the first day that a test is available for purchase by a private payor. After the "initial period of three quarters," Medicare will pay a "weighted median" of the private payor rates the laboratory reported during the "second quarter of the

[14] Social Security Act § 1834A(b)(2) (42 U.S.C. § 1395m-1(b)(2)).

[15] Social Security Act § 1834A(b)(4) (42 U.S.C. § 1395m-1(b)(4)).

initial period." When the actual list charge is more than 130 percent of the weighted median rate, CMS may recoup the difference between the two rates.[16]

For new tests that are not ADLTs, Medicare payment shall be determined using crosswalking or gapfilling. Additionally, the statute requires CMS to provide a detailed and transparent explanation regarding the basis for payment rates for these tests, what criteria were applied, and how. The law also calls for CMS to establish an "expert outside advisory panel," subject to the Federal Advisory Committee Act, to provide input on payment rates, factors to consider for coverage and payment processes, and any other issues raised under the CLFS reform law. The size of the panel is not specified. The panel is to be assembled no later than July 1, 2015, and it is to consist of a cross section of individuals with experience in laboratory science, health economics, molecular pathology, clinical laboratory tests, and similar fields. This panel will not take the place of CMS's annual clinical laboratory meeting.

B. Issues, Questions, and Suggestions

1. Development of weighted median rates. The text of the law does not provide CMS with much direction about how to determine weighted median rates for each test. When CMS proposes a method for developing each weighted median, we ask that the agency provide the public with a detailed explanation of how it will array all of the private payor data for each individual laboratory test to arrive at the weighted median.

2. Transparency and re-review of published rates. We hope that the data reporting mechanism that CMS develops will be efficient and reliable and that the agency will be capable of accepting and storing the enormous amount of data that applicable laboratories will report to it. Given the large amount of data, it is reasonable to expect that, from time to time, errors will occur due to information management challenges and/or inaccurate calculations. While the law precludes administrative or judicial review of payment amounts,[17] it does not prohibit CMS from establishing a process to accept requests for re-review of proposed rates. Such systems already exist in other contexts in the Medicare program (*e.g.*, PFS and OPPS).

- ***Recommendation: We urge CMS to ensure that there is sufficient transparency in the rate-calculation and rate-setting processes. CMS should allow stakeholders to review preliminary payment rates prior to their effective date and request that CMS review potentially inaccurate rates. To facilitate this step, CMS should publish preliminary payment rates at least three months prior to their effective date.***

3. Adjustments to rates. The statute states that, once established and until the year following the next data collection period, weighted median rates shall not be subject to adjustments such as geographic adjustments, budget neutrality adjustments, annual updates, or

[16] Social Security Act § 1834A(d) (42 U.S.C. § 1395m-1(d)).

[17] *See* Social Security Act § 1834A(h)(1) (42 U.S.C. § 1395m-1(h)(1)). This refers to formal reviews by an administrative law judge and to review of a final administrative decision in a federal court.

"other adjustments." It seems clear that these rates would not be subject to the multifactor productivity adjustment added by the Section 3401(l) of the Affordable Care Act; it is not named specifically in the law, yet it would be fairly encompassed by "other adjustments." We ask for confirmation of this interpretation.

- ***Recommendation: CMS should confirm that the rates established under Section 216 of PAMA will not be adjusted by the multi-factor productivity adjustment added by Section 3401(l) of the Affordable Care Act.***

4. "Initial period" for new ADLTs. Congress intended for payment during an "initial period of three quarters" to mean the period when a test first is covered and payable by a Medicare contractor. Congress clearly contemplated that laboratories would be paid by Medicare for new ADLTs during this period or it would not have included the possibility of recoupment when payment based on actual list charges exceeds 130 percent of the rate established on the basis of private payor data.

As set forth in the law, the payment rate during this initial period will be based upon the publicly-available actual list charge offered by the laboratory for the test on the first date on which the test is commercially available for coverage and payment by private payors.

Laboratories are required to report private payor data for the initial period for new ADLTs no later than the end of the second quarter of the initial period. The statute is silent, however, on the time period that such initial report should cover. Insofar as there may be fewer payors covering and paying for a new ADLT during this period, it would be appropriate for the reporting period to be longer than just the first quarter of the initial period of Medicare coverage and payment. If there are private payor data that reach a certain volume threshold from the quarter before the first quarter of Medicare coverage and payment, these data should be included to allow for at least six months of data collection.

- ***Recommendation: For new ADLTs, the "initial period of three quarters" for rate reporting that is referenced in the statute should begin once a Medicare administrative contractor ("MAC") determines that an ADLT is covered by Medicare and a unique Healthcare Common Procedure Coding System ("HCPCS") code has been issued to identify the test. The reporting period should include the first quarter after Medicare coverage and payment has commenced, and if there are sufficient data from the quarter prior to commencement of Medicare coverage and payment, those data should be included, as well.***

5. Recoupment. CMS may recoup funds from an applicable laboratory if it determines that the actual list charge it paid to a laboratory for a new ADLT in the initial period exceeds 130 percent of the calculated weighted median rate. We assume that, in such cases, CMS would recoup the difference between the actual list charge and 130 percent of the weighted median. CMS should advise laboratories about how it will recoup such funds. CMS's process also should include a mechanism for a laboratory to dispute any such recoupment before the recoupment occurs.

- ***Recommendation: CMS should provide laboratories with guidance regarding the recoupment process, confirming that the amount of excess payments to be recouped (if any) is the difference between the actual list charge and 130 percent of the weighted median.***

6. ADLTs that meet similar criteria to those established in statute. CMS should establish criteria under which a test furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory can be classified as an ADLT if it is similar to those mentioned in the statute.

7. Process of ADLT determination. MACs should have the authority to determine whether a test meets criteria for classification as an ADLT, and this determination could be made at the time of establishing Medicare coverage and payment. Pursuant to section 1834A(e)(1) of the Social Security Act, a new test determined to be an ADLT would be assigned a temporary HCPCS code.

- ***Recommendation: CMS should consider establishing a process whereby laboratories may request that either CMS or the MACs may determine if a test is eligible to be classified as an ADLT for purposes of Section 216 of PAMA.***

8. New tests that are not ADLTs. CMS is to use crosswalking or gapfilling for new tests that are not ADLTs. The recent gapfilling exercise for molecular diagnostic codes was challenging for laboratories, both because of data problems between the MACs and CMS and because of inadequate transparency in the process and gapfilling results. We are heartened that the statute includes language directing CMS to explain how it arrived at each payment rate for each new test that is not an ADLT and what factors it considered in developing the payment rate, and that CMS is to consider recommendations on payment rates from the newly-created expert advisory panel. We urge CMS to provide more than simple, cursory explanations of its rate determinations and to draw upon the resources it has in the expert advisory panel to consider carefully how new tests are paid.

9. Expert advisory panel. The expert advisory panel is to be assembled before applicable laboratories begin reporting private payor data to CMS. It is clear that Congress intended this panel to lend its expertise and advice to CMS on the assignment of payment rates to new tests through the crosswalk or gapfill process and on the reporting process and structure in general. It is our hope that CMS will give serious consideration to the panel's advice and that it will make clear to the public how it is using the panel to develop coverage and payment policies. We are convinced that to derive the most value from the panel, CMS should include on it those individuals who have recent direct experience in the clinical laboratory industry. Individuals with this real-world experience can shed light on how policies can be operationalized by clinical laboratories and not be at odds with the way that laboratories actually function. The statute leaves CMS discretion to include experts on the panel beyond those suggested by the statute, and we strongly urge CMS to include those with technical expertise in developing, validating, and performing clinical laboratory tests; patient representatives; clinicians who use clinical laboratory test results; laboratorians; and individuals with expertise in pharmacoeconomics and/or health technology assessments. The panel's membership also should reflect the laboratory industry's geographic and size diversity and the viewpoints of independent clinical

laboratories, hospital laboratories, and physician office laboratories. CMS should take full advantage of the resources it will have available in the expert advisory panel and draw upon the panel's members for advice on how new tests should be paid.

To maximize the value of the panel, CMS must consider carefully when during the year the panel should convene and the agendas for each of meeting. We hope to have further opportunities to interact with CMS to explore fully the issues related to the composition and functions of the expert panel.

- ***Recommendation: CMS should ensure that at least some panel members have recent industry experience with clinical laboratory operations, commercial test development, and diagnostics reimbursement, and it also should account for patient and clinician perspectives. Stakeholders should be afforded an opportunity to provide input on the advisory panel's charter, role, processes, and meeting agendas.***

III. CODING

A. The Law

CMS is required to develop temporary HCPCS codes for new ADLTs and new FDA-cleared or –approved tests that will be effective until permanent HCPCS codes are established (but not longer than two years). For existing ADLTs and FDA-cleared or –approved test that are paid for by Medicare and that do not have uniquely-assigned HCPCS codes, CMS is to assign unique HCPCS codes and publicly report payment rates. The statute also allows a laboratory to request a "unique identifier" for an ADLT or FDA-cleared or –approved test "for purposes of tracking and monitoring".[18]

B. Issues, Questions, and Suggestions

1. Existing ADLTs or FDA-cleared or approved tests without unique HCPCS codes. CMS should develop a process through subregulatory guidance to issue, as soon as possible, unique HCPCS codes and publish the payment rates for existing ADLTs and clinical laboratory tests that were cleared or approved by the FDA and paid by Medicare as of the date of enactment under a miscellaneous code or otherwise not reported under a uniquely assigned code (*e.g.*, a non-specific method code that does not describe a specific ADLT or FDA-cleared or –approved test). CMS should allow laboratories and manufacturers to submit requests for unique HCPCS codes through an expedited process. This will facilitate data collection for rate-setting by having a common coding system to report payments from private payors in 2015.

- ***Recommendation: CMS should develop a process as soon as possible through subregulatory guidance to issue unique HCPCS codes and publish the payment rates for existing ADLTs and existing clinical laboratory tests that were cleared or approved by the FDA and paid by Medicare as of the date of enactment***

[18] Social Security Act § 1834A(e) (42 U.S.C. § 1395m-1(e)).

under miscellaneous codes or otherwise not reported under uniquely-assigned codes.

2. Expedited code assignment for new ADLTs and new FDA-cleared or approved tests. The statute requires CMS to adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests and new tests that are cleared or approved by the FDA. CMS should develop a process for expedited application, consideration, and approval of HCPCS codes for these tests; each code should be unique to a test and the codes should not be the "not otherwise classified" codes currently in use. Further, CMS should allow laboratories and manufacturers to submit requests on a quarterly basis for determination and issuance of new codes in a four month timeframe consistent with the timeframe by which CMS evaluates applications for pass-through codes and payment, assigning codes as necessary, under the Outpatient Prospective Payment System (*e.g.*, applications submitted by March 1 would result in codes effective July 1).

- ***Recommendation: CMS should establish an expedited code establishment process that includes quarterly review of tests and issuance of unique HCPCS codes to describe tests.***

3. Unique identifiers. The statute authorizes CMS to adopt a process whereby a laboratory or manufacturer offering an ADLT or an FDA-cleared or approved test may request a unique identifier for the test. The statute authorizes CMS to adopt such unique identifiers by means of a HCPCS code, a modifier, or other means. Insofar as currently-covered and new ADLTs and FDA-cleared or -approved tests would be assigned unique HCPCS codes under the provisions discussed above, it would appear appropriate that the unique identifiers should be uniquely assigned HCPCS codes rather than modifiers or other designators that are not entered in the code field of a claim form.

If a CPT code is assigned that is less granular than the HCPCS code and that does not identify the test uniquely, a laboratory or manufacturer should be able to request a unique test identifier for the test. Such a request could be fulfilled by reviving the expired HCPCS code or through adoption of some other unique test identifier. This would ensure that MACs and other payors that adopt coverage and/or payment policies specific to the ADLT or the FDA-cleared or –approved test would be able to continue to implement such policies without pending claims for manual adjudication.

- ***Recommendation: CMS should consider using HCPCS codes as the "unique identifier" contemplated under Section 216 of PAMA. In addition, CMS should substitute granular HCPCS codes for more general CPT codes when appropriate.***

IV. COVERAGE

A. The Law

The CLFS reform law establishes parameters for how MACs may establish coverage policies through local coverage determinations ("LCDs") on or after January 1, 2015. It also

permits CMS to designate up to four MACs to establish coverage policies, or both to establish coverage policies and to process claims for payment, for clinical diagnostic laboratory tests.

B. Issues, Questions, and Suggestions

1. Local Coverage Determinations. We are encouraged that the law ensures that LCDs henceforth are to be developed according to the process already spelled out in Section 1869 of the Social Security Act and implementing regulations. Coverage policies for clinical diagnostic laboratory tests have been issued recently through less formal processes, such as articles, without following the existing notice-and-comment requirements of the Social Security Act. We would like to hear from CMS how the agency intends to enforce this section of the law.

2. Medicare Administrative Contractors. We still are studying the issues around consolidating coverage or coverage and payment processing in a small group of MACs. Of utmost importance to us is the fairness and transparency of coverage and payment processes, rather than the number of MACs that are involved.

V. IMPLEMENTATION

The timeline for implementing the CLFS reform provisions of the Protecting Access to Medicare Act of 2014 is extremely tight, given the complexity of the provisions and the magnitude of data involved. The expert advisory panel is to be assembled and functioning by July 1, 2015, and CMS is to issue regulations regarding payment rate reporting no later than June 30, 2015. Actual data reporting is to begin January 1, 2016, and CMS must calculate weighted medians for each individual test in time for them to take effect on January 1, 2017.

We are concerned about the short amount of time – just six months – between the date by which CMS must issue final regulations on data reporting and the time when the agency may require applicable laboratories to begin reporting private payor data. Congress gave CMS the authority to determine when each applicable laboratory needs to report private payor data, so long as the date is not before January 1, 2016. It will take laboratories time to understand and operationalize what CMS includes in a final rule, regardless of a laboratory's size. Larger laboratories may be challenged by the sheer volume of data they must collect and report for each payor, plan, and test code in a very short period of time, while smaller and medium-sized laboratories may be at a disadvantage from not having information technology, coding, and/or billing resources that are equal to the task. All laboratories will need a number of months to develop internal data collection systems that meet the requirements of the final rule, once it is issued.

We also are sensitive to the fact that CMS will need adequate time to accept, organize, analyze, and use the data that applicable laboratories report and that it must have calculated all of the weighted medians for each clinical laboratory test in time for the new rates to take effect January 1, 2017. From the agency's perspective, this may weigh against setting a date that is too far into 2016 by which applicable laboratories must report data. The laboratory industry wants CMS to have an adequate amount of time to organize the data and to calculate accurate weighted medians. It is not in our interest for CMS to have to rush through the process of setting new payment rates for more than one thousand clinical laboratory tests.

We would like to work with CMS to find a balance between leaving an adequate amount of time between the issuance of the final rule and the date by which private payor data must be reported on the one hand, and leaving enough time between data reporting and the effective dates of the new Medicare rates on the other hand, so that the agency can calculate accurate rates. We hope to continue our dialogue with the agency about this point to develop a solution that is workable for all parties.

We agree with CMS that given the complexity of the new law and the limited timeframe until publication of the CY 2015 PFS proposed rule, implementation of Section 216 of PAMA will require its own rulemaking. However, the upcoming CY 2015 CLFS public meeting presents an excellent opportunity for CMS and stakeholders to continue a constructive dialogue about implementation.

We hope that CMS will give serious consideration to conducting a test, perhaps one that involves limited rate reporting and limited Medicare reimbursement calculations, to ensure that both laboratories and the agency are ready to implement the process fully and to allow the agency and applicable laboratories the opportunity to learn from what worked and what did not work. Such testing also could help the agency determine how long it will take to accept and organize reported data, the steps involved in calculating and verifying the accuracy of the weighted median rates and the length of time to do so, and the unanticipated challenges of the overall private payor data reporting and Medicare reimbursement rate-setting program. It also would provide CMS, applicable laboratories, and other interested stakeholders an opportunity to collaborate further on how to improve the reporting program.

- ***Recommendation: Given how soon laboratories will have to collect data to report to CMS early in 2016, it is important for the agency to proceed with the regulatory implementation process as soon as possible. CMS also should formally withdraw the regulation that appears at 42 C.F.R. § 414.511 regarding adjusting payment rates on the CLFS based on technological changes, which relied on a statutory provision that Congress eliminated in PAMA.***

- ***Recommendation: CMS should consider establishing a reporting test, possibly limited to a small yet statistically appropriate number of codes and laboratories, and calculate "draft" weighted median Medicare rates so that applicable laboratories can review their ability to collect, array, and submit rates to the agency and so that CMS can verify its ability to collect data and calculate correct payment rates, before the reporting system is used for all clinical laboratory test rates.***

* * * * *

We thank you again for your willingness to work collaboratively with the clinical laboratory industry and with other interested stakeholders toward successful implementation of Section 216 of PAMA. We look forward to a constructive ongoing dialogue with CMS, and we welcome your thoughts and questions.

Sincerely,

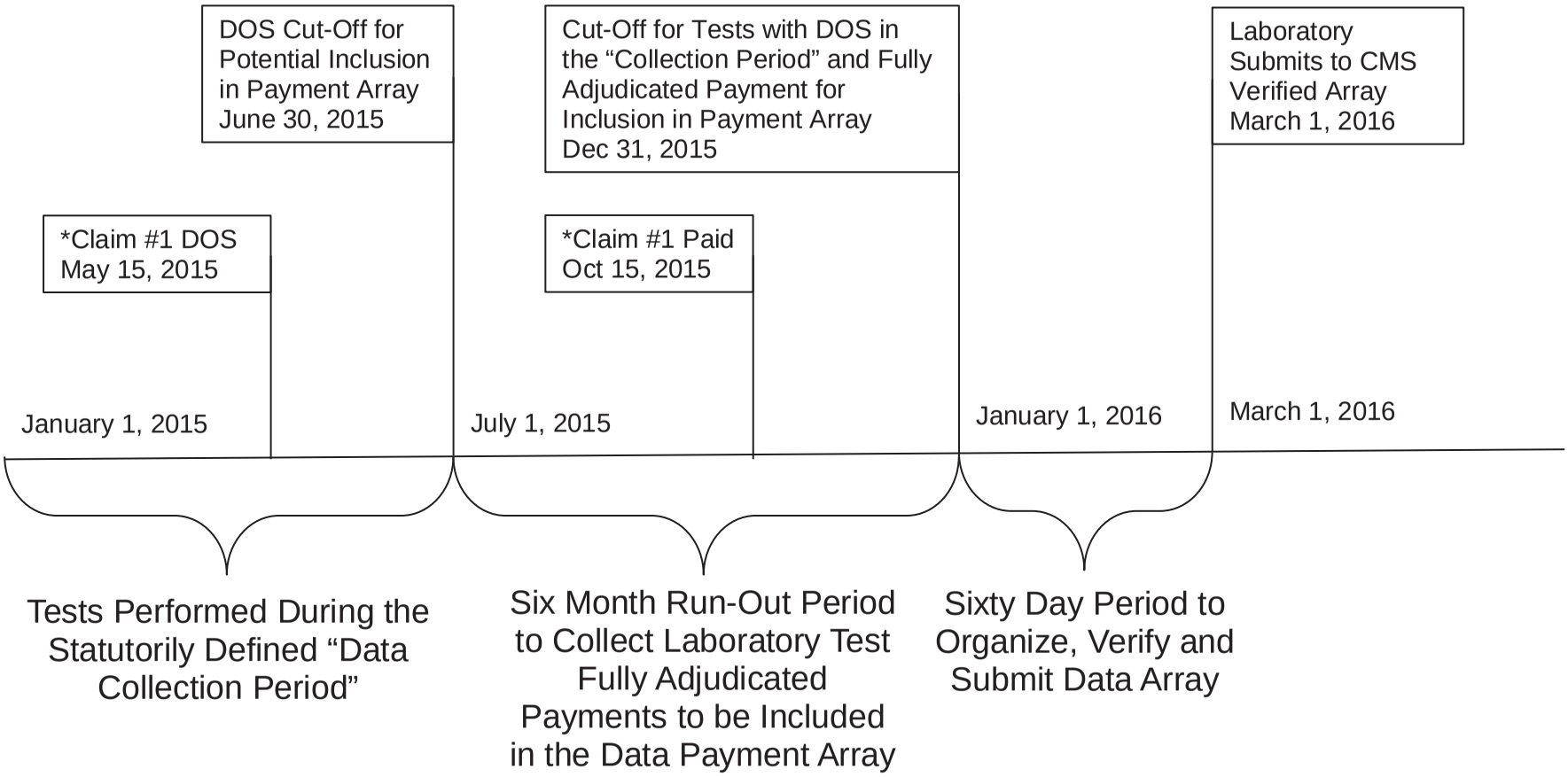
Alan Mertz, President
American Clinical Laboratory Association

Donald May, Executive Vice President
AdvaMedDx

John Hanna, Chair, Reimbursement & Policy Workgroup
Coalition for 21st Century Medicine

cc: Sean Cavanaugh
Marc Hartstein

Data Array Collection & Submission Timeline



*Claim #1 is an illustrative example of a diagnostic test that is performed with a date of service (DOS) of May 15, 2015, and is fully adjudicated and paid on October 15, 2015. Since Claim #1 is fully adjudicated within the six month run-out period, it is included in the payment data array reported to CMS. If Claim #1 was adjudicated after December 31, 2015, it would not be reported in the payment data array.

Khani Declaration Exhibit 4

American Clinical Laboratory Association

STATEMENT OF THE AMERICAN CLINICAL LABORATORY ASSOCIATION ON CLINICAL LABORATORY-RELATED PROVISIONS IN THE PROTECTING ACCESS TO MEDICARE ACT OF 2014

The American Clinical Laboratory Association ("ACLA") is pleased to submit its recommendations to the Centers for Medicare & Medicaid Services ("CMS") on various aspects of implementation of Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which modifies the Medicare reimbursement rate methodology under the Clinical Laboratory Fee Schedule ("CLFS") for the first time in about three decades.[1] ACLA is a trade association representing national, regional, and esoteric laboratories that perform millions of tests each year that are paid for under the CLFS. The way in which CMS proceeds in implementing this reimbursement reform provision and the choices it makes will have a major impact on ACLA members.

Congress has directed CMS to accomplish a great deal in a very short period of time. By June 30, 2015, the agency must develop, propose, refine, and finalize a method for laboratories to report each reimbursement rate and volume for each test code on the CLFS for each private payor and develop its own method for calculating the weighted medians from that data that will become the applicable Medicare rates. To do so, CMS must develop or clarify definitions of several key terms, determine when private payor rates must be reported and for what timeframe, build a technology platform capable of accepting millions of discrete pieces of data, and establish coding processes for certain new tests, among other tasks. All of this must be completed in time to give laboratories clear direction about what data to report and how to do so, and with enough lead time for laboratories to develop their own internal systems to compile and report the data.

[1] Pub. L. 113-93, Sec. 216, adding Sec. 1834A to the Social Security Act ("the Act") (codified at 42 U.S.C. § 1395m-1(2014)).

The way in which CMS defines the parameters, participants, methods, and timeframes for rate and volume reporting can have a substantial impact on the rates that the Medicare program pays for clinical laboratory tests. It also has the potential to have an impact on other payors' rates, as many private payors and state Medicaid programs base their reimbursement rates on Medicare rates.

This is a tremendously complex undertaking, and ACLA and its members are prepared to continue to work with CMS to ensure that implementation proceeds smoothly and in a manner that works for CMS and clinical laboratories alike. We urge CMS to work collaboratively with stakeholders in the coming months as the agency develops definitions, standards, processes and procedures to implement Section 216 of PAMA.

Our statement today focuses on reporting payment rates and volumes for clinical laboratory tests and on Medicare payment rate development. While our statement concentrates primarily on rate and volume reporting, we will discuss additional issues in our written comments. In addition, ACLA has worked closely with AdvaMedDx and the Coalition for 21st Century Medicine, and we have reached consensus on recommendations in many key areas, which will also be reflected in our written submission.

I. BACKGROUND ON RATE AND VOLUME REPORTING AND RATE-SETTING

Beginning January 1, 2016 and generally every three years thereafter, each "applicable laboratory" is to report to CMS information, with respect to a defined data collection period, about the payment rates paid by each private payor for each test code on the CLFS and about the volumes for each test paid at each of those rates.[2] An "applicable laboratory" is a laboratory that receives

[2] The timetable and data reported differs for "Advanced Diagnostic Laboratory Tests" ("ADLTs"), which are tests offered or sold only by one laboratory and that meet certain other criteria. Rate and volume reporting is yearly for ADLTs.

a majority of its Medicare revenue under the CLFS, the Medicare Physician Fee Schedule ("PFS"), or new Sec. 1834A of the Act.[3] Neither the term "laboratory" nor the term "revenue" is defined in PAMA or in the Act. A "private payor" is a health insurance issuer, a group health plan, a Medicare Advantage plan, or a Medicaid managed care organization.[4]

Once "applicable laboratories" have reported this data to CMS, CMS is to develop a "weighted median" based on the data, which for most tests will become the Medicare payment rate for the following three years. (Rates for ADLTs are to be in effect for one year, as reporting and rate-setting will occur annually for this subset of tests.)

II. REPORTING

A. "Applicable Laboratory"

Section 216 of PAMA gives CMS some direction about what it considers an "applicable laboratory," but the agency will have to define the parameters of that term further. In order to reflect true market rates for laboratory services, the definition must be broad enough to encompass the many types of laboratories that perform testing services paid for by Medicare. It is logical that most independent clinical laboratories would be included in the definition of "applicable laboratory," but other types of laboratories also fit the definition.

Congress's intent with respect to the private payor rate reporting requirements in Section 216 of PAMA was to ensure that Medicare rates for clinical laboratory services reflect private market rates and that all sectors of the laboratory market are represented in the calculation of the weighted median, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the CLFS. The plain text of the statute reflects

[3] Social Security Act § 1834A(a)(2) (42 U.S.C. § 1395m-1(a)(2)).
[4] Social Security Act § 1834A(a)(8) (42 U.S.C. § 1395m-1(a)(8)).

this intent, as does a colloquy on the Senate floor between Sen. Orrin Hatch (R-UT), the Ranking Member of the Senate Finance Committee, and Sen. Richard Burr (R-NC).[5]

It is appropriate for hospital outreach laboratories to be included in the ambit of the definition of "applicable laboratory," and they should be required to report private payor rates to CMS. In the text of the law, an "applicable laboratory" is a "laboratory" that receives the majority of its Medicare revenues under the CLFS, the PFS, or new Section 1834A of the Act. When a hospital laboratory serves non-patients and hospital outpatients (when those services are not bundled in an APC payment), and a majority of the laboratory's separately-identifiable Medicare revenues are derived from the CLFS, the PFS, or Section 1834A of the Act, then the hospital laboratory should be considered an "applicable laboratory."

Similarly, it may be appropriate in some instances for physician office laboratories to be encompassed by the term "applicable laboratory." Certain physician offices perform a significant number of point-of-care tests, so data from physician office laboratories may be particularly important for setting accurate rates for such tests. Some physician office laboratories also perform more complex tests, as well. Categorical exclusion of physician office laboratories would deny CMS important information about a significant market sector. At the same time, we recognize that, as complex as rate reporting is bound to be, the burden on some smaller physician office laboratories could outweigh the information gleaned from them. CMS was given the authority to

[5] Sen. Richard Burr (R-NC) is a member of the Senate Finance Committee and Sen. Orrin Hatch (R-UT), Ranking Member of that committee. On the floor of the U.S. Senate, Sen. Burr noted that it was his understanding that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule." Sen. Hatch agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories." *See* 160 Cong. Rec. S2860 (daily ed. May 8, 2014).

establish a "low-volume or low-expenditure" threshold, and it may be appropriate to exercise that authority with respect to some physician office laboratories.

In sum, ACLA urges CMS to define the term "applicable laboratory" in a way that reflects the wide variety of entities that receive payment for lab tests under the CLFS and that allows CMS to account for the full spectrum of private payor rates for laboratory tests.

B. Private Payor Rates and Volumes

1. The Law

The law requires each applicable laboratory to report the payment rate paid by each private payor for each test during the defined reporting period, and each applicable laboratory also must report the volume for each such payor for each test.[6] When an applicable laboratory has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, it is to report each such payment rate and the volume for the test at each such rate.[7]

2. Payment Rate

CMS must make it clear to applicable laboratories what it considers to be a "payment rate." In most cases, the rate that a private payor sets for a laboratory test accounts not only for the amount that the private payor will pay, but also any copayment from a patient. Patients also sometimes have deductibles to meet, meaning that a private payor may be involved in rate-setting for a particular service but not involved in the payment. To ensure consistency among reported rates across applicable laboratories, applicable laboratories should report the final total approved payment rates for covered services during the reporting period – the total "allowed amount" paid

[6] Social Security Act § 1834A(a)(3) (42 U.S.C. § 1395m-1(a)(3)).
[7] Social Security Act § 1834A(a)(6) (42 U.S.C. § 1395m-1(a)(6)).

by the private payor, as that term is used in the context of HIPAA 5010 transactions, including any copayments, coinsurance, deductible amounts, and other patient cost-sharing.

3. Complexity of the Reporting Exercise

In discussing the reporting requirements with our members over the past several weeks, we have been reminded of the vast amount of data that this reporting will yield and the complexity of CMS accepting and organizing the data and using it properly to calculate accurate weighted medians. ACLA's members also have considered the information technology resources they will have to expend in order to collect, organize, duplicate, verify, and report the data to CMS.

The challenges that applicable laboratories are likely to face have been foreshadowed by laboratories' experience reporting private payor rates to the California Medicaid program ("Medi-Cal"). There, labs were required to report rates for about 400 tests (only about a third of the tests included on the CLFS), and for at least their top five payors by volume for each test. Many labs that participate in Medi-Cal had difficulty assembling the required information in time to meet the first reporting deadline, and the program was forced to extend the reporting deadline by three months so that laboratories could comply. It is conceivable that the same thing could happen in the context of this private payor rate and volume reporting exercise.

The amount of information that labs will be reporting to CMS – and the number of labs reporting – dwarfs the amount that had to be reported to the Medi-Cal program. Just one laboratory may have payor agreements with over one thousand private payors, as that term is defined in the statute, with separate rates for each of the more than one thousand test codes on the CLFS, and different rates for each of the private payor's plan offerings. Layered on to each of these separate data points is the volume for each test code for each private payor's own plan offerings. Each laboratory that is considered an "applicable laboratory" is to report all of this data to CMS. CMS

must be prepared to receive an overwhelming amount of data and to provide laboratories with flexibility about how they report such data.

ACLA believes there may be alternative reporting methods that would reduce the burden on both labs and CMS, and still result in Medicare reimbursement rates that reflect true market rates for laboratory services. We are exploring alternatives with our membership and other laboratory stakeholders, and encourage the agency to research and consider proposing alternatives as well.

C. Data Collection Period and Reporting Deadline

1. The Law

For most clinical laboratory tests the new market-based rates are to take effect on January 1, 2017.[8] CMS is to issue a final rule implementing the data collection provisions of Section 216 of PAMA no later than June 30, 2015, and reporting is to begin no sooner than January 1, 2016.[9] (CMS may issue a final rule earlier than June 30, 2015, and it may select a data reporting deadline that is months after January 1, 2016.) The law does not specify the length of the data collection period nor its timing; it simply defines the data collection period as "a period of time, such as a previous 12 month period, specified by the Secretary."[10]

2. Length and Timing of the Data Collection Period

ACLA believes that the data collection period that CMS establishes should be long enough to allow the agency to collect enough data to develop accurate market-based payment rates, but it should not require laboratories to report more data than is necessary. For some commonly performed high-volume tests, such as a complete blood count, one calendar quarter worth of data

[8] Social Security Act § 1834A(b)(1)(A) (42 U.S.C. § 1395m-1(b)(1)(A)).
[9] Social Security Act §§ 1834A(a)(1), 1834A(a)(12) (42 U.S.C. §§ 1395m-1(a)(1), 1395m-1(a)(12)).
[10] Social Security Act § 1834A(a)(4) (42 U.S.C. § 1395m-1(a)(4)).

should be sufficient for CMS to calculate a weighted median that reflects private payor rates in the market. For other tests that are not as common, that are performed by just a handful of laboratories, or that are not covered and paid for by as many private payors, the data collection period may have to be longer for CMS to assemble enough data points to reflect the private payor market. Generally, we believe that six months' worth of data will be sufficient for CMS to develop accurate rates.

The timing of the data collection period also is important. The data that applicable laboratories are to report is to include information on "each laboratory test that the laboratory furnishes during the [data collection] period."[11] Of course, some tests furnished during the data collection period may not be adjudicated for months after the data collection period's close. This lag in payment is particularly pronounced for an out-of-network laboratory that does not have a contract with a given payor to whom it has submitted a claim. A claim must be adjudicated in order for a laboratory to report its payment rate; otherwise, the laboratory cannot know what the payment rate is. Therefore, we suggest that there be some time between the end of the data collection period and the date by which payment rates must be reported in order to account for this adjudication lag and to allow laboratories to collect and assemble all information. Six months appears to be a reasonable amount of time to ensure that most claims are adjudicated. ACLA and its members are available to consult with CMS further about the length of the data collection period and its timing.

D. Other Reporting Issues

ACLA suggests that CMS establish an electronic reporting mechanism, such as an internet-based portal, for laboratories to use to report their private payor rates. CMS also should provide

[11] Social Security Act §1834A(a)(1) (42 U.S.C. § 1395m-1(a)(1)).

opportunities for laboratories to test their own rate reporting capabilities prior to the actual reporting deadline, which also would allow the agency to evaluate its own readiness to accept the information electronically. Whatever reporting mechanism the agency develops, it must be workable for many different kinds of laboratories with different information technology capabilities and resources, and it must be user-friendly and secure. We hope that CMS will consider convening a meeting of its information technology experts with those working in the laboratory industry to develop plans for an easy-to-use and reliable reporting mechanism.

III. RATE DEVELOPMENT

A. Development of Weighted Median

For a clinical laboratory test furnished on or after January 1, 2017 (other than a new test or an ADLT), the Medicare payment amount is to be the "weighted median" for the most recent data collection period. The weighted median is to be derived by "arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory."[12] An ADLT will be paid initially at the "actual list charge," and after three calendar quarters, Medicare will pay a weighted median of the private payor rates reported during the second quarter.[13]

As important as how CMS collects private payor data from applicable laboratories is what the agency does with the data once it has been submitted. It is critical to ACLA's members that the Medicare payment rates are developed accurately and transparently to ensure appropriate Medicare payments and because many other payors base their rates on Medicare rates. Congress did not give CMS much direction about how to determine weighted medians, but transparency is

[12] Social Security Act § 1834A(b)(2) (42 U.S.C. § 1395m-1(b)(2)).
[13] Social Security Act § 1834A(d) (42 U.S.C. § 1395m-1(d)).

of utmost importance to bolstering the credibility of the process. We ask that the agency provide the public with a detailed explanation of its proposed method for developing weighted medians and how it will array private payor data for each test code.

The rate-setting method for ADLTs will apply to fewer tests, yet it is important the CMS carefully consider how it implements this provision of the law. The initial "three quarters" during which the "actual list charge" applies should begin once a Medicare Administrative Contractor ("MAC") determines that an ADLT is covered by Medicare. The weighted median should be developed based on as much data as possible. There may be fewer private payors covering and paying for a new ADLT early in its development, so CMS should consider a data collection period that includes payment by private payors even before the date of Medicare coverage.

B. Data Review

While we hope that CMS's rate-setting method is reliable and accurate, it is reasonable to expect that from time to time, some calculations may not be accurate. CMS should permit stakeholders to review preliminary payment rates prior to their effective dates and to request that CMS review potentially inaccurate rates. One way to facilitate this is publishing preliminary payment rates at least three months prior to their effective date.

C. Confidentiality of Data

Congress clearly intended for CMS to guard the confidentiality of data reported by applicable laboratories and for such data to be disclosed in a manner that may identify a laboratory or a payor only in very limited situations.[14] ACLA seeks assurance from CMS that disclosures

[14] "Notwithstanding any other provision of law, information disclosed by a laboratory under this subsection is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identify of a specific payor or laboratory, or prices charged or payments made to any laboratory, except (A) as the Secretary determines to be necessary to carry out this section; (B) to permit the Comptroller General to review the information provided; (C) to permit the Congressional Budget Office to review the information provided; and (D) to permit the Medicare Payment Advisory Commission to review the information provided." Social Security Act § 1834A(a)(10) (42 U.S.C. § 1395m-1(a)(10)).

made "as the Secretary determines to be necessary to carry out" the law will be arrived at judiciously and that no more identifiable data will be revealed than is truly required. To maintain the integrity and legitimacy of the reporting process, CMS should apprise the public of the situations in which the Secretary would find such disclosures to be necessary and to set a high bar for disclosing information that might reveal the identity of a laboratory and/or a private payor.

IV. OTHER ISSUES

A. Expert Advisory Panel

The law calls for the establishment of an "expert outside advisory panel" no later than July 1, 2015 to provide input to CMS on payment rates, factors to consider for coverage and payment processes, and any other issues raised under the CLFS reform law. It is to consist of a cross section of individuals with experience in laboratory science, health economics, molecular pathology, clinical laboratory tests, and similar fields.[15] ACLA believes that to derive the most value from the panel, CMS should include on it those individuals who have recent direct experience in the clinical laboratory industry. Individuals with this real-world experience can shed light on how policies can be operationalized by clinical laboratories and not be at odds with the way that laboratories actually function. The statute leaves CMS discretion to include experts on the panel beyond those suggested by the statute, and we strongly urge CMS to include those with technical expertise in developing, validating, and performing clinical laboratory tests; patient representatives; and clinicians who use clinical laboratory test results. It is our hope that CMS will give serious consideration to the panel's advice and that it will make clear to the public how it is using the panel to develop coverage and payment policies.

[15] Social Security Act §1834A(f) (42 U.S.C. §1395m-1(f)).

B. Local Coverage Determinations

ACLA is encouraged that the law ensures that Local Coverage Determinations henceforth are to be developed according to the process already spelled out in Section 1869 of the Social Security Act and implementing regulations. Coverage policies for clinical diagnostic laboratory tests have been issued recently through less formal processes, such as articles, without following the existing notice-and-comment requirements of the Social Security Act. We would like to hear from CMS how the agency intends to enforce this section of the law.

V. CONCLUSION

We appreciate the opportunity to share our comments and recommendations with you, and we look forward to continuing to work with CMS in the coming years on implementing Section 216 of PAMA.

Khani Declaration Exhibit 5

American
Clinical Laboratory
Association

August 4, 2014

VIA E-MAIL AND FIRST CLASS MAIL

Mr. Glenn McGuirk
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Mr. McGuirk,

The American Clinical Laboratory Association ("ACLA") appreciates the opportunity to submit this written statement on implementation of section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which adds section 1834A to the Social Security Act to reform reimbursement rate setting under Medicare's Clinical Laboratory Fee Schedule ("CLFS").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in how CMS implements this provision of the new law.

This statement expands upon our oral statement at the July 14, 2014 Clinical Laboratory Public Meeting, and we have worked closely with AdvaMedDx and the Coalition for 21st Century Medicine on development of the questions and recommendations included herein. Our statement addresses five general categories of issues, questions, and suggestions related to the CLFS reform provisions contained in Section 216: (1) reporting of private payor rates and volumes; (2) Medicare payment rate development; (3) coding; (4) coverage; and (5) steps involved in the overall implementation of the new law.

I. Reporting Private Payor Rates and Volumes

Reporting of payment rates and volumes for clinical diagnostic laboratory tests and advanced diagnostic laboratory tests ("ADLTs") is the most critical area for discussion and consideration. Reporting could begin as early as January 1, 2016, and the statute requires regulations to be issued not later than June 30, 2015. There are a remarkable number of details to be worked out before laboratories can begin to prepare to report data to CMS. The way in which CMS defines the parameters, participants, methods, and time frames for reporting can have a substantial impact on the rates that the Medicare program pays for clinical laboratory tests. It will be an enormous undertaking for CMS to prepare to receive millions of pieces of information from thousands of laboratories and for each one of those laboratories to collect, organize, and transmit the data. While we recognize that CMS must address many facets of implementation concurrently, reporting is one area that we believe should be a primary focus for the agency in the near term.

[1] Pub. L. 113-93 (codified at 42 U.S.C. § 1395m-1 (2014)).

A. The Law

Beginning January 1, 2016 and generally every three years thereafter, an applicable laboratory is to report certain information to the Secretary about private payor data for laboratory tests. An "applicable laboratory" is a laboratory that receives a majority of its Medicare revenue under the CLFS, the Physician Fee Schedule ("PFS"), or the new section 1834A of the Social Security Act, as added by PAMA. For most clinical diagnostic laboratory tests furnished during a specified data collection period, an applicable laboratory must report both the payment rates paid by each private payor for the tests during the period and the volume of such tests for each private payor for the period (except for tests paid on a capitated basis). When an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the lab is to report each of those rates and the corresponding volumes (the Secretary may allow aggregate reporting of this data starting January 1, 2019). A "private payor" is "a health insurance issuer and a group health plan," a Medicare Advantage plan, or a Medicaid managed care organization.

The timetable for reporting is different for ADLTs. During the initial reporting period, an applicable laboratory is to report private payor rates and volumes for ADLTs no later than the "last day of the second quarter" of such initial period, and afterward, reporting is to be annual for these tests (rather than every three years).

Information reported by an applicable laboratory is confidential and is not to be disclosed by CMS or any Medicare contractor in a form that reveals the identity of a payor or laboratory, except "as the Secretary determines to be necessary to carry out this section," or to the Comptroller General of the United States, the Congressional Budget Office, or MedPAC.

B. Issues, Questions, and Suggestions

1. "Applicable laboratories". The law defines an "applicable laboratory" as a "laboratory" that receives the majority of its Medicare revenues under the CLFS, the PFS, or the new section 1834A of the Social Security Act, yet neither the term "laboratory" nor the term "revenues" is defined in PAMA or elsewhere in the Social Security Act. The law also permits CMS to exclude certain laboratories from the definition of "applicable laboratory" by establishing low volume or low expenditure thresholds. Laboratory services can be furnished by a variety of entities, and CMS will have to determine what types of laboratories are encompassed by the term "applicable laboratories." The range of laboratories includes:

- Independent clinical laboratories: national, regional, and local laboratories that are not affiliated with hospitals or physician offices. Some independent clinical laboratories perform a full range of laboratory testing, while others offer a handful of specialized tests. Specimens may be collected in the community by the laboratory or collected and referred by physicians, health care facilities, and other laboratories and sent to independent laboratories.

- Hospital laboratories: perform laboratory testing for the benefit of hospital inpatients and outpatients. Many hospitals also have laboratory outreach

programs through which they serve members of the community, much in the same way that many independent clinical laboratories do.

- Physician office laboratories: Many physician offices have in-office laboratories and perform point-of-care testing for their own patients. They also may perform moderate- and high-complexity laboratory tests and tests for other physicians, as well.

For hospitals, CMS first must determine whether an "applicable laboratory" includes a hospital laboratory, where a majority of the laboratory's Medicare revenue comes from the CLFS, the PFS, or the new section 1834A of the Social Security Act. It would not be appropriate to look at the sources of the entire hospital's Medicare revenue. If Congress intended for CMS to look at an entire hospital's revenues, then it presumably would have used a broader term in the law, such as "entity," rather than using the narrower term "laboratory."[2] The law is clear that the appropriate inquiry is from what sources a *laboratory's* Medicare revenues are derived. To answer that, it is appropriate to look at the laboratory within the hospital, which is a distinct and identifiable cost center.

The second question is what is meant by "revenues." A hospital may provide laboratory services in three different ways, but in most situations, it will not receive what would be considered laboratory "revenues." First, it can provide laboratory services to hospital inpatients, in which case the hospital is paid a bundled rate (a global DRG payment) that includes the laboratory services. The laboratory receives no separate "revenues" attributable to the laboratory services in this case. Second, a hospital laboratory can provide services to hospital outpatients. As results of the bundling requirement that CMS established in the CY 2014 Hospital Outpatient Prospective Payment System ("OPPS") rule, hospitals are not paid separately for most laboratory services furnished to outpatients.[3] The payment for the laboratory service is included in the Ambulatory Payment Classification ("APC") payment; therefore, the hospital laboratory does not receive any separate laboratory "revenues" in this situation either. Finally, a hospital can provide "outreach" services, *i.e.*, where a hospital obtains specimens from physicians who see patients in their own offices, just like independent clinical laboratories do. In that case, a hospital is paid separate laboratory "revenue" for those services under the CLFS.[4]

In sum, a hospital laboratory has separately-identifiable "revenues" when it is paid separately for its outreach testing services furnished to non-patients.[5] CMS has noted on several occasions that when a hospital furnishes testing services for non-hospital patients, it is

[2] *See* Social Security Act § 1834A(a)(2) (42 U.S.C. § 1395m-1(a)(2)) ("[T]he term 'applicable laboratory' means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848.").
[3] *See* 78 Fed. Reg. 74229, 74939 (Dec. 12, 2013).
[4] CMS itself has recognized these distinctions, and it recently has given instructions to hospitals on how to distinguish separately-billable outreach services from outpatient services that are bundled under an APC. *See* CMS Transmittal 2845, Change Req. 8572 (Dec. 27, 2013); *see also* CMS Transmittal 2971, Change Req. 8776 (May 23, 2014).
[5] As noted, hospitals also are permitted to be paid separately for laboratory services furnished to outpatients if those services are for molecular pathology services. However, if those payments are included as revenues, it would not affect the outcome, as they still would constitute revenues from 1833(h) of the Social Security Act, which is one of the applicable sections included in Section 216 of PAMA.

"functioning as an independent clinical laboratory."[6] Thus, it seems reasonable, and justified by the terms of the statute, to determine that a hospital laboratory performing outreach testing is an "applicable laboratory."

Moreover, it is reasonable as a matter of policy to require hospitals to be included in rate reporting for purposes of section 216 of PAMA. In drafting this law, Congress clearly contemplated that the Medicare rates that CMS derives from private payor data would apply to laboratory tests furnished by hospital laboratories when such tests are not part of a bundled payment (*i.e.*, when provided on an outreach basis).[7] Therefore, it stands to reason that the same hospital laboratories should report their private payor data to CMS for those tests that are not bundled. Because Congress's intent is for Medicare rates to approximate private market rates for clinical laboratory tests, data reflecting the entire market must be included to set rates accurately.[8]

- ***Recommendation: Hospital laboratories performing outreach testing should be included in the definition of "applicable laboratory" and should report their private payor data for clinical laboratory tests that are not part of a bundled payment.***

Similarly, it seems appropriate that certain physician office laboratories for which the majority of Medicare revenues come from the CLFS, the PFS, or section 1834A also should be included in the definition of "applicable laboratory" and report their private payor data. Certain physician office laboratories perform a significant number of point-of-care tests, so data from physician office laboratories may be particularly important for setting accurate rates for such tests, and physician office laboratories may perform more complex tests, as well. As noted above, if the intent is for Medicare rates to reflect market rates, then the full range of pricing data should be included. At the same time, we acknowledge that CMS must balance the importance of complete information about private payor data against the burden on physician office laboratories that may have limited resources to submit complete and accurate rate information.

- ***Recommendation: CMS should solicit public comments on the inclusion of physician office laboratories in the definition of "applicable laboratory," and it also should seek input on how to strike the appropriate balance between complete private payor market data and the burden that a reporting obligation could impose on physician office laboratories.***

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[6] *See, e.g.*, Medicare Claims Processing Manual, Chapter 16, § 10 ("When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory…").

[7] *See* Social Security Act § 1834A(b)(1)(B) (42 U.S.C. § 1395m-1(b)(1)(B)).

[8] Congress's intent was made explicit in a colloquy between Sen. Richard Burr (R-NC), a member of the Senate Finance Committee, and Sen. Orrin Hatch (R-UT), Ranking Member of that committee. *See* 160 Cong. Rec. S2860 (daily ed. May 8, 2014). Sen. Burr noted that it was his understanding that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule." Sen. Hatch agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."

2. Private payor rates and volumes. CMS must be mindful of the vast number of individual private payor rates paid to just a single major laboratory and the significant task of collecting and reporting each individual rate and associated volume. One laboratory may have contracts with more than a thousand private payors, as that term is defined in the law, with separate payment rates for many or all of the individual plan offerings by each of the payors, and separate payment rates for each one of the more than one thousand codes on the CLFS. The individual plans may pay different payment rates for each of the codes, depending on a number of factors. Rates also may differ for services offered in different states. These thousands of individual rates then will be multiplied by the number of applicable laboratories participating in the Medicare program and reporting their own rates. CMS's information technology challenge in accepting and organizing this much data and using it properly to calculate accurate payment rates is equaled by the information technology challenges that will be faced by each laboratory that must collect, organize, de-duplicate, and transmit data to CMS.

Recent events in California demonstrate how difficult and complex this exercise is bound to be. In 2012, the California legislature enacted similar reporting requirements to establish new payment levels for clinical laboratory tests paid for by the California Medicaid program ("Medi-Cal"). The law requires laboratories to report their pricing information for more than 400 separate tests to the California Department of Health Care Services ("DHCS"). Affected laboratories are required to submit rates for at least their top five payors for California, not including Medicare and Medi-Cal. Many laboratories that participate in Medi-Cal had difficulty assembling the required information by the first deadline on May 31, 2013, and DHCS was forced to extend the deadline for data submission by three months in order for laboratories to complete the process. The amount of information that each applicable laboratory must report under section 216 of PAMA dwarfs the amount that had to be reported in California. CMS should be prepared to receive an overwhelming amount of data and to give laboratories flexibility in how they are required to report such data.

"Private payor" is a term that is defined in the law, yet laboratories will need additional guidance from CMS about how to distinguish payors when reporting. The definition of a "private payor" includes "a health insurance issuer" and a "group health plan," as those terms are defined in the Public Health Service Act. A "health insurance issuer" is "an insurance company, insurance service, or insurance organization (including an [HMO]) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance…". A "group health plan" is an employee welfare benefit plan, to the extent that the plan provides medical care to employees and their dependents directly or through insurance, reimbursement, or otherwise.[9] A "health insurance issuer" often is an enormous corporation that is licensed in many or all states to sell health insurance coverage through a variety of products.

Notwithstanding the statutory definition noted above, CMS will need to define exactly how "private payor" is to be understood in this context to provide clear instruction to applicable laboratories about how to assemble and report data. For example, laboratories do not have a "United Healthcare" rate for a given laboratory test – United Healthcare pays thousands of different rates for a test, based on the plan, location, place of service, and health care provider.

[9] Public Health Service Act § 2719 (42 U.S.C. § 300gg-91). *See* Social Security Act § 1834A(a)(8)(A) (42 U.S.C. § 1395m-1(a)(8)(A)).

Similar complexity will arise with Medicare Advantage and Medicaid managed care organization plans. Adding to the complexity of the task of determining which rates applicable laboratories will report to CMS is the fact that laboratories that are out-of-network are paid varying rates, sometimes by the same payor in the same year.[10]

CMS also will need to be clear about what constitutes a payment rate. In most cases, the rates that private payors set for laboratory tests account not only for the amount that the health insurer will pay, but also the copayment that a patient will pay to the laboratory. For example, when a private payor rate for a laboratory test is $100 and there is a 20 percent coinsurance liability, a laboratory counts on a private payor to pay $80 and on the patient to pay $20. Patients also sometimes have deductibles to meet, meaning that a private payor may be involved in the rate-setting for a particular service but not involved in payment if the deductible exceeds the rate set by the payor for the test. In addition, some patients may have multiple payors on a claim (including a primary and a secondary payor) that may have different rates allowed for the same claim.

CMS's definitions of "private payor rates" and volumes should lead to a reporting system that yields the most complete information for the agency about how laboratories are compensated for their services to support calculation of accurate Medicare rates and that places the least burden possible on the reporting laboratories.

- ***Recommendation: To ensure consistency among reported rates, laboratories should report the final total approved payment rates for covered services during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. The approved payment rate should be the total "Allowed Amount" paid by a private plan, as that term is understood in the context of HIPAA 5010 transactions, including any copayments, coinsurance, deductible amounts, and other patient cost-sharing.***

3. Length of the data collection period. CMS should require laboratories to report as much data as the agency needs to calculate accurate market-based Medicare payment rates, but it should not require laboratories to report any more data than is necessary. For example, one calendar quarter's worth of private payor data may be sufficient for the agency to derive a Medicare rate reflecting the private payor market rate for a high-volume, broadly-distributed laboratory test such as a complete blood count ("CBC"). This is one of the most commonly performed laboratory tests, so one quarter's worth of data would yield a sufficient volume and cross-section of claims to develop an accurate Medicare payment rate, as contemplated by the law. For other tests that are performed more rarely, the volume in a given quarter may be lower, and data from one quarter may not be sufficient to reflect private market rates accurately. We

[10] When a laboratory is out-of-network, it may bill a payor the charge for a test and be paid just a fraction of that amount by the payor, based on the payor's policy for determining its liability for out-of-network services without regard for any negotiation with the laboratory about the rate for a specific test. Under such circumstances, the payor may allow the laboratory to collect the remainder of its charge from the patient as the patient's cost-sharing for the out-of-network test. The total amount allowed by the payor and due to the laboratory, and not just the amount paid by the payor, is what is relevant and should be reported.

believe CMS can strike the right balance for all tests, regardless of volume or frequency, by requiring laboratories to report data for tests furnished in a six-month period.

- ***Recommendation: The first data collection period should be six months, and it should cover the first six months of 2015. We believe future data collection periods also should span six months, although the initial experience may indicate the desirability of some change. CMS should establish reporting periods via notice-and-comment rulemaking.***

4. Time period for reporting. The text of the statute says that an applicable laboratory shall report the rate and test volume at each rate "for each clinical diagnostic laboratory test that the laboratory furnishes during [the data collection] period".[11] While the data collection period will have a defined beginning and end during which tests are furnished (*i.e.*, the date of service of the laboratory test), it can take months for payors to adjudicate a claim fully and to determine the rate that ultimately is allowed for a given test. Thus, the date of the service of the laboratory test may be within the data reporting period, but final adjudication of the allowed rate may fall on a date well after the end of the reporting period. The lag in payment is particularly pronounced for out-of-network laboratories that do not have contracts with a given payor to which they submit claims.

In order to report accurate rates and test volumes to CMS, laboratories will need time to collect fully adjudicated payments between the end of a data reporting period and the date on which payment arrays must be reported to the agency. Laboratories also will require some time after payments are made to gather all relevant data and prepare an array for reporting.

- ***Recommendation: Applicable laboratories should report private payor rates for tests with a date of service that falls within the six month data reporting period and that have been fully adjudicated within six months after the end of the reporting period. Thus, CMS should leave at least six months between the end of the data reporting period and the end of a follow-up period that allows laboratories adequate time to collect payment data so that they may submit accurate payment rates and volumes to CMS. This also would allow a lab to factor into its reported rates any volume-based discounts, rebates, and price concessions. Laboratories should have an additional sixty days following the conclusion of the follow-up period to organize, review, verify, and report their data arrays.***

5. Mechanism for reporting data. Laboratories will be required in some cases to report thousands of private payor rates to CMS, and CMS will need to accept a huge amount of data from hundreds or even thousands of laboratories. CMS must develop a reporting mechanism that is workable for many different kinds of laboratories (that may have very different information technology capabilities and resources), that is secure, that is user-friendly, and that allows CMS to organize the data to derive accurate Medicare payment rates. Ideally, this should be through an Internet reporting portal. (CMS has experience with this for reporting drug payment rates under the Medicaid drug rebate law. However, the volume of data required

[11] Social Security Act § 1834A(a)(1) (42 U.S.C. § 1395m-1(a)(1)).

to be reported in this instance is substantially greater than that reported for Medicaid rebates.) CMS should consider convening a meeting of its information technology experts with those working in the laboratory industry to develop plans for an easy-to-use and reliable reporting mechanism that will be effective for the agency and for reporting laboratories alike.

- ***Recommendation: An electronic reporting mechanism, such as an internet-based portal, should be established for laboratories to report their private payor data. CMS should provide opportunities for laboratories to test their rate-reporting capabilities in an "end-to-end" fashion and for CMS to test its information technology infrastructure prior to the actual reporting date.***

6. Confidentiality of data. Congress clearly intended for CMS to guard the confidentiality of data reported by applicable laboratories and for such data to be disclosed in a manner that may identify a laboratory or a payor only in very limited situations. We seek assurance from CMS that disclosures made "as the Secretary determines to be necessary to carry out" the law will be arrived at judiciously and that no more identifiable data will be revealed than is truly required.

- ***Recommendation: To maintain the integrity and legitimacy of the reporting process, CMS should apprise the public of the situations in which the Secretary would find such disclosures to be necessary and to set a high bar for disclosing information that might reveal the identity of a laboratory and/or a private payor.***

II. Medicare Payment Rate Development

Just as important as how CMS collects data on private payor data from applicable laboratories is how it uses the data to arrive at Medicare rates that will apply until the next data collection cycle. It is crucial that the Medicare payment rates are developed accurately and transparently to ensure appropriate Medicare payments and because many other payors (including many Medicaid programs) base their rates on Medicare rates.

A. The Law

For a clinical laboratory test furnished on or after January 1, 2017 (that is not a new test or an ADLT), the Medicare payment amount is to be the "weighted median" for the most recent data collection period. The "weighted median" payment for a laboratory test is to be calculated by "arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory." Once a rate is established, it is to remain in effect until the year following the next data collection period, and it "shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)". Also, for the years 2017 through 2019, the amount of a reduction in the Medicare rate (if any) shall not exceed 10 percent from the prior year's rate, and for 2020 through 2022, any reduction shall not exceed 15 percent from the prior year's rate.

An ADLT will be paid "during an initial period of three quarters" at the "actual list charge," which is the publicly-available rate on the first day that a test is available for purchase

by a private payor. After the "initial period of three quarters," Medicare will pay a "weighted median" of the private payor rates the laboratory reported during the "second quarter of the initial period." When the actual list charge is more than 130 percent of the weighted median rate, CMS may recoup the difference between the two rates.

For new tests that are not ADLTs, Medicare payment shall be determined using crosswalking or gapfilling. Additionally, the statute requires CMS to provide a detailed and transparent explanation regarding the basis for payment rates for these tests, what criteria were applied, and how. The law also calls for CMS to establish an "expert outside advisory panel," subject to the Federal Advisory Committee Act, to provide input on payment rates, factors to consider for coverage and payment processes, and any other issues raised under the CLFS reform law. The size of the panel is not specified. The panel is to be assembled no later than July 1, 2015, and it is to consist of a cross section of individuals with experience in laboratory science, health economics, molecular pathology, clinical laboratory tests, and similar fields. This panel will not take the place of CMS's annual clinical laboratory meeting.

B. Issues, Questions, and Suggestions

1. Development of weighted median rates. The text of the law does not provide CMS with much direction about how to determine weighted median rates for each test. When CMS proposes a method for developing each weighted median, we ask that the agency provide the public with a detailed explanation of how it will array all of the private payor data for each individual laboratory test to arrive at the weighted median.

2. Transparency and re-review of published rates. We hope that the data reporting mechanism that CMS develops will be efficient and reliable and that the agency will be capable of accepting and storing the enormous amount of data that applicable laboratories will report to it. Given the large amount of data, it is reasonable to expect that, from time to time, errors will occur due to information management challenges and/or inaccurate calculations. While the law precludes administrative or judicial review of payment amounts,[12] it does not prohibit CMS from establishing a process to accept requests for re-review of proposed rates. Such systems already exist in other contexts in the Medicare program (*e.g.*, PFS and OPPS).

- ***Recommendation: CMS should ensure that there is sufficient transparency in the rate-calculation and rate-setting processes. CMS should allow stakeholders to review preliminary payment rates prior to their effective date and request that CMS review potentially inaccurate rates. To facilitate this step, CMS should publish preliminary payment rates at least three months prior to their effective date.***

3. Adjustments to rates. The statute states that, once established and until the year following the next data collection period, weighted median rates shall not be subject to adjustments such as geographic adjustments, budget neutrality adjustments, annual updates, or "other adjustments." It seems clear that these rates would not be subject to the multifactor

[12] *See* Social Security Act § 1834A(h)(1) (42 U.S.C. § 1395m-1(h)(1)). This refers to formal reviews by an administrative law judge and to review of a final administrative decision in a federal court.

productivity adjustment added by the section 3401(l) of the Affordable Care Act; it is not named specifically in the law, yet it would be fairly encompassed by "other adjustments." We ask for confirmation of this interpretation.

- ***Recommendation: CMS should confirm that the rates established under section 216 of PAMA will not be adjusted by the multi-factor productivity adjustment added by section 3401(l) of the Affordable Care Act.***

4. "Initial period" for new ADLTs. Congress intended for payment during an "initial period of three quarters" to mean the period when a test first is covered and payable by a Medicare contractor. Congress clearly contemplated that laboratories would be paid by Medicare for new ADLTs during this period or it would not have included the possibility of recoupment when payment based on actual list charges exceeds 130 percent of the rate established on the basis of private payor data.

As set forth in the law, the payment rate during this initial period will be based upon the publicly-available actual list charge offered by the laboratory for the test on the first date on which the test is commercially available for coverage and payment by private payors.

Laboratories are required to report private payor data for the initial period for new ADLTs no later than the end of the second quarter of the initial period. The statute is silent, however, on the time period that such initial report should cover. Insofar as there may be fewer payors covering and paying for a new ADLT during this period, it would be appropriate for the reporting period to be longer than just the first quarter of the initial period of Medicare coverage and payment. If there are private payor data that reach a certain volume threshold from the quarter before the first quarter of Medicare coverage and payment, these data should be included to allow for at least six months of data collection.

- ***Recommendation: For new ADLTs, the "initial period of three quarters" for rate reporting that is referenced in the statute should begin once a Medicare administrative contractor ("MAC") determines that an ADLT is covered by Medicare and a unique Healthcare Common Procedure Coding System ("HCPCS") code has been issued to identify the test. The reporting period should include the first quarter after Medicare coverage and payment has commenced, and if there are sufficient data from the quarter prior to commencement of Medicare coverage and payment, those data should be included, as well.***

5. Recoupment. CMS may recoup funds from an applicable laboratory if it determines that the actual list charge it paid to a laboratory for a new ADLT in the initial period exceeds 130 percent of the calculated weighted median rate. We assume that, in such cases, CMS would recoup the difference between the actual list charge and 130 percent of the weighted median. CMS should advise laboratories about how it will recoup such funds. CMS's process also should include a mechanism for a laboratory to dispute any such recoupment before the recoupment occurs.

- ***Recommendation: CMS should provide laboratories with guidance regarding the recoupment process, confirming that the amount of excess payments to be recouped (if any) is the difference between the actual list charge and 130 percent of the weighted median.***

6. ADLTs that meet similar criteria to those established in statute. CMS should establish criteria under which a test furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory can be classified as an ADLT if it is similar to those mentioned in the statute.

7. Process of ADLT determination. MACs should have the authority to determine whether a test meets criteria for classification as an ADLT, and this determination could be made at the time of establishing Medicare coverage and payment. Pursuant to section 1834A(e)(1) of the Social Security Act, a new test determined to be an ADLT would be assigned a temporary HCPCS code.

- ***Recommendation: CMS should consider establishing a process whereby laboratories may request that either CMS or the MACs may determine if a test is eligible to be classified as an ADLT for purposes of section 216 of PAMA.***

8. New tests that are not ADLTs. CMS is to use crosswalking or gapfilling for new tests that are not ADLTs. The recent gapfilling exercise for molecular diagnostic codes was challenging for laboratories, both because of data problems between the MACs and CMS and because of inadequate transparency in the process and gapfilling results. We are heartened that the statute includes language directing CMS to explain how it arrived at each payment rate for each new test that is not an ADLT and what factors it considered in developing the payment rate, and that CMS is to consider recommendations on payment rates from the newly-created expert advisory panel. We urge CMS to provide more than simple, cursory explanations of its rate determinations and to draw upon the resources it has in the expert advisory panel to consider carefully how new tests are paid.

9. Expert advisory panel. The expert advisory panel is to be assembled before applicable laboratories begin reporting private payor data to CMS. It is clear that Congress intended this panel to lend its expertise and advice to CMS on the assignment of payment rates to new tests through the crosswalk or gapfill process and on the reporting process and structure in general. It is our hope that CMS will give serious consideration to the panel's advice and that it will make clear to the public how it is using the panel to develop coverage and payment policies. To derive the most value from the panel, CMS should include on it those individuals who have recent direct experience in the clinical laboratory industry. Individuals with this real-world experience can shed light on how policies can be operationalized by clinical laboratories and not be at odds with the way that laboratories actually function. The statute leaves CMS discretion to include experts on the panel beyond those suggested by the statute, and we strongly urge CMS to include those with technical expertise in developing, validating, and performing clinical laboratory tests; patient representatives; clinicians who use clinical laboratory test results; laboratorians; and individuals with expertise in pharmacoeconomics and/or health technology assessments. The panel's membership also should reflect the laboratory industry's geographic and size diversity and the viewpoints of independent clinical laboratories, hospital laboratories,

and physician office laboratories. CMS should take full advantage of the resources it will have available in the expert advisory panel and draw upon the panel's members for advice on how new tests should be paid.

- ***Recommendation: CMS should ensure that at least some panel members have recent industry experience with clinical laboratory operations, commercial test development, and diagnostics reimbursement, and it also should account for patient and clinician perspectives. Stakeholders should be afforded an opportunity to provide input on the advisory panel's charter, role, processes, and meeting agendas.***

III. Coding

A. The Law

CMS is required to develop temporary HCPCS codes for new ADLTs and new FDA-cleared or –approved tests that will be effective until permanent HCPCS codes are established (but not longer than two years). For existing ADLTs and FDA-cleared or –approved test that are paid for by Medicare and that do not have uniquely-assigned HCPCS codes, CMS is to assign unique HCPCS codes and publicly report payment rates. The statute also allows a laboratory to request a "unique identifier" for an ADLT or FDA-cleared or –approved test "for purposes of tracking and monitoring."

B. Issues, Questions, and Suggestions

1. Existing ADLTs or FDA-cleared or approved tests without unique HCPCS codes. CMS should develop a process through subregulatory guidance to issue, as soon as possible, unique HCPCS codes and publish the payment rates for existing ADLTs and clinical laboratory tests that were cleared or approved by the FDA and paid by Medicare as of the date of enactment under a miscellaneous code or otherwise not reported under a uniquely assigned code (*e.g.*, a non-specific method code that does not describe a specific ADLT or FDA-cleared or –approved test). CMS should allow laboratories and manufacturers to submit requests for unique HCPCS codes through an expedited process. This will facilitate data collection for rate-setting by having a common coding system to report payments from private payors in 2015.

- ***Recommendation: CMS should develop a process as soon as possible through subregulatory guidance to issue unique HCPCS codes and publish the payment rates for existing ADLTs and existing clinical laboratory tests that were cleared or approved by the FDA and paid by Medicare as of the date of enactment under miscellaneous codes or otherwise not reported under uniquely-assigned codes.***

2. Expedited code assignment for new ADLTs and new FDA-cleared or approved tests. The statute requires CMS to adopt temporary HCPCS codes to identify new ADLTs and new tests that are cleared or approved by the FDA. CMS should develop a process for expedited application, consideration, and approval of HCPCS codes for these tests; each code should be unique to a test and the codes should not be the "not otherwise classified" codes currently in use.

Further, CMS should allow laboratories and manufacturers to submit requests on a quarterly basis for determination and issuance of new codes in a four month timeframe consistent with the timeframe by which CMS evaluates applications for pass-through codes and payment, assigning codes as necessary, under the Outpatient Prospective Payment System (*e.g.*, applications submitted by March 1 would result in codes effective July 1).

- ***Recommendation: CMS should establish an expedited code establishment process that includes quarterly review of tests and issuance of unique HCPCS codes to describe tests.***

3. Unique identifiers. The statute authorizes CMS to adopt a process whereby a laboratory or manufacturer offering an ADLT or an FDA-cleared or approved test may request a unique identifier for the test. The statute authorizes CMS to adopt such unique identifiers by means of a HCPCS code, a modifier, or other means. Insofar as currently-covered and new ADLTs and FDA-cleared or -approved tests would be assigned unique HCPCS codes under the provisions discussed above, it would appear appropriate that the unique identifiers should be uniquely assigned HCPCS codes rather than modifiers or other designators that are not entered in the code field of a claim form.

If a CPT code is assigned that is less granular than the HCPCS code and that does not identify the test uniquely, a laboratory or manufacturer should be able to request a unique test identifier for the test. Such a request could be fulfilled by reviving the expired HCPCS code or through adoption of some other unique test identifier. This would ensure that MACs and other payors that adopt coverage and/or payment policies specific to the ADLT or the FDA-cleared or –approved test would be able to continue to implement such policies without pending claims for manual adjudication.

- ***Recommendation: CMS should consider using HCPCS codes as the "unique identifiers" contemplated under section 216 of PAMA. In addition, CMS should substitute granular HCPCS codes for more general CPT codes when appropriate.***

IV. Coverage

A. The Law

Section 216 of PAMA establishes parameters for how MACs may establish coverage policies through local coverage determinations ("LCDs") on or after January 1, 2015. It also permits CMS to designate up to four MACs to establish coverage policies, or both to establish coverage policies and to process claims for payment, for clinical diagnostic laboratory tests.

B. Issues, Questions, and Recommendations

1. Local Coverage Determinations. The law requires LCDs for clinical laboratory tests to be developed according to the process already spelled out in section 1869 of the Social

Security Act and implementing regulations.[13] Coverage policies for clinical diagnostic laboratory tests have been issued recently through less formal processes, such as articles, without following the existing notice-and-comment requirements of the Social Security Act. We have expressed our concerns about this to CMS on several occasions.

The CY 2015 PFS proposed rule includes a proposed new LCD process for new LCDs published on or after January 1, 2015.[14] The proposal would shorten the amount of time that the public has to comment on a draft LCD (to 30 days from 45 days currently) and make a final LCD effective upon publication in the Medicare Coverage Database, no later than 45 days after the close of a comment period. The proposal also would eliminate the requirement for a MAC to hold an open meeting on a draft LCD. The proposal does not address directly the permissibility of MACs using articles to issue coverage polices. ACLA will comment on CMS's proposal for the LCD process in our formal comments on the CY 2015 PFS proposed rule, including the proposal to shorten the LCD comment period.

2. Medicare Administrative Contractors. We still are studying the issues around consolidating coverage or coverage and payment processing in a small group of MACs. Of utmost importance to us is the fairness and transparency of coverage and payment processes, rather than the number of MACs that are involved.

V. Implementation of the New Law

The timeline for implementing the CLFS reform provisions of the Protecting Access to Medicare Act of 2014 is extremely tight, given the complexity of the provisions and the magnitude of data involved. The expert advisory panel is to be assembled and functioning by July 1, 2015, and CMS is to issue regulations regarding payment rate reporting no later than June 30, 2015. Actual data reporting is to begin January 1, 2016, and CMS must calculate weighted medians for each individual test in time for them to take effect on January 1, 2017.

We are concerned about the short amount of time – just six months – between the date by which CMS must issue final regulations on data reporting and the time when the agency may require applicable laboratories to begin reporting private payor data. Congress gave CMS the authority to determine when each applicable laboratory needs to report private payor data, so long as the date is not before January 1, 2016. It will take laboratories time to understand and operationalize what CMS includes in a final rule, regardless of a laboratory's size. Larger laboratories may be challenged by the sheer volume of data they must collect and report for each payor, plan, and test code in a very short period of time, while smaller and medium-sized laboratories may be at a disadvantage from not having information technology, coding, and/or billing resources that are equal to the task. All laboratories will need a number of months to

[13] 42 U.S.C. § 1395m-1(g) ("A Medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1869(f)(2)(B) [of the Social Security Act], including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations)."). Section 1869(f)(2)(B) of the Social Security Act (42 U.S.C. § 1395ff(f)(2)(B) defines an LCD as "a determination by a fiscal intermediary or carrier under Part A or Part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts…"

[14] 79 Fed. Reg. 40318, 40378 (Jul. 11, 2014).

develop internal data collection systems that meet the requirements of the final rule, once it is issued.

We also are sensitive to the fact that CMS will need adequate time to accept, organize, analyze, and use the data that applicable laboratories report and that it must have calculated all of the weighted medians for each clinical laboratory test in time for the new rates to take effect January 1, 2017. From the agency's perspective, this may weigh against setting a date that is too far into 2016 by which applicable laboratories must report data. ACLA wants CMS to have an adequate amount of time to organize the data and to calculate accurate weighted medians. It is not in our interest for CMS to have to rush through the process of setting new payment rates for more than one thousand clinical laboratory tests.

We hope that CMS will give serious consideration to conducting a test, perhaps one that involves limited rate reporting and limited Medicare reimbursement calculations, to ensure that both laboratories and the agency are ready to implement the process fully and to allow the agency and applicable laboratories the opportunity to learn from what worked and what did not work. Such testing also could help the agency determine how long it will take to accept and organize reported data, the steps involved in calculating and verifying the accuracy of the weighted median rates and the length of time to do so, and the unanticipated challenges of the overall private payor data reporting and Medicare reimbursement rate-setting program. It also would provide CMS, applicable laboratories, and other interested stakeholders an opportunity to collaborate further on how to improve the reporting program.

- ***Recommendation: Given how soon laboratories will have to collect data to report to CMS early in 2016, it is important for the agency to proceed with the regulatory implementation process as soon as possible.***

- ***Recommendation: CMS should consider establishing a reporting test, possibly limited to a small yet statistically appropriate number of codes and laboratories, and calculate "draft" weighted median Medicare rates so that applicable laboratories can review their ability to collect, array, and submit rates to the agency and so that CMS can verify its ability to collect data and calculate correct payment rates, before the reporting system is used for all clinical laboratory test rates.***

VI. Conclusion

Thank you for your consideration of ACLA's written statement on implementation of section 216 of the Protecting Access to Medicare Act of 2014. We look forward to a continued dialogue with CMS on this very important matter.

Sincerely,

Alan Mertz, President
American Clinical Laboratory Association

Khani Declaration Exhibit 6

American
Clinical Laboratory
Association

Protecting Access to Medicare Act
Sec. 216 (SSA § 1834A)

October 1, 2014

American Clinical Laboratory Association
1100 New York Avenue, NW
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Washington, DC 20005
(202) 637-9466
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Overview

American Clinical Laboratory Association

- **Background** on PAMA Sec. 216
- **Impact** on laboratory industry
- **Differences** between ASP reporting and reporting payment rates for lab tests
- **Key definitions**
- **Timeline and implementation**

Background on PAMA Sec. 216

- Beginning 2016 and every three years, an "applicable laboratory" reports the volume and payment rate for each private payor for each lab test on the CLFS during a "data collection period".
- Reporting for "advanced diagnostic laboratory tests" is annual.
- Secretary may choose to allow data aggregation beginning in 2019.
- Payment under the CLFS for each test will be the weighted median of all reported rates for the test in the data collection period.
- Rate reductions are to be phased in.

Impact on Laboratory Industry

- First major reform to CLFS since its creation 30 years ago.
- Dissimilar from other price reporting systems.
- Very tight timeline for implementation.
- Great risk of "getting it wrong" if systems are not tested on both the lab side and CMS side.

Differences Between ASP and Reporting Payment Rates for Lab Tests

- ASP reporting for drug manufacturers is fundamentally different from what is required of labs under PAMA
  - ASP reporting is for a small fraction of prescription drugs, while PAMA requires a laboratory to report all rates for all CLFS tests for which it received payment from a private payor.
  - Drug manufacturers report one blended rate for each drug, while laboratories will be required to report every private payor rate along with volumes.
  - Drug manufacturers are experienced with reporting, but this is entirely new to laboratories.

Key Definitions

- **Applicable laboratory**: "A laboratory that, with respect to its revenues under [title XVIII], a majority of such revenues are from [the new SSA § 1834A], the [CLFS], or the [PFS]."
  - Should include a hospital lab when a majority of the hospital lab's revenue comes from one of those sources.
  - Rates will apply to hospitals for outreach/non-patient services; therefore, hospitals' private payor rates should be included.
  - Hospitals do not receive separate "revenue" for services furnished to their own inpatients and outpatients.
  - Also should include larger physician office laboratories.
- **Payment rate:** Not defined in statute.
  - Should be the entire allowable amount due to a laboratory from all sources for a fully-adjudicated claim, including copayments, deductibles, and third-party payor amounts.

Timing and Implementation

- **Extremely tight timeline** for implementation—
  - CMS to issue final regulations by June 30, 2015
  - Rate reporting to begin Jan. 1, 2016
  - Weighted medians calculated and applied by Jan. 1, 2017
- **Just 6 months** between final regs and start of rate reporting
- **Labs need time** to assemble data and for QA before submitting; **CMS needs time** to organize data before announcing weighted medians/applying rates on Jan. 1, 2017.
- **California Medicaid** rate reporting is an object lesson:
  - One-third the number of tests, reporting only top five private payors.
  - Medi-Cal had to extend the data submission deadline because labs had so much difficulty with that relatively small amount of data.
  - To date, Medi-Cal has been unable to calculate rates based on private payer data

Timing and Implementation

Recommendations:

- **Six month data reporting period** (Jan. 1-June 30, 2015)
- Applicable laboratories report rates **by June 30, 2016**
- Establish a **"test run"** with limited reporting/rate calculations to ensure both labs and CMS are ready to implement
- Create and test **web-based portal for reporting** (far larger amount of data than ASP)
- Provide an opportunity for labs to **review rates before they become effective**
- Develop mechanism through which a lab can **request an audit** of a weighted median rate (*e.g.*, through a de-identified public use file)

Other Key Issues

- IOAS
- Local Coverage Determinations

American
Clinical Laboratory
Association

Thank You

Khani Declaration Exhibit 7

January 13, 2015

Mr. Marc Hartstein
Director, Hospital and Ambulatory Policy Group
Centers for Medicare and Medicaid Services
Mail Stop C4-01-26
7500 Security Boulevard
Baltimore MD 21244

Dear Mr. Hartstein:

As you work towards implementation of Section 216 of the Protecting Access to Medicare Act (PAMA), the American Clinical Laboratory Association (ACLA) is writing to provide you further thoughts on the definition of "applicable labs." As you know PAMA requires applicable labs to report private payor reimbursement rates to CMS for the purposes of revising the Clinical Laboratory Fee Schedule (CLFS). As we have discussed with you and your staff, we believe the inclusion of hospital laboratories in the definition of applicable labs is consistent with congressional intent, and is critical to ensuring that Medicare reimbursement rates accurately reflect market prices for laboratory services.

ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory services, including national, regional and esoteric labs. We offer these comments in the spirit of ensuring changes in the Clinical Laboratory Fee Schedule (CLFS) are made in a manner that allows Medicare beneficiaries to maintain access to clinical laboratory services.

Applicable Laboratories

The Protecting Access to Medicare Act (PAMA) establishes a new method for pricing clinical laboratory services billed to Medicare. For the first time, those services are to reflect the payment received by laboratories from other third-party payors. A key question in implementing this provision concerns what laboratories are required to report their prices in the private market. As noted below, in many instances, laboratory services are furnished by hospitals, which provide outreach services, just as independent laboratories do, and in competition with them. Therefore, not only is it appropriate from a policy standpoint to include hospitals in the reporting requirements, but the law itself envisions that hospital laboratories will be included.

PAMA defines applicable laboratories as those laboratories which must report pricing information to CMS. According to the statute, an applicable laboratory is:

> A laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848.

As discussed below, in this case, a hospital's outreach revenues should be included, since the hospital laboratory is a distinct part of the hospital, and that laboratory's outreach revenues are paid under the sections specified in the statute.

II. From a policy standpoint, it is reasonable to include outreach testing.

The clear intention of Section 216 is to ensure that going forward, laboratory payments by Medicare reflect the payments in the broader laboratory market. Hospitals represent a significant part of Medicare spending for clinical laboratory services. According to the most recent Medicare Trustees report, in 2013, Medicare spent about $4.6 billion on clinical laboratory services provided by hospitals. This was about 47% of the total.[1] In fact, according to the CLIA website, out of over 240,000 different laboratories certified by CLIA, hospitals represent about 3.61% and independent laboratories represent only 2.41%. Physician office laboratories represent the single largest category, at 48.96%. [2]

Medicare itself has recognized that when hospital laboratories perform work for non-hospital patients, they are acting as independent laboratories. For example, the Medicare Claims Processing Manual states: "When a hospital laboratory performs laboratory tests for non-hospital patients, the laboratory is functioning as an independent laboratory…" [3] The Manual makes the same point later in the same section. At one time, hospitals doing outpatient testing were paid at a level that was set at 62% of the fee schedule medians, while independent labs were paid at 60% of the medians. In the Claims Processing Manual, CMS noted that the higher level did not apply to hospital labs doing outreach work, however. "If a hospital laboratory acts as an independent laboratory, i.e., performs tests for persons who are non-hospital patients," then payment is made based on the fee schedule that reflects 60% of prevailing charges, the level applicable to independent laboratories. [4] Thus, CMS appears to recognize there are circumstances when the hospital is acting as an independent lab.

Given that the hospital is acting as an independent lab when it is providing outreach services, it seems reasonable to include its prices in this exercise, as the whole point of the statute was to set prices based on market rates and hospitals are clearly a significant player in the market. Moreover, under the statute, hospital laboratories performing outreach testing will be paid at the new prices established by Section 216. As a result, it seems only reasonable, as they will be subject to these prices, to also require them to have some input into how those prices are set. As a result, from the standpoint of policy, it seems reasonable to include at least the outreach testing in this process.

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[1] Medicare Trustees Report, at 144 (July, 2014). This figure is projected to drop in 2014 due to the fact that laboratory payments for outpatient hospital patients will be bundled into the APC payment made to the hospital under changes to the HOPPS rule. Even so, after that change occurs, the Trustees report projects about 1.8 billion in payments to hospitals, all of which is attributable to outreach testing.

[2] "Laboratories by Type of Facility" available at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html (accessed July 30, 2014).

[3] CMS, Medicare Claims Processing Manual (Pub. 100-04), Chap. 16, §10.

[4] *Id.* at §20.1

III. Congress intended for hospital laboratories to be included.

As drafted, it is clear that Section 216 is broad enough to encompass hospital laboratories doing outreach testing and that appears to also have been Congress' intention. In a colloquy on the Senate floor, Senators Burr and Hatch specifically discussed this issue and noted that the intent of the provision was to ensure "that Medicare rates reflect true market prices for laboratory services, and as such, that all sectors of the lab market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule." This language demonstrates Congress' clear intent that in establishing market pricing, CMS should look at the entire market, including hospital outreach laboratories.

IV. Section 216 is written to include hospital outreach services.

The language of the statute was written in such a way to include outreach services furnished by hospitals. As noted, the language of section 216 states that an "applicable laboratory," which is the entity that must report pricing information, is a "a laboratory" that has a majority of its revenues from section 216 of PAMA; section 1833(h), which is the section that established the CLFS, and section 1848, which covers physician fees. Therefore, in interpreting this section, CMS must first decide how to define the "laboratory" whose revenues it must look at. Then, it must determine what "revenues" are to be looked at. And, having done all that, it must look to see if a majority of the laboratory's revenues come from the cited statutory provisions.

It is fairly easy to determine what the "laboratory" is with regard to independent laboratories, as there the laboratory entity is easily identifiable. It is somewhat more complicated with regard to a hospital laboratory. In that case, is CMS to treat the whole hospital entity, with all of its various revenue centers, as the laboratory, or is it to look only at that part of the hospital that furnishes laboratory services? It seems inappropriate to look at the entire hospital, as that entity is far broader than the laboratory (and its revenues include non-laboratory revenues.). If Congress had intended for CMS to look at the entire hospital, it presumably would have used a broader term in the law, such as "entity," rather than their narrower term "laboratory." (Further, the colloquy cited above makes clear that Congress intended for hospital laboratories to be included.) Therefore, it appears most appropriate to look at the laboratory within the hospital, which is a distinct and identifiable cost center.

The second question to be resolved under section 216 is: What "revenues" are to be looked at, when determining whether a majority come from the sections specified in the statute? In looking at this issue, CMS should look at the instances in which the laboratory itself receives "revenues" for its services. It does not seem appropriate to include all revenues received by the hospital for any of its services, as those are not revenues received by the laboratory. In fact, a hospital laboratory will only receive revenues in very limited circumstances. For example, when a hospital provides laboratory services to inpatients and outpatients, the laboratory does not receive revenues as such. Rather, the hospital receives a bundled payment that covers all of the services provided by the hospital. While some small amount of that payment may be attributable to hospital services, those amounts are not broken out or identified, nor is there any way to determine what portion constitutes revenues of the laboratory. For inpatients, these payments are made in the form of the DRG payment made to the hospital, which covers an inpatient's entire hospital stay. For outpatients, the hospital receives a payment under the outpatient prospective payment system, which pays for services based on the applicable APC. Although at one time, hospitals were paid

for outpatient services based on the Clinical Laboratory Fee Schedule, beginning in 2014 hospitals are not separately paid for most laboratory services furnished to outpatients. The payment for the laboratory services is bundled and included in the ambulatory payment classification. Therefore, as with the DRG, the laboratory does not receive any identifiable revenues for these services.

It is only when a hospital provides "outreach services" that a hospital laboratory may be said to be receiving revenues. In those instances, a hospital obtains specimens from physicians who see patients in their own offices or the patient comes to the hospital with a prescription and the hospital draws the specimen and then furnishes the test. In those circumstances, the hospital bills for the testing and is paid based on the Clinical Laboratory Fee Schedule, just as any independent laboratory is.[5] In that case, there are identifiable revenues that are being paid to the hospital laboratory. [6] Those are the revenues that should be considered in determining whether the requirements of section 216 are met.

In that case, those revenues all are currently paid under section 1833(h), which establishes the current fee schedules, which are also applicable to hospital outreach services. In short, the only time a hospital laboratory is receiving actual revenues is when it is acting as an outreach laboratory, and in that case, it will meet the requirements of section 216 because virtually all of its Medicare revenues will be from section 1833(h). It seems reasonable to require hospital laboratories to report their prices because, as CMS itself acknowledges, in those circumstances, they are acting as independent laboratories. As noted above, they are a significant part of the market and compete with independent laboratories for business. Thus, if CMS is to obtain an accurate picture of the market, it should include the prices charged and received by hospital laboratories doing outreach testing.

Conclusion

In sum, based on policy, Congressional intent, and a plain reading of the statute, it is clear that hospitals doing outreach testing should be required to report their prices under section 216 of PAMA. We hope you find this information useful, and we look forward to continuing to work with you on successful implementation of the CLFS provisions of PAMA.

Sincerely,

Alan Mertz
President

[5] After section 216 is implemented, the hospital laboratory doing outreach testing will be paid at the new market based prices, just as independent laboratories are.

[6] In implementing the laboratory bundling provisions included in the HOPPS Rule, CMS has clearly delineated when the laboratory is to be paid separately. Under Transmittal 2845 (issued December 27, 2013), the hospital's only paid separately in the following circumstances: (1) it is non-patient specimen; (2) the hospital collects the specimen and furnishes only the outpatient labs on a given date; and (3) a hospital conducts outpatient tests that are clinically unrelated to the other outpatient services furnished the same day. According to a recent MLN Matters, "CMS assumed that a hospital functions as an independent laboratory in these circumstances," and hospitals are instructed to bill using a separate revenue code in order to designate that they are to be paid separately for these situations. CMS, MLN Matters, Number SE1412, "Update to 2014 Hospital Outpatient Clinical Diagnostic Laboratory Test Payment and Billing" (Related CR Release Date: Dec. 27, 2013).

Khani Declaration Exhibit 8

American Clinical Laboratory Association

21st century medicine

March 23, 2015

The Honorable Sean Cavanaugh
Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services
M/S C5-01-27
7500 Security Blvd.
Baltimore, MD 21244

Dear Mr. Cavanaugh:

On behalf of the Coalition for 21st Century Medicine (C21) and the American Clinical Laboratory Association (ACLA), we are writing to express concern that CMS has yet to publish a proposed rule implementing Section 216 of the *Protecting Access to Medicare Act* (PAMA) and to urge the agency to publish this proposed rule as soon as possible. As you know, PAMA requires the final rule to be published no later than June 30, 2015. Congress set this deadline to allow adequate time for both CMS and clinical laboratories to prepare for implementation of the new market-based payment system in 2017. Further delay in publication of the proposed rule not only will compromise CMS's ability to comply with the statutory deadline for the final rule, it also will compress the time laboratories will have to prepare and submit data to CMS, and their ability to meet their statutory obligations.

C21 and ACLA together represent laboratories that furnish millions of tests to Medicare beneficiaries each year. We supported the inclusion of the CLFS reform provisions in PAMA and have attempted to be collaborative partners with CMS since PAMA's enactment. We are hopeful that these reforms, the first since 1984, will establish a transparent and predictable market-based payment model that reflects the broad scope of the laboratory market and will encourage continued advancements in diagnostic innovation by providing a pathway to consistent coding and pricing decisions for all diagnostics.

While C21 and ACLA support changes made by PAMA, we fully appreciate that the transition to the market-based system will be complex and challenging for all involved. The new reporting process alone will require a significant shift in the way all labs manage their claims data and will require labs to overhaul their claims systems, as well as develop and validate internal processes to facilitate accurate and timely reporting of data.

C21 and ACLA have made recommendations to CMS in previous communications on the timeframes that will be needed for clinical laboratories to develop and implement reporting systems before reporting obligations begin. For example, assuming that the final rule would be released timely, we recommended that the initial data collection period should cover the first six months of 2015. Depending on when a final rule is published, however, this may or may not be the appropriate time period for data collection. Further, following this initial collection period, laboratories will need at least six months to collect, organize, review and verify data before submitting it to CMS.

We appreciate the complexity of the task before CMS and want to ensure the agency has ample time to receive, review, and thoughtfully respond to stakeholder comments before a final rule is published. We are extremely concerned that since CMS has yet to publish a proposed rule the time for providing and reviewing comments may be truncated and rushed. CMS must have time to provide adequate consideration of public comments, address comments in a final rule, and fully implement the new reporting and pricing reforms in the timeframe contemplated by Congress. Laboratories must have ample time to create reporting systems based on the new data parameters, certify the data, and transmit it to CMS.

C21 and ACLA appreciate the effort CMS is undertaking and applaud the agency for the efforts it has dedicated thus far. We are growing increasingly concerned, however, that a proposed rule has not been published, and we urge the agency to do so as soon as possible. We look forward to continuing to work with CMS to ensure successful implementation of PAMA.

Sincerely,

John Hanna, Chair, Reimbursement & Policy Workgroup
Coalition for 21st Century Medicine

Julie Khani, Senior Vice President
American Clinical Laboratory Association

Khani Declaration Exhibit 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

March 30, 2015

Julie Khani
Senior Vice President
American Clinical Laboratory Association
1100 New York Ave, NW, Suite 725 West
Washington, DC 20005

Dear Ms. Khani:

Thank you for your letter Deputy Administrator and Director of the Center for Medicare Management Sean Cavanaugh regarding the timing of the notice of proposed rulemaking implementing section 216 of the Protecting Access to Medicare Act (PAMA) of 2014. The Deputy Administrator and Director asked me to respond to your letter. The Centers for Medicare and Medicaid Services (CMS) greatly appreciates knowing of your concerns.

CMS has been working diligently since shortly after the PAMA legislation was enacted to develop provisions of the proposed rule implementing section 216's requirements for the clinical laboratory fee schedule. We appreciate that reporting private payer payment data is a new undertaking for laboratories. We are actively working on the numerous technical issues involved in implementing such as system and are continuing to work towards publish a proposed rule at the soonest possible date.

I appreciate your interest in this important issue for making your concerns known to CMS. I will also provide this response to Mr. Hanna.

Sincerely,

Marc Hartstein
Director
Hospital and Ambulatory Policy Group

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

March 30, 2015

John Hanna
Chair, Reimbursement and Policy Workgroup
Coalition for 21st Medicine
P.O. Box 15519
Arlington, VA 22215-0519

Dear Mr. Hanna:

Thank you for your letter Deputy Administrator and Director of the Center for Medicare Management Sean Cavanaugh regarding the timing of the notice of proposed rulemaking implementing section 216 of the Protecting Access to Medicare Act (PAMA) of 2014. The Deputy Administrator and Director asked me to respond to your letter. The Centers for Medicare and Medicaid Services (CMS) greatly appreciates knowing of your concerns.

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I appreciate your interest in this important issue for making your concerns known to CMS. I will also provide this response to Ms. Khani.

Sincerely,

Marc Hartstein
Director
Hospital and Ambulatory Policy Group

Khani Declaration Exhibit 10

Protecting Access to Medicare Act of 2014

Section 216 – SSA §1834A
Improving Policies for Clinical Diagnostic Laboratory Tests

Centers for Medicare & Medicaid Services

April 3, 2015

AGENDA

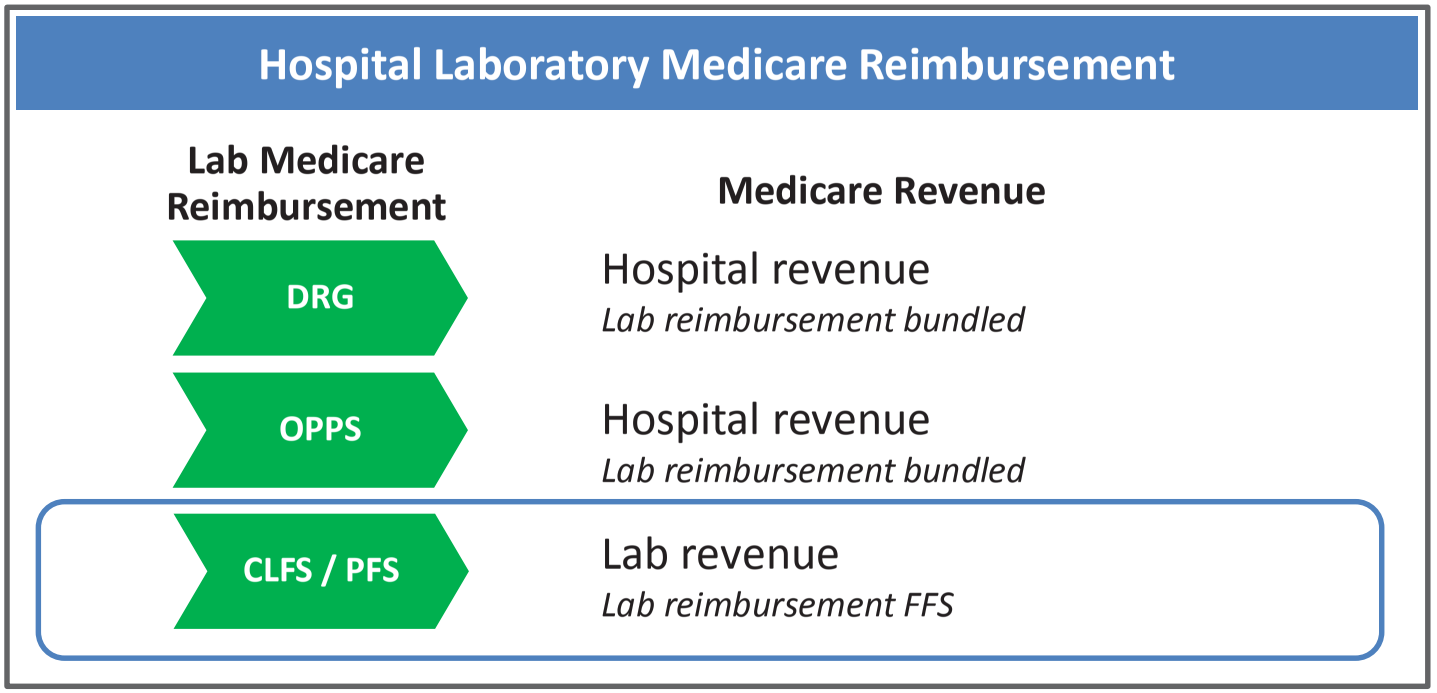
- Welcome & Introductions
- Review of Key Stakeholder Concerns
  - Implementation Process & Timeline
  - Key Definitions
  - Reporting Recommendations
- Comments & Questions
- Adjourn

PAMA Reporting Recommendations

- **CMS must strive for the simplest reporting requirements possible**
  - Help drive comprehensive market representation
  - Apply lessons from other rate data collection process
  - Laboratories should report the health plan "allowed amount"
  - Recognize limitations in payment data in laboratory billing systems
- **Applicable labs include hospital laboratories**
  - Hospital lab Medicare revenue consists of FFS payments from the CLFS and PFS. Bundled Medicare payments (DRG and OPPS) are not hospital lab revenue.
  - Some hospital and physician office labs may be exempt due to low volume

Applicable Labs – Hospitals

"Laboratories where the majority of its Medicare revenue is derived from the Clinical Laboratory Fee Schedule (CLFS) and Physician Fee Schedule (PFS)"

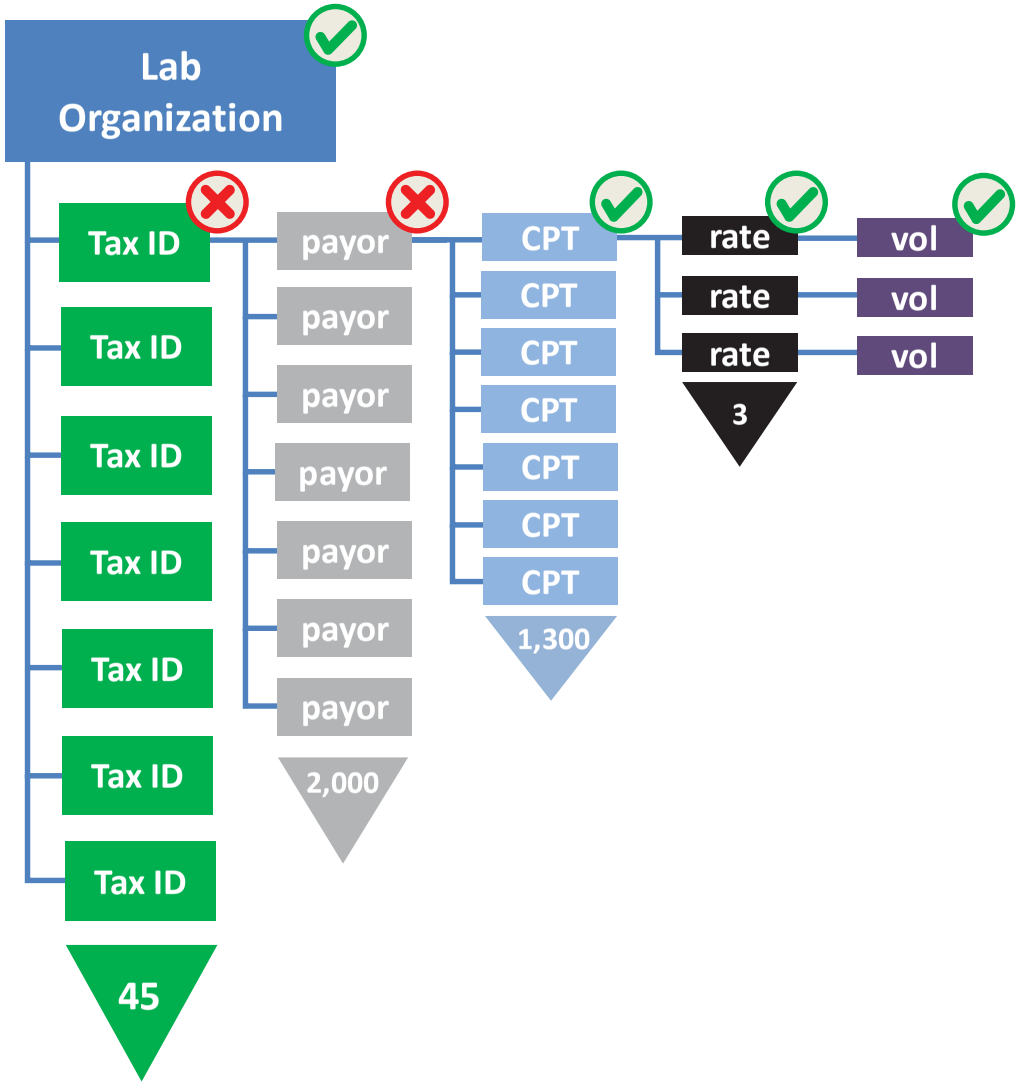


- No portion of Medicare bundled payments to hospitals for inpatients or outpatients can be attributed to the lab as Medicare lab revenue.
- Hospital laboratory revenue derives from the CLFS and PFS.
- Thus, hospital laboratories that bill Medicare under any fee for service fee schedule are applicable labs.

Simple Reporting

- Many laboratory organizations operate complex networks of many testing sites across multiple legal entities
- Laboratory organizations should be permitted to report their private payor rate data by CPT code as one entity and combine rate data across testing sites, tax ID numbers and payors to minimize complexity without affecting the weighted median calculation
- While CMS commonly associates an NPI number with its providers and suppliers, reporting should not be organized by NPI number or CLIA number.

Unnecessary classification of private payor rate data will overwhelm all involved



- Reporting becomes exponentially complex when separating data by tax ID and payor. Similar to tax ID, reporting should not be done by NPI.
- In this example, one applicable laboratory organization could stand to be required to report over 350,000,000 data points; many with the same rate.
- CMS would need to combine data points across tax ID and payor for the same rate as part of the weighted median calculation.

The simplest reporting will help ensure the most comprehensive market participation

Lab Organization Include tax ID list		
CPT	**rate**	**volume**
85025	$11.00	900,000
85025	$10.75	950,000
85025	$10.50	1,000,000
85025	$10.25	950,000
85025	$10.00	900,000
85027	$9.25	450,000
85027	$9.00	475,000
85027	$8.75	500,000
85027	$8.50	475,000
85027	$8.25	450,000
etc	etc	etc

hypothetical data

- One data file with three fields per applicable laboratory organization – CPT, rate & volume
- Volume (occurrences of the same rate) should carry the same weight, regardless of payor or tax ID, in the weighted median calculation
- A file uploading mechanism on the CMS website would allow for easy reporting
- File layout should be as simple as possible

CMS should allow laboratories to disclose known imperfections in the data, and consider reporting complete if the imperfections are not statistically significant, such as:

- Payors paying the incorrect fee
- Small volume payors who remit manually; CPT-level data not captured by the laboratory
- Encounter-level payments not broken out by CPT code
- Other situations

CMS should clearly instruct labs to report the "allowed amount" from private payor remittances, which often differs from the health plan portion of the payment

Health Plan Remittance Advice						
member	**group**	**CPT**	**charge**	**allowed**	**paid by plan**	**member co-pay**
John Doe	Plan Sponsor A	85025	$15.00	$11.00	$11.00	$0
Mary Smith	Plan Sponsor B	85025	$15.00	$11.00	$8.00	$3.00

hypothetical data

- Although the laboratory may have one negotiated fee schedule with a given health plan, the actual plan payment may vary, depending on the level of benefits the member's employer / plan sponsor has negotiated with the heath plan
- In this example, the appropriate amount the lab should report to CMS under PAMA is $11.00 for both claims
- CMS should articulate this point in its Rulemaking to avoid confusion and aberrancies in the data

Thank You

Comments & Questions

Khani Declaration Exhibit 11

American
Clinical Laboratory
Association

June 24, 2015

Mr. Marc Hartstein
Director, Hospital and Ambulatory Policy Group
Centers for Medicare and Medicaid Services
Mail Stop C4-01-26
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Hartstein:

As you continue your efforts to implement Section 216 of the Protecting Access to Medicare Act (PAMA), the American Clinical Laboratory Association (ACLA) is writing to provide you with additional information on several issues that we believe are key to successful implementation of the law.

As you know, ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory and anatomic pathology services, including national, regional and esoteric labs. We appreciate our ongoing collaboration with CMS on PAMA implementation thus far, and we hope that our additional recommendations on applicable labs, payment and coding for Existing Advanced Diagnostic Laboratory Tests (ADLTs) and data collection will assist the Agency as you move towards publication of a proposed rule. We feel our past discussions on various aspects of PAMA implementation have been productive and we look forward to continuing the collaboration.

ACLA, however, remains concerned that the proposed rule for implementing the most significant change in laboratory reimbursement in 30 years has still not been published, despite the statutory deadline that a final rule be published by June 30, 2015. The delay in rulemaking significantly compresses the time laboratories will have to gather, prepare, validate and submit data to CMS, and limits the time that CMS will have to analyze the information submitted and establish new prices. For both CMS and clinical laboratories, the time to prepare for a system under which Medicare rates are based on private payor rates will also be significantly shortened.

We would like to meet with you and your team as soon as the Proposed Rule is released to discuss the issues outlined below.

1. **"Applicable Laboratories"**

PAMA establishes a new method for pricing clinical laboratory services billed by Medicare. Applicable laboratories are required to report private market pricing to CMS to determine Medicare rates. PAMA defines an applicable laboratory as:

A laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848.

Given the compressed implementation timeline, it will be critical for CMS to establish clear guidelines in rulemaking for laboratories to determine whether or not they are subject to reporting. Absent clear direction from CMS, many laboratories may be unsure of their reporting obligations. In order to facilitate a smooth reporting process, ACLA recommends that CMS:

- Clearly define "laboratory" to enable the entity whose revenues must be reviewed to determine if it is an applicable laboratory; and

- Clearly define the "revenues" that are to be reviewed to determine whether a majority come from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule, the sections specified in the statute.

A. PAMA Rates Should Reflect the Full Clinical Laboratory Market

Clear guidance from CMS will help to ensure that PAMA rates are reflective of the full market, as required by the statute and congressional intent, and help laboratories to avoid the penalties associated with not reporting. For example, hospital laboratories, which make up nearly half of Medicare spending for clinical laboratory services, will need guidance on what revenue is laboratory revenue and how to determine the sources of hospital laboratory revenue.

In many instances, laboratory services are furnished by hospital laboratories, which provide outreach services, just as independent laboratories do. In these cases, independent laboratories and hospital laboratories directly compete in the marketplace. Given that hospital laboratories are acting as independent laboratories when providing outreach services, and that hospital laboratories performing outreach testing will be paid at the new prices established by PAMA, these hospitals laboratories should be considered applicable laboratories subject to PAMA reporting requirements.

Rulemaking will need to determine what "revenues" are to be looked at when determining whether a majority come from the sections specified in the statue. Hospital laboratories receive revenue in limited circumstances. It is only when a hospital provides outreach services that a hospital laboratory receives revenues. In those instances, a hospital obtains specimens from physicians who see patients in their own offices or the patient comes to the hospital with a prescription and the hospital draws the specimen and then furnishes the test. In those circumstances, the hospital bills for the testing and is paid based on the Clinical Laboratory Fee Schedule or the Physician Fee Schedule, just as any independent laboratory is. In that case, there are identifiable revenues that are being paid to the hospital laboratory, and those are the revenues that should be considered in determining whether the hospital is an applicable laboratory subject to the PAMA reporting requirements. No portion of bundled Medicare payments made to a hospital for inpatient and outpatient care, which includes reimbursement for laboratory testing, is remitted from Medicare to the hospital's laboratory individually.

B. Exclusion of Specialty Laboratories

Independent clinical laboratories will need clear guidance about their reporting obligations, including whether they are required to report private payor rates. For example, specialty laboratories that receive the majority of their Medicare revenues as part of a Medicare bundled payment structure rather than a fee-for-service payment from the Clinical Laboratory Fee Schedule or Physician Fee Schedule, should not be subject to PAMA reporting requirements. Our interpretation is that dialysis specialty laboratories receiving the majority of Medicare revenues as

part of the end stage renal disease (ESRD) Prospective Payment System (PPS) are not subject to PAMA reporting requirements. ACLA seeks clear guidance that CMS agrees with this interpretation.

2. Payment and Coding for Existing Advanced Diagnostic Laboratory Tests (ADLTs)

PAMA established special payment and coding rules for certain "Existing ADLTs" paid for by the Medicare program. By January 1, 2016, the statute requires CMS to assign a unique HCPCS code for each Existing ADLT and publicly report the payment rate for each test. Due to the delay in rulemaking, there is risk this statutory deadline will be missed.

Currently, eight existing ADLTs applied for Category 1 CPT codes through an expedited "Existing ADLT" process established by the American Medical Association (AMA). These codes, which are listed below, clearly meet the statutory definition of an ADLT: a laboratory test offered and furnished solely by the original developing laboratory and the test is a multi-biomarker test of DNA, RNA, or proteins with a unique algorithm.

Vectra DA (Crescendo Bioscience)	81490
Corus CAD (Cardio Dx	81493
AlloMap (Care Dx)	81495
Oncotype DX Colon Cancer Assay (Genomic Health)	81525
Chemo FX (Helomics)	81535 + 81536
VeriStrat (Biodesix)	81538
CancerTYPE ID (bioTheranostics)	81540
Afirma Gene Expression Classifier (Veracyte)	81545

Due to the delay in rulemaking, these eight codes have been included on the 2015 Clinical Laboratory Public Meeting agenda. ACLA believes Existing ADLTs should not be included in the annual crosswalk or gapfill processes at the upcoming Clinical Laboratory public meeting. Instead, these test codes should have their local MAC contractor rates as of April 1, 2014 reported by HHS in accordance with the PAMA requirement and should enter the PAMA reporting period with other CLFS tests in 2016.

3. Data Collection

PAMA requires each applicable laboratory to report the payment paid by each private payor along with volume for each test during the defined reporting period. When an applicable laboratory has more than one payment rate for the same test, it is to report each such payment rate separately along with the volume. This data will then be used by CMS to calculate a weighted median. As we are sure you appreciate, creating the reporting structure for this process is a tremendously complex undertaking for CMS, and it will require collaboration between CMS and laboratories, as well as the creation of a technology platform capable of accepting and organizing millions of discrete data points. Certain aspects of laboratories' interactions with private payors may complicate the task further. While electronic payor remittances generally are received by laboratories in a HIPAA-compliant ANSI835 standard format, there are no standards for hard-copy remittance advices that laboratories receive from private payors. Where CMS's contractors have the ability to reject hard-copy claims that are filed either incompletely or otherwise not in accordance with CMS standards, there are no such format and content standards for hard-copy remittance advices, and laboratories do not have the ability to reject those that contain insufficient detail or are in unusual formats.

As laboratories prepare to comply with the reporting requirements, it has become clear that providing every payment rate for every test may in fact not be achievable and condensed timeframes will further exacerbate the situation. Just as existing reporting systems allow for the exclusion of certain data, we believe similar policies will be necessary for PAMA reporting. Allowing laboratories to exclude certain payments, in limited cases, would not lead to statistically significant changes in the weighted medians of all rates, but would greatly reduce the burdens of reporting for laboratories. Examples of payments that CMS should allow a laboratory to exclude from reporting if they so desire are:

- Manual remittances where CPT-level payment data is not captured, and the formatting of the hard-copy remittance advice is not conducive to OCR scanning of the data.
- Manual remittances where the payor has grouped test-level payments into an encounter-level (claim-level) payment.
- Payments that were made in error, which usually are corrected either in bulk or at a CPT-level or claim-level months after the incorrect payment was received.
- Bulk settlements, payments that include post payment activity such as recoupments, or other payments that are not reflected at the CPT level.

These types of payments reflect a small minority of overall payments to laboratories, and in fact, these payment are likely to be paid at a higher rate when compared to other private payor rates received by the laboratory. However, due to the complexity and difficulty of reporting these rates, we believe CMS should permit laboratories to exclude these types of payments from reporting if they choose to.

Conclusion

Thank you for your consideration of these important issues. We appreciate your willingness to work with us on PAMA implementation, and we look forward to discussing this with you in more detail.

Sincerely,

Julie Khani
Senior Vice President

Khani Declaration Exhibit 12

American Clinical Laboratory Association

Protecting Access to Medicare Act

Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule

November 4, 2015

AGENDA

American Clinical Laboratory Association

- Welcome & Introductions
- Review of Key Stakeholder Concerns
  - Key Definitions
  - Implementation Process & Timeline
  - Reporting Recommendations
- Comments & Questions
- Adjourn

Key Stakeholder Concerns

American Clinical Laboratory Association

- Key Definitions
  - Applicable Laboratory
  - Advanced Diagnostic Laboratory Test

Key Stakeholder Concerns

American Clinical Laboratory Association

- Applicable Laboratory
  - Statute
    - "a laboratory that, with respect to its revenues under [title XVIII of the Social Security Act], a majority of such revenues are from [the Physician Fee Schedule or the Clinical Laboratory Fee Schedule].
  - Proposed Rule
    - TIN level entity
  - **ACLA Recommendation**
    - **Define applicable laboratory by CLIA number**

Key Stakeholder Concerns

American Clinical Laboratory Association

Proposed Rule Will Result in Rates That Do Not Reflect Laboratory Market

Medicare Payments for Clinical Laboratory Services*, 2013 (millions)				
	Type of Lab Provider			
	Independent	Hospital	Other	Total
1. Part B Carrier/BMAC	$ 3,769	$ 133	$ 1,263	$ 5,165
2. Institutional Claims				
a. Separately-Paid OPPS excluded with lab services only		$ 1,474		$ 1,474
b. Non-Patient Claims (14X bill type)		$ 508		$ 508
c. Separately-Paid OPPS Excluded (claims include non-lab services)		$ 1,993		$ 1,993
Totals, Separately Paid Labs	$ 3,769	$ 4,108	$ 1,263	$ 9,140
Share	*41%*	*45%*	*14%*	*100%*

**Clinical laboratory services were identified using the 2013 Clinical Lab Fee Schedule (CLFS)*

Key Stakeholder Concerns

American Clinical Laboratory Association

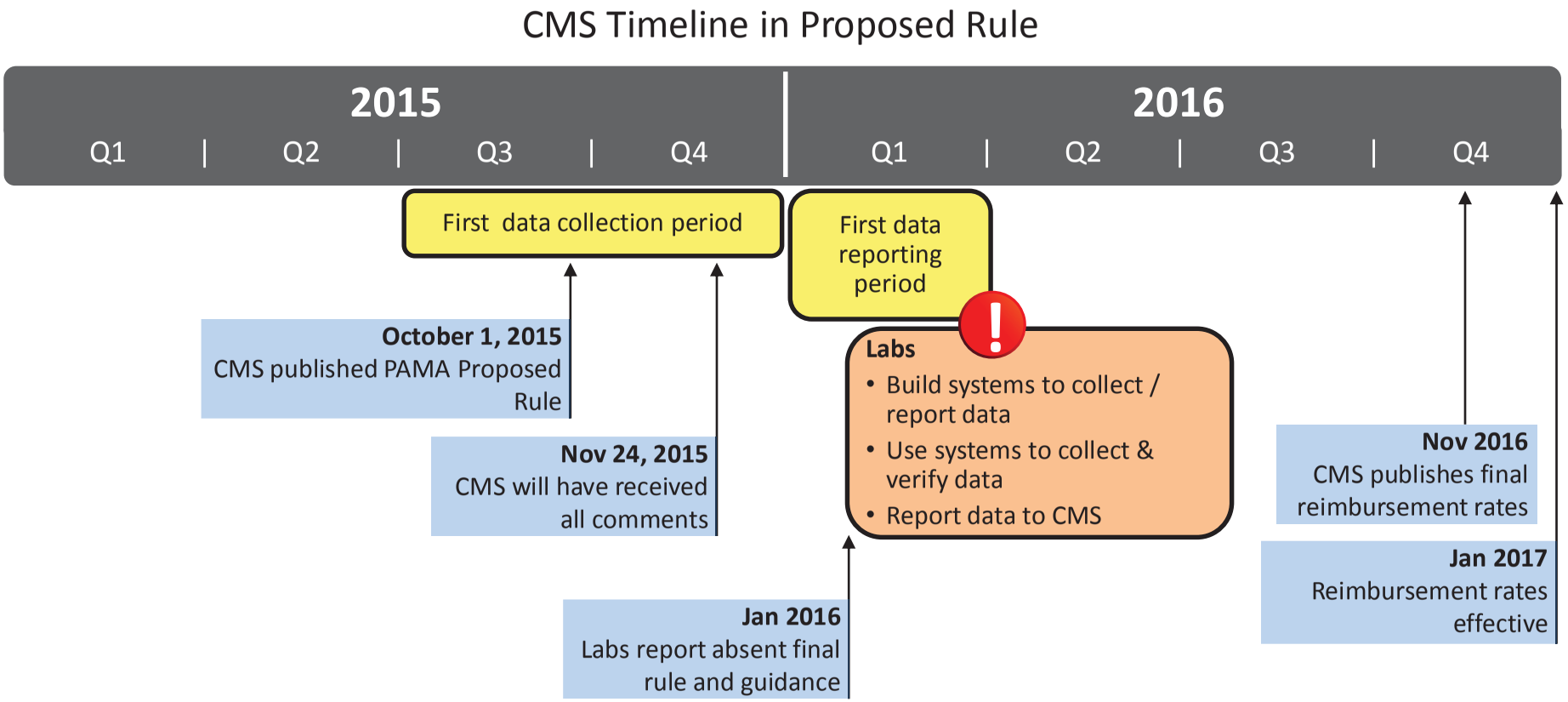
- Advanced Diagnostic Laboratory Test
  - Statute
    - "an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result"
  - Proposed Rule
    - "we interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA…a molecular pathology analysis of DNA or RNA"
  - **ACLA Recommendation**
    - **Define ADLT to include tests that are solely comprised of proteins.**

Key Stakeholder Concerns

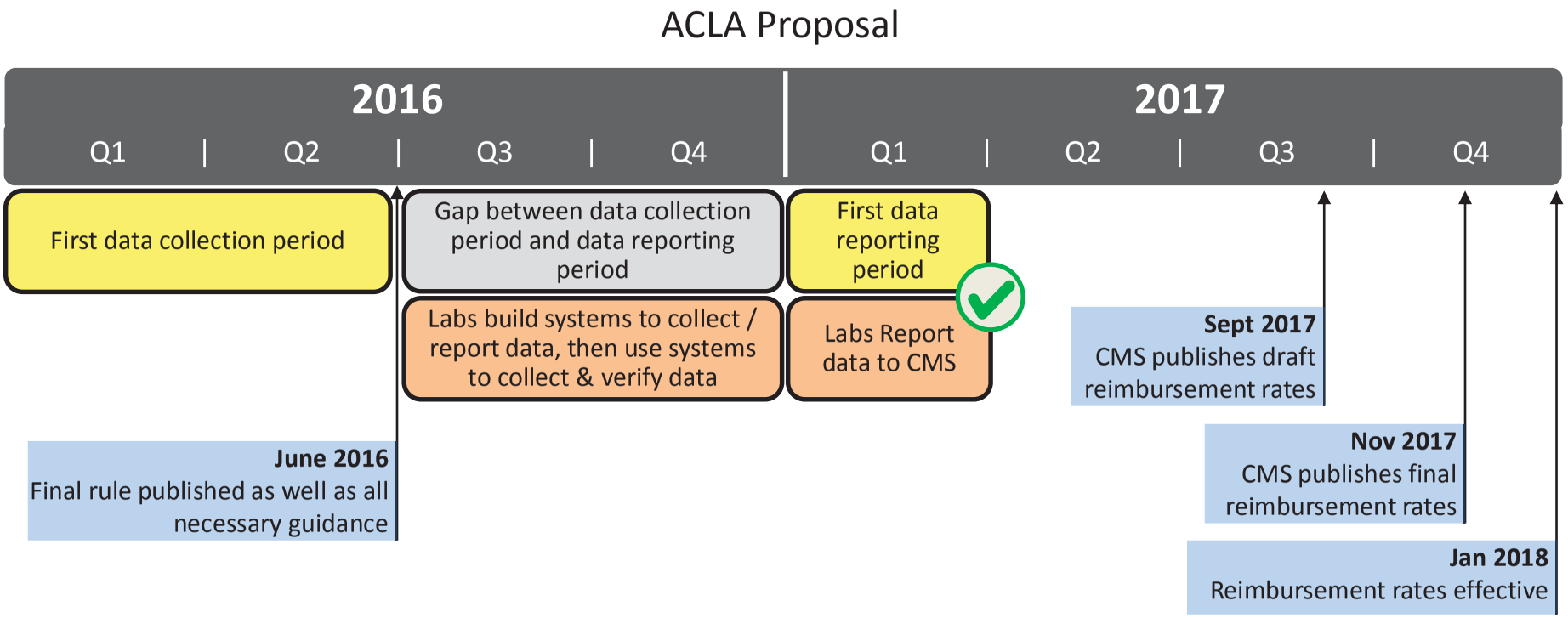
American Clinical Laboratory Association

- Implementation Process and Timeline
  - Laboratories unable to meet proposed timeline
  - Key issues unresolved
  - Insufficient time to build systems, collect and report data
  - Exposure to civil monetary penalties
  - Six months required to finish building systems, collect and verify data

Implementation Process and Timelines



Implementation Process and Timelines



- Time must be allowed for laboratories to use the Final Rule and necessary guidance to (a) finish building systems, and (b) use the systems to collect data
- A gap between the data collection period for the first cycle of PAMA data reporting will enable laboratories to have enough time to comply

Key Stakeholder Concerns

American Clinical Laboratory Association

- Reporting Recommendations
  - Report by TIN
  - Reporting period should not immediately follow collection period
  - Recognize limitations in reporting “every rate”

The simplest reporting will help ensure the most comprehensive market participation

Lab Organization Include tax ID list		
CPT	**rate**	**volume**
85025	$11.00	900,000
85025	$10.75	950,000
85025	$10.50	1,000,000
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hypothetical data

- One data file with three fields per applicable laboratory organization – CPT, rate & volume
- Volume (occurrences of the same rate) should carry the same weight, regardless of payor or tax ID, in the weighted median calculation
- A file uploading mechanism on the CMS website would allow for easy reporting
- File layout should be as simple as possible

American Clinical Laboratory Association

Thank You!

Comments and Questions

Khani Declaration Exhibit 13

American Clinical Laboratory Association

Protecting Access to Medicare Act

Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule

November 17, 2015

AGENDA

American Clinical Laboratory Association

- Welcome & Introductions
- Review of Key Stakeholder Concerns
  - Applicable Laboratories
  - ADLTs
  - Implementation Process & Timeline
  - Applicable Information
  - Reporting Recommendations
- Comments & Questions
- Adjourn

Key Stakeholder Concerns

American Clinical Laboratory Association

- Applicable Laboratory
  - Statute
    - "a laboratory that, with respect to its revenues under [title XVIII of the Social Security Act], a majority of such revenues are from [the Physician Fee Schedule or the Clinical Laboratory Fee Schedule].
  - Proposed Rule
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Key Stakeholder Concerns

American Clinical Laboratory Association

Proposed Rule Will Result in Rates That Do Not Reflect Laboratory Market

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Share	*41%*	*45%*	*14%*	*100%*

**Clinical laboratory services were identified using the 2013 Clinical Lab Fee Schedule (CLFS)*

Key Stakeholder Concerns

American Clinical Laboratory Association

- Applicable Laboratory
  - Low Medicare Revenue Threshold
    - Labs Furnishing New ADLTs
  - ESRD Laboratories
    - Small percentage of total Medicare revenue derived from separately billed tests payable under the CLFS.

Key Stakeholder Concerns

American Clinical Laboratory Association

- Advanced Diagnostic Laboratory Test
  - Statute
    - "furnished only by a single laboratory"
  - Proposed Rule
    - "an entity with multiple CLIA certificates would not be a single laboratory"
  - **ACLA Recommendation**
    - **For purposes of an ADLT, a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable.**

Key Stakeholder Concerns

American Clinical Laboratory Association

- Advanced Diagnostic Laboratory Test
  - Statute
    - "an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result"
  - Proposed Rule
    - "we interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA…a molecular pathology analysis of DNA or RNA"
  - **ACLA Recommendation**
    - **Define ADLT to include tests that are solely comprised of proteins.**

Key Stakeholder Concerns

American Clinical Laboratory Association

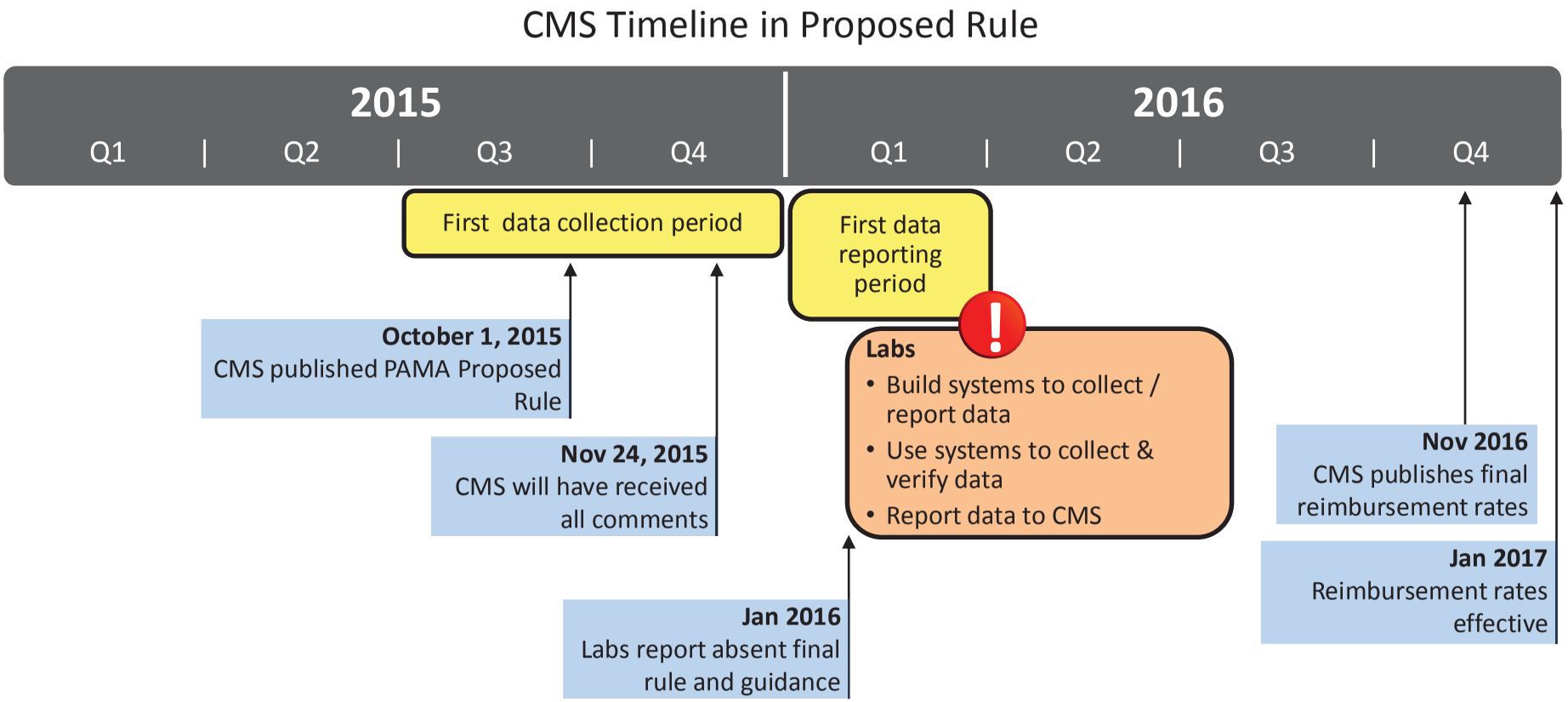
- Advanced Diagnostic Laboratory Test
  - Statute
    - "is combined with a unique algorithm to yield a single patient-specific result"
  - Proposed Rule
    - "provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests"
  - **ACLA Recommendation**
    - **Strike the additional "newness" requirements in the proposed rule; the algorithm must be unique to qualify as an ADLT.**

Key Stakeholder Concerns

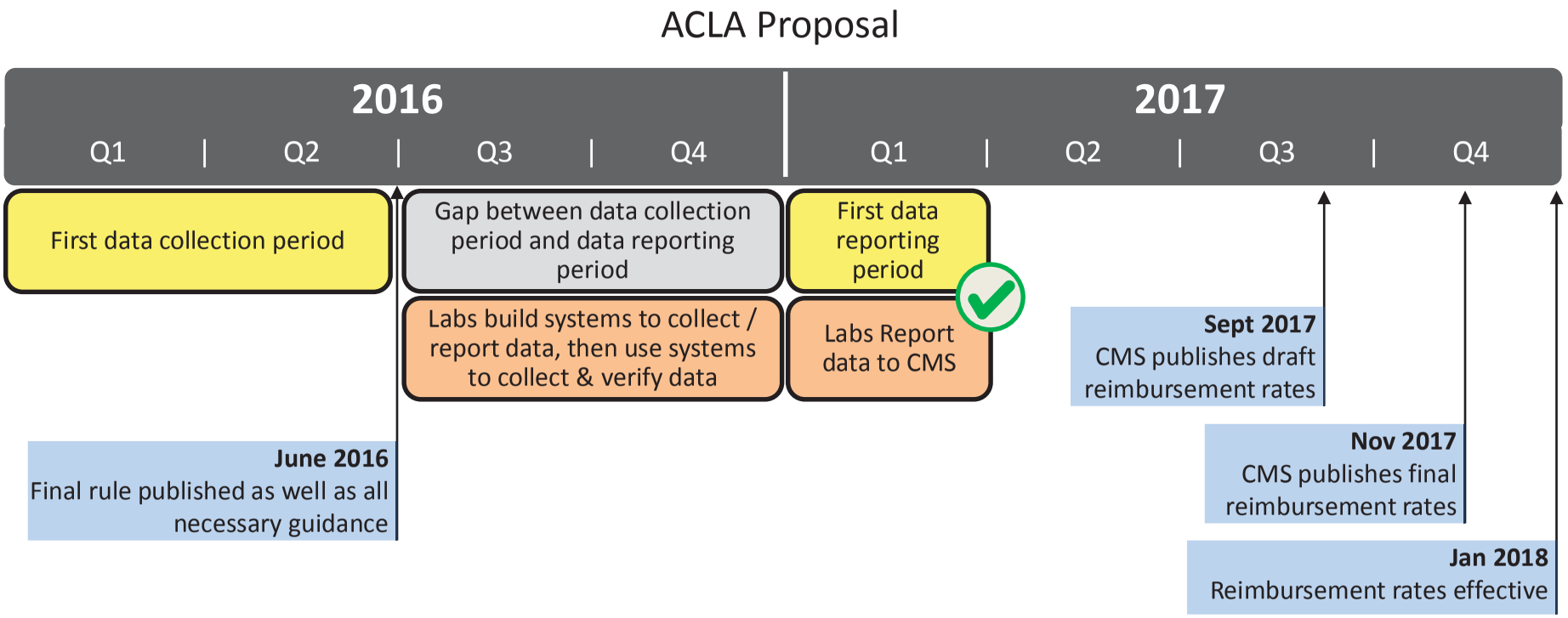
American Clinical Laboratory Association

- Implementation Process and Timeline
  - Laboratories unable to meet proposed timeline
  - Key issues unresolved
  - Insufficient time to build systems, collect and report data
  - Exposure to civil monetary penalties
  - Six months required to finish building systems, collect and verify data

Implementation Process and Timelines



Implementation Process and Timelines



- Time must be allowed for laboratories to use the Final Rule and necessary guidance to (a) finish building systems, and (b) use the systems to collect data
- A gap between the data collection period for the first cycle of PAMA data reporting will enable laboratories to have enough time to comply

Implementation Process and Timelines

ACLA Proposed Timeline

Initial data collection period	January 1, 2016 – June 30, 2016
Final rule has been published; data collection and reporting guidance has been finalized	June 2016
Labs build information systems to collect and report data; period between end of data collection period and beginning of data reporting period	July 2016 – December 2016
Initial data reporting period	January 1, 2017 – March 31, 2017
CMS publishes preliminary weighted median payment rates	September 2017
CMS publishes final weighted median payment rates	November 2017
Weighted median payment rates take effect	January 1, 2018

Key Stakeholder Concerns

American Clinical Laboratory Association

- Applicable Information
  - Lack of clarity in statute and proposed rule
  - **ACLA Recommendation**
    - **Final payment rates and volumes for tests furnished and paid during the data collection period**
  - Publication of HCPCS codes

Key Stakeholder Concerns

American Clinical Laboratory Association

- Reporting Recommendations
  - Report by TIN
  - Reporting period should not immediately follow collection period
  - Recognize limitations in reporting “every rate”

The simplest reporting will help ensure the most comprehensive market participation

Lab Organization Include tax ID list		
CPT	**rate**	**volume**
85025	$11.00	900,000
85025	$10.75	950,000
85025	$10.50	1,000,000
85025	$10.25	950,000
85025	$10.00	900,000
85027	$9.25	450,000
85027	$9.00	475,000
85027	$8.75	500,000
85027	$8.50	475,000
85027	$8.25	450,000
etc	etc	etc

hypothetical data

- One data file with three fields per applicable laboratory organization – CPT, rate & volume
- Volume (occurrences of the same rate) should carry the same weight, regardless of payor or tax ID, in the weighted median calculation
- A file uploading mechanism on the CMS website would allow for easy reporting
- File layout should be as simple as possible

American Clinical Laboratory Association

Thank You!

Comments and Questions

Khani Declaration Exhibit 14

American
Clinical Laboratory
Association

November 23, 2015

Mr. Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare Program; Medicare Clinical Diagnostic Laboratory Test Payment System (CMS-1621-P)

Dear Mr. Slavitt,

Please accept the comments of the American Clinical Laboratory Association ("ACLA") on the above-referenced proposed rule.[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing services are developed openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

Since Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA") and President Obama signed it into law, ACLA has been actively engaged in discussions with the Centers for Medicare and Medicaid Services ("CMS") about implementation of Section 216 of the law. That section revamps the way that clinical laboratory tests are to be priced on the Clinical Laboratory Fee Schedule ("CLFS"), the first major overhaul of the fee schedule in three decades. All ACLA members will be impacted greatly by implementation of this law, and we appreciate the opportunity to share our thoughts, concerns, and suggestions.

Summary of ACLA's Comments

"Applicable laboratory". For purposes of determining which entities are "applicable laboratories" and are required to report private payor data to CMS, ACLA believes that the agency should define the term in a way that includes all laboratories that derive a majority of their Medicare revenues from the CLFS and Physician Fee Schedule ("PFS"). For this reason, ACLA strongly disagrees with CMS's current proposal to define an "applicable laboratory" as the taxpayer identification number-level ("TIN-level") entity with which all of its National Provider Identifier ("NPI") entities are associated. A TIN-level definition by itself would not capture all such laboratories or result in CLFS rates that reflect the market for laboratory tests in the United States, which was the underlying purpose of Section 216 of PAMA. In 2014, fully one quarter of Medicare Part B spending on clinical laboratory tests was for tests performed by hospital laboratories, yet CMS's proposal would have the effect of excusing virtually all hospitals from reporting their private payor data. CMS itself has recognized that hospital laboratories are acting as independent laboratories when providing outreach services, and

[1] 80 Fed. Reg. 59386 (Oct. 1, 2015).

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hospital laboratories performing outreach testing will be paid at the new prices that CMS establishes, so CMS should ensure that such hospital laboratories are included among "applicable laboratories" for purposes of PAMA's reporting requirements. Since each laboratory is identified by a CLIA number, we believe that it is the best approach for defining "applicable laboratory". It would allow the "majority of Medicare revenues" test to be applied to the laboratory's Medicare revenue, rather than to the entire entity's Medicare revenue. As an alternative, ACLA recommends an approach that would allow a hospital to determine what portion of its overall Medicare revenues are attributable to the hospital laboratory and to determine whether or not the hospital laboratory itself derives a majority of its Medicare revenues from the CLFS and/or PFS.

Data collection period and data reporting period. Because of the delay in issuance of the proposed rule to implement PAMA, and because it is unlikely that CMS will issue a final rule until sometime well into 2016, the agency should amend its timeline for the initial data collection period, initial data reporting period, and the date on which the weighted median payment rates first take effect. ACLA recommends an initial data collection period that spans the first six months of 2016 (January 1 through June 30) and an initial data reporting period from January 1, 2017 through March 31, 2017. The weighted median rates that CMS calculates should take effect on January 1, 2018. This would provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS and adequate time to collect and report the information, and it would give CMS enough time to process the information and calculate new rates and to publish the new rates at least 60 days prior to their effective date. Subsequent data collection periods also should span six months, which we believe will provide CMS with sufficient data to calculate weighted median rates that accurately reflect the private payor market. There should be six months in between each data collection period and data reporting period to allow applicable laboratories time to extract the information from their billing systems and verify the accuracy of the data.

"Applicable information". An applicable laboratory should report information about tests both that it furnishes during the data collection period and for which it receives final payments during the data collection period, from the first day of the data collection period to the last day of the data collection period. The private payor rates that an applicable laboratory reports should be the final total approved payment rates for tests furnished during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. Certain payments should be excluded from "applicable information," such as hard copy (manual) remittances, payments made in error, payments that do not reflect specific HCPCS code-level amounts, secondary insurance payments, and other similar payments. CMS should allow a measure of flexibility regarding the entity that reports applicable information on behalf of an applicable laboratory and allow applicable information to be reported at the TIN-level, the NPI-level, or the CLIA number-level.

ADLTs. ACLA disagrees with the definition that CMS has proposed for an advanced diagnostic laboratory test ("ADLT") because it does not reflect the text of the statute or Congress' intent. We have provided alternatives to CMS's proposals to define a "single laboratory" as one with a single CLIA certificate, to disqualify protein-based biomarker tests

from qualifying as ADLTs, and to require that an ADLT be a test that provides new clinical information that cannot be derived from any other test or procedure currently available. We believe that an application to qualify as an ADLT should require only publicly-available information, which would be sufficient for CMS to make a determination about whether a test is an ADLT. With regard to payment for new ADLTs, ACLA believes that the start of the "initial three quarters" during which a laboratory offering and furnishing an ADLT is paid the actual list charge for the test should be the first calendar quarter after the first day that Medicare pays for the ADLT, rather than the calendar quarter after the first day that the new ADLT is performed. Under CMS's proposal, a laboratory offering and furnishing a new ADLT likely would have very few payments from private payors to report to CMS by the end of the second quarter, and in many cases, the laboratory would never be paid at the actual list charge by Medicare.

Coding. A unique HCPCS code should be assigned for an ADLT or an FDA-cleared or -approved test if a laboratory or manufacturer requests a unique code, but CMS should not automatically issue a new code for every distinct existing ADLT or FDA-cleared or -approved test. ACLA prefers for the American Medical Association's ("AMA's") Common Procedural Terminology ("CPT") Editorial Panel to assign HCPCS codes to ADLTs and FDA-cleared or -approved tests, instead of CMS assigning HCPCS codes to the tests, because G-codes are viewed as Medicare-only codes by other payors and generally are not accepted.

Data integrity. CMS should create a certification form for applicable laboratories to submit with information they report that includes the following language: "All information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith." Given that most laboratory Presidents, CEOs, and CFOs are not personally familiar with the volume and private payor rates for each laboratory test their labs offer, a laboratory officer should be expected to certify only to his or her good-faith belief in the data's integrity and that he or she does not have any information to the contrary.

Subregulatory guidance. ACLA believes that it is impermissible for CMS to issue subregulatory guidance interpreting the various provisions in PAMA until the agency has issued the final rule. Much of the subregulatory guidance by necessity requires resolution in the final rule of certain issues, such as the meanings of "applicable laboratory," "applicable information," and "private payor rate." CMS cannot resolve those issues until it has had the opportunity to review all stakeholder comments and publish a final rule. Until all terms are defined and other issues are resolved, it is not appropriate for CMS to issue subregulatory guidance.

ACLA's Comments

I. Definition of "Applicable Laboratory"

As defined in the statute, an "applicable laboratory" means a laboratory that receives a majority of its Medicare revenues under the new section 1834A of the Social Security Act, the CLFS, or the PFS.[2] CMS proposes that an "applicable laboratory" would mean an entity that reports tax-related information to the Internal Revenue Service under a TIN with which all of the

[2] 42 U.S.C. § 1395m-1(a)(2).

NPIs in the entity are associated. An applicable laboratory either itself would be a laboratory, as defined in 42 C.F.R. § 493.2, or, if it is not itself a laboratory, would have at least one component that is. In a data collection period, an applicable laboratory would receive, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from either the CLFS or PFS.[3]

A. CMS's Proposal for Identifying an "Applicable Laboratory"

Under the proposed rule, an "applicable laboratory" would be a TIN-level entity that derives more than 50 percent of its entire Medicare revenues from the CLFS or PFS. ACLA strongly disagrees with this proposed definition of "applicable laboratory" because, in its current form, it is inconsistent with the statutory definition and would not result in CLFS rates that reflect the market for laboratory tests in the United States, which was the underlying purpose of Section 216 of PAMA. The proposed definition, coupled with the proposed low-revenue threshold, would remove the overwhelming majority of hospital laboratories and physician office laboratories from the entities reporting private payor rates, and it would remove more than half of all independent laboratories from reporting.

We vehemently disagree with CMS's inaccurate assumption that "the statute intends to limit reporting primarily to independent laboratories and physician offices…and not include other entities (such as hospitals, or other health care providers)…" Rather, Congress intended that all sectors of the laboratory market are to be represented in private payor rates reported to CMS, including hospital outreach laboratories.[4] If Congress meant to exclude all hospitals from the universe of "applicable laboratories," it easily could have done so directly, but it did not. It is reasonable for hospital laboratories with robust outreach programs to report private payor data to CMS because, as CMS itself has noted, "when a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory."[5] Since hospital outreach laboratories are competing directly with independent laboratories, it is appropriate to include them among the entities reporting private payor data so CMS can obtain information about the entire laboratory market.

By not including hospitals among "applicable laboratories," CMS would exclude a significant part of the laboratory market. The Department of Health and Human Services Office of Inspector General ("OIG") found that in 2014, fully one quarter of Medicare Part B spending on clinical laboratory tests was for tests performed by hospital laboratories, and an independent analysis for ACLA by the Moran Company of 2013 Medicare CLFS expenditures reached the

[3] 80 Fed. Reg. 59394.

[4] *Id*. at 59393. Congress's intent was made explicit in a colloquy between Sen. Richard Burr (R-NC), a member of the Senate Finance Committee, and Sen. Orrin Hatch (R-UT), Ranking Member of that committee. *See* 160 Cong. Rec. S2860 (daily ed. May 8, 2014). Sen. Burr noted that it was his understanding that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule." Sen. Hatch agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."

[5] Medicare Claims Processing Manual, Pub. No. 100-04, Ch. 16, § 10.1.

same conclusion about the share of expenditures for services furnished by hospital laboratories and paid under the CLFS.[6] Significantly, the statute specifically applies the payment rates that CMS calculates to hospitals providing outreach services.[7] It is reasonable that these hospital laboratories should be included among "applicable laboratories" for purposes of PAMA's reporting requirements.

CMS suggests in the proposed rule that even though its TIN-level definition of "applicable laboratory" would prohibit reporting of private payor rates by the vast majority of hospital laboratories, physician office laboratories, and independent laboratories, its definition would be appropriate because the majority of Medicare spending for and utilization of laboratory services still would be represented by those laboratories required to report. But CMS's proposal completely misses the point of Section 216 of PAMA, which is to calculate new CLFS rates based on the weighted medians of the broad spectrum of price points in the private market. The fact that laboratories required to report under CMS's proposal may represent the majority of Medicare spending and utilization of laboratory services says nothing about the spectrum of price points in the market that those reporting laboratories would represent.

CMS also considered using the NPI as a criterion for defining an "applicable laboratory." ACLA disagrees with this approach for the same reasons that it disagrees with CMS's proposal for identifying an "applicable laboratory" at the TIN-level. Since HIPAA covered entities have significant flexibility in how they enumerate their organizations with NPIs, not all laboratories are identified separately by an NPI. Very few hospital laboratories have laboratory-specific NPIs – even those with robust laboratory outreach programs – and they generally submit claims under the hospital's NPI. Defining "applicable laboratory" at the NPI level would lead to the same result in most cases as defining the term at the TIN-level, as proposed: the "majority of Medicare revenues" test would be applied to the entire entity's revenue, rather than to the laboratory's revenue.

Determining the source of a majority of a laboratory's Medicare revenue need not – and should not – include an analysis of an entire entity's Medicare revenue, because Medicare revenue outside of the laboratory is not relevant to whether a laboratory is an "applicable laboratory" under the statute. As crafted, CMS's proposal to apply the "majority of Medicare revenues" test at the TIN level would result in reviewing the source of Medicare revenue received by portions of the entity that are far removed from laboratory services. For example, a hospital identified by a TIN may have as one component a laboratory with a robust laboratory outreach program, a significant portion of whose test volume is reimbursed under the CLFS. While a large portion of the hospital laboratory's revenue will be derived from the CLFS and/or

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[6] *See* Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data (OEI-09-15-00210) at 4, *available at* http://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf; *see also* Appendix A. In the CY 2016 Hospital Outpatient Prospective Payment System ("OPPS") final rule, CMS recognized that a large volume of hospital laboratory tests is paid under the CLFS. It said that because hospital laboratory expenditures under the CLFS in CY 2014 were $1 billion more than the agency anticipated, it would include a two percent cut in the conversion factor in 2016 to offset those expenditures.

[7] 42 U.S.C. § 1395m-1(b)(1)(B) ("The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately and not as part of a bundled payment under section 1833(t).").

PFS, a TIN-level analysis of the hospital's Medicare revenue will include significant reimbursement that is not relevant to the laboratory's reimbursement under the CLFS (*e.g.*, surgery, radiology, oncology, intensive care). Under CMS's proposed TIN-level analysis, the agency would not be able to determine whether a majority of the laboratory's Medicare revenue is derived from the CLFS and/or PFS, as called for in the statute.

B. ACLA's Proposal for Identifying an "Applicable Laboratory"

We believe that defining "applicable laboratory" as a facility that is identified by a CLIA number would be the most accurate reflection of Congress' intent: to receive information about private payor rates for those laboratories that derive a majority of their Medicare revenues from the CLFS and/or PFS. Every laboratory is identified by a CLIA number, and CMS recognized the utility of the CLIA number when it proposed to define "laboratory" by reference to the definition in regulations implementing CLIA, which focuses on the laboratory facility itself and not the larger entity of which it may be a part. While a "CLIA-number" approach would allow an analysis of a laboratory's Medicare revenues at the most granular level, ACLA understands that this approach may be problematic to the agency.

In the event that CMS decides not to define "applicable laboratory" as a facility identified by a CLIA number, ACLA proposes an alternative approach that would facilitate an analysis of a hospital laboratory's Medicare revenues to determine whether a majority of such revenues are derived from the CLFS and/or PFS. Naturally, independent laboratories and physician office laboratories derive the majority of their Medicare revenues from the CLFS and/or PFS, but it may be less obvious when a hospital laboratory derives a majority of its Medicare revenues from those sources. To determine whether a majority of a hospital laboratory's Medicare revenues are from the CLFS and/or PFS, first it is necessary to identify the "universe" of Medicare revenues paid to the hospital for laboratory services. These are:

1. Laboratory services furnished to inpatients, which are paid as part of the hospital's Medicare Severity-Diagnosis Related Group ("MS-DRG") payments;

2. Laboratory services furnished to outpatients, which are paid as part of the hospital's Ambulatory Payment Classification ("APC") payments, with certain exceptions;

3. Laboratory services furnished to non-patients, which are paid under the CLFS or PFS, as applicable; and

4. Laboratory services furnished to outpatients who receive only those laboratory services on the date of service, which are paid under the CLFS or PFS, as applicable.

In the last two circumstances above, a hospital laboratory acts as an independent laboratory: when it furnishes services to non-patients, and when it furnishes services to outpatients who receive no other hospital services on the same day. In one circumstance, the services are identical to services furnished by an independent laboratory. In the other

circumstance, an outpatient goes to a hospital for a blood draw and the testing is performed there; this is analogous to a physician directing a patient to get blood drawn at an independent laboratory's patient service center, which then forwards the specimen to the laboratory for testing. In both circumstances, the hospital receives separate payment under the CLFS or PFS, as applicable, for the services. Hospital laboratories with many such services have significant laboratory outreach businesses, compete directly with independent laboratories, and should be required to report their private payor rates to CMS.

The statute applies the "majority of Medicare revenues" test to a laboratory's Medicare revenues,[8] rather than to an entire entity's revenue. While it is obvious that hospital laboratory services paid for under the CLFS or PFS are "Medicare revenues" to the laboratory, it is more difficult to identify laboratory revenues when the laboratory services are included in bundled payments (MS-DRG and APC payments) received by the TIN-level entity. ACLA proposes that CMS should require hospitals to use a basic calculation to determine what portion of the bundled Medicare payments received at the TIN-level are attributable to laboratory services.

Working with the Moran Company, we developed an approach to determine the portion of a hospital's overall Medicare revenues that is attributable to laboratory services. We applied the national hospital payment-to-charges ratio to the laboratory services billed by all hospitals to determine the approximate percentage of revenues paid to hospital for all inpatient and outpatient hospital laboratory services. (We used the 2013 data for this calculation because it was the most recent and complete data set available.)[9] We added other separately-paid laboratory revenues, such as for services furnished to non-patients. That gave us the total amount paid for laboratory services for hospitals in 2013. We then divided that number by the total Medicare expenditures for hospital services to determine what percentage of total hospital Medicare revenues are hospital laboratory-related Medicare revenues. Based on the Moran Company's analysis, this percentage is 6 percent.[10]

To determine whether a hospital is an "applicable laboratory" for purposes of PAMA, the hospital would determine what portion of its total hospital laboratory Medicare revenues were represented by its outreach services (CLFS and PFS services). First it would determine its hospital laboratory Medicare revenues by multiplying its total inpatient and outpatient Medicare revenues by 6 percent,[11] and it then would add that revenue to its Medicare revenue for individually-paid laboratory services (the "denominator"). It then would total its CLFS and PFS revenues (the "numerator"). It would divide the sum of its CLFS and PFS revenues by the total hospital laboratory Medicare revenues. If the result is 50 percent or greater, the hospital,

[8] 42 U.S.C. § 1395m-1(a)(2) ("[T]he term 'applicable laboratory' means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, [the CLFS, or the PFS].").
[9] CMS could use the same process to determine the adjustment factor using 2014 data if it is available when the final rule is issued.
[10] A more detailed description of this methodology is shown in Appendix B.
[11] For an explanation of why this should not include Medicare Advantage payments under Medicare Part C or prescription drug payments under Medicare Part D, please see Section I.D, below.

together with all of its hospital laboratories identified by CLIA numbers, would be an "applicable laboratory."[12] The equation is below:

Hospital Laboratory Revenues from CLFS/PFS

$$\frac{\text{CLFS revenues + PFS revenues}}{\text{(0.06 * (MS-DRG and APC payments)) + CLFS revenues + PFS revenues}} = \text{\% of Medicare rev. from CLFS + PFS}$$

The following is an illustration of how this equation would be applied to a hospital laboratory's Medicare revenues.

Example: XYZ Hospital

Inpatient revenues	$125 million	Apply 6 % adjustment factor	$7.5 million
Outpatient revenues	$50 million	Apply 6 % adjustment factor	$3 million
Non-patient lab revenues	$8 million		$8 million
Non-bundled outpatient laboratory revenues	$4 million		$4 million
Total outreach services (CLFS + PFS)			$12 million
Total hospital lab revenues			$22.5 million
Percentage of total laboratory Medicare revenues from CLFS and PFS			53 %

In this example, because more than 50 percent of XYZ Hospital's laboratory Medicare revenues are from the CLFS and PFS, it would be considered an "applicable laboratory" and would report its private payor rates to CMS.

We recognize that this analysis requires the development of an adjustment factor to determine hospital laboratory Medicare revenues. Therefore, a hospital would be permitted to use its actual revenues and payment-to-charges ratio to show that its Medicare revenues from the CLFS and/or the PFS were more or less than 50 percent of the hospital laboratory's total

[12] This is consistent with CMS's proposal that the determination of whether an entity is an "applicable laboratory" would be made across the entire entity. *See* 80 Fed. Reg. 59393.

Medicare revenues or it could use the 6 percent adjustment factor, which would be a "safe harbor" for purposes of this calculation. A hospital also could show that it did not meet the low Medicare revenue threshold and is excluded from reporting. CMS could spot-check hospitals for compliance with reporting requirements, as the agency would have all the information required to perform the calculation itself.

ACLA believes that under this approach, many hospitals would not qualify as applicable laboratories, but the calculation would capture those hospitals with significant laboratory outreach programs. We believe this approach is a good compromise and serves all stakeholders' needs. It reflects Congress' intent to capture data from all laboratories with a majority of their Medicare revenues coming from the CLFS and/or PFS, including hospitals with significant laboratory outreach programs. It is consistent with the purpose of the statute, in that it would lead to reporting by all significant participants in the laboratory market. It is fair to hospitals, including in reporting only those hospitals whose laboratories compete directly with independent laboratories. We strongly urge CMS to adopt this approach for defining which hospitals are "applicable laboratories."

C. Low Medicare Revenue Threshold

CMS has proposed that an entity that otherwise would be an applicable laboratory, but that has less than $50,000 in Medicare revenues from the CLFS during a 12-month data collection period, would not be required to report (the amount would be $25,000 for the first six month data collection period). With one exception, ACLA does not object to this low revenue threshold. This low revenue threshold should not apply to those applicable laboratories that offer and furnish new ADLTs. Under PAMA, a laboratory with a new ADLT is paid at an "initial list price" for a period of three quarters and then at the weighted median of reported prices. A laboratory offering a new ADLT must report its prices prior to the end of the second quarter. It may be that the laboratory will have less than $50,000 in Medicare CLFS revenues by the time it must report private payor rates. If it is excluded from reporting by the low revenue threshold, then the new ADLT may be priced through crosswalking or gapfilling and negate the very intention of the law. Given that Congress clearly intended for new ADLTs to be priced based on reported private payor rates, it would be inappropriate to exclude a laboratory offering a new ADLT if it did not meet the low revenue threshold. It is more reasonable simply not to apply the low revenue threshold to applicable laboratories offering and furnishing new ADLTs.

If CMS does apply a low revenue threshold to laboratories offering and furnishing new ADLTs, it should be consistent with the low revenue threshold for the initial data collection period ($25,000 in Medicare revenues under the CLFS), as each of those data collection periods are just six months long, rather than a year.

D. Medicare Revenues

In the preamble to the proposed rule, CMS said it would define "Medicare revenues" as "payments received from the Medicare program, which would include fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary

deductible or coinsurance amounts for Medicare services furnished during the data collection period."[13]

CMS should remove from its proposed definition "Medicare Advantage payments under Medicare Part C," because those payments are included among the private payor payments about which applicable laboratories would report applicable information.[14] These payments cannot be both "Medicare revenues" and "private payor" payments at the same time. CMS also should remove from the proposed definition "prescription drug payments under Medicare Part D" because under no circumstances would such payments be related to laboratory testing.

E. Prohibition on Reporting

Oddly, the agency proposes to prohibit any entity that does not meet the definition of "applicable laboratory" from reporting applicable information, a prohibition that does not appear in the statute, that is not inferable from the statute, and that could be detrimental to achieving the goal of acquiring applicable information in the most efficient and effective manner possible. CMS does not say whether or how it would enforce this prohibition; while the regulatory text includes the possibility of civil monetary penalties ("CMPs") for failure to report or for misreporting data, there are no penalties proposed for violating this "prohibition." A laboratory that does not have to report private payor data to CMS and have an officer of the company certify to the accuracy and completeness of the data is extremely unlikely to do so, but in the event that such laboratories may be subject to the new CLFS rates resulting from this process, they should not be prohibited from contributing to the data on which such new rates are to be based. Further, an entity that is not itself an applicable laboratory, but that can report applicable information from any applicable laboratories it owns or controls more efficiently and effectively than the applicable laboratories themselves, should be permitted to do so. CMS should remove this language from the proposed regulatory text at 42 C.F.R. § 414.504(g).

F. End Stage Renal Disease Laboratories

CMS should use its authority under 42 U.S.C. § 1395m-1(a)(2) to establish a low-volume threshold that would exclude end-stage renal disease ("ESRD") laboratories – dialysis specialty laboratories – from the definition of "applicable laboratory." ESRD laboratories provide services primarily for patients receiving chronic renal dialysis treatments in ESRD facilities. Approximately 85 percent of patients with ESRD are covered under the Medicare ESRD benefit. These dialysis specialty laboratories receive a small minority of their Medicare revenues from the CLFS. This is because almost all ESRD-related laboratory testing is bundled into a per-patient payment that Medicare pays directly to the dialysis facility, and the ESRD laboratory is paid by the dialysis facility for the bundled laboratory services they furnish to Medicare beneficiaries. The only Medicare revenues ESRD laboratories receive directly are for laboratory tests that are not related to renal disease. Because of the anomaly in the way ESRD laboratories are paid, the non-ESRD-related laboratory tests they furnish would be their only "Medicare revenues," as CMS has proposed defining that term. This minority of non-ESRD-related

[13] 80 Fed. Reg. 59392.
[14] *See* 42 U.S.C. § 1395m-1(a)(8)(B).

laboratory tests that they furnish to Medicare beneficiaries would result in them being considered "applicable laboratories," although they have little private payor data to report.

The statute does not establish any parameters for the type of low-volume threshold that CMS may establish to exclude a laboratory from the definition of "applicable laboratory." It leaves it up to the agency's discretion to determine what threshold is appropriate. CMS would be acting within its authority if it established a low-volume threshold that excludes specialty laboratories like ESRD laboratories that furnish laboratory services to only certain types of patients and that receive a small amount of "Medicare revenues" from the CLFS.

II. Data Collection Period and Data Reporting Period

The statute calls for the Secretary to define a "data collection period", and it calls for an applicable laboratory to report applicable information for the data collection period "beginning January 1, 2016."[15] The statute also calls for CMS to have issued a final rule to implement data collection and reporting by June 30, 2015. CMS did not issue a proposed rule until several months after that deadline, and ACLA believes that it is virtually impossible for the agency to issue a final rule by January 1, 2016, which was supposed to be the start of the initial data reporting period. In light of this, we comment specifically on the timing of the first data collection period and first data reporting period, and more generally on subsequent data collection periods and data reporting periods.

A. Initial Data Collection Period and Initial Data Reporting Period

CMS proposes that the first data collection period would be six months long, running from July 1, 2015 through December 31, 2015. It proposes that the first data reporting period would be three months long, starting on January 1, 2016 and running through March 31, 2016.[16] The agency proposes to "specify the form and manner for reporting applicable information in guidance prior to the first data reporting period" and that "applicable information must be reported in the form and manner specified by CMS."[17]

Some aspects of CMS's proposed data collection and reporting schedule may have been achievable if the agency had issued a final rule by the June 30, 2015 deadline set by Congress in Section 216 of PAMA. However, because CMS did not issue even a proposed rule by the June 30, 2015 deadline, the agency's proposed timeline is unrealistic. Laboratories should not bear the burden of the agency's failure to meet the statutory deadline.

The agency has stated that in determining what the data collection and reporting periods should be, its objectives were to "(1) Provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS; (2) allow applicable laboratories enough time to collect and report applicable information; (3) give CMS enough time to process applicable information to determine a CLFS payment rate for each laboratory test; and (4)

[15] 42 U.S.C. § 1395m-1(a)(1).
[16] 80 Fed. Reg. 59400.
[17] *Id*. at 59401.

publish new CLFS payment rates at least 60 days in advance of January 1 so laboratories will have sufficient time to review the data used to calculate CLFS payment rates and prepare for implementation of the new CLFS payment rates on January 1."[18] ACLA agrees with these objectives, and as such, we are recommending the schedule below that will enable all stakeholders to accomplish these objectives in a reasonable timeframe. As discussed in more detail below, for the initial data collection period and data reporting period, ACLA recommends the following:

Initial data collection period	January 1, 2016 – June 30, 2016
Final rule has been published; data collection and reporting guidance has been finalized	June 2016
Labs build information systems to collect and report data; period between end of data collection period and beginning of data reporting period	July 2016 – December 2016
Initial data reporting period	January 1, 2017 – March 31, 2017
CMS publishes preliminary weighted median payment rates	September 1, 2017
CMS publishes final weighted median payment rates	November 1, 2017
Weighted median payment rates take effect	January 1, 2018

Final rule and data collection and reporting guidance: The comment period for the proposed rule does not close until November 24, 2015, and it seems impossible for CMS to have issued a final rule by January 1, 2016 (the proposed start of the initial data reporting period). ACLA's recommended timeline is based on the reasonable assumption that CMS will not have published a final rule and final guidance on data collection and reporting until sometime well into 2016.

There is some suggestion in the proposed rule that CMS intends to issue subregulatory guidance prior to the issuance of a final rule, and it may even require applicable laboratories to report private payor rates prior to publication of the final rule, based on such subregulatory guidance. To be clear, ACLA believes that it is impermissible for CMS to issue subregulatory guidance interpreting various aspects of PAMA until it has issued the final rule. Much of the subregulatory guidance by necessity requires resolution in the final rule of certain issues, such as the meanings of "applicable laboratory," "applicable information," and "private payor rate." CMS cannot resolve those issues until it has had the opportunity to review all stakeholder comments and publish a final rule. Until all terms are defined and other issues are resolved, it is not appropriate for CMS to issue guidance on reporting and it certainly would not be possible for laboratories to comply. In the absence of a final rule and subregulatory guidance that reflects the substance of the final rule, laboratories cannot know whether they are required to report private payor data, what data they are to report to CMS, for what time period, and in what format.

[18] *Id.* at 59399.

It is reasonable to assume that it will take CMS until well into 2016 to complete the final rule and any subregulatory guidance. It is difficult to see how the new payment rates could go into effect on January 1, 2017. We recognize that this will mean that the schedule set out in the statute will not be met, owing primarily to the delay in the issuance of the proposed rule. This should not result in any serious legal consequences, as more time is necessary to implement the law than Congress may have anticipated.[19]

Period between final rule and initial data reporting period: The agency seeks to "provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS" and "allow applicable laboratories enough time to collect and report applicable information." To meet these objectives, laboratories need a period of at least six months between publication of the final rule and the start of the initial data reporting period. Congress contemplated this six month gap when it called for CMS to issue a final rule by June 30, 2015 and for data reporting to begin on January 1, 2016.[20] It will take time for laboratories to read and understand the final rule and their obligations under it, determine what "applicable information" they are required to collect, design and program internal information collection systems that meet the requirements of the final rule, troubleshoot, extract the information from their billing systems, and verify the accuracy of the data. Larger laboratories may be challenged by the sheer volume of data they must collect and report for each payor and test code, while smaller and medium-sized laboratories may have yet to develop information technology, coding, and/or billing resources equal to the task. We emphasize that the programming tasks associated with extracting the required information will be monumental, and those tasks must be completed while companies also are using their computer systems for routine functions such as submitting claims and posting and reconciling payments. Further, although many laboratories have begun to design the necessary programs to extract the required information from their billing systems, nothing can be finalized until CMS issues a final rule and any subregulatory guidance. In short, it is not reasonable for the data reporting period to start immediately after the release of a final rule (and certainly not before a final rule and any subregulatory guidance are released), as is envisioned in the proposed rule.

Initial data collection period: Given the amount of time it typically takes to finalize a rule this complex and ACLA's proposal for an initial data reporting period that begins at least six months after a final rule, we believe the initial data collection period should be January 1, 2016 through June 30, 2016. ACLA supports CMS's proposal that the first data collection period would span six months, both for clinical diagnostic laboratory tests ("CDLTs") and ADLTs. As we have conveyed to CMS in the past, we believe the agency should require laboratories to

[19] For example, Congress directed CMS to implement the Inpatient Rehabilitation Facility Prospective Payment System, effective for cost reporting periods beginning on or after October 1, 2000, yet CMS did not issue a final rule until August 7, 2001, and the rule was not effective until January 1, 2002. *See* 66 Fed. Reg. 41316 (Aug. 7, 2001). Another example is the Inpatient Psychiatric Rehabilitation Facility Prospective Payment System ("IPF PPS"), which Congress said was to be effective for cost reporting periods beginning on or after October 1, 2002. In the final rule, issued more than two years after the statutory implementation deadline, CMS said, "With respect to the creation of the IPF PPS, more lead time than usual was necessary" due to the complexity of the issues involved, and the payment system ultimately become effective for cost reporting periods starting on or after January 1, 2005. *See* 69 Fed. Reg. 66922 (Nov. 15, 2004).

[20] *See* 42 U.S.C. §§ 1395m-1(a)(1), 1395m-1(a)(12).

report as much data as the agency needs to calculate accurate market-based Medicare payment rates, but it should not require laboratories to report any more than necessary. When ACLA members evaluated their payment experience for six months of test claims, compared with 12 months of test claims, the resulting median payment amounts generally were consistent with each other. We believe that CMS is able to capture the data it needs, regardless of a test's volume or frequency, by requiring laboratories to report data for tests furnished and paid for in a six month period. Congress also contemplated a data collection period that would be six months or shorter for new ADLTs, indicating it viewed that amount of time as sufficient to gather relevant information on private payor rates.[21]

Initial data reporting period: ACLA recommends that the initial data reporting period should run from January 1, 2017 through March 31, 2017. We believe that if laboratories have adequate time between issuance of a final rule, including all subregulatory guidance, and the start of the reporting period, three months will be a sufficient amount of time to report applicable information.

In the first round of reporting applicable information, it is not reasonable for CMS to propose a data reporting period that begins immediately after the close of the data collection period. (And, as we discuss below, it is not a reasonable approach for subsequent data reporting periods, either.) Laboratories will be required to collect and report thousands, and in some cases hundreds of millions, of data points that include payors, rates, and volume. Expecting a designated official of the laboratory to attest to the completeness and accuracy of such a report, and expecting any laboratory to be able to report such information within 90 days of the close of a data collection period, is not realistic. It makes even less sense when CMS has proposed that the initial reporting period would begin before a final rule is issued.

CMS should amend the proposed regulation at 42 C.F.R. § 414.504(a) to read:

> (a) *General Rule.* In a data reporting period, an applicable laboratory must report applicable information for each CDLT furnished during the corresponding data collection period, as follows—
>
> > (1) For CLDTs that are not new CDLTs, every 3 years beginning January 1, 2017.
> >
> > (2) For ADLTs that are not new ADLTs, every year beginning January 1, 2017.

Preliminary weighted median rates: CMS should publish the preliminary weighted median rates around September 1, 2017, and CMS also should give stakeholders an opportunity to request that CMS review potentially inaccurate rates. Given the large amount of data that CMS will collect, it is reasonable to expect that errors will occur due to information management challenges and/or inaccurate calculations, especially with respect to the initial data reporting period. While the law precludes administrative or judicial review of payment amounts, it does

[21] 42 U.S.C. § 1395m-1(d)(2).

not prohibit CMS from establishing a process to accept requests for review of proposed rates.[22] Such systems already exist in other contexts in the Medicare program (*e.g.*, the PFS and the Hospital Outpatient Prospective Payment System ("OPPS")). Reporting preliminary rates sometime around September 1, 2017 would give the agency approximately five months to process applicable information to determine a Medicare payment rate for each laboratory test.

Final weighted median rates: We agree with CMS's proposal to publish final weighted median payment rates approximately 60 days in advance of their effective date. Our recommendation is that CMS should publish the rates initially around November 1, 2017 for a January 1, 2018 effective date. CMS should amend the proposed regulation at 42 C.F.R. § 414.507(a) to read: "Except as provided in paragraph (d) of this section, and § 414.508 and § 414.522, the payment rate for a CDLT furnished on or after January 1, 2018 is equal to the weighted median for the test…"

B. Subsequent Data Collection Periods and Data Reporting Periods

Data collection periods: CMS proposes that after the initial data collection period, subsequent data collection periods would be a full year, rather than six months.[23] For the reasons outlined above, ACLA believes that six months of data is sufficient, both for CDLTs and ADLTs. The weighted median rates derived from six months of private payor data has been found to be consistent with the weighted median rates derived from a full year of data. Continuing to base weighted median rates on six months of data also would mitigate laboratories' reporting burden. Further, a data collection period should be the first six months of the year prior to the year during which the data reporting period falls. This would provide laboratories with sufficient time during the second six months of the year to determine final total approved payment rates for each payor and test, prior to the data reporting period, which may include relevant discounts, rebates, coupons, and other price concessions applied annually by a payor.

CMS should amend its proposed definition of "data collection period" at 42 C.F.R. § 414.502 to read: "*Data collection period* is the first six months of the calendar year that precedes the year in which a data reporting period occurs."

Data reporting periods: CMS proposes that, like the initial data reporting period, subsequent data reporting periods would span the period between January 1 and March 31. ACLA does not object to a three month data reporting period, as long as there is a period of six months between the conclusion of a data collection period and the start of the data reporting period. Laboratories will continue to need time between the conclusion of a data collection period and the start of a data reporting period to go through the process of collecting final payment rates and assembling data.

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[22] *See* 42 U.S.C. § 1395m-1(h)(1). This refers to a formal review by an administrative law judge and to review of final administrative action in a federal court.
[23] 80 Fed. Reg. 59399.

CMS should amend its proposed definition of "data reporting period" at 42 C.F.R. § 414.502 to read: "*Data reporting period* is the initial 3-month period of the calendar year following the year in which a data collection period occurs and is the period during which an applicable laboratory reports applicable information to CMS."

Publication of preliminary and final weighted median rates: Each time CMS calculates weighted median rates from data that is collected and reported by applicable laboratories, it should publish preliminary weighted median rates in September of the data reporting period year, allow laboratories to request review of possibly erroneous weighted medians, and publish final weighted median rates around November 1 in the year before the rates are to take effect.

We expect that as CMS and laboratories gain experience during the initial data collection and data reporting periods, both the agency and stakeholders may develop proposals for how to adjust data collection and reporting schedules to decrease burdens while still yielding weighted median rates that accurately reflect the private payor market. This may include aggregated reporting in subsequent data collection and reporting periods, as authorized in the statute.[24] ACLA hopes to maintain an open dialogue with CMS about these issues in the coming years, and we hope that the agency is amenable to making adjustments, if needed, in future rulemakings.

III. Definition of "Applicable Information"

The statute requires an applicable laboratory to report "applicable information…for each clinical diagnostic laboratory test that the laboratory furnishes during [a data collection] period."[25] As defined in the statute, "applicable information" means "with respect to a laboratory test for a data collection period, the following: (i) the payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period; (ii) the volume of such tests for each such payor for the period."[26] Paragraph 5, in turn, states that payment rates shall reflect "all discounts, rebates, coupons, and other price concessions…"[27] CMS's proposed definition at 42 C.F.R. § 414.502 reads: "*Applicable information* means, with respect to each CDLT for a data collection period—(1) Each private payor rate. (2) The associated volume of tests performed corresponding to each private payor rate. (3) The specific HCPCS code associated with the test. (4) Does not include information about a test for which payment is made on a capitated basis." Following are ACLA's recommendations for defining "applicable information."

A. Tests about which Applicable Information is to be Reported

1. Furnished and Paid During a Data Collection Period

When addressing "applicable information", the statute refers in one place to a test that a laboratory furnishes during a data collection period, and in another place, it refers to the payment

[24] 42 U.S.C. § 1395m-1(a)(6).
[25] 42 U.S.C. § 1395m-1(a)(1).
[26] 42 U.S.C. § 1395m-1(a)(3).
[27] 42 U.S.C. § 1395m-1(a)(5).

rate that was paid during the collection period. CMS's own definition for "applicable information" refers to "each CDLT for a data period," but the agency does not clarify in the preamble whether a "CDLT for a data period" is one that is furnished during the data period or paid during the data period or both.

The truest interpretation of the statute is that applicable information is to be reported about a test that an applicable laboratory both furnishes during the data collection period and for which the laboratory receives a final payment during the data collection period. In the statute, under the heading "In general", Congress directs applicable laboratories to report applicable information about "each clinical diagnostic laboratory test that the laboratory *furnishes during*" the data collection period.[28] Then, in the definition of "applicable information," Congress requires an applicable laboratory to report the payment rate "that was paid by each private payor for the test *during the period*."[29] Taken together, this indicates that the set of tests about which an applicable laboratory is to report applicable information are those that are furnished during a data collection period and that are fully paid during a data collection period.

This is the only truly workable solution. As CMS is aware, a laboratory is not paid by a private payor on the same day that it furnishes a test. By limiting the data set to those tests both furnished and paid during a data collection period, each applicable laboratory will be able to identify a discreet set of laboratory services about which it is to report information to CMS. Requiring information about tests that are furnished during a data collection period, regardless of when they are paid, would result in an applicable laboratory not being able to "close the data set" until the very last day of the data reporting period. This is because it would never know whether it was going to receive payment for a test and, consequently, whether it would need to change the volume of tests paid at a particular rate or add a new payment rate for a payor. Failing to establish a payment cut-off date also would make it impossible for a laboratory to develop and run a billing system query that captures all applicable information. Given the potentially serious consequences in the form of civil monetary penalties for an omission in reporting information to CMS, it is important that the data set be finite.

2. HCPCS Codes

Well in advance of a data reporting period, CMS should publish a list of HCPCS codes for which it expects applicable laboratories to report information. For various reasons, some tests that are offered by laboratories do not appear on the CLFS, especially if the test is contractor-priced or if no codes are available for the test. Presumably, these tests now would receive unique codes. Nevertheless, to avoid confusion, CMS should publish a list of those codes on which it expects laboratories to report applicable information.

B. Private Payor Rates

CMS must be clear what constitutes a "private payor rate." The proposed definition at 42 C.F.R. § 414.502 is: "*Private payor rate*, with respect to applicable information: (1) Is the

[28] 42 U.S.C. § 1395m-1(a)(1) (emphasis added).
[29] 42 U.S.C. § 1395m-1(a)(3)(A)(i) (emphasis added).

amount that was paid by a private payor for a CDLT after all price concessions were applied; (2) Includes any patient cost-sharing amounts if applicable." In most cases, the rates that private payors set for laboratory tests account not only for the amount that the insurer will pay, but also the patient's obligation. Patients also sometimes have deductibles to meet, meaning that a private payor may be involved in the rate-setting for a particular service, but the payor may shift responsibility for payment to the insured individual, depending on the structure and application of a deductible. In addition, some patients may have multiple payors on a claim (including a primary and secondary payor) that may have different rates allowed for the same claim.

To ensure consistency among reported rates, laboratories should report the final total approved payment rates for tests furnished during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. The approved payment rate should be the total "allowed amount", as that term is understood in the context of HIPAA 5010 transactions, and should include any copayment or coinsurance amounts, deductible amounts, and any other patient cost-sharing amounts. It appears that CMS intended to include all patient cost-sharing within the definition, and we recommend including "deductible amounts," as it was missing from the itemized list in the proposed rule.

CMS should amend its proposed definition of "private payor rate" to read:

> *Private payor rate*, with respect to applicable information:
>
> (1) is the allowed amount indicated on a remittance described at 45 C.F.R. § 162.1102(b)(2)(iii); and
>
> (2) includes any patient cost-sharing and deductible amounts, if applicable.

C. Exclusions from Reporting

CMS should amend its proposed regulation to allow a laboratory to exclude information about certain tests from its data reporting. It will be virtually impossible for a laboratory to ensure that it has captured every single test performed and every private payor rate for each test. Just as other Medicare reporting systems allow for the exclusion of certain data, we believe similar policies are necessary for reporting under PAMA. Removing information about certain claims from reporting would not have a material effect on the weighted medians that are calculated but would reduce the burden on applicable laboratories. Examples of payments that CMS should allow a laboratory to exclude from reporting are:

- Hard copy (manual) remittances where HCPCS-level payment data is not captured or the formatting of the hard copy remittance advice is not conducive to optical character recognition ("OCR") scanning;

- Manual remittances where the payor has grouped test-level payments into an encounter-level (claim-level) payment;

- Payments that were made in error, which oftentimes are corrected months after the incorrect payment was received;
- Bulk settlements;
- Payments that include post-payment activity such as recoupments;
- Payments from secondary payors;
- Payments that do not reflect specific HCPCS code-level amounts; and
- Other similar payments.

Due to the complexity and difficulty of reporting these rates and their associated volumes, and due to their minimal impact on the private payor market for laboratory tests, CMS should permit applicable laboratories to exclude these types of payments, should they occur, from reporting if the laboratories so choose. CMS should include language in the proposed definition of "applicable information" at 42 C.F.R. § 414.502 that reflects these exclusions and that allows some measure of flexibility for an applicable laboratory to exclude from reporting those payments where the administrative burden of discerning the payment rates and volume exceeds the value to CMS. The agency should issue subregulatory guidance after publication of the final rule to specify the information that laboratories may exclude from reporting.

D. Reporting Mechanism

The mechanism for reporting applicable information is a totally separate issue from the definition of "applicable laboratory" and should be flexible enough to meet the needs of a wide variety of applicable labs with vastly different sizes and structures. CMS should allow the entity reporting applicable information to be: (a) an applicable laboratory reporting its own applicable information, (b) a TIN-level entity that owns multiple applicable laboratories reporting in a single report on behalf of all of its applicable laboratories, or (c) a TIN-level entity reporting on behalf of its TIN-level subsidiaries and all of its subsidiaries' applicable laboratories, whether in a single report or at the subsidiary level. In each case, each applicable laboratory would be identified by its CLIA number, and CMS would get the same information about the volume of laboratory tests furnished at each private payor rate regardless of the entity reporting the applicable information.

Nothing in the statute prohibits this flexible approach, and efficiency demands it. While the statute requires applicable laboratories to report applicable information, it does not specify the manner in which such reports are to be made, and therefore it permits flexibility in the reporting mechanism, such as allowing entities that own or control multiple applicable laboratories to report the applicable information of those applicable laboratories on their behalf. Such consolidated reporting may be necessary for entities with centralized billing systems where the applicable laboratories themselves currently do not have the capability to report applicable information directly to CMS themselves. To demand them to do so would be prohibitively expensive, and would multiply unnecessarily the number of reports that CMS would have to

receive and analyze. The definition of "applicable laboratory" determines whose applicable information is to be reported, not who will report the applicable information. As long as the right data is reported, it should not matter who reports it to CMS.

E. Summary of Recommendations on "Applicable Information"

In sum, CMS should revise the proposed definitions at 42 C.F.R. § 414.502 to read:

> *Applicable information* means, with respect to each CDLT furnished and paid during a data collection period—
>
> (1) Each private payor rate.
>
> (2) The associated volume of tests that are furnished and paid during the data collection period that corresponds to each private payor rate.
>
> (3) The specific HCPCS code associated with the test.
>
> The following shall not be applicable information—
>
> (1) Information about a test for which payment is made on a capitated basis.
>
> (2) Information about a test for which CMS has determined that the administrative burden of collecting information outweighs the value of that information in determining private payor rates.
>
> (3) Information about a test for which appeals are outstanding or for which a final private payor rate has not been determined.
>
> *Private payor rate*, with respect to applicable information:
>
> (1) is the allowed amount indicated on a remittance described at 45 C.F.R. § 162.1102(b)(2)(iii); and
>
> (2) includes any patient cost-sharing and deductible amounts, if applicable.

IV. Advanced Diagnostic Laboratory Tests

A. Definition of an ADLT

Congress defined an ADLT as a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and that meets one of the following criteria: (1) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the FDA; (3) the test meets other similar criteria established by the Secretary. We address CMS's interpretation of, and proposal for, each segment of this definition below.

1. Single Laboratory

CMS should change its proposed definition of "single laboratory" at 42 C.F.R. § 414.502. ACLA vehemently disagrees with CMS's proposal that "a single laboratory" offering and furnishing an ADLT would be one with a single CLIA certificate and that "an entity with multiple CLIA certificates would not be a single laboratory."[30]

The agency's proposal does not comport with the reality of how laboratories operate, and it would be an insurmountable barrier for many laboratories whose tests Congress meant to include among ADLTs. As you know, a separate CLIA certificate is required for each laboratory location.[31] There are several reasons why an ADLT developer may have more than one CLIA certificate, none of which is relevant to whether a laboratory sells the ADLT for use by another laboratory. For example, a laboratory may have a CLIA certificate for the laboratory facility where the ADLT service is performed and another CLIA certificate for a different facility that performs activities wholly unrelated to the ADLT service, such as research. Or, a laboratory may have a CLIA certificate for a laboratory facility where an ADLT service is performed, and due to higher-than-expected demand for its testing, it may have to open a new laboratory facility next door that then then is required to obtain its own CLIA certificate, simply because of its different mailing address or location. Or, a laboratory that developed, offers, and furnishes an ADLT may merge with another laboratory company that has its own CLIA certificate, creating a company with multiple CLIA certificates. Or, a laboratory may have multiple sites, each with its own CLIA certificate, but it furnishes the ADLT at only one of those sites. So long as the offering and furnishing laboratory does not sell the test for use by another laboratory, then the number of CLIA certificates the entity holds should not be relevant to whether a test can qualify as an ADLT.

CMS says that it believes the statute intends "to award special payment status to the one laboratory that is expending the resources for all aspects of the test—developing it, marketing it to the public, performing it, and selling it."[32] One laboratory may expend resources for all aspects of the test, but that "laboratory" is not necessarily an entity that holds only one CLIA certificate. It is possible for CMS to determine that a test is an ADLT without resorting to a cramped definition for "single laboratory" that is based on whether the ADLT developer holds more than one CLIA certificate.

The agency should amend the definition of a "single laboratory" to read: "*Single laboratory*, for purposes of an ADLT, means a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable."

2. "Offered and Furnished" vs. "Marketed and Performed"

The statute says that an ADLT is one that is "offered and furnished" by a single laboratory. The words "offered and furnished" are sufficiently clear that CMS does not need to

[30] 80 Fed. Reg. 59396.
[31] 42 C.F.R. § 493.43(a).
[32] 80 Fed. Reg. 59396.

redefine them as "marketed and performed", and the terms "offered and furnished" are well-understood in the Medicare program. Furthermore, the words "offered and furnished" when read in the context of the statutory definition for an ADLT, indicate that the single laboratory furnishes the test and does not sell it as a kit to another laboratory so that the other laboratory may offer it and furnish it. It is not uncommon for a small laboratory to contract with a third party to provide marketing support while still performing and billing for its tests because of resource constraints. Some may misconstrue the proposed language as disqualifying a test offered by such a laboratory from ADLT status. This is not what Congress intended, and CMS should not complicate the definition by needlessly substituting its own words for those of Congress.

3. Multiple Biomarkers of DNA, RNA, or Protein

When it defined the term "ADLT" in Section 216 of PAMA, Congress could not have been clearer that a laboratory test can meet the first of the three criteria set forth above when it is an "analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm…" CMS has interpreted this simple phrase to mean that "a test must be a molecular pathology analysis of DNA or RNA" and that "an ADLT could include assays in addition to the biomarker assays," such as "a component that analyzes proteins" but that an analysis of multiple biomarkers of proteins combined with a unique algorithm cannot meet Congress's definition.

CMS must change the proposed regulation at 42 C.F.R. § 414.502 to comport with the statutory text. Proteins are included in the statute in the same way and in the same phrase as DNA and RNA. CMS has not offered any support for its interpretation that the statute requires that a "test analyze, at a minimum, biomarkers of DNA or RNA" and that the criterion is limited to molecular pathology analyses.[33] It cannot be that Congress included the words "or protein" in its definition of ADLT but intended that the words be ignored by CMS.

At its October 19, 2015 meeting, the Advisory Panel on Clinical Diagnostic Laboratory Tests ("Advisory Panel") discussed CMS's confounding omission of proteins from the definition, and it made a unanimous formal recommendation to CMS that the regulation should reflect the statutory text and include "DNA, RNA, or proteins".[34] During the meeting, the Advisory Panel moderator stated that CMS interpreted the word "advanced" in the statutory definition of ADLT to preclude the inclusion of a test made up of multiple biomarkers of proteins without analysis of biomarkers of DNA or RNA, as well. Several Advisory Panel members spoke in great detail about why protein testing is "advanced" and may even provide more information than DNA or RNA testing. Unlike DNA testing, which shows the "blueprint" for a patient's disease, protein testing can show how the body is acting upon this blueprint. The Advisory Panel issued a unanimous formal recommendation to CMS that the regulation should reflect the statutory langue and should not require the inclusion of a DNA or RNA marker and

[33] *Id*. at 59397.

[34] *See* Advisory Panel on Clinical Diagnostic Laboratory Tests, Voting results and recommendations as recorded from written ballots, Oct. 19, 2015, at 7, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2015-10-19-Lab-Panel-Results.pdf.

exclude protein-only tests. The notion that protein-based tests cannot be "advanced" is unfounded.

It is not helpful that CMS states in the preamble to the proposed rule that it "would not disqualify a test from ADLT status consideration" if the test analyzes DNA or RNA and it also analyzes proteins.[35] Of course, there are tests that analyze only proteins and apply a unique algorithm to the analysis. There is no basis in the statutory text for CMS to disqualify such a test from consideration as an ADLT.

CMS must amend the relevant portion of the proposed definition of an ADLT to read: "Must be an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins…"

4. Patient-Specific Result

CMS has interpreted the requirement that an ADLT that is not FDA-cleared or –approved must "yield a single patient-specific result" to mean that the test must be diagnostic of a certain condition, a prediction of the possibility of an individual developing a certain condition or conditions, or the probability of an individual's response to a particular therapy or therapies.[36]

CMS should amend the proposed regulation so that it reflects the text of the statute. That is, the proposed regulation at 42 C.F.R. § 414.502 should read: "(ii) when combined with a unique algorithm, yields a patient-specific result." The Advisory Panel on CLDTs reached the same conclusion and recommended that the definition reflect the text of the statute. "Single patient-specific result" is sufficiently clear that it does not require further interpretation by CMS, and it is unwise for the definition of ADLT to be overly prescriptive in a way that may prevent otherwise qualified tests from being considered ADLTs in the future.

5. New Clinical Diagnostic Information

CMS should remove from its proposed definition of an ADLT the requirement that the test must "provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests." In the preamble to the proposed rule, CMS says that this proposed policy derives from its "view that ADLTs that meet the criterion are innovative tests that are new and different from any prior test already on the market and provide the individual patient with valuable genetic information to predict the trajectory of the patient's disease process or response to treatment of the patient's disease that could not be gained from another test or tests on the market."[37]

While the statute describes an ADLT's algorithm as unique, Congress did not intend that the information that comes from the test must be new and otherwise unobtainable. Additionally, CMS should encourage development of multiple diagnostic tools that seek to answer the same clinical answer using different methods in order to foster competition among test developers.

[35] 80 Fed. Reg. 59398.
[36] Proposed 42 C.F.R. § 414.502.
[37] 80 Fed. Reg. 59398.

ACLA objects to the inclusion of this additional criterion, which is more suitable for a coverage determination than for a determination of whether a test qualifies as an ADLT.

6. Definitions

In sum, CMS should revise its proposed definitions of "advanced diagnostic laboratory test" and "single laboratory" to read:

> *Advanced diagnostic laboratory test* means a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner of that laboratory) and meets one of the following criteria:
>
> (1) The test—
>
> (i) must be an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;
>
> (ii) is combined with a unique algorithm to yield a single patient-specific result; and
>
> (iii) may include other assays.
>
> (2) The test is cleared or approved by the Food and Drug Administration.
>
> *Single laboratory*, for purposes of an ADLT, means a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable.

B. Application to Qualify as an ADLT

The agency proposes to establish, through subregulatory guidance, a process through which a laboratory may apply for its test to qualify as an ADLT, and it proposes to do so prior to January 1, 2016. As a threshold matter, CMS should not issue subregulatory guidance to implement any aspect of the rule until after the rule has been finalized. CMS cannot create an application format or provide instructions to applicants about the standards for information they submit in an application for an ADLT because the definition of "ADLT" has not been finalized.

The statutory definition of an ADLT is straightforward, and the application process should be equally straightforward to minimize the administrative burden on CMS. Just as a laboratory's President, CEO, or CFO must attest to the completeness and accuracy of private payor data reported to CMS, one of these individuals should be required to attest to the information provided in an ADLT application. The attestation will be key to determining whether a test is offered and furnished by a single laboratory. The President, CEO, or CFO of the laboratory should be asked to attest that to the best of his or her knowledge, the laboratory is the only laboratory to offer and furnish the test and that the test is not sold for use by another laboratory. Supplying information in an application about the type(s) of biomarkers (DNA, RNA, and/or proteins), the number of biomarkers, the patient population, and application of the

score or patient-specific result will assist the agency in its determination of whether an applicant is the only laboratory offering and furnishing a test.

Only public information should be required to support an ADLT application. Published clinical data provides sufficient detail to support an ADLT application and show that the test is an analysis of biomarkers of DNA, RNA, or proteins combined with an algorithm that yields a single patient-specific result. A full review of the clinical and analytical validity and clinical utility of a test is unnecessary for an ADLT application, as a full technical review is conducted during the coverage process. Other publicly-available information also may be useful to support an ADLT application, such as patents and evidence of FDA-clearance or -approval. Congress clearly did not intend for a laboratory's confidential information to be necessary to determine whether a test meets the definition of an ADLT, as it did not confer protection from disclosure under the Freedom of Information Act to information included in an ADLT application. If a laboratory wishes to include in an ADLT information trade secrets or other confidential information, it should be allowed to do so, but it is not necessary for CMS to require any such information in an ADLT application.

C. Payment for New ADLTs

The statute says that for a new ADLT for which payment was not made under the CLFS as of the date of enactment of PAMA, during the "initial period of three quarters," the payment amount is based on the actual list charge for the laboratory test.[38] A laboratory is to report private payor data for an ADLT no later than the last day of the second quarter, and market rates are to apply after the initial three quarters.[39] We address aspects of the statutory requirements below.

1. New ADLT

CMS proposes to define a "new ADLT" as one for which payment has not been made under the CLFS prior to January 1, 2017. ACLA agrees with this proposal.

2. "Actual List Charge"

The statute defines the "actual list charge" as the "publicly-available rate on the first day at which the test is available for purchase by a private payor."[40] CMS expands upon this and proposes a definition at 42 C.F.R. § 414.502 for "actual list charge," meaning "the publicly available rate on the first day the new [ADLT] is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date." CMS should not finalize its proposed definition. Instead, CMS should adopt the definition that Congress included in the statute, which is clear and gives laboratories sufficient guidance.

[38] 42 U.S.C. § 1395m-1(d)(1)(A).
[39] 42 U.S.C. § 1395m-1(d)(2-3).
[40] 42 U.S.C. § 1395m-1(d)(1)(B).

3. "Initial Period of Three Quarters"

CMS proposes that the "initial period of three quarters" would begin on the first day of the first full calendar quarter following the first day on which an ADLT is "performed."[41] CMS should amend this proposal so that the "initial period of three quarters" begins on the first day of the first full calendar quarter following the first day on which the ADLT is paid for by Medicare. ACLA has several reasons for making this recommendation to CMS.

Congress did not say to which "initial three quarters" it was referring. Because the issue is payment for a new ADLT by Medicare, the date on which the test is performed on a commercially-insured patient or in a clinical trial is not relevant. Payment for an ADLT by Medicare will not come until after CMS designates a test as an ADLT, the agency assigns the ADLT a unique code, and a Medicare Administrative Contractor makes a coverage determination, which can come long after a test first is "performed." Indeed, if the clock starts to run on the first day the test is offered to the public, the entire three quarters may pass before a test is covered and paid by Medicare. In that case, the entire reporting process for new ADLTs would be irrelevant, which is an unreasonable result, given Congress' explicit directions on this issue.

Further, not long after the start of the first of the "initial three quarters," a laboratory will have to report private payor data to CMS for the new ADLT. If the "initial three quarters" begins at the start of the quarter after the day when test first is performed, the laboratory may not have sufficient private payor data to report, which will not give CMS adequate data to develop a truly market-based rate. By starting the "initial three quarters" after the date that an ADLT is paid for by Medicare, CMS is likely to get more private payor data in the initial reporting period for the ADLT and be able to calculate a weighted median payment rate that more accurately reflects the private payor market.

CMS should amend the proposed regulation at 42 C.F.R. § 414.504(c) to read: "A laboratory seeking a new ADLT status for its test must, in its new ADLT application, attest to the actual list charge." Because the "initial three quarters" will start on the first day when the ADLT is paid for by Medicare, it is not necessary for the laboratory to attest to "the date the new ADLT is first performed." Information will be readily available to the agency about the first day the test is paid for by Medicare, making an attestation regarding that fact unnecessary.

V. Coding

The statute requires the Secretary to adopt temporary HCPCS codes (effective up to two years) to identify new ADLTs and new laboratory tests that are cleared or approved by the Food and Drug Administration. For an existing ADLT or FDA-cleared or –approved test (paid under Medicare Part B before April 1, 2014) that does not have a unique HCPCS code, the Secretary is

[41] 80 Fed. Reg. 59408.

to assign a unique HCPCS code for the test and publicly report the payment rate for the test.[42] CMS proposes to assign a unique G-code to each such test.

CMS no longer can meet the deadline set forth in the statute to assign unique HCPCS codes to existing ADLTs and FDA-cleared or –approved tests by January 1, 2016.[43] The agency currently does not have information about the universe of existing FDA-cleared or –approved tests that may require new codes. Therefore, CMS cannot include the codes and payment amounts on the electronic CLFS payment file it makes available prior to January 1, 2016, as proposed in the preamble, and it should not do so until after a final rule is issued.

A unique HCPCS code should be assigned for an ADLT or an FDA-cleared or –approved test if a laboratory or manufacturer requests a unique code, but CMS should not automatically issue a new code for every distinct existing ADLT or FDA-cleared or -approved test. Automatically assigning new codes to all such tests would generate a tremendous number of new codes that would have to be crosswalked to existing CPT codes.

The statute does not specify whether the HCPCS codes must be Level I or Level II HCPCS codes. ACLA prefers for the American Medical Association's ("AMA's") Common Procedural Terminology ("CPT") Editorial Panel to assign HCPCS codes to ADLTs and FDA-cleared or –approved tests, instead of CMS assigning HCPCS Level II G-codes to the tests. As you know, G-codes are viewed as Medicare-only codes by other payors and generally are not accepted, and using them can be an administrative burden for laboratories and other healthcare providers, particularly if the purpose is to collect private payor rates for purposes of rate-setting. We are encouraged by the AMA CPT Editorial Panel's efforts to craft a solution to the problem posed by assignment of G-codes, and we are looking forward to hearing the details of any such potential solution.

VI. Data Integrity

A. Civil Monetary Penalties

The statute allows the Secretary of HHS to impose a civil monetary penalty ("CMP") for an applicable laboratory's failure to report or for misrepresentation or omission in reporting applicable information. CMS proposes regulatory language to implement this provision of the law that is similar to the regulation at 42 C.F.R. § 414.806 on CMPs for misrepresentations by pharmaceutical manufacturers reporting Average Sales Price for drugs covered under Medicare Part B. As we have recommended with other parts of the law, CMS should not issue any clarifying guidance on this provision until after publication of a final rule.

The severity of the proposed CMP – $10,000 per day per violation – warrants the agency's reconsideration. If left unchanged, the proposed timeline could expose many laboratories unfairly to draconian punishment for failure to comply with reporting requirements, even though the compressed reporting schedule would not be the laboratories' own fault.

[42] 42 U.S.C. § 1395m-1(e).
[43] 42 U.S.C. § 1395m-1(e)(2).

B. Certification

To implement the provision of the statute requiring an officer of an applicable laboratory to certify the accuracy and completeness of applicable information reported by the lab, CMS proposes that the President, CEO, or CFO of an applicable lab may sign such a certification statement, or it may be signed by an individual who has been delegated authority to sign for, and reports directly to, one of those officers. The certification would be that the applicable information provided is "accurate, complete, and truthful, and meets all the reporting parameters."[44] CMS proposes to provide additional parameters for such a certification in subregulatory guidance before January 1, 2016.

CMS should create a certification form for applicable laboratories to submit with information they report, similar to the form used for reporting Medicare Part B ASP information.[45] Like the ASP certification form, the applicable information form should include the following language: "All information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith." Given that most laboratory Presidents, CEOs, and CFOs are not – and cannot be – personally familiar with the volume and private payor rates for each laboratory test their labs offer, a laboratory officer should be expected to certify only to his or her good-faith belief in the data's integrity and that he or she does not have any information to the contrary.

VII. Local Coverage Determinations and Medicare Administrative Contractors

When PAMA became law in 2014, we were encouraged that it included language to ensure that local coverage determinations ("LCDs") henceforth are to be developed according to the process already spelled out in Section 1869 of the Social Security Act and implementing regulations. Coverage policies for clinical diagnostic laboratory tests have been issued recently through less formal processes, such as articles, without following the existing notice-and-comment requirements of the Social Security Act. We are disappointed that CMS does not make any proposals for implementing or enforcing this section of the statute.

PAMA also permits the Secretary to designate one or more (not to exceed four) Medicare Administrative Contractors ("MACs") to establish coverage policies or establish coverage policies and process claims for CDLTs. Of utmost importance to us is the fairness and transparency of coverage and payment processes, rather than the number of MACs that are involved. We agree with CMS's approach, which is to proceed cautiously before making any such changes, and to determine the feasibility and desirability of assigning coverage and claims processing functions for laboratory tests to fewer MACs. We also agree with CMS about the potential problems with a smaller number of MACs making coverage determinations that then would have to be implemented by other A/B MACs. ACLA hopes to continue a dialogue with CMS about this in the future and to work with the agency on implementation, if CMS and stakeholders determine that it would be appropriate.

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[44] 80 Fed. Reg. 59402.

[45] Average Sales Price Data Addendum B, *available at*: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/aspdata_addendumb.pdf.

VIII. Subregulatory Guidance

CMS plans to issue subregulatory guidance to implement many important provisions of the law, and the details of many of those provisions can have a material impact on how Medicare pays for clinical laboratory tests and on applicable laboratories' operations. These include the method for reporting applicable information, the application for ADLT status, certification to the accuracy and completeness of reported data, and the imposition of civil monetary penalties. As we have stated throughout our comments on the proposed rule, we do not believe that CMS should issue any subregulatory guidance to implement any portion of the reporting system until after it has published a final rule addressing all substantive issues, including those identified in these comments. When CMS does issue subregulatory guidance, as part of the agency's ongoing collaboration with laboratories and other interested stakeholders on implementation of PAMA, the agency should issue the guidance in draft form first, to allow interested stakeholders to provide input and suggestions before guidance is finalized.

* * * * *

Thank you for your consideration of ACLA's comments on the proposed rule to implement Section 216 of PAMA. It is of utmost importance to ACLA's members, and ultimately to Medicare beneficiaries, that CMS implements the law in a way that results in fair and accurate market-based prices for clinical laboratory tests and that causes the least disruption to the clinical laboratories reporting data to the agency. We look forward to our continued work with CMS and remain available to assist the agency in any way we can.

Sincerely,

Alan Mertz

Alan Mertz, President
American Clinical Laboratory Association

APPENDIX A

	$ Expenditures	% Non-Patient Expenditures	% Total CLFS
A. Independent Laboratories	$ 3,769	53%	41%
B. Physician Office Laboratories and Other	$ 1,263	18%	14%
C. Hospital Non-Patient*			
1. Non-Patient Carrier Claims	$ 133		
2. Non-Patient OPPS Excluded (lab svc. only)	$ 1,474		
3. Non-Patient Inst. Claim (14X bill type)	$ 508		
Hospital Non-Patient Total	$ 2,115	30%	23%
Total Non-Patient CLFS Spending	**$ 7,147**	**100%**	**78%**
D. Hospital OPPS Patient Excluded (includes non-lab services)**	$ 1,993		22%
Total CLFS Spending	**$ 9,140**		**100%**
E. Hospital Packaged Laboratory Services			
1. IPPS (imputed)	$ 5,570		
2. OPPS (imputed)	$ 199		
Total Hospital Packaged Laboratory Spending	**$ 5,769**		

*Non-Patient is a patient where no non-laboratory outpatient or inpatient services were filed on the same day claim.

**OPPS Excluded claims, which include non-lab services, moved from CLFS spending to the OPPS bundles beginning with 2014 claims.

APPENDIX B

As discussed in Section I.A., to calculate a hospital's total laboratory Medicare revenues, it is necessary to develop an adjustment factor that a hospital can apply to its inpatient and outpatient Medicare revenues to determine the percentage that is attributable to laboratory services. The Moran Company calculated this percentage based on the information in the table in Appendix A.

As the table in Appendix A shows, in certain situations (line C.2), hospitals furnished only laboratory services to outpatients; in 2013, hospitals were paid $1.474 billion for this type of service. In other situations (line C.3), hospitals furnished laboratory services to non-patients; hospitals were paid $508 million in 2013 for this type of service. In both of these situations, hospitals competed directly with independent laboratories. Thus, $1.982 billion of Part B laboratory services were provided by hospitals in situations where they acted as independent laboratories.

The Moran Company determined what percentage of inpatient and outpatient bundled Medicare payments were attributable to laboratory services. The Moran Company took the laboratory charges included in inpatient and outpatient Medicare claims and applied the hospitals' specific payment-to-charges ratios to the amounts shown and totaled the results. Based on the analysis, the Moran Company determined that of all inpatient and outpatient services furnished by hospitals to Medicare beneficiaries, $5.769 billion was for laboratory services (line E.1 plus line E.2). That is the amount that the Medicare program paid for laboratory services that were part of inpatient and outpatient Medicare bundled payments.

Then, the Moran Company determined the share of all hospital services that were represented by laboratory services to develop the "adjustment factor". That calculation is shown below.

A	B	C	D	E	F
Description of services	Payments for outpatient hospital services	Payments for inpatient hospital payments (excluding DSH and IME payments)	Total inpatient and outpatient payments (Col. B + C)	Payments from hospital lab services*	Hospital lab service payments/total inpatient and outpatient services (Col E/D)
OPPS/IPPS claims	40.88	121.95	162.83	9.744	6%

** Total of lines C.2, C.3, D., E.1, and E.2.*

To determine whether a hospital is an "applicable laboratory" under the "majority of Medicare revenues" test, the hospital would calculate the "denominator" by applying the adjustment factor of 6 percent to its inpatient and outpatient bundled Medicare revenues and then adding its other separately-paid laboratory revenues (payments made under the CLFS and PFS). The "nominator" would be the sum of the hospital laboratory's Medicare revenues under the

CLFS and PFS. If more than 50 percent of the hospital laboratory's total Medicare revenues is from the CLFS and PFS, the hospital would be considered an "applicable laboratory."

Khani Declaration Exhibit 15

American Clinical Laboratory Association

Protecting Access to Medicare Act

Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule

December 14, 2015

AGENDA

American Clinical Laboratory Association

- Welcome & Introductions
- Review of Key Stakeholder Concerns
  - Applicable Laboratories
  - ADLTs
  - Implementation Process & Timeline
  - Applicable Information
  - Reporting Recommendations
- Comments & Questions
- Adjourn

Key Stakeholder Concerns

American Clinical Laboratory Association

- Applicable Laboratory
  - Statute
    - "a laboratory that, with respect to its revenues under [title XVIII of the Social Security Act], a majority of such revenues are from [the Physician Fee Schedule or the Clinical Laboratory Fee Schedule].
  - Proposed Rule
    - TIN level entity
  - **ACLA Recommendation**
    - **Define applicable laboratory by CLIA number or alternative approach that allows hospitals to determine laboratory % of Medicare revenue**

Key Stakeholder Concerns

American Clinical Laboratory Association

- Advanced Diagnostic Laboratory Test
  - Statute
    - "furnished only by a single laboratory"
  - Proposed Rule
    - "an entity with multiple CLIA certificates would not be a single laboratory"
  - **ACLA Recommendation**
    - **For purposes of an ADLT, a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable.**

Key Stakeholder Concerns

American Clinical Laboratory Association

- Advanced Diagnostic Laboratory Test
  - Statute
    - "an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result"
  - Proposed Rule
    - "we interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA…a molecular pathology analysis of DNA or RNA"
  - **ACLA Recommendation**
    - **Define ADLT to include tests that are solely comprised of proteins.**

Key Stakeholder Concerns

American Clinical Laboratory Association

- Implementation Process and Timeline
  - Laboratories unable to meet proposed timeline
  - Key issues unresolved
  - Insufficient time to build systems, collect and report data
  - Exposure to civil monetary penalties
  - Six months required to finish building systems, collect and verify data

Implementation Process and Timelines

ACLA Proposed Timeline

Initial data collection period	January 1, 2016 – June 30, 2016
Final rule has been published; data collection and reporting guidance has been finalized	June 2016
Labs build information systems to collect and report data; period between end of data collection period and beginning of data reporting period	July 2016 – December 2016
Initial data reporting period	January 1, 2017 – March 31, 2017
CMS publishes preliminary weighted median payment rates	September 2017
CMS publishes final weighted median payment rates	November 2017
Weighted median payment rates take effect	January 1, 2018

Key Stakeholder Concerns

American Clinical Laboratory Association

- Applicable Information
  - Lack of clarity in statute and proposed rule
  - **ACLA Recommendation**
    - **Final payment rates and volumes for tests furnished and paid during the data collection period**
  - Publication of HCPCS codes

Key Stakeholder Concerns

American Clinical Laboratory Association

- Reporting Recommendations
  - Report by TIN
  - Reporting period should not immediately follow collection period
  - Recognize limitations in reporting “every rate”

American Clinical Laboratory Association

Thank You!

Comments and Questions

Khani Declaration Exhibit 16

American Clinical Laboratory Association

Protecting Access to Medicare Act

Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule

January 6, 2016

AGENDA

American Clinical Laboratory Association

- Welcome & Introductions
- Review of Key Stakeholder Concerns
  - Applicable Laboratories
  - ADLTs
  - Implementation Process & Timeline
  - Applicable Information
  - Reporting Recommendations
- Comments & Questions
- Adjourn

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- Applicable Laboratory
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    - TIN level entity
  - **ACLA Recommendation**
    - **Define applicable laboratory by CLIA number or alternative approach that allows hospitals to determine laboratory % of Medicare revenue**

Key Stakeholder Concerns

American Clinical Laboratory Association

Proposed Rule Will Result in Rates That Do Not Reflect Laboratory Market

Medicare Payments for Clinical Laboratory Services*, 2013 (millions)				
	Type of Lab Provider			
	Independent	Hospital	Other	Total
1. Part B Carrier/BMAC	$ 3,769	$ 133	$ 1,263	$ 5,165
2. Institutional Claims				
a. Separately-Paid OPPS excluded with lab services only		$ 1,474		$ 1,474
b. Non-Patient Claims (14X bill type)		$ 508		$ 508
c. Separately-Paid OPPS Excluded (claims include non-lab services)		$ 1,993		$ 1,993
Totals, Separately Paid Labs	$ 3,769	$ 4,108	$ 1,263	$ 9,140
Share	*41%*	*45%*	*14%*	*100%*

**Clinical laboratory services were identified using the 2013 Clinical Lab Fee Schedule (CLFS)*

Key Stakeholder Concerns

American Clinical Laboratory Association

- Advanced Diagnostic Laboratory Test
  - Statute
    - "furnished only by a single laboratory"
  - Proposed Rule
    - "an entity with multiple CLIA certificates would not be a single laboratory"
  - **ACLA Recommendation**
    - **For purposes of an ADLT, a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable.**

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American Clinical Laboratory Association

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  - Statute
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    - "we interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA…a molecular pathology analysis of DNA or RNA"
  - **ACLA Recommendation**
    - **Define ADLT to include tests that are solely comprised of proteins.**

Key Stakeholder Concerns

American Clinical Laboratory Association

- Advanced Diagnostic Laboratory Test
  - Statute
    - "is combined with a unique algorithm to yield a single patient-specific result"
  - Proposed Rule
    - "provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests"
  - **ACLA Recommendation**
    - **Strike the additional "newness" requirements in the proposed rule; the algorithm must be unique to qualify as an ADLT.**

Key Stakeholder Concerns

American Clinical Laboratory Association

- Implementation Process and Timeline
  - Laboratories unable to meet proposed timeline
  - Key issues unresolved
  - Insufficient time to build systems, collect and report data
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Key Stakeholder Concerns

American Clinical Laboratory Association

- Reporting Recommendations
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  - Recognize limitations in reporting “every rate”

The simplest reporting will help ensure the most comprehensive market participation

Lab Organization Include tax ID list		
CPT	**rate**	**volume**
85025	$11.00	900,000
85025	$10.75	950,000
85025	$10.50	1,000,000
85025	$10.25	950,000
85025	$10.00	900,000
85027	$9.25	450,000
85027	$9.00	475,000
85027	$8.75	500,000
85027	$8.50	475,000
85027	$8.25	450,000
etc	etc	etc

hypothetical data

- One data file with three fields per applicable laboratory organization – CPT, rate & volume
- Volume (occurrences of the same rate) should carry the same weight, regardless of payor or tax ID, in the weighted median calculation
- A file uploading mechanism on the CMS website would allow for easy reporting
- File layout should be as simple as possible

American Clinical Laboratory Association

Thank You!

Comments and Questions

Khani Declaration Exhibit 17

American Clinical Laboratory Association

Protecting Access to Medicare Act

Medicare Clinical Diagnostic Laboratory Tests Payment System

March 2, 2016

AGENDA

American Clinical Laboratory Association

- Welcome & Introductions
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American Clinical Laboratory Association

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American Clinical Laboratory Association

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- Volume (occurrences of the same rate) should carry the same weight, regardless of payor or tax ID, in the weighted median calculation
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- File layout should be as simple as possible

American Clinical Laboratory Association

Thank You!

Comments and Questions

Khani Declaration Exhibit 18

American
Clinical Laboratory
Association

March 11, 2016

Ms. Sarah Ambrose
Ms. China Tantameng
Mr. Joe Chiarenzelli
Department of Health and Human Services Office of Inspector General
90 7th Street, Ste. 3-600
San Francisco, California 94103

Dear Ms. Ambrose, Ms. Tantameng, and Mr. Chiarenzelli,

Thank you for taking the time to meet with representatives of the American Clinical Laboratory Association ("ACLA") on March 2, 2016 to discuss issues related to implementation of Section 216 of the Protecting Access to Medicare Act ("PAMA"). As you know, ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing are developed openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

Section 216(c)(2) of PAMA requires the OIG to prepare two reports relevant to clinical laboratory testing: an annual analysis of the top 25 laboratory tests by expenditure, and an analysis of the implementation and effect of the new system created by PAMA for paying for clinical laboratory tests under Medicare. ACLA stands ready to serve as a resource to the OIG as the agency prepares these reports, and we are willing to provide background, context, and real-world information about how implementation of the law affects both clinical laboratories and Medicare beneficiaries. Below is a summary of some of the issues we discussed, as well as answers to questions you asked during the meeting.

A. Background on Section 216 of PAMA

The Centers for Medicare and Medicaid Services ("CMS") was required to issue a final rule implementing Section 216 of PAMA by June 30, 2015. The proposed rule was published in the Federal Register on September 25, 2015, and we expect CMS to issue a final rule sometime later in 2016.

Section 216 of PAMA overhauls the way that rates are set on the Medicare Clinical Laboratory Fee Schedule ("CLFS"), the first major reform of the CLFS in three decades. It requires "applicable laboratories" to report "applicable information" to CMS every three years, which includes the rates paid during a data collection period by all private payors for the more than 1,200 clinical laboratory tests on the CLFS, along with the volume of tests reimbursed at each rate. The new rate for a test paid for under the CLFS will be the weighted median of all private payor rates reported to CMS, and any payment reductions will be phased in over a number of years. An "applicable laboratory" is defined in the statute as a laboratory that receives a majority of its Medicare revenues under the CLFS and/or Medicare Physician Fee Schedule ("PFS").

A different pricing mechanism applies to "advanced diagnostic laboratory tests" ("ADLTs"), which the statute defines as a Medicare-covered test offered and furnished only by a single laboratory that is cleared or approved by the Food and Drug Administration ("FDA") or that is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result. New ADLTs are to be paid initially at the actual list charge for the test; laboratories offering ALDTs then will report private payor rates annually, and the weighted median of those private payor rates will be the rates paid on the CLFS.

B. Applicable Laboratory

ACLA and many other stakeholders recommended to CMS that the term "applicable laboratory" be defined in a way that includes hospital laboratories that have robust outreach programs. This is because those outreach programs that serve a significant number of individuals who are non-patients – neither hospital inpatients nor outpatients – compete in the marketplace with independent laboratories, making their private payor rates relevant to calculations of market rates for laboratory tests. CMS proposed that an "applicable laboratory" be identified by its tax identification number ("TIN") and if a TIN-level entity receives a majority of its Medicare revenues under the PFS and/or CLFS, only then would it be an applicable laboratory. The result would be that very few hospital laboratories would report their private payor rates for laboratory tests – even those hospital laboratories with extensive outreach programs.

ACLA suggested to CMS that it identify an "applicable laboratory" by its CLIA number and apply the "majority of Medicare revenues" test to the CLIA-level entity. This would ensure that data reported to CMS reflects market rates for clinical laboratory tests for the entire market, including hospitals that perform a large number of tests for non-patients, because each hospital laboratory and independent laboratory has its own CLIA number.

CMS also asked for input on applying the "majority of Medicare revenues" test to an entity identified by an NPI, and ACLA disagrees with this approach for the same reason it disagrees with using a TIN to identify an "applicable laboratory." Very few hospitals have laboratory-specific NPIs, and they generally submit claims under the hospital's NPI. Thus, few hospitals, if any, would be able to meet the "majority of Medicare revenues" test under the TIN or NPI approach, and the weighted medians that CMS eventually developed under either approach would not reflect the market for clinical laboratory tests accurately.

As we discussed in our meeting, while many laboratory tests performed by hospitals for Medicare beneficiaries now are bundled under the Outpatient Prospective Payment System ("OPPS"), we are concerned primarily about including private payor data on tests that hospitals furnish to <u>non-patients</u>. Additionally, most molecular diagnostic tests still are excluded from the OPPS bundling policy and are paid by Medicare separately. Indeed, the statue specifically states: "The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately, and not as

part of a bundled payment under section 1833(t) [of the Social Security Act]," which refers to the OPPS.

C. Advanced Diagnostic Laboratory Tests ("ADLTs")

Like many other stakeholders, ACLA was perplexed by CMS's proposal to define an ADLT, in part, as an analysis of multiple biomarkers of DNA or RNA combined with a unique algorithm, rather than to hew to the statutory language and define an ADLT as an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm. Tests that analyze multiple biomarkers of proteins play a critical role in precision medicine, a developing area in laboratory science. CMS's approach needlessly would disqualify countless tests from being ADLTs – tests that would qualify under the statutory definition.

The statute also states that a test can be an ADLT if it is offered and furnished only by a single laboratory. CMS proposed a cramped definition of "single laboratory" that also would have the effect of disqualifying a number of tests from being ADLTs, stating that a laboratory that has multiple CLIA certificates would not be a single laboratory. As you know, there are many reasons why a single corporate entity that offers and furnishes an ADLT may have multiple CLIA certificates, in that a separate CLIA certificate is required wherever tests are performed. Thus, even if a laboratory performs a test in only one of its locations, represented by a single CLIA certificate, the test could not be an ADLT if the laboratory holds more than one CLIA certificate, even for facilities that have nothing to do with the test. ACLA recommended to CMS that for ADLT purposes, a "single laboratory" should be defined as a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership.

If CMS finalized its proposals, it would severely limit the number of tests that could qualify as ADLTs and undermine the purpose of this provision of PAMA.

D. Implementation Process and Timeline

ACLA included a suggested implementation timeline in our comment letter to CMS, which is set forth below:

Initial data collection period	January 1, 2016 – June 30, 2016
Final rule has been published; data collection and reporting guidance has been finalized	June 2016
Labs build information systems to collect and report data; period between end of data collection period and beginning of data reporting period	July 2016 – December 2016
Initial data reporting period	January 1, 2017 – March 31, 2017
CMS publishes preliminary weighted median payment rates	September 1, 2017
CMS publishes final weighted median payment rates	November 1, 2017
Weighted median payment rates take effect	January 1, 2018

As we discussed in our meeting with you, the implementation timeline that CMS included in the proposed rule is not realistic. Beyond the obvious impossibility of laboratories reporting data to CMS before a final rule is released, it is important that the data collection and data reporting timeline takes into account the enormous volume of data involved and the challenges associated with building the technology infrastructure to extract the data from laboratory billing systems.

Some larger laboratories serve as many as a half a million patients per day, and laboratories can receive reimbursement from hundreds or thousands of private payors. The tasks of readying for data collection and reporting can be analogized to building an airplane while flying it. Laboratories need to know and understand the parameters of the data they are supposed to collect for reporting purposes and they must dedicate resources to the task of programming their billing systems to yield that information. Very few laboratories will be in a position to assign IT staff specifically to preparing for PAMA reporting, and those laboratories that can assign dedicated staff most likely will be ones with an overwhelming amount of data to report.

As a threshold matter, ACLA and many other stakeholders proposed that CMS delay implementation of PAMA's data collection and reporting requirements for a year, such that the new rates would not take effect until 2018. Given that the proposed rule did not come out until almost three months after the final rule was supposed to be published, and given that CMS is not expected to issue a final rule until later in 2016, many of the implementation deadlines included in the proposed rule are unrealistic.

ACLA has recommended to CMS that the agency allow for a period of at least six months between publication of the final rule and the beginning of the initial data reporting period. This would give most laboratories time to understand what is required of them and to build the information systems they need to collect and report data. Furthermore, there should be a period of at least three months between the data collection period and the data reporting period to give laboratories time to ensure the accuracy and completeness of the private payor date they

have collected. It also would allow an applicable laboratory to do things like apply a volume-based discount retroactively to claims when it has such an arrangement with a private payor.

CMS has proposed to publish new CLFS payment rates at least 60 days in advance of their January 1 effective date to give laboratories "sufficient time to review the data used to calculate CLFS payment rates and prepare for implementation of the rates." It is unclear whether CMS has contemplated allowing laboratories to review the weighted medians for errors. Because of the high likelihood that the first set of weighted median rates that CMS releases will include mistakes, it is important to ACLA and its members that there be sufficient time to review the calculations and for CMS to make corrections. Therefore, we suggested to the agency that it publish preliminary weighted median rates by September 1 of a data reporting year and final weighted median rates by November 1 of the same year.

E. Applicable Information

Applicable laboratories need clarity from CMS on what private payor rates to report and for what tests. ACLA has recommended to CMS that it publish a list of HCPCS codes for which it expects applicable laboratories to report information. For various reasons, some tests that are offered by laboratories do not appear on the CLFS, especially if a test is contractor-priced or if no codes are available for the test. Presumably, these tests now would receive unique codes. Nevertheless, to avoid confusion, CMS should publish a list of those codes on which it expects laboratories to report applicable information.

An applicable laboratory should report information about tests both that it furnishes during the data collection period and for which it receives final payments during the data collection period, from the first day of the data collection period to the last day of the data collection period. For the sake of accuracy of the weighted medians that CMS eventually calculates, the private payor rates that an applicable laboratory reports should be the final total approved payment rates for tests furnished during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. Certain payments should be excluded from "applicable information," such as hard copy (manual) remittances, payments made in error, payments that do not reflect specific HCPCS code-level amounts, secondary insurance payments, and other similar payments.

F. Reporting Recommendations

ACLA has urged CMS to allow the entity reporting applicable information to be: (a) an applicable laboratory reporting its own applicable information, (b) a TIN-level entity that owns multiple applicable laboratories reporting in a single report on behalf of all of its applicable laboratories, or (c) a TIN-level entity reporting on behalf of its TIN-level subsidiaries and all of its subsidiaries' applicable laboratories, whether in a single report or at the subsidiary level. In each case, CMS would get the same information about the volume of laboratory tests furnished at each private payor rate regardless of the entity reporting the applicable information.

The statute calls for applicable laboratories to report applicable information for "each clinical diagnostic laboratory test that the laboratory furnishes" during a data collection period, with certain specified exceptions (*e.g.*, tests paid on a capitated basis). We hope that CMS recognizes the extreme difficulty of reporting private payor rates and their corresponding volumes for each and every test. For the majority of tests that a laboratory furnishes, it can be certain about the rate that a private payor paid. In some cases, a laboratory enters into a settlement with a private payor to discharge the payor's obligation for a set of claims, making it impossible to know the rate paid for each individual test. We are confident that ACLA members will make every effort to comply with the letter and the spirit of the law, and we are hopeful that there is a measure of flexibility built into enforcement of the reporting requirements, as well.

G. **Conclusion**

Thank you again for your time on March 2. ACLA and its members are ready to serve as a resource for the OIG as it prepares reports required by PAMA and on laboratory-related issues in general. We look forward to continuing a productive relationship with you and your colleagues.

Sincerely,

Julie Khani, Executive Vice President
American Clinical Laboratory Association

Khani Declaration Exhibit 19

April 13, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Medicare Clinical Diagnostic Laboratory Test Payment System (CMS-1621-P)

Acting Administrator Slavitt:

As the Centers for Medicare & Medicaid Services (CMS) moves forward with final rulemaking to implement Section 216 of the Protecting Access to Medicare Act (PAMA), we are writing to express our concerns with the proposed definition of the term "applicable laboratory" included in the proposed rule published on October 1, 2015.[1] Under the proposed rule, the overwhelming majority of hospital laboratories would not be considered "applicable laboratories" and would be prohibited from providing data to CMS about private payor rates for clinical laboratory tests they have furnished. CMS's failure to include such a large portion of the laboratory market in rate reporting would result in reimbursement rates for laboratory services that do not reflect the market and may threaten access to laboratory testing services for Medicare beneficiaries. We believe applicable laboratory should be defined as a facility identified by a CLIA number that derives the majority of its Medicare revenue from the Clinical Laboratory Fee Schedule (CLFS) and the Physician Fee Schedule ("PFS"), and request a meeting with you at your earliest convenience to discuss this important issue.

Congress enacted Section 216 of PAMA with the goal of establishing Medicare Clinical Laboratory Fee Schedule (CLFS) reimbursement rates that reflect market rates. According to a September 2015 report by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), 57 percent of CLFS payments are made to independent laboratories, 24 percent of payments are made to hospital laboratories, and 19 percent are made to physician office laboratories.[2] Thus, hospital laboratories comprise a significant portion of the laboratory sector in the United States.

Section 216 of PAMA overhauls the method CMS will use to establish CLFS rates, the first major reform of the CLFS in three decades. It requires "applicable laboratories" to report "applicable information" to CMS every three years, which includes the rates paid during a data collection period by all private payors for the more than 1,200 clinical laboratory tests on the CLFS, along with the volume of tests reimbursed at each rate. The new rate for a test paid for under the CLFS will be the weighted median of all private payor rates reported to CMS. An

[1] Medicare Program; Medicare Clinical Diagnostic Laboratory Test Payment System, 80 Fed. Reg. 59386, 59391 (Oct. 1, 2015), *available at* https://www.gpo.gov/fdsys/pkg/FR-2015-10-01/pdf/2015-24770.pdf.
[2] Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data (Sept. 2015), *available at* http://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf.

"applicable laboratory" is defined in the statute as a laboratory that receives a majority of its Medicare revenues under the CLFS and/or Medicare Physician Fee Schedule ("PFS").

Despite the make-up of the laboratory market, CMS's proposed definition of "applicable laboratory" would apply the "majority of Medicare revenues" test to a Taxpayer Identification Number (TIN)-level entity, which CMS acknowledges would result in private payor rate reporting by virtually no hospital laboratories and only four percent of physician office laboratories. Furthermore, as proposed, an entity that does not meet the regulatory definition of "applicable laboratory" would be prohibited from reporting private payor data.

We are deeply troubled that, as proposed, the majority of the laboratory market would be prohibited from supplying private payor data to CMS to calculate new CLFS reimbursement rates. Since all components of the laboratory market will be reimbursed using the newly created reimbursement rates, all components of the laboratory market should be part of data reporting.

We recommend that CMS define the term "laboratory" as a facility identified by a Clinical Laboratory Improvement Amendments (CLIA) number, rather than a TIN. Each laboratory facility, including each hospital laboratory, has a CLIA number. This approach would ensure that a hospital laboratory's status as an "applicable laboratory" is based on whether the part of a hospital furnishing laboratory services receives a majority of Medicare revenue from the CLFS and PFS, rather than applying that test to an entire hospital, even those parts of the hospital furnishing services that are reimbursed under the inpatient and outpatient prospective payment systems. Use of CLIA number would be the most accurate reflection of Congress' intent and would ensure that the resulting CLFS rates are reflective of all sectors of the laboratory market. The statute allows CMS to implement a low Medicare revenue threshold to exclude some laboratories from reporting. We support the use of a reasonable Medicare revenue threshold, used in conjunction with CLIA number, in order to exclude those laboratories whose private payor data would have little or no impact on the weighted median. While exclusions are calculated and "applicable laboratory" is defined at the CLIA level, data certification and submission will occur at either the individual CLIA level or, in aggregate at the TIN level, with a listing of all CLIA numbers under the TIN to afford flexibility and reduce administrative burden for reporting laboratories.

Section 216 of PAMA dramatically changes how clinical laboratory testing services are reimbursed by the Medicare program. The success of CLFS payment reform hinges on accurate, market based payment rates calculated in a manner consistent with the statute. We urge CMS to define applicable laboratory as a facility identified by a CLIA number that derives the majority of its Medicare revenue from the CLFS and PFS, with appropriate low Medicare revenue thresholds to reduce the reporting burden for small laboratories.

We look forward to discussing this issue with you in greater detail. Thank you.

Sincerely,

Barbara Bigler
President
ACL Laboratories

Mark S. Birenbaum, Ph.D.
Administrator
National Independent Laboratory Association

Mike Black, MBA, MT(ASCP), DLM
Assistant Vice President of the Clinical Laboratory
Avera Health System

Patty J. Eschliman, MHA, MLS(ASCP) DLM
President
Clinical Laboratory Management Association

James Flanigan, CAE
Executive Vice President
American Society for Clinical Laboratory Science

Richard C. Friedberg, MD, Ph.D., FCAP
President
College of American Pathologists

Don Henderson, MSA, MT(ASCP)
Vice President and Chief Administrative Officer
Beaumont Laboratory

Mike Hiltunen
Executive Director
Great Lakes Laboratory Network

Julie Khani
Executive Vice President
American Clinical Laboratory Association

David P. King
Chairman and CEO
Laboratory Corporation of America Holdings

John Kolozsvary
Chief Executive Officer
Joint Venture Hospital Laboratories

David N.B. Lewin, MD, FASCP
President
American Society for Clinical Pathology

Seth Rainford
Vice President
HealthLab, a member of Northwestern Medicine

Beth Rokus, SPHR, CHC, M.ED
Chief Operating Officer/Chief Compliance Officer
Health Network Laboratories

Stephen H. Ruskcowksi
President and Chief Executive Office
Quest Diagnostics

Khosrow R. Shotorbani, MBA, MT(ASCP)
President and Chief Executive Officer
TriCore Reference Laboratories

Francisco R. Velázquez, M.D., S.M.
President and Chief Executive Officer
PAML, LLC and PAML Ventures

Ran Whitehead
President
PeaceHealth Laboratories

Khani Declaration Exhibit 20

American
Clinical Laboratory
Association

August 30, 2016

Carol Blackford, Acting Director
Center for Medicare, Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-07-27
Baltimore, Maryland 21244
Via email: carol.blackford@cms.hhs.gov

Dear Ms. Blackford,

I am writing on behalf of the American Clinical Laboratory Association ("ACLA") to request a meeting to discuss subregulatory guidance issued recently by CMS on collecting and reporting applicable information for the private payor rate-based payment system created under Sec. 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), and other related matters. As you know, we have worked closely with CMS since Congress passed PAMA to ensure that the law's clinical laboratory payment provisions are implemented in a way that results in fair and accurate market-based prices for clinical laboratory tests and that causes the least disruption for Medicare beneficiaries who need such tests.

We have a number of questions about guidance the agency has issued since the final rule was published, and we also would like to talk with you about the timing and substance of future guidance. Below is a summary of the issues we would like to discuss with you.

A. Guidance on Collecting and Reporting Applicable Information

Reporting applicable information individually for NPI-level components. In the final rule, as an alternative to each applicable laboratory reporting applicable information to CMS, the agency instead said it would require a "reporting entity" – the entity that reports tax-related information to the IRS using its TIN for its components that are applicable laboratories – to report applicable information to CMS on behalf of its applicable laboratory components. The agency did this, it said, to "require reporting by fewer entities, which will be less burdensome to the laboratory industry."[1] We were surprised to see that in the subregulatory guidance, the agency said that the reporting entity "must report applicable information *individually for all its NPI-level components* that are applicable laboratories."[2] This is just as burdensome to the laboratory industry as each NPI-level component reporting applicable information to CMS, and it does not seem to satisfy the agency's goal of decreasing the administrative burden the laboratory industry. Generally, laboratories do not bill private payors using an NPI, but rather a TIN. Particularly for larger laboratory organizations with large networks of testing sites, they will have to go to great lengths not previously contemplated to deconstruct their revenue from private payors to assign specific payments to particular NPIs. In most cases, each of an independent laboratory's NPI-level components is an applicable laboratory, and separating payment data in the manner described by CMS is not necessary and is tremendously burdensome.

[1] 81 Fed. Reg. 41036, 41047 (Jun. 23, 2016).
[2] MLN Matters Number SE1619 at 11, *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1619.pdf (emphasis added).

We would like to discuss CMS's purpose for requiring applicable information to be reported individually for each NPI-level component. The crucial issue, as CMS itself said in the final rule, is "the same applicable information being reported to CMS," whether aggregated or reported separately. It does not matter if applicable information is aggregated at the reporting entity level or separated out by NPI-level entity: the agency will get the same information about private payor rates and volume for each relevant HCPCS code. We continue to believe that the reporting mechanism must be flexible enough to meet the needs of a wide variety of applicable labs with vastly different sizes and structures, while not creating unnecessary administrative burdens on reporting laboratories.

Examples for determination of "applicable laboratory" status. We are concerned about inconsistencies between the final rule and examples given in the subregulatory guidance regarding a determination of whether an entity is an "applicable laboratory" for purposes of PAMA. In the subregulatory guidance, CMS provides seven scenarios with various combinations of CLIA-certified laboratories and associated NPIs and states how the "majority of Medicare revenues" and "low expenditure" thresholds should be applied. CMS also says in the subregulatory guidance that for a CLIA-certified laboratory that bills Medicare Part B under its own NPI to be an applicable laboratory, it must receive more than 50 percent of its total Medicare revenues from payments under the CLFS and/or PFS. It also must receive at least $12,500 in CLFS revenues during a data collection period "by its own billing NPI."[3]

CMS had proposed in the proposed rule that an "applicable laboratory" is any combination of entities sharing a TIN that meets the majority of Medicare revenues and low expenditure thresholds and includes (but may not be limited to) a CLIA-certified lab.[4] CMS rejected that approach in the final rule, defining "applicable laboratory" as a CLIA-certified laboratory that bills Medicare Part B under its own NPI and meets the majority of Medicare revenues threshold and low expenditure threshold.[5] However, certain examples in the subregulatory guidance (specifically examples 2, 4, and 7) suggest that an "applicable laboratory" is any combination of entities sharing an NPI that meets the majority of Medicare revenues and low expenditure thresholds and includes (but may not be limited to) a CLIA-certified lab – a very different definition than that adopted under the final rule.

In the examples given in the subregulatory guidance, CMS purports to apply the four criteria of an "applicable laboratory" that are included in the definition at 42 C.F.R. § 414.502. But based on the finalized regulatory definition, a CLIA-certified laboratory that does not bill under its own NPI would not appear to be an "applicable laboratory." It seems that the inquiry should stop there, and there is no need to apply the "majority of Medicare revenues" and "low expenditure" threshold tests. Nothing in the statute or the final rule suggests that it is permissible for the "majority of Medicare revenues" or "low-expenditure" thresholds to be "applied based on

[3] MLN Matters Number SE1619 at 3-4.
[4] *See* 80 Fed. Reg. 59386, 59392 (Oct. 1, 2015).
[5] *See* 42 C.F.R. § 414.502 ("*Applicable laboratory* means an entity that: (1) Is a laboratory, as defined in § 493.2; (2) Bills Medicare Part B under its own NPI; (3) In a data collection period, receives more than 50 percent of its Medicare revenues…from the following sources: (i) [the CLFS]; (ii) [the PFS]; (4) Receives at least $12,500 of its Medicare revenues from [the CLFS]…")

the combined revenues of all CLIA-certified laboratories in the organization that use the same billing NPI" or "applied based on the combined revenues of all components of the entity that bill for services under the same NPI." Yet CMS has done just that in examples, 2, 4 and 7 in the subregulatory guidance.[6] Further, example 7 suggests that the majority of Medicare revenues threshold and low expenditure threshold would be applied to the NPI of an entire hospital where a CLIA-certified laboratory shares an NPI with the hospital, which neither the statute nor the final rule would permit.[7] This approach appears to be a relic of language that was included in the proposed rule but rejected in the final rule. The examples in the guidance, as written, represent a significant departure from both the statute and the final rule and will cause laboratories to make inconsistent determinations about whether a laboratory is an "applicable laboratory" for reporting purposes.

B. Codes on which Applicable Information is to be Reported

We would like to have a discussion about the CMS's selection of the list of codes about which applicable laboratories are to report applicable information.[8] Our expectation was that, because CMS must collect this information for purposes of calculating CLFS rates, the list would be comprised of the codes appearing on a particular year's CLFS. However, the list includes not only codes appearing on and paid under the CLFS, but also codes that are not on the CLFS (*e.g.*, general health panel – 80050), some that are on the CLFS but that are not paid on the CLFS (*e.g.*, drug screening tests), and others that appear on the CLFS with a CPT code but for which claims are submitted to the MAC using an unlisted code (*e.g.*, OncotypeDx – 81519, submitted to Palmetto with 81479). The list also includes Tier II molecular codes (CPT codes 81400 through 81408), which consist of general descriptions and a list of different tests that meet the description.[9] On the other hand, not included on the list are the "Automated Test Panel" codes (HCPCS codes ATP02 through ATP23), which describe automated multichannel chemistry ("AMCC") tests for which CMS bundles payments and which do appear on the CLFS.

Certain codes included on the list of codes about which applicable information is to be reported conflict with statements CMS made in the preamble to the final rule. CMS said that "only private payor rates for CLDTs paid for under the CLFS are considered for private payor rates."[10] However, the list includes several tests that are not on the CLFS. The agency also said that it would not collect information about "miscellaneous/not otherwise classified (NOC)" codes because the codes "do not describe a single test and may be used to bill and pay for multiple types of tests."[11] Yet the Tier II molecular codes, which are "used to bill and pay for multiple types of

[6] MLN Matters Number SE1619 at 4-5.
[7] MLN Matters Number SE1619 at 5.
[8] CMS Applicable Information HCPCS Codes, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.
[9] For example, the description of CPT code 81400 is "identification of single germline variant (*e.g.*, SNP) by techniques such as restriction enzyme digestion or melt curve analysis", but then it is followed by individual tests that meet that description. The individual tests do not have their own CPT codes.
[10] 81 Fed. Reg. 41055.
[11] *Id.* at 41053.

tests" have been included on the list. We would like to gain a better understanding from you of how the agency determined which tests should and should not be included on the list.

C. Issues Not Addressed in the Subregulatory Guidance

Given the short period of time until applicable laboratories are to begin reporting information to CMS, we are eagerly awaiting guidance on:

- The mechanics of how an applicable laboratory will report applicable information to CMS, and whether CMS will allow laboratories to test any electronic reporting system;
- The application and approval process for Advanced Diagnostic Laboratory Tests ("ADLTs"), including whether a laboratory may request that ADLT designation be withdrawn;
- How CMS intends to collect applicable information on and price AMCC tests;
- Whether CMS will release only preliminary weighted medians in September 2017, or whether it also will release raw data to allow stakeholders to make informed comments on the preliminary rates; and
- Whether the comment period after release of preliminary rates will be the only opportunity for a stakeholder to object to the weighted median.

D. Conclusion

We would appreciate the opportunity to discuss these issues with you in person. ACLA hopes to continue working collaboratively with CMS on implementation of Sec. 216 of PAMA, and we remain available to you as a resource in this process. Thank you for your attention to these matters.

Sincerely,

Julie Khani, Executive Vice President
American Clinical Laboratory Association

Khani Declaration Exhibit 21

March 24, 2017

The Honorable Tom Price, MD
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

DELIVERED BY ELECTRONIC MAIL

Dear Secretary Price:

We, the undersigned, are writing to express our continued significant concerns about the implementation of the Medicare Clinical Laboratory Fee Schedule (CLFS) reform as enacted by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA). While our organizations have worked closely with our members and the Centers for Medicare and Medicaid Services (CMS) toward PAMA implementation, we believe that under the current regulatory requirements, the new program will not reflect accurate private market rates for clinical laboratory services as required by PAMA. Given the significance of these ongoing concerns, we respectfully request CMS delay the implementation of the CLFS reforms under PAMA for one year to resolve these significant issues. By ensuring smooth and successful implementation, we can maintain Medicare beneficiary access to clinical laboratory services without disruption.

Our organizations represent a diverse cross section of clinical laboratory stakeholders, including national, community and regional independent laboratories, hospital laboratories, physician office laboratories, academic laboratories, manufacturers of IVD test kits and supplies, clinical laboratory professionals, and the broad physician community.

The data reporting period for PAMA is scheduled to conclude on March 31, 2017, but many laboratories are still in the data *collection* phase as they struggle with CMS regulatory requirements. Furthermore, we are concerned that CMS' data collection system is not yet functioning at adequate capacity as many operational problems from the 2016 test phase appear unresolved and are hampering laboratory data submissions. CMS and laboratories simply must have more time to address data collection concerns, collect, and ensure accurate submission of all applicable data as this will impact final PAMA rates.

Beyond operational data issues, the significant regulatory definition for "applicable laboratory" must be reassessed and redefined. PAMA payment reforms depend on an accurate measurement of true private market rates; however, the Health and Human Services (HHS) Office of Inspector General (OIG) analysis of the current CMS definition for "applicable laboratory" assessed that only 5 percent of clinical laboratories will report data, with an estimated complete exclusion of hospital laboratories.[1]

[1] [1] *HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040), Sept 2016*, https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf, pages 7-8.

The exclusion of an entire laboratory sector, particularly hospitals operating large outreach laboratories, negatively affects the integrity of rate calculations under PAMA. The implications are immense and would ultimately threaten to reduce laboratory infrastructure across the country, and therefore, limit beneficiary access to laboratory test services that support patient clinical care management. The applicable laboratory definition should be redefined to appropriately capture the true laboratory market.

Given the widespread impact of these issues, we respectfully ask that CLFS reform implementation under PAMA be delayed for one year to allow an opportunity for all stakeholders to work with the Administration on solutions. We are committed to working in partnership with you to address our concerns. If we can answer any questions or provide additional information, please contact Julie Allen, NILA Washington Representative at 202-230-5126 or julie.allen@dbr.com or Julie Khani, President, ACLA at 202-637-4865 or jkhani@acla.com.

Sincerely,

AdvaMedDx
American Association for Clinical Chemistry (AACC)
American Association of Bioanalysts (AAB)
American Clinical Laboratory Association (ACLA)
American Medical Technologists (AMT)
American Society for Clinical Laboratory Science (ASCLS)
American Society for Clinical Pathology (ASCP)
Clinical Laboratory Management Association (CLMA)
College of American Pathologists (CAP)
National Independent Laboratory Association (NILA)

Cc: The Honorable Seema Verma, Administrator, Centers for Medicare and Medicaid Services
The Honorable Orrin Hatch, Chairman, Senate Finance Committee
The Honorable Ron Wyden, Ranking Member, Senate Finance Committee
The Honorable Kevin Brady, Chairman, House Ways and Means Committee
The Honorable Richard Neal, Ranking Member, House Ways and Means Committee
The Honorable Greg Walden, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee

Khani Declaration Exhibit 22

American Clinical Laboratory Association

Summary of Issues for April 27th Meeting with the American Clinical Laboratory Association (ACLA): Implementation of PAMA and Inadequacy of Pricing for Innovative Laboratory Tests

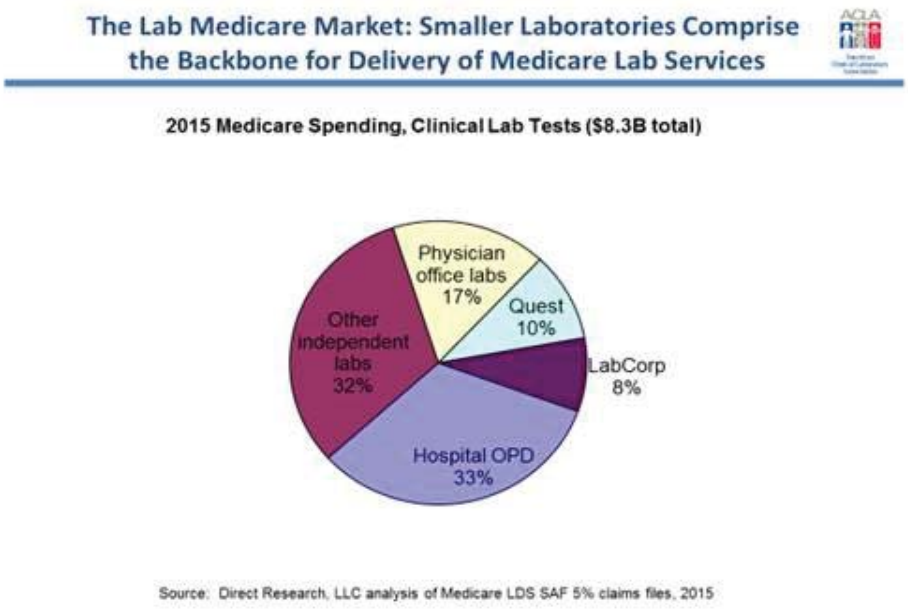
ACLA is an association representing the nation's leading providers of clinical laboratory services, including large national independent laboratories, reference laboratories, esoteric laboratories, hospital laboratories and nursing home laboratories. The services our members offer Medicare and Medicaid beneficiaries include commonly ordered lab tests (*e.g.*, glucose monitoring and blood counts), as well as innovative molecular diagnostic lab tests such as genomic sequencing panels and algorithm-based tests. Whether tests on the cutting edge of medicine or more routine tests, clinical laboratory services provide cost effective tools which aid in guiding diagnosis, prevention, and treatment, thereby, avoiding more costly patient interventions and outcomes later.

ACLA values its collaborative relationship with the Centers for Medicare & Medicaid Services (CMS), and our members strive to provide high-quality and clinically-valuable laboratory services to beneficiaries. However, we are concerned that beneficiary access to laboratory services may be at risk due to implementation of Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) and, separately, how prices are initially set for new, innovative tests under the Clinical Laboratory Fee Schedule (CLFS). These reimbursement shortcomings threaten access to important clinical services used by Medicare and Medicaid beneficiaries.

The Interpretation and Implementation of Section 216 of PAMA Threatens Medicare and Medicaid Beneficiary Access to Laboratory Tests

Congress enacted Section 216 of PAMA to replace the static Clinical Laboratory Fee Schedule (CLFS) with reimbursement based on private market rates. ACLA supported enactment of Section 216, as Congress clearly intended rates to be based on the broad scope of the laboratory market. Most critically, the Final Rule interpretation of which labs must submit data (i.e. "applicable laboratories") will deliver skewed rates that are not reflective of the true market rates originally intended by Congress. Further, we are concerned that the data system promulgated by CMS may not be prepared to accept, analyze, and audit the voluminous data some providers must submit to CMS as required by the law. The data reporting burden and volume, as currently designed, exacerbates the applicable laboratory issue as laboratories that might otherwise submit data will be wary to assume the cost of reporting.

The Health and Human Services (HHS) Office of the Inspector General (OIG) estimated that only 5 percent of clinical laboratories will be required to submit private market data under the law because of CMS's definition of the statutory term "applicable laboratory." A 5 percent sample does not reflect the private market. The entities that would qualify and report as "applicable laboratories" under this interpretation by CMS make up a small percentage of the types of laboratories providing services in the market. The graph below describes the laboratory market serving Medicare beneficiaries.



We appreciated CMS's March 30th decision to exercise enforcement discretion to extend the data reporting period 60 days to May 30th, which will provide both CMS and laboratories more time to comply. We hope that during these 60 days, CMS and other stakeholders can work together to begin the collaborative process to revise the applicable lab definition to match Congress's intent for the CLFS to accurately reflect private market rates.

ACLA seeks a one year delay in implementation of Section 216, and asks CMS to revise the regulatory definition of applicable laboratory to ensure that the agency receives a representative data set required to establish a laboratory fee schedule that reflects private market rates.

Inadequacy of Current Methodologies for Pricing New, Innovative Laboratory Tests

New laboratory tests are initially priced by CMS using one of two methodologies – cross-walking the rate assigned to the test to a test currently priced on the CLFS, because it shares similarities with the existing test; or gap-filling the test, in which the Medicare Administrative Contractors (MAC) are asked to recommend rates for tests which can't be cross-walked. Whether a test is cross-walked or gap-filled, in too many instances, especially for an innovative, cutting edge tests, the price does not include critical components of the test or fails to account for resources necessary for and costs of performing the test. CMS too often fails to account for the resources required to develop, maintain, and perform these types of innovative tests, resulting in inadequate reimbursement levels which threaten patient access.

ACLA asks CMS to revisit how the crosswalks and gap-fill rates are being established for the genomic sequencing procedures, and adopt the recommendations from multiple stakeholders to use a rate-setting methodology that accounts for variations in the size of the genomic panels being performed.

Khani Declaration Exhibit 23

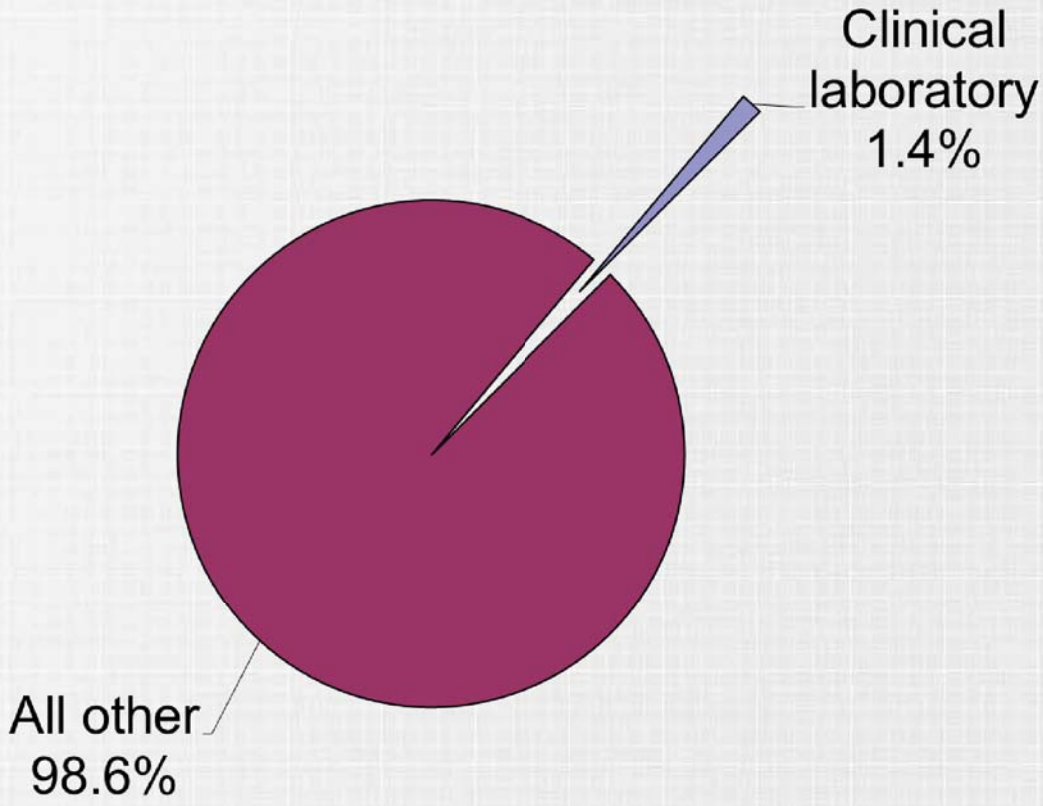
ACLA Meeting With CMS Administrator Regarding Implementation Of PAMA CLFS Reform

April 27, 2017

American Clinical Laboratory Association

Clinical Lab Services Are Less Than 2% Of Medicare Spend

American Clinical Laboratory Association



Source: Medicare Payment Advisory Commission: A Data Book: Health Care Spending and the Medicare Program, June 2016, page 197

ACLA Supported PAMA And Continues To Support A Market-Based Fee Schedule

American Clinical Laboratory Association

ACLA NEWS

American Clinical Laboratory Association Supports Senate Passage of Provisions for Clinical Laboratory Fee Schedule in SGR Extension Legislation

April 01, 2014 *Categories: ACLA News, News, Reimbursement and Coverage, Featured News, ACLA Press Releases*

WASHINGTON, D.C. – The American Clinical Laboratory Association (ACLA) – a not-for-profit association representing the nation's leading national and regional clinical laboratories on key federal and state government reimbursement and regulatory policies – voiced support for provisions in the SGR extension legislation passed by the U.S. Senate today that reform the Clinical Laboratory Fee Schedule (CLFS) by providing a more rational process for transitioning to changes in reimbursement.

"The ACLA worked diligently with Congress on many of the lab industry's key priorities and we are pleased that the Senate included in the SGR extension bill several of our proposals for modernizing how Medicare reimburses clinical laboratories," said Alan Mertz, President of the ACLA. "When the president signs this bill, clinical labs will avoid another potential round of indiscriminate, across-the-board payment cuts and most importantly, seniors' access to diagnostic testing will be protected."

Mertz noted the SGR extension legislation will bring predictability in reimbursement over the next several years, provide more transparency, and allow more time for laboratories and other stakeholders to prepare for changes as well as ensure that Medicare reimbursement for anatomic pathology services will not suffer significant cuts. In addition, it will provide more opportunity for stakeholders to work with the Centers for Medicare and Medicaid Services (CMS) on implementing these important reforms.

https://www.acla.com/american-clinical-laboratory-association-supports-senate-passage-of-provisions-for-clinical-laboratory-fee-schedule-in-sgr-extension-legislation/

OIG Estimates Zero Hospitals Will Report

American Clinical Laboratory Association

Figure 5. Which Labs Will Be Required to Report Their Private Payer Data?

INDEPENDENT LABS	PHYSICIAN OFFICE LABS	HOSPITAL LABS
Independent labs that received **at least $12,500** from Medicare Part B for lab tests during the first half of 2016 or any labs that perform advanced diagnostic lab tests will be required to report	Physician-office labs that received **at least $12,500** from Medicare Part B for lab tests during the first half of 2016 will be required to report	Generally, no hospital labs will be required to report, because 50% or **less of their Medicare revenue** is for Clinical Laboratory Fee Schedule or Physician Fee Schedule services
1,398 out of 3,211: Estimated number of labs that will be required to report	**11,149 out of 235,928**: Estimated number of labs that will be required to report	**0 out of 6,994**: Estimated number of labs that will be required to report (excludes hospital outreach labs, which function as independent labs)
$3.8 billion out of $3.9 billion: Medicare payments to reporting labs	**$1.0 billion of $1.4 billion**: Medicare payments to reporting labs	**$0 of $1.7 billion**: Medicare payments to reporting labs

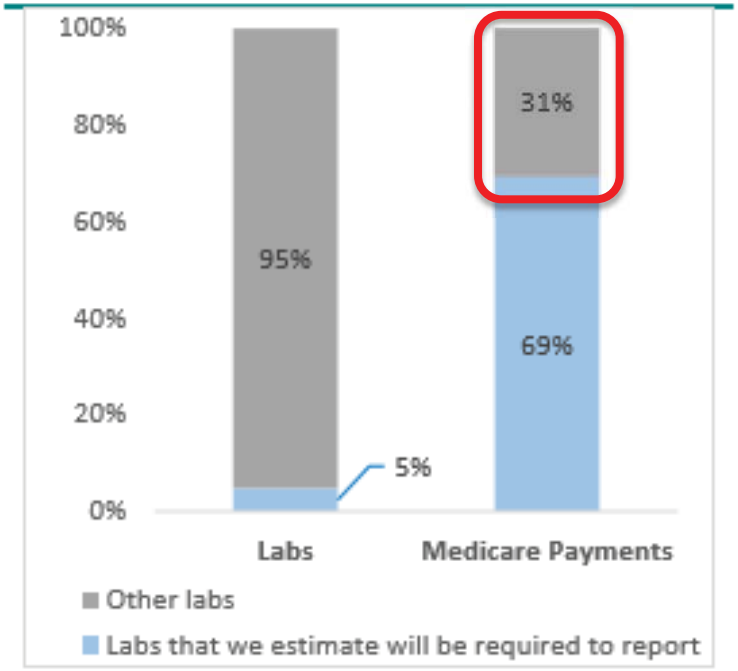
Source: OIG analysis of Medicare Part B lab test payments, 2016. See endnote 10 for more information about the criteria identifying applicable laboratories, i.e., laboratories that will be required to report.

Note: Figures regarding how many labs will be required to report are estimates. We assumed that all independent labs and physician office labs will receive more than 50 percent of their Medicare revenue from the Clinical Lab Fee Schedule or Physician Fee Schedule.

Labs Responsible For 31% Of Medicare CLFS Dollars May Not Report Data

American Clinical Laboratory Association

Figure 4. Labs That We Estimate Will Report Private Payer Data Represented More Than Two-Thirds of Medicare Payments in 2015

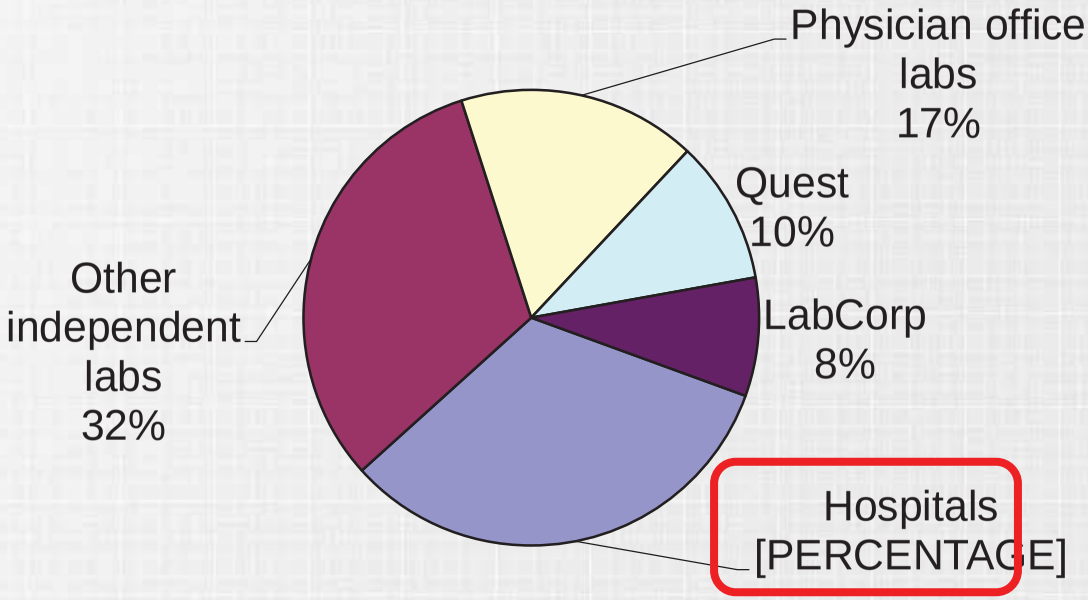


Source: OIG analysis of Medicare Part B lab test payments, 2016.

33% Of Clinical Lab Test Spending Under Medicare Is Served By Hospitals

American Clinical Laboratory Association

2015 Medicare Spending, Clinical Lab Tests ($8.3B total)



Source: Direct Research, LLC analysis of Medicare LDS SAF 5% claims files, 2015

Hospital And Rural Labs Serve Distinct Patient Populations

American Clinical Laboratory Association

- "In many communities, the rural hospital is likely to be the sole provider of outpatient surgery, radiology, and clinical laboratory services."*
- Critical Access Hospitals' non-patients are reimbursed off the CLFS.
- Zero private market data from these entities will be reported to CMS, as estimated by OIG.
- Hospital-based labs rely more heavily on Medicare reimbursement.**

* Solutions to the Problems of Rural Hospitals Must Address the Need for Adequate Clinical Laboratory and Anatomic Pathology Testing Services | Dark Daily http://www.darkdaily.com/solutions-to-the-problems-of-rural-hospitals-must-address-the-need-for-adequate-clinical-laboratory-and-anatomic-pathology-testing-services-424#ixzz4e4G3a42S

**Barclays Lab Director Survey: Views on PAMA; January 4, 2017 and February 27, 2017

Current Reporting Burden Exacerbates Applicable Lab Issue

American Clinical Laboratory Association

- Final rule requires submission of hundreds of millions of private rate data points
- Even sophisticated laboratories have expended hundreds of FTE's to amass the required data, including manual input of paper claims (as required by the rule)
- Continued errors in the CMS data portal have increased the burden and uncertainty of data reporting
- The cost and burden of reporting has given pause for additional laboratories from engaging and seeking to submit data

Members Who Wrote PAMA Support Including All Market Segments, Hospitals

American Clinical Laboratory Association

- 5/8/14: Senators Orrin Hatch and Richard Burr's Colloquy*:
  - **Burr:** "…the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services…**all sectors of the laboratory market should be represented in the reporting system, including independent clinical laboratories and hospital outreach laboratories…"**
  - **Hatch:** "The Senator is correct. [T]hat **commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."**
- 9/18/14: Senators Orrin Hatch and Richard Burr wrote to CMS Administrator Marilyn Tavenner:
  - "Absent the inclusion of all sectors of the laboratory industry, including independent labs, hospital outreach labs, and larger physician office labs, we are concerned that the resulting reimbursement rates will not be reflective of the true market."
- 12/14/15: Nineteen Senators wrote to CMS Acting Administrator Andy Slavitt "concerned with the proposed rule's approach [that] a significant part of the laboratory market is excluded from participation."

(Emphasis added)

* Congressional Record from May 8, 2014: https:/www.congress.gov/congressional-record/2014/05/08/senate-section/article/S2860-1

Members Who Wrote PAMA Support Including All Market Segments, Hospitals (cont'd.)

American Clinical Laboratory Association

- 12/16/15: Forty-four Representatives wrote to CMS Acting Administrator Andy Slavitt concerned that **"a number of laboratories are prohibited from participating in the reporting process. [T]his prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices."**

- 1/6/16: Finance Chairman Orrin Hatch and Ranking Member Ron Wyden wrote to CMS Acting Administrator Andy Slavitt that "laboratories reporting the private sector data" should be "representative of the marketplace." They continue that **Medicare payment rates should "reflect information from important segments of the laboratory market, especially hospital outreach laboratories** paid under the Clinical Laboratory Fee Schedule. Hospital outreach laboratories, a well-defined market segment, serve beneficiary needs and compete with other community-based laboratories."

(Emphasis added)

ACLA Requests

American Clinical Laboratory Association

1. Delay implementation of PAMA by one year to revise the regulatory definition of Applicable Laboratory to satisfy the intent of Congress and capture true private market rates.

2. Simplify the data reporting requirements to reduce the cost, burden, and error-risk of data submission.

Khani Declaration Exhibit 24

American
Clinical Laboratory
Association

June 7, 2017

CMS Administrator Seema Verma
Office of the Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Rm. 314-G
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Verma,

Thank you for meeting with representatives of the American Clinical Laboratory Association (ACLA) on April 27 for a productive meeting to discuss implementation of Section 216 of the Protecting Access to Medicare Act (PAMA).[1] That section of the law aims to establish Medicare Clinical Laboratory Fee Schedule (CLFS) prices that are based on rates paid by private payors for laboratory tests. We are encouraged by your willingness to work with ACLA and other stakeholders to ensure that Section 216 is implemented in a manner consistent with Congressional intent and to ensure that all sectors of the laboratory market are represented in the data CMS uses to calculate the new CLFS rates.

As we discussed during our meeting, the current regulations effectively remove an entire piece of the laboratory market – hospital outreach laboratories – from data reporting. An "applicable laboratory" is one that bills under its own NPI number, receives a majority of its Medicare revenues under the CLFS and/or Physician Fee Schedule (PFS), and receives more than a certain amount of CLFS revenue in a given period.[2] Only applicable laboratories are required or allowed to report their private payor rates and associated volumes to CMS, yet because of the way CMS defined that term in the final rule, only a very small number of hospitals provided their data to the agency. As a result, the data that CMS will use to calculate CLFS rates is incomplete and not reflective of the entire laboratory market. This is the first major change to the CLFS in more than 30 years, and ACLA believes strongly that this change should not be implemented in a way that results in incorrect rates and that threatens Medicare beneficiary access to laboratory services.

We also are very concerned about difficulties during the recently-completed data reporting period, faced both by CMS in accepting the data and laboratories reporting data. These issues affect the quality and the integrity of the data that CMS has received to date. Despite CMS's best efforts to provide clear direction through the regulations, the final rule's preamble language, webinars, and FAQs, we know from talking with other stakeholders that reporting entities took a variety of approaches to determining which private payor rates and volumes to report. The data CMS will use to calculate CLFS rates is likely to be inconsistent and possibly incomplete.

During our April 27 meeting, you asked ACLA to provide you with specific recommendations for changes that would result in the entire laboratory market being represented in data that CMS uses to calculate new CLFS rates. Since then, ACLA member companies have had numerous meetings to work together toward a viable solution that can be implemented administratively, and we have reached out to other stakeholders, as well. As we worked together

[1] Pub. L. 113-93.
[2] 42 U.S.C. § 1395m-1(a)(2).

to develop a reasonable approach to resolving these issues, we also have been mindful of the agency's own timeline for implementing the law.

We considered a variety of approaches to rectifying the flawed applicable laboratory definition in the final rule and resulting incomplete data collection, and we continue to believe that **CMS should not implement the new CLFS rates until it has collected private payor rates and volumes from all sectors of the laboratory market, including hospital outreach laboratories.** Below, we propose a revised definition of "applicable laboratory" that would include both hospital outreach laboratories and those entities described in the current definition. We also have proposed a revised implementation timeline that would allow CMS to collect this data from hospital outreach laboratories and integrate it into the data it already has collected from other applicable laboratories.

Rather than calculate weighted medians based on incomplete data, CMS should issue an interim final rule to: (1) postpone its calculation and publication of new CLFS rates; (2) amend the definition of "applicable laboratory" to include all hospital outreach laboratories that exceed the minimum CLFS revenue threshold and meet the "majority of Medicare revenues" test; and (3) establish dates for hospital outreach laboratories to report private payor rates to CMS and for publication of the new CLFS rates.

Postpone calculation of new CLFS rates: CMS should not calculate and publish CLFS rates that are based on incomplete data. The agency should issue an interim final rule that delays implementation of new CLFS rates for at least six months, until it has collected private payor data from the remainder of the laboratory market and until it has integrated that data with data that already has been reported. Prior to the effective date of the new CLFS rates, rates for CY 2018 would be determined under Sec. 1833(h) of the Social Security Act, in the same manner as the rates were determined for CY 2017.

Definition of "applicable laboratory": In the final rule, CMS defined "applicable laboratory" at the NPI level, reasoning that a hospital outreach laboratory that already had its own NPI number could qualify as an applicable laboratory, and a hospital outreach laboratory that did not have one could obtain one and then qualify as an applicable laboratory.[3] However, very few hospital outreach laboratories have their own NPI numbers – almost all bill under the NPI number used by the entire hospital. As a practical matter, a hospital outreach laboratory will not obtain its own NPI number voluntarily solely for the purpose of qualifying as an applicable laboratory. We have no evidence that any hospital outreach laboratories proactively sought separate NPI numbers since issuance of the final rule.

CMS should amend the definition of "applicable laboratory" to make clear that for the purpose of determining whether an entity receives a majority of its Medicare revenues under the CLFS and/or the PFS, "Medicare revenues" means payment for claims submitted on a CMS 1500, a CMS 1450 using a 14X Type of Bill, or their electronic equivalents.[4] A 14X Type of Bill is used only to submit claims for hospital laboratory outreach (non-patient) claims, so this approach would account only for the hospital laboratory business that competes in the marketplace with independent clinical laboratories. The revised definition would not have the effect of excluding

[3] 81 Fed. Reg. 41036, 41045 (Jun. 23, 2016).
[4] The appendix includes proposed regulatory language for a revised definition of "applicable laboratory."

from the definition of "applicable laboratory" any laboratory that already has reported private payor data to CMS. It also would effectuate Congress' intent to determine whether a majority of Medicare revenues attributable to the laboratory – as opposed to the entire hospital – was from the CLFS and/or PFS.

Timeline for data reporting and new rate implementation: The data collection period for hospital outreach laboratories that qualify as applicable laboratories under the revised definition should be January 1 through June 30, 2016, the same data collection period as other applicable laboratories. CMS then would have a complete "snapshot" of the national laboratory market in its data. Hospital outreach laboratories would report their applicable information to CMS between November 1, 2017 and January 31, 2018. CMS would calculate weighted medians from data reported during the just-completed data reporting period and data reported by newly-eligible hospital outreach laboratories. The new CLFS rates, representing the weighted medians of the entire clinical laboratory testing market, would be effective starting July 1, 2018 or a later date. In recognition of hospital outreach laboratories reporting their data in 2018, CMS should consider postponing the next data reporting period from 2020 to 2021 for all applicable laboratories, to give hospital outreach laboratories a reasonable interval between reporting periods. The implementation schedule for this approach is summarized below:

> Aug. 2017: CMS issues an interim final rule delaying calculation and publication of new CLFS rates, setting forth a new definition of "applicable laboratory", and revising the implementation timeline.
>
> Nov. 1, 2017 – Jan. 31, 2018: Data reporting period for newly-eligible applicable laboratories (reporting data for the period Jan. 1 – June 30, 2016).
>
> Mar. 31, 2018: CMS publishes preliminary CLFS rates that include hospital outreach laboratory data, for a 30 day comment period.
>
> May 31, 2018: CMS publishes final CLFS rates, taking stakeholder comments into account.
>
> July 1, 2018: New CLFS rates are effective (or a later date, if this date is not feasible).

* * * * *

In the final rule implementing Sec. 216 of PAMA, CMS said: "We believe that it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting CLFS payment amounts."[5] The approach set forth above would allow the agency to have and to use information from all parts of the national laboratory market to set new CLFS rates. All entities submitting claims under the CLFS will be subject to the new rates, and all sectors of the laboratory market should be represented in the data used to develop those rates.

We sincerely appreciate your willingness to work with ACLA and other stakeholders to address this issue, and we look forward to our continued collaboration with you.

[5] 81 Fed. Reg. 41045.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association

APPENDIX

The statutory definition of "applicable laboratory" set forth at 42 U.S.C. § 1395m-1(a)(2) is "a laboratory that, with respect to its revenues under [title XVIII] a majority of such revenues are from this section, section 1833(h), or section 1848. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary deems appropriate." Below is a proposed regulatory definition of "applicable laboratory" that would include hospital outreach laboratories. Additions to the current regulatory language appear in bold type, and deletions are struck through.

42 C.F.R. § 414.502. Definitions.

Applicable laboratory means an entity that:

(1) Is **itself** a laboratory, as defined in § 493.2 of this chapter, **or if it is not itself a laboratory, has at least one component that is a laboratory.**

(2) Bills Medicare Part B under its own National Provider Identifier (NPI)**, or bills Medicare Part B on a CMS 1450 or its electronic equivalent using a 14X Type of Bill**;

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which ~~includes~~ **means** fee-for-service payments **for claims submitted on a CMS 1500 or its electronic equivalent or on a CMS 1450 or its electronic equivalent using a 14X Type of Bill** under Medicare Parts A**,** ~~and~~ B, ~~Medicare Advantage payments under Medicare Part~~ C, **and** ~~prescription drug payments under Medicare Part~~ D, and any associated Medicare beneficiary deductible or coinsurance, for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) **In a data collection period,** receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

Khani Declaration Exhibit 25

June 26, 2017

The Honorable Thomas E. Price, M.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

DELIVERED VIA E-MAIL

Dear Secretary Price:

We respectfully request to meet with you on imminent issues with implementation of the Clinical Laboratory Fee Schedule (CLFS) provisions (Section 216) of the Protecting Access to Medicare Act of 2014 (PAMA). Our organizations represent a diverse cross section of clinical laboratory stakeholders, including physicians, independent laboratories, hospital laboratories, and manufacturers of IVD test kits and supplies.

We have worked closely with Congress and the Centers for Medicare and Medicaid Services (CMS) on PAMA implementation. However, given the exclusion of most hospital and physician office laboratories from data reporting, and concerns with data accuracy and integrity, we believe that under the current regulatory requirements, the new program will not reflect accurate private market rates that are representative of the full laboratory market, including physician office, hospital and independent laboratories.[1] Given the significance and urgency of these ongoing concerns, we respectfully request a delay in the implementation of the CLFS rates under PAMA until the rule is fixed and accurate. By ensuring smooth and successful implementation, we can maintain Medicare beneficiary access to clinical laboratory services without disruption.

PAMA established Medicare CLFS prices based on rates paid by private payors for laboratory tests.[2] The exclusion of laboratory sectors, particularly physician office and hospital outreach laboratories, harms the integrity of rate calculations under PAMA and is inconsistent with the clear intent of Congress. This could ultimately threaten beneficiary access to laboratory services from laboratory closures and significant consolidation of the laboratory market. Maintaining access to needed clinical testing is critical to the diagnosis, prevention and treatment of disease.

We request a meeting with you to discuss implementation of PAMA in a manner that is consistent with congressional intent and maintains beneficiary access to laboratory services. There is great urgency to guarantee accuracy as the proposed rates are scheduled to be published in September 2017 and go into effect on January 1, 2018. We believe it is important for CMS to work with the broad stakeholder community to ensure accurate reporting of private rates, and ultimately, new CLFS payment rates that are based on the broad scope of the clinical laboratory market.

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[1] *HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040), Sept 2016*, https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf, pages 7-8.
[2] Pub. L. 113-93.

We look forward to meeting with you to discuss these important issues. Please contact Julie Khani, president, American Clinical Laboratory Association, (202) 637-9466, jkhani@acla.com, to answer any questions or to schedule a meeting.

Sincerely,

AdvaMedDx
American Clinical Laboratory Association
College of American Pathologists
National Independent Laboratory Association

Khani Declaration Exhibit 26

American Clinical Laboratory Association

Protecting Access to Medicare Act: Medicare Clinical Diagnostic Laboratory Tests Payment System

June 28, 2017

Agenda

American Clinical Laboratory Association

- Welcome & Introductions
- Review of Key Concerns
  - Applicable Laboratory Definition
  - Advanced Diagnostic Laboratory Tests (ADLTs)
  - Data Collection and Reporting
- Comments & Questions
- Adjourn

Applicable Laboratory Definition is Incomplete

American Clinical Laboratory Association

- **Applicable Laboratory Statute**
  - "a laboratory that, with respect to its revenues under [title XVIII of the Social Security Act], a majority of such revenues are from [the Physician Fee Schedule or the Clinical Laboratory Fee Schedule]"
- **CMS Definition Leaves Out Major Laboratory Sectors**
  - HHS OIG analysis of the current CMS definition for "applicable laboratory" assessed that only 5 percent of clinical laboratories will report data, with an estimated complete exclusion of hospital laboratories.[1]
- **ACLA Recommends Capturing Data from All Market Sectors**
  - "Medicare revenues" must include payments for claims submitted on a CMS 1500, a CMS 1450 using a 14X Type of Bill, or their electronic equivalents as this is only used by hospital outreach laboratories, direct competitors with independent and physician office laboratories

[1] HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040), Sept 2016, https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf, pages 7-8.

CMS Has Not Issued ADLT Guidance or Application

American Clinical Laboratory Association

- **PAMA Includes Unique Method of Payment for New ADLTs**
  - ADLT designations require necessary information from CMS.

- **CMS Has Not Issued ADLT Sub-regulatory Guidance Documents or ADLT Application**
  - Due to lack of instructions, there are currently no tests designated as ADLTs.
  - There has been no announcement on a timeline of when CMS will issue this information.

- **ACLA Recommends that CMS Publish the ADLT Application and Associated Sub-regulatory Guidance Documents**
  - CMS providing the necessary information on ADLTs would help to fulfill congressional intent and increase certainty for clinical laboratories looking to designate their tests as ADLTs.

ADLT Interpretation is Incorrect and Unworkable

American Clinical Laboratory Association

- **ADLT Statute**
  - "…unique algorithm to yield a single patient-specific result."
- **CMS Definition Incorrectly Applies "Uniqueness" to the "Patient-specific Result" Rather than the "Algorithm"**
  - In the Final Rule, CMS requires ADLTs provide new information that cannot be obtained from any other existing test on the market or combination of tests.
  - This interpretation is a deterrent to applicants to take advantage of this category created by Congress.
- **ACLA Recommends CMS Apply "Uniqueness" to the Algorithm Alone**
  - If CMS does not revert to the statute's intent, laboratories will be unable to prove a negative that no similar test exists. CMS's interpretation threatens the stability of an ADLT designation with regard to future tests.

Khani Declaration Exhibit 26
Page 5 of 9

Burdensome Data Collection and Reporting Requirements

American Clinical Laboratory Association

- **Examples of Data Collection Challenges**
  - Insufficient time to build systems, collect, verify, and report data
  - Manual claims
  - Multiple billing system vendors
  - Non-standardized EOBs/RAs
  - Inconsistent payments, recoupments, denials, appeals
  - Bundling of CPT codes and disparity in code sets

Burdensome Data Collection and Reporting Requirements

American Clinical Laboratory Association

- **Examples of Reporting Challenges**
  - Challenges with submitting large files
  - Issues with reporting system not prompting where “errors” occurred
  - Reporting at TIN/breaking out by NPI
  - Certifying data

Key Questions

American Clinical Laboratory Association

- How many laboratories successfully completed and certified data through the CLFS Data Collection System?
- How do these numbers compare with the estimates in the 2016 OIG report?
- How many of these laboratories were independent laboratories, hospital outreach laboratories, and physician office laboratories?
- When will CMS issue ADLT guidance/application?
- How will CMS verify the accuracy of the data submitted by laboratories?
- What steps will CMS take to simplify future data collection and submission?

American Clinical Laboratory Association

Thank You!

Khani Declaration Exhibit 27

ACLA Meeting With Executive Office of the President Regarding Implementation Of PAMA CLFS Reform

July 13, 2017

American Clinical Laboratory Association

ACLA Supported PAMA's Enactment in 2014

American Clinical Laboratory Association

ACLA NEWS

American Clinical Laboratory Association Supports Senate Passage of Provisions for Clinical Laboratory Fee Schedule in SGR Extension Legislation

April 01, 2014 Categories: *ACLA News, News, Reimbursement and Coverage, Featured News, ACLA Press Releases*

WASHINGTON, D.C. – The American Clinical Laboratory Association (ACLA) – a not-for-profit association representing the nation's leading national and regional clinical laboratories on key federal and state government reimbursement and regulatory policies – voiced support for provisions in the SGR extension legislation passed by the U.S. Senate today that reform the Clinical Laboratory Fee Schedule (CLFS) by providing a more rational process for transitioning to changes in reimbursement.

"The ACLA worked diligently with Congress on many of the lab industry's key priorities and we are pleased that the Senate included in the SGR extension bill several of our proposals for modernizing how Medicare reimburses clinical laboratories," said Alan Mertz, President of the ACLA. "When the president signs this bill, clinical labs will avoid another potential round of indiscriminate, across-the-board payment cuts and most importantly, seniors' access to diagnostic testing will be protected."

Mertz noted the SGR extension legislation will bring predictability in reimbursement over the next several years, provide more transparency, and allow more time for laboratories and other stakeholders to prepare for changes as well as ensure that Medicare reimbursement for anatomic pathology services will not suffer significant cuts. In addition, it will provide more opportunity for stakeholders to work with the Centers for Medicare and Medicaid Services (CMS) on implementing these important reforms.

https://www.acla.com/american-clinical-laboratory-association-supports-senate-passage-of-provisions-for-clinical-laboratory-fee-schedule-in-sgr-extension-legislation/

ACLA Continues To Support PAMA's Intent: A Market-Based Fee Schedule

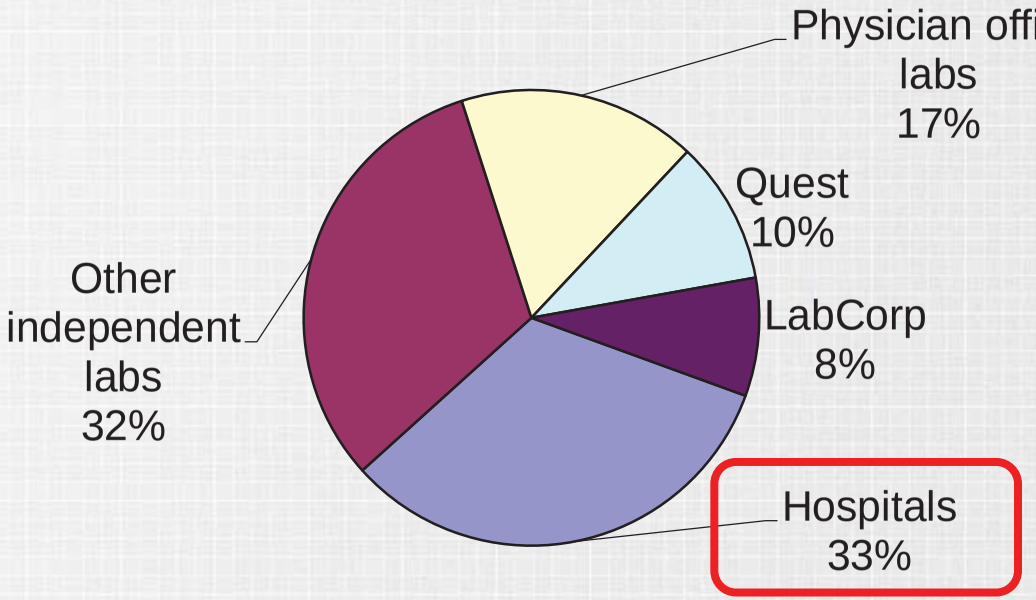
American Clinical Laboratory Association

- Market-based system including all sectors of the market
  - Independent Labs
  - Hospital Outreach Labs
  - Physician Office Labs
- All sectors of the market will be reimbursed by PAMA rates, all should be part of data reporting
- Successful PAMA implementation
  - Maintain access for beneficiaries
  - Savings to the Medicare program
  - Market rates and pricing stability for labs

The Medicare Laboratory Market

American Clinical Laboratory Association

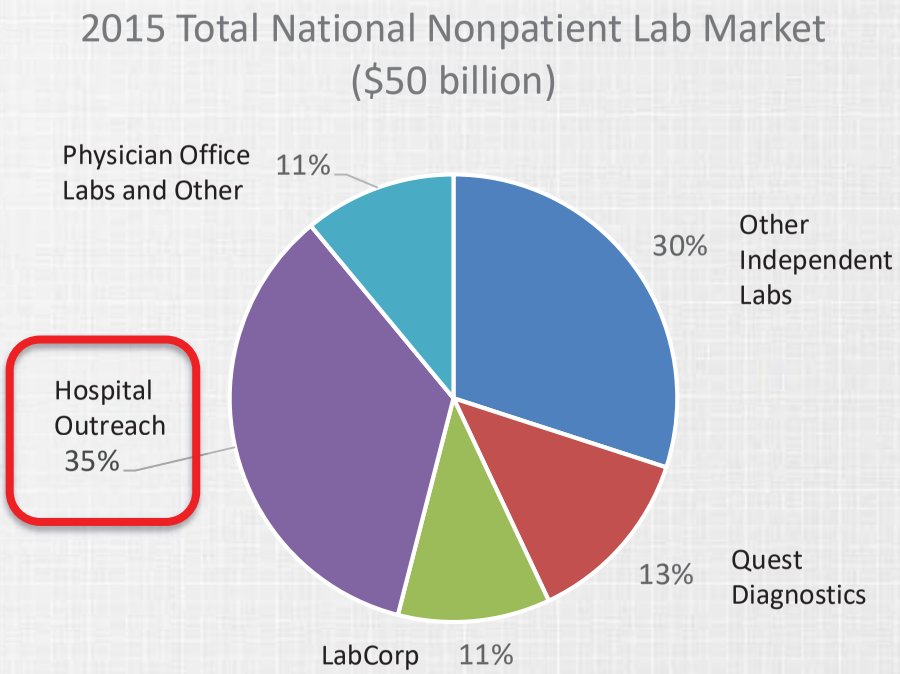
2015 Medicare Spending, Clinical Lab Fee Schedule ($8.3B total)



Source: Direct Research, LLC analysis of Medicare LDS SAF 5% claims files, 2015

"Outside the Hospital" Laboratory Market

American Clinical Laboratory Association



Source: ACLA analysis sourced from *Laboratory Economics* and ACLA member analysis

Issues with PAMA Implementation – Applicable Laboratories

American Clinical Laboratory Association

- Final rule's applicable laboratory definition excludes most of the market
- 2016 OIG Report confirms most POLs, ALL hospitals prohibited from reporting
- Number of labs that submitted data to CMS reportedly below estimates
- Although CMS likely received large volumes of data, the data are not reflective of the full market
- Resulting reimbursement rates will be flawed, hospital, nursing home, rural labs, labs with high Medicare volume will face greatest impact

OIG Estimates Zero Hospitals Will Report

American Clinical Laboratory Association

Figure 5. Which Labs Will Be Required to Report Their Private Payer Data?

INDEPENDENT LABS	PHYSICIAN OFFICE LABS	HOSPITAL LABS
Independent labs that received **at least $12,500** from Medicare Part B for lab tests during the first half of 2016 or any labs that perform advanced diagnostic lab tests will be required to report	Physician-office labs that received **at least $12,500** from Medicare Part B for lab tests during the first half of 2016 will be required to report	Generally, no hospital labs will be required to report, because 50% or **less of their Medicare revenue** is for Clinical Laboratory Fee Schedule or Physician Fee Schedule services
1,398 out of 3,211: Estimated number of labs that will be required to report	**11,149 out of 235,928**: Estimated number of labs that will be required to report	**0 out of 6,994**: Estimated number of labs that will be required to report (excludes hospital outreach labs, which function as independent labs)
$3.8 billion out of $3.9 billion: Medicare payments to reporting labs	**$1.0 billion of $1.4 billion**: Medicare payments to reporting labs	**$0 of $1.7 billion**: Medicare payments to reporting labs

Source: OIG analysis of Medicare Part B lab test payments, 2016. See endnote 10 for more information about the criteria identifying applicable laboratories, i.e., laboratories that will be required to report.

Note: Figures regarding how many labs will be required to report are estimates. We assumed that all independent labs and physician office labs will receive more than 50 percent of their Medicare revenue from the Clinical Lab Fee Schedule or Physician Fee Schedule.

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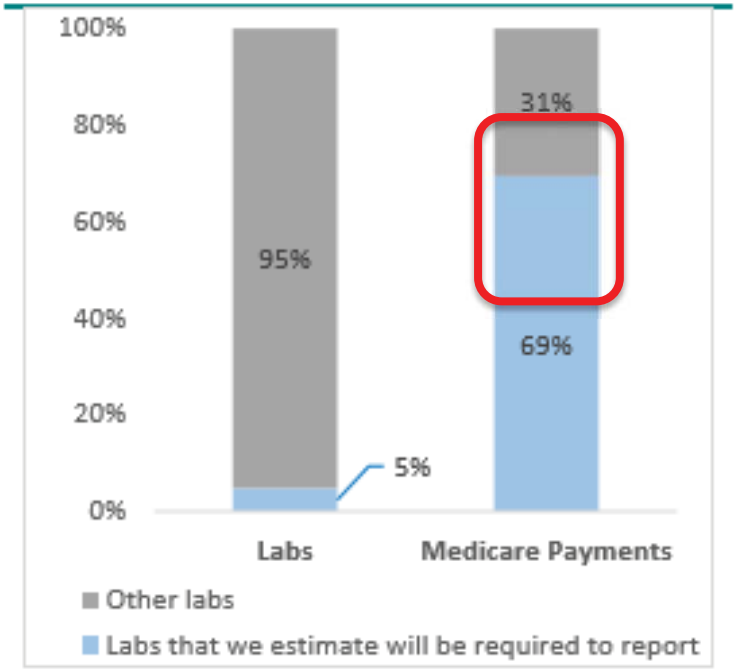
Page 7 of 14

Source: Murrin, Suzanne (Deputy Inspector General for Evaluation and Inspections), *HHS OIG Data Brief Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data*, https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf, September 2016, Figure 5, Page 8.

Labs Responsible For 31% Of Medicare CLFS Dollars May Not Report Data

American Clinical Laboratory Association

Figure 4. Labs That We Estimate Will Report Private Payer Data Represented More Than Two-Thirds of Medicare Payments in 2015



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Khani Declaration Exhibit 27
Page 8 of 14

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Members Who Wrote PAMA Support Including All Market Segments, Hospitals

American Clinical Laboratory Association

- 5/8/14: Senators Orrin Hatch and Richard Burr's Colloquy*:
  - **Burr:** "…the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services…**all sectors of the laboratory market should be represented in the reporting system, including independent clinical laboratories and hospital outreach laboratories…"**
  - **Hatch:** "The Senator is correct. [T]hat **commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."**
- 9/18/14: Senators Orrin Hatch and Richard Burr wrote to CMS Administrator Marilyn Tavenner:
  - "Absent the inclusion of all sectors of the laboratory industry, including independent labs, hospital outreach labs, and larger physician office labs, we are concerned that the resulting reimbursement rates will not be reflective of the true market."
- 12/14/15: Nineteen Senators wrote to CMS Acting Administrator Andy Slavitt "concerned with the proposed rule's approach [that] a significant part of the laboratory market is excluded from participation."

Khani Declaration Exhibit 27
Page 9 of 14

(Emphasis added)

* Congressional Record from May 8, 2014: https:/www.congress.gov/congressional-record/2014/05/08/senate-section/article/S2860-1

Members Who Wrote PAMA Support Including All Market Segments, Hospitals (cont'd.)

American Clinical Laboratory Association

- 12/16/15: Forty-four Representatives wrote to CMS Acting Administrator Andy Slavitt concerned that **"a number of laboratories are prohibited from participating in the reporting process. [T]his prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices."**

- 1/6/16: Finance Chairman Orrin Hatch and Ranking Member Ron Wyden wrote to CMS Acting Administrator Andy Slavitt that "laboratories reporting the private sector data" should be "representative of the marketplace." They continue that **Medicare payment rates should "reflect information from important segments of the laboratory market, especially hospital outreach laboratories** paid under the Clinical Laboratory Fee Schedule. Hospital outreach laboratories, a well-defined market segment, serve beneficiary needs and compete with other community-based laboratories."

(Emphasis added)

Concerns with Data Quality

American Clinical Laboratory Association

- Final rule requires submission of hundreds of millions of private rate data points
- Even sophisticated laboratories have expended hundreds of FTE's to amass the required data, including manual input of paper claims (as required by the rule)
- Retroactive reporting period prevented system edits to assist with collection and reporting
- Continued errors in the CMS data portal increased the burden and uncertainty of data reporting
- The cost and burden of reporting has given pause to non-applicable laboratories from engaging and seeking to submit data

Weighted Median

American Clinical Laboratory Association

- Weighted median untested as a rate-setting metric
- Applicable lab definition that prohibited hospitals and physician office labs from reporting/skewed data collection exacerbated by weighted median
- Medicare rates need to account for varying costs of serving the Medicare population and the diversity of laboratories that make up the network that provides access to Medicare beneficiaries
- Lack of representation of important sectors of market will prevent the calculation of truly market-based rates.

ACLA Requests

American Clinical Laboratory Association

- Delay implementation of PAMA to allow time to work with the stakeholder community to address key flaws in PAMA implementation
- Revise the regulatory definition of Applicable Laboratory to satisfy the intent of Congress and capture true private market rates
- Address data quality issues and simplify the data reporting requirements to reduce the cost, burden, and error-risk of data submission

American Clinical Laboratory Association

Thank You!

Comments and Questions

Khani Declaration Exhibit 28

American
Clinical Laboratory
Association

August 18, 2017

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) respectfully submits these comments in response to the notice issued by the Centers for Medicare and Medicaid Services (CMS) on August 7 about codes on the Clinical Laboratory Fee Schedule (CLFS) for which CMS received no applicable information or insufficient applicable information to calculate a weighted median under Sec. 216 of the Protecting Access to Medicare Act (PAMA).[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing services are developed openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

There are 60 codes about which CMS is soliciting stakeholder feedback. CMS reports that in CY 2016, the Medicare program received no claims for some of the tests and up to 2,350 claims during the year for others. CMS is seeking feedback on the following questions for each test code:

- Should the code be included on the CLFS?
- If included, what method of payment should be used to price the test code (crosswalking or gapfilling)?
- If crosswalking is recommended for a code, to what code(s) should the code be crosswalked?

General comments: CMS should not determine whether a code remains on the Clinical Laboratory Fee Schedule based on whether or not the agency received applicable information about the code during a data reporting period. There are many reasons why CMS may not receive applicable information about a test code. A test may be offered primarily by laboratories that did not meet the agency's definition of "applicable laboratory," or a test may be offered by a single laboratory that did not meet the definition. A laboratory may have stopped offering a test temporarily and did not receive payments for it during the six month data collection period, even if performance of the test resumed after the data collection period. It is possible that applicable laboratories that do offer a test did not report payment rates for the test because the payments were bundled and payment rates were not separately identifiable. A test may be performed by one or

[1] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/FY2017-CLFS-Test-Codes-No-Data.pdf.

more laboratories for patients covered by Medicare or other payors, and yet not be reflected in "applicable information" reported for a single six month period in 2016.

A code's inclusion on the CLFS is important for laboratories seeking to be paid for those tests furnished to Medicare beneficiaries. Given the size and influence of the Medicare program, a test's inclusion on the CLFS matters, because other payors look to the CLFS to establish their own payment rates, as well. We believe that CMS's decision to remove a code from the CLFS should be based on other factors, not on receipt of applicable information during a data collection period.

Specific crosswalks: ACLA recommends crosswalks for the codes listed below:

CPT	2017 NLA	Crosswalk	2017 Crosswalk NLA	Comment
82759	$29.47	82963	$29.47	Crosswalked to another enzyme test with a similar NLA.
86327	$31.12	86320	$30.75	The test is IFE two-dimensional method on serum. Crosswalk to IFE, serum.
87152	$7.18	87158	$7.18	Crosswalk to "other methods" ID code.
87495	$27.51	87797	$27.51	Crosswalk to infectious agent, not otherwise specified, direct probe technique.
88130	$20.65	87209	$24.66	88130 uses a special stain to look for Barr bodies manually, similar to using a special stain for ova and parasites.
88245	$204.20	88264	$170.98	88264 is the code on the CLFS that is most similar to 88245.
0002M	N/A	Sum of 82172; 82247; 82465; 82947; 82977; 83010; 83883; 84450; 84460; 84478	$107.53	Crosswalk represents the sum of the 2017 CLFS fees for the test components listed

ACLA members do not have enough information about remaining codes to offer advice on whether the tests should be crosswalked or gapfilled.

Thank you for your consideration of our comments.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association

Khani Declaration Exhibit 29

Meeting With HHS Regarding Implementation Of PAMA CLFS Reform

August 22, 2017

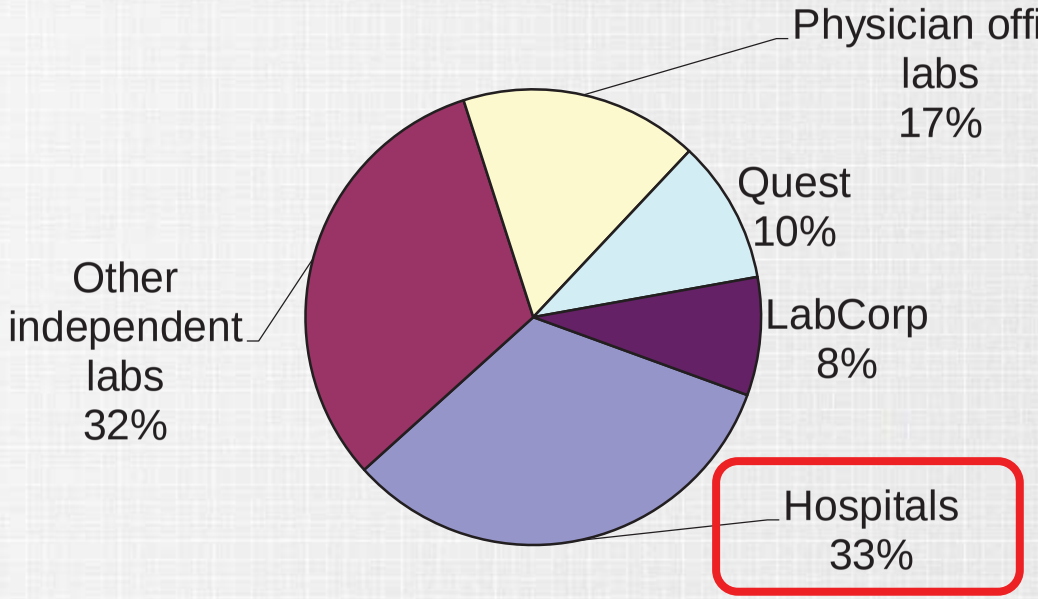
AdvaMedDx
American Clinical Laboratory Association
College of American Pathologists
National Independent Laboratory Association
Navicent Health

PAMA CLFS Reform Implementation Status

- Draft PAMA rates are expected to be published in September, final rates published in November, and rates effective on January 1, 2018
- **Significant parts of the laboratory market have been excluded. As a result, rates may be based on lowest pricing in the private market, and could threaten Medicare beneficiary access to laboratory services**
- Rural labs, labs that serve the most vulnerable patients such as nursing home labs, and hospital and physician office laboratories with high Medicare volume will be most seriously impacted
- **We request PAMA implementation be delayed so that CMS can work with stakeholders to fix key flaws in the current reform**

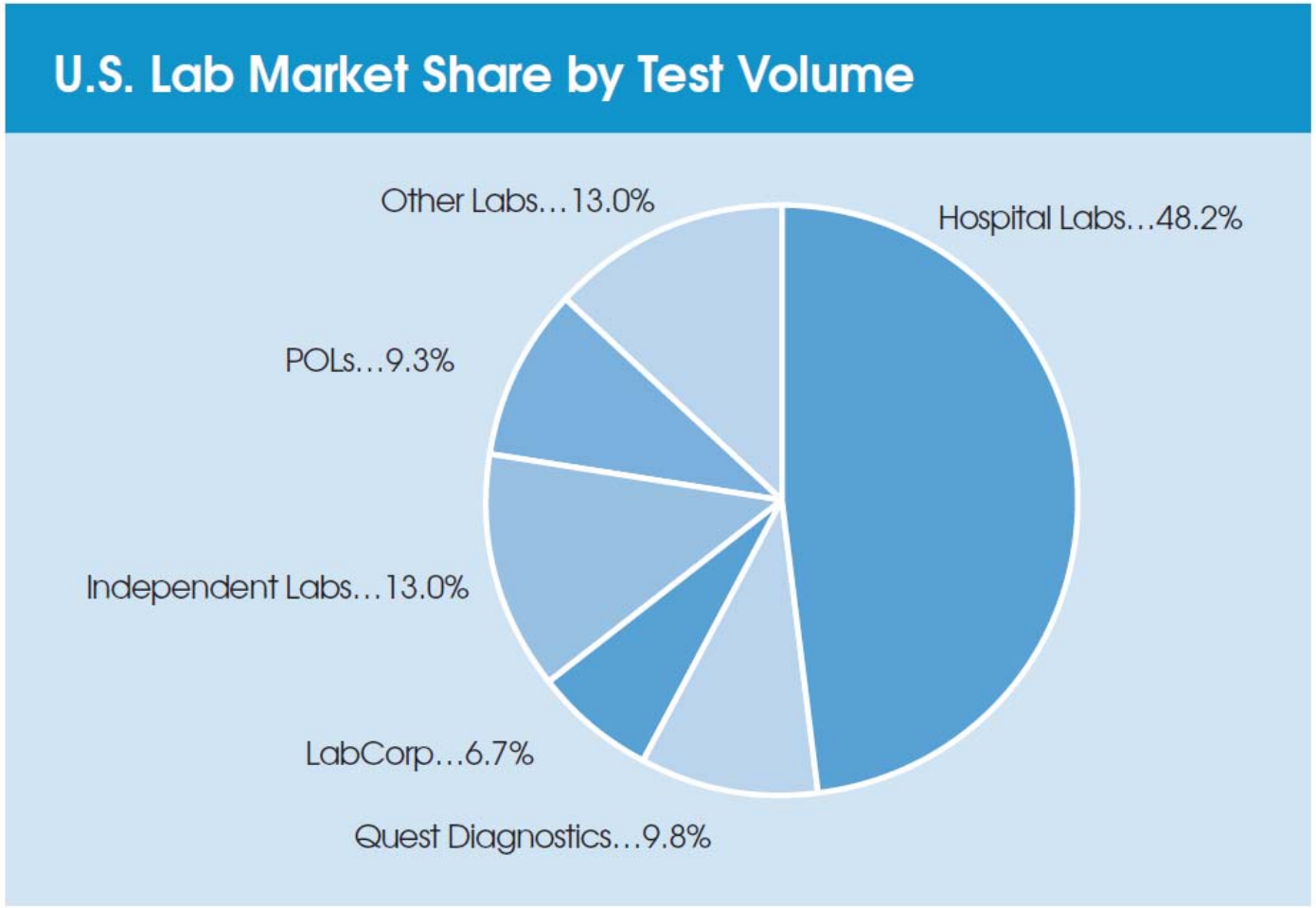
The Medicare Laboratory Market

2015 Medicare Spending, Clinical Lab Fee Schedule ($8.3B total)



Source: Direct Research, LLC analysis of Medicare LDS SAF 5% claims files, 2015

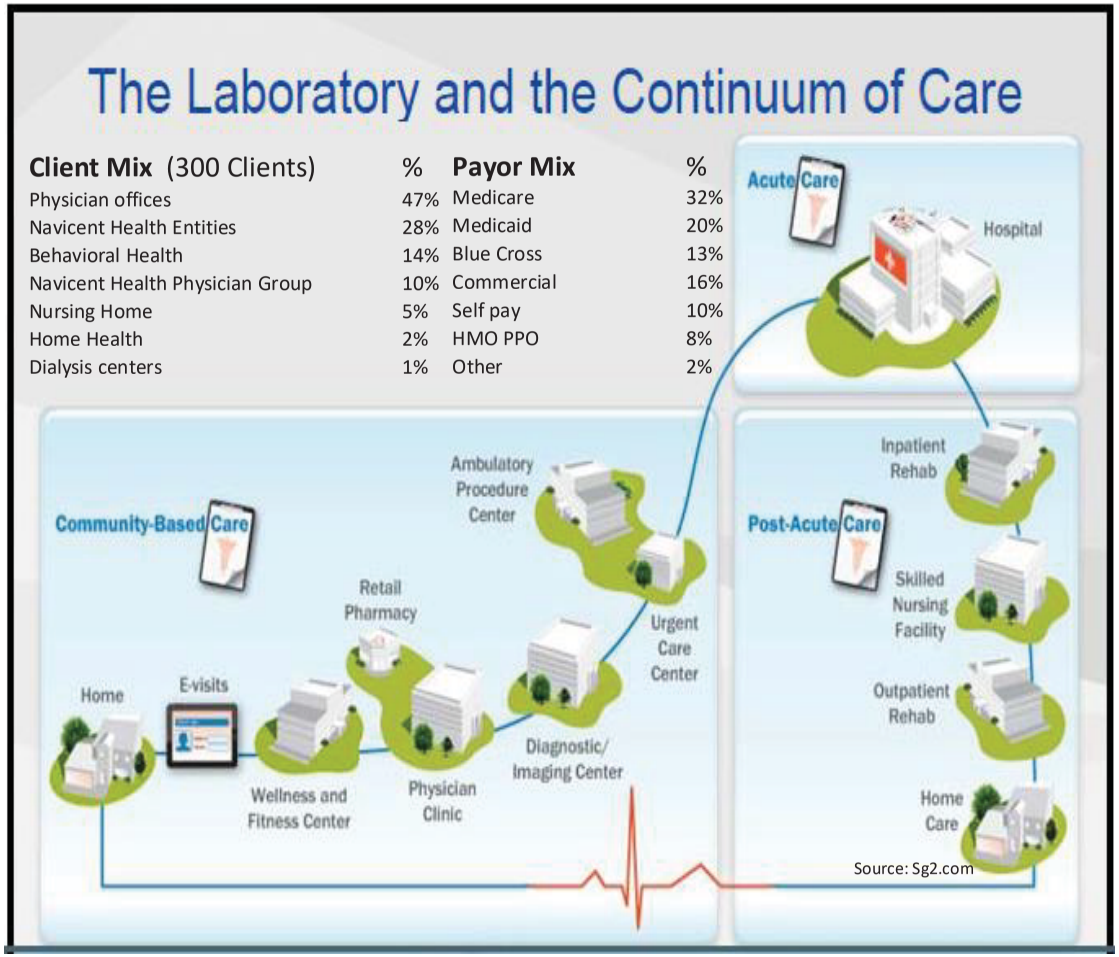
The U.S. Laboratory Market



Source: Laboratory Economics, June 2017

Diagnostics
NavicentHealth

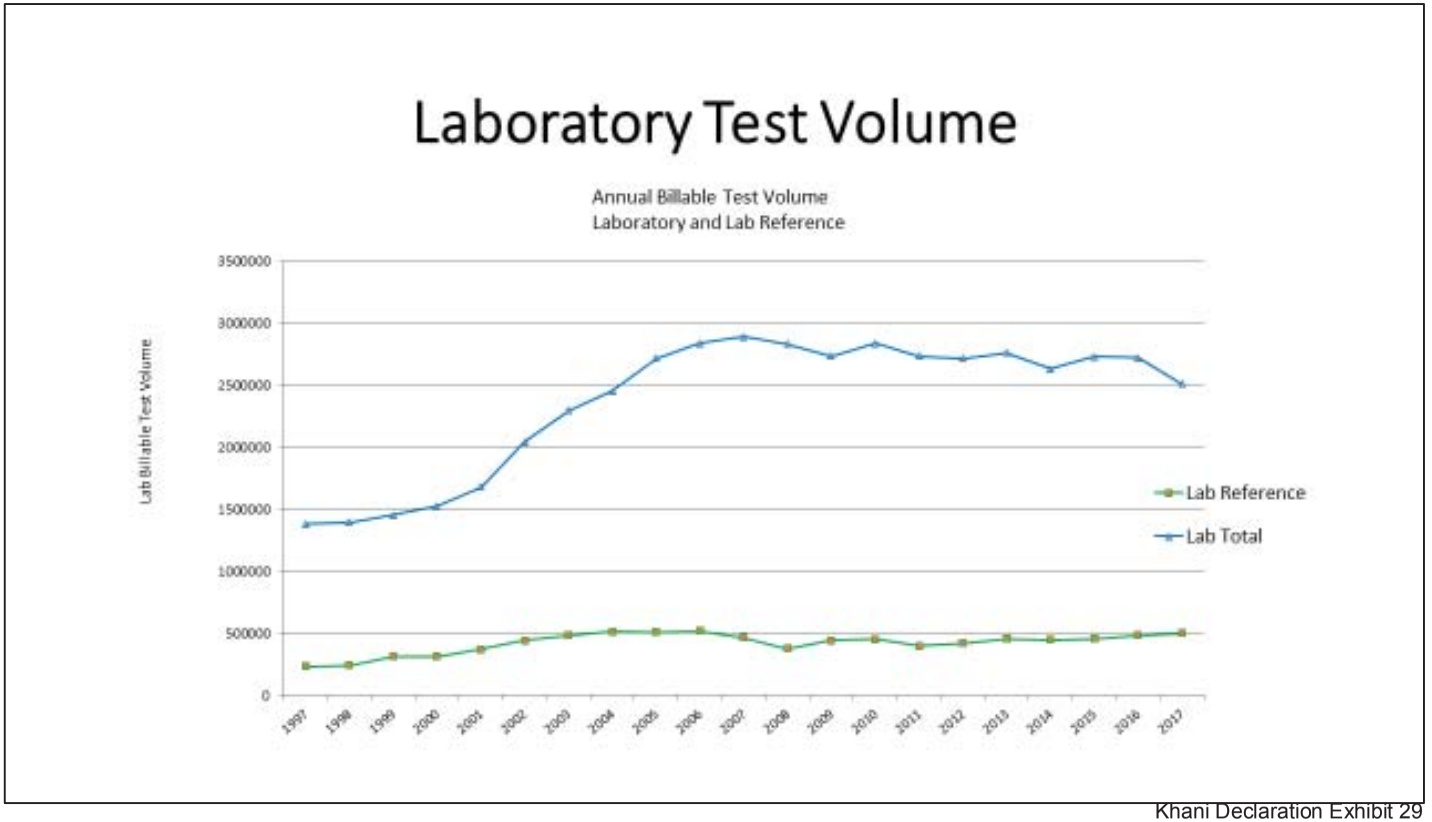
Role of Hospital Outreach



Diagnostics
NavicentHealth

Role of Hospital Outreach

Lab Reference	FY 2017 Annualized	FY 2016	FY 2015
Outreach Test Volume	494,744	483,366	450,753
Total Laboratory Test Volume	2,519,665	2,719,110	2,730,018
% Lab Reference	20%	18%	17%



Intent of PAMA Section 216

- Establish market-based pricing for the Medicare Clinical Laboratory Fee Schedule (CLFS)
- Rates of all sectors of the laboratory market included in reporting
  - Independent labs
  - Hospital outreach labs
  - Physician office labs
- Successful PAMA implementation will:
  - Maintain access for beneficiaries
  - Provide savings to the Medicare program
  - Market rates and pricing stability for labs

Members Who Wrote PAMA Support Including All Market Segments, Hospitals

- 5/8/14: Senators Orrin Hatch and Richard Burr's Colloquy*:

  Burr: "…the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services…**all sectors of the laboratory market should be represented in the reporting system, including independent clinical laboratories and hospital outreach laboratories…"**

  Hatch: "The Senator is correct. [T]hat **commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."**

- 9/18/14: Senators Orrin Hatch and Richard Burr wrote to CMS Administrator Marilyn Tavenner:

  "Absent the inclusion of all sectors of the laboratory industry, including independent labs, hospital outreach labs, and larger physician office labs, we are concerned that the resulting reimbursement rates will not be reflective of the true market."

- 12/14/15: Nineteen Senators to CMS:

  "concerned with the proposed rule's approach [that] a significant part of the laboratory market is excluded from participation."

Khani Declaration Exhibit 29
Page 8 of 13

(Emphasis added)

* Congressional Record from May 8, 2014: https:/www.congress.gov/congressional-record/2014/05/08/senate-section/article/S2860-1

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  "a number of laboratories are prohibited from participating in the reporting process. [T]his prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices."

- 1/6/16: Finance Chairman Orrin Hatch and Ranking Member Ron Wyden to CMS:

  "It is critical that the laboratories reporting the private sector data used to determine Medicare payment rates are representative of the marketplace. […] Hospital outreach laboratories, a well-defined market segment, serve beneficiary needs and compete with other community-based laboratories. **We urge that CMS establish an alternative, more expansive methodology for identifying laboratories that must report private payment rates in the final rule.**"

- 3/29/16: Rep. Price signed a letter with other Ways & Means Members recommending CMS delay the PAMA changes to the CLFS.

(Emphasis added)

2016 OIG Report on PAMA Implementation

- Final rule's applicable laboratory definition excludes most of the market
- Only 5% of all labs required to report private market data
  - 44% of independent labs
  - 5% of physician office labs
  - **Zero hospital labs**
- Excluded labs prohibited from reporting, but new rates will apply to all labs

Flaws with Data Submitted in 2017 Data Reporting Period

- Number of labs that submitted data to CMS reportedly below agency estimates
- Final rule requires submission of hundreds of millions of private rate data points
- Although CMS *did* collect "large" volumes of data, the data are not reflective of the full market
- Even sophisticated laboratories have expended hundreds of FTE's to amass the required data, including manual input of paper claims (as required by the rule); for community laboratories data assessment largely manual
- Retroactive reporting period prevented system edits to assist with collection and reporting and ensure accuracy
- Few laboratories have contract agreements with payors, therefore no uniformity on what payment remitted for even one test
- Continued errors in the CMS data portal increased the burden and uncertainty of data reporting
- OIG stated complete and accurate reporting critical, yet CMS reported no plans to verify quality and accuracy of data

Stakeholder Requests

- Delay implementation of PAMA to allow time to work with the stakeholder community to address key flaws in PAMA implementation:
  - All sectors of the laboratory market must be part of data collection process that determines Medicare rates
  - Data collecting and reporting process must be simplified to reduce the cost, burden, and error-risk of data submission

Thank You!

Comments and Questions

Khani Declaration Exhibit 30

Meeting With CMS Regarding Implementation Of PAMA CLFS Reform

August 30, 2017

AdvaMedDx
American Clinical Laboratory Association
College of American Pathologists
National Independent Laboratory Association
Navicent Health

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- **We request PAMA implementation be delayed so that CMS can work with stakeholders to fix key flaws in the current reform**

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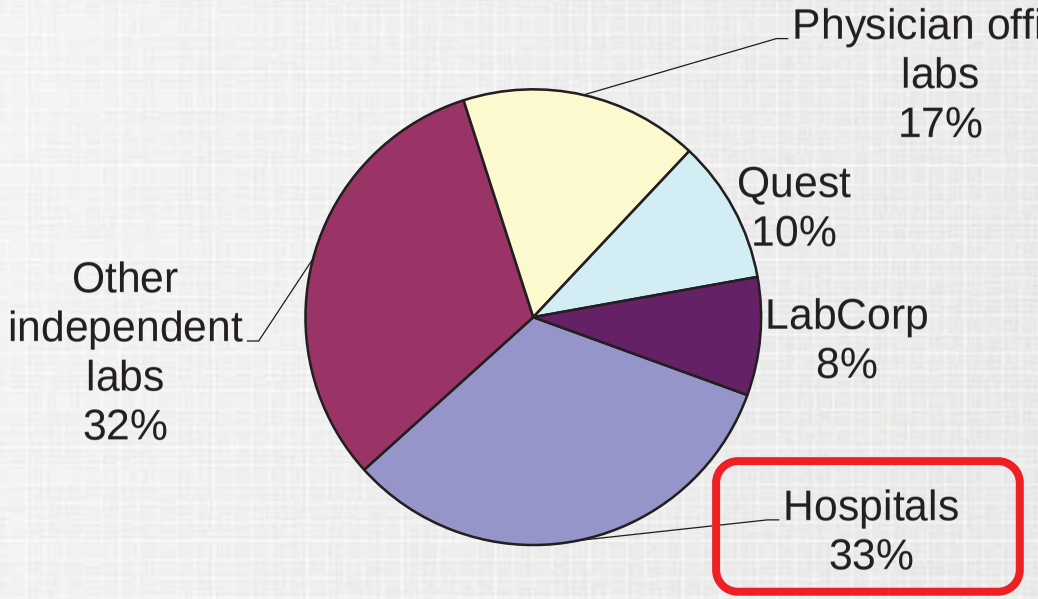

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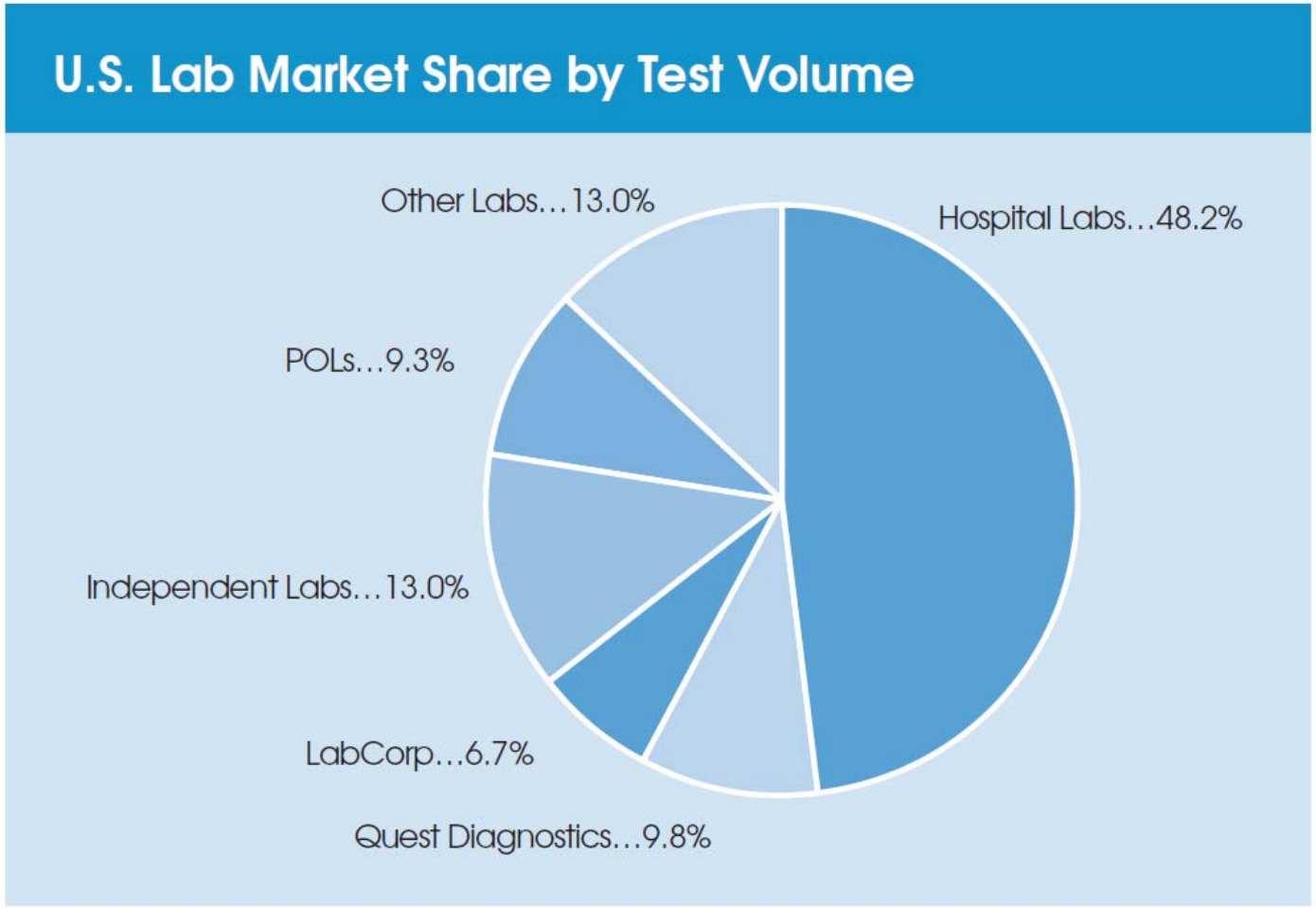
The U.S. Laboratory Market



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Diagnostics
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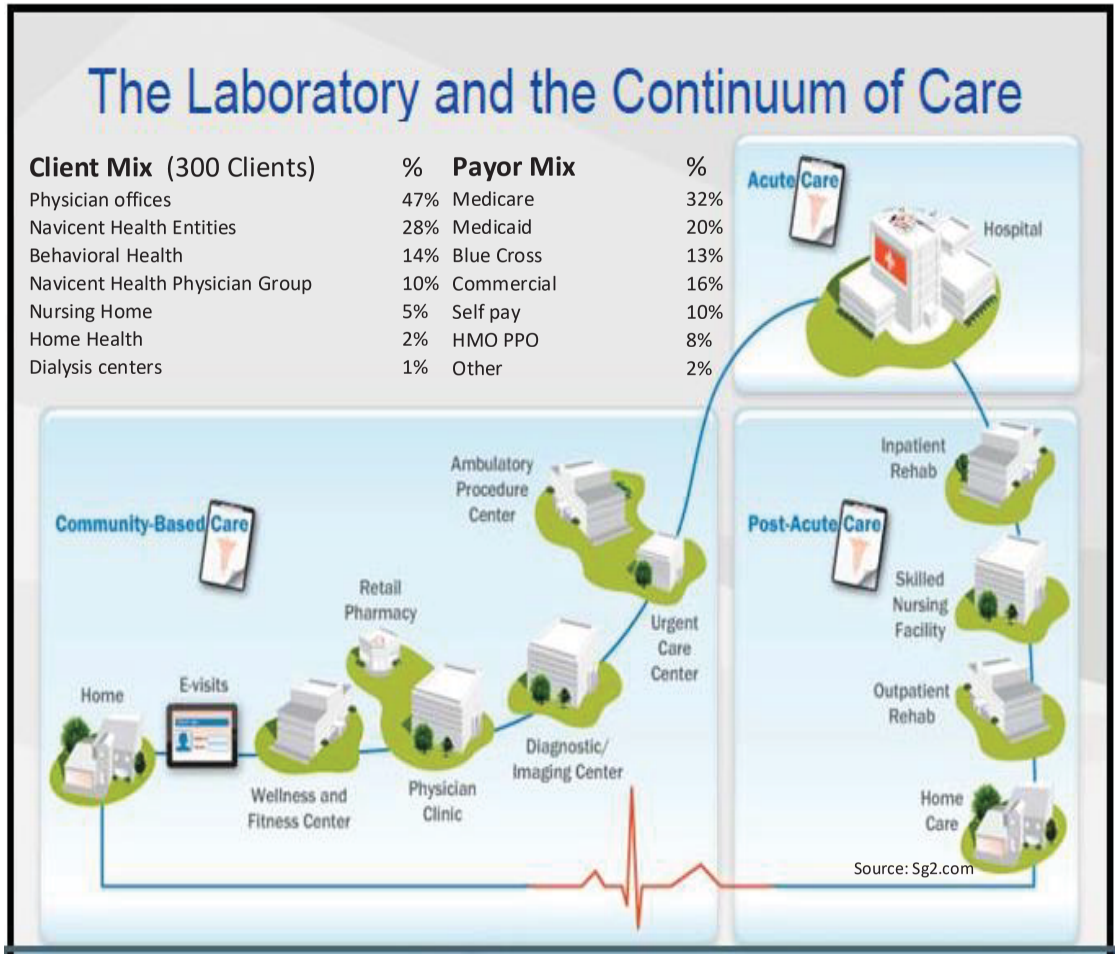
Role of Hospital Outreach



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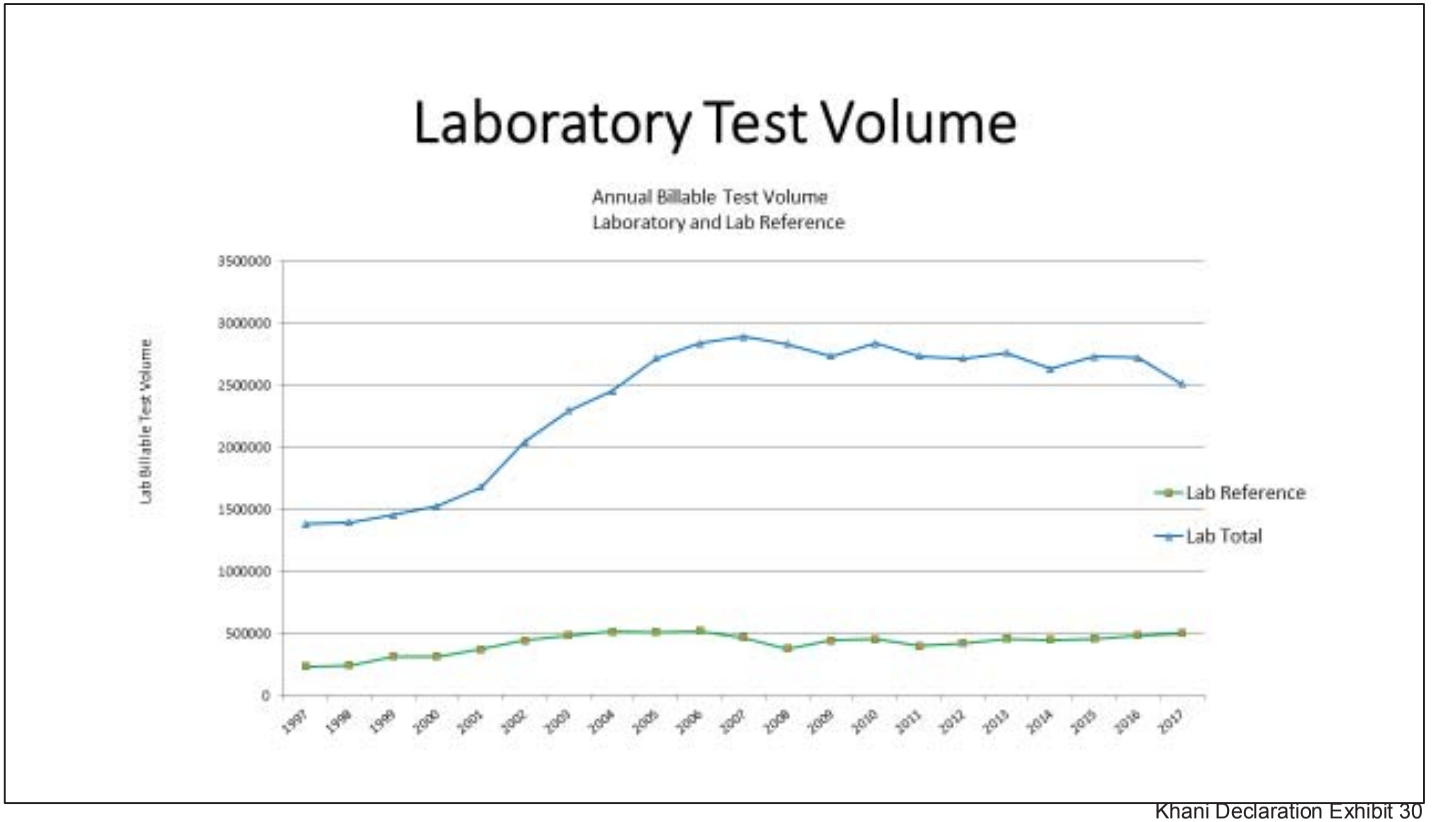

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Thank You!

Comments and Questions

Khani Declaration Exhibit 31

Meeting With HHS/CMS Regarding Implementation Of PAMA CLFS Reform

September 18, 2017

American Clinical Laboratory Association

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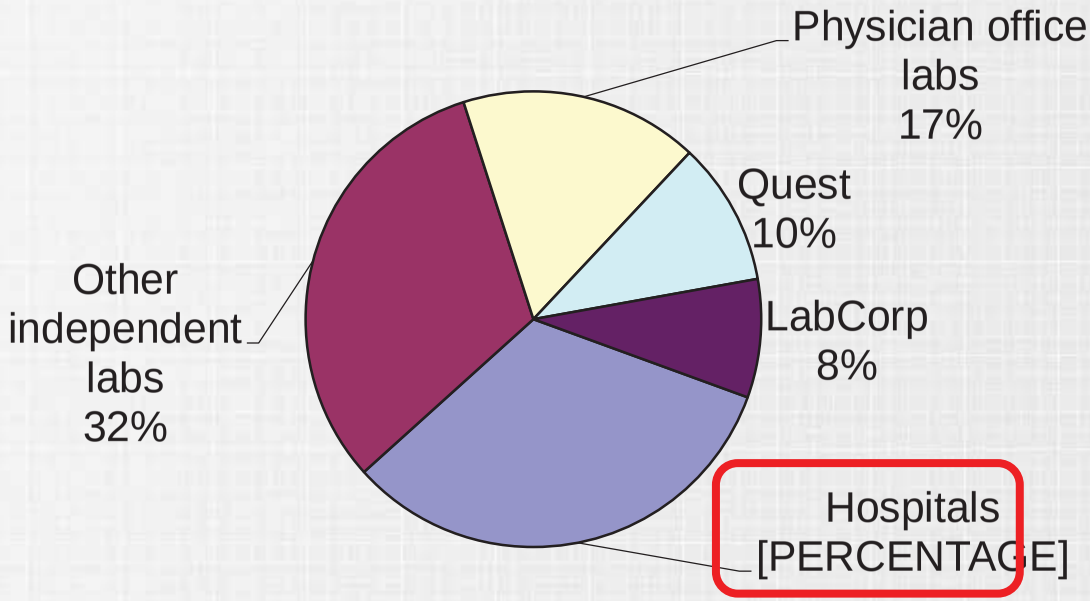
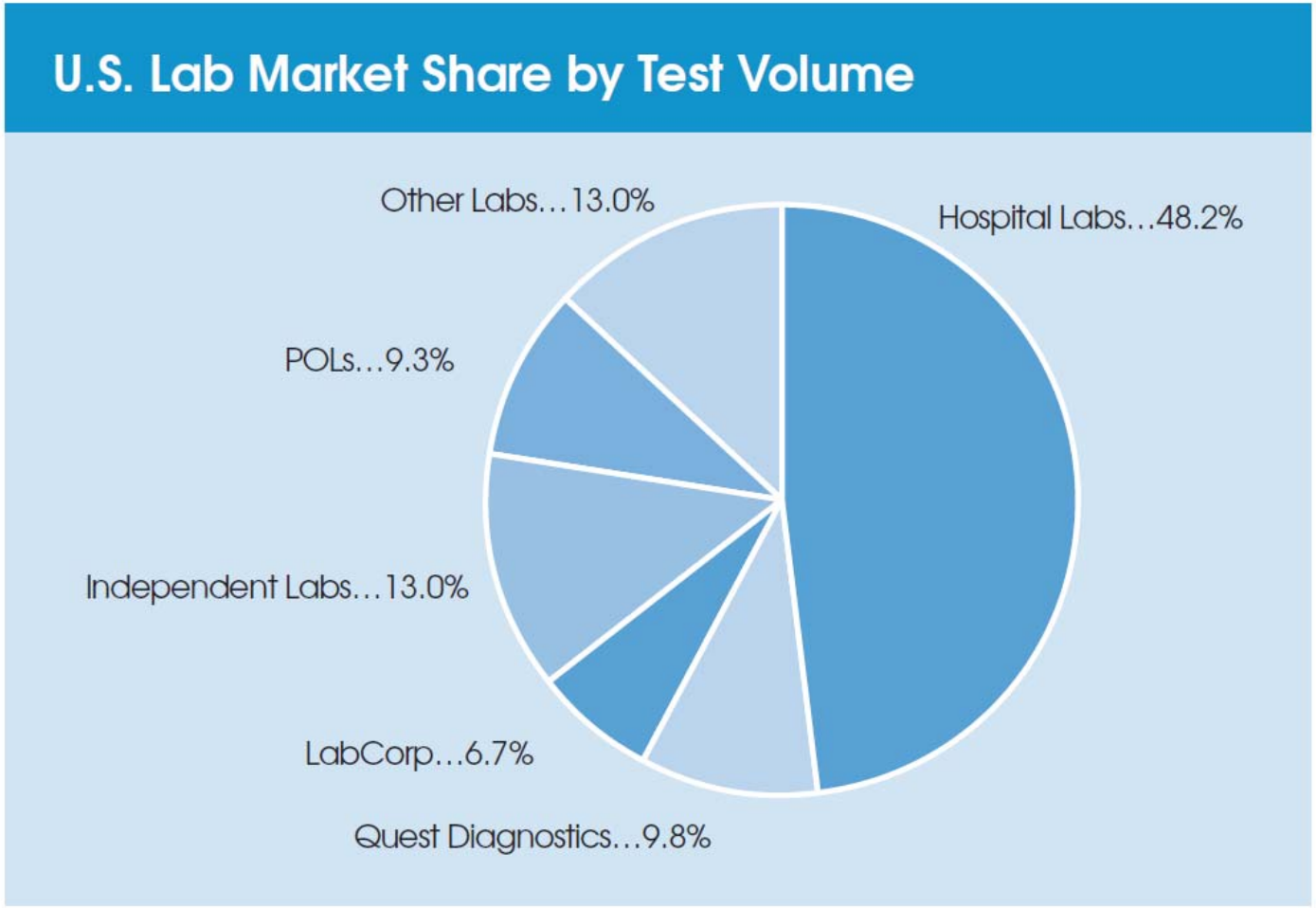


Source: Direct Research, LLC analysis of Medicare LDS SAF 5% claims files, 2015

The U.S. Laboratory Market



Source: Laboratory Economics, June 2017

Intent of PAMA Section 216

- Establish market-based pricing for the Medicare Clinical Laboratory Fee Schedule (CLFS)
- Rates of all sectors of the laboratory market included in reporting
  - Independent labs
  - Hospital outreach labs
  - Physician office labs
- Successful PAMA implementation will:
  - Maintain access for beneficiaries
  - Provide savings to the Medicare program
  - Market rates and pricing stability for labs

Members Who Wrote PAMA Support Including All Market Segments, Hospitals

- 5/8/14: Senators Orrin Hatch and Richard Burr's Colloquy*:

  Burr: "…the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services…**all sectors of the laboratory market should be represented in the reporting system, including independent clinical laboratories and hospital outreach laboratories…"**

  Hatch: "The Senator is correct. [T]hat **commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."**

- 9/18/14: Senators Orrin Hatch and Richard Burr wrote to CMS Administrator Marilyn Tavenner:

  "Absent the inclusion of all sectors of the laboratory industry, including independent labs, hospital outreach labs, and larger physician office labs, we are concerned that the resulting reimbursement rates will not be reflective of the true market."

- 12/14/15: Nineteen Senators to CMS:

  "concerned with the proposed rule's approach [that] a significant part of the laboratory market is excluded from participation."

Khani Declaration Exhibit 31
Page 6 of 11
(Emphasis added)

* Congressional Record from May 8, 2014: https:/www.congress.gov/congressional-record/2014/05/08/senate-section/article/S2860-1

Members Who Wrote PAMA Support Including All Market Segments, Hospitals (cont'd.)

- 12/16/15: Forty-four Representatives (including Rep. Price) to CMS:

  "a number of laboratories are prohibited from participating in the reporting process. [T]his prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices."

- 1/6/16: Finance Chairman Orrin Hatch and Ranking Member Ron Wyden to CMS:

  "It is critical that the laboratories reporting the private sector data used to determine Medicare payment rates are representative of the marketplace. […] Hospital outreach laboratories, a well-defined market segment, serve beneficiary needs and compete with other community-based laboratories. **We urge that CMS establish an alternative, more expansive methodology for identifying laboratories that must report private payment rates in the final rule.**"

- 3/29/16: Rep. Price signed a letter with other Ways & Means Members recommending CMS delay the PAMA changes to the CLFS.

(Emphasis added)

2016 OIG Report on PAMA Implementation

- Final rule's applicable laboratory definition excludes most of the market
- Only 5% of all labs required to report private market data
  - 44% of independent labs
  - 5% of physician office labs
  - **Zero hospital labs**
- Excluded labs prohibited from reporting, but new rates will apply to all labs

Flaws with Data Submitted in 2017 Data Reporting Period

- Number of labs that submitted data to CMS reportedly below agency estimates
- Final rule requires submission of hundreds of millions of private rate data points
- Although CMS *did* collect "large" volumes of data, the data are not reflective of the full market
- Even sophisticated laboratories have expended hundreds of FTE's to amass the required data, including manual input of paper claims (as required by the rule); for community laboratories data assessment largely manual
- Retroactive reporting period prevented system edits to assist with collection and reporting and ensure accuracy
- Few laboratories have contract agreements with payors, therefore no uniformity on what payment remitted for even one test
- Continued errors in the CMS data portal increased the burden and uncertainty of data reporting
- OIG stated complete and accurate reporting critical, yet CMS reported no plans to verify quality and accuracy of data

Stakeholder Requests

- Delay implementation of PAMA to allow time to work with the stakeholder community to address key flaws in PAMA implementation:
  - All sectors of the laboratory market must be part of data collection process that determines Medicare rates
  - Data collecting and reporting process must be simplified to reduce the cost, burden, and error-risk of data submission

Thank You!

Comments and Questions

Khani Declaration Exhibit 32

October 6, 2017

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

Dear Administrator Verma:

As stakeholders representing all segments of the U.S. laboratory market – national, regional, and community independent laboratories; hospital laboratories; physician office laboratories; and diagnostic manufacturers, and patients served, we urge the Centers for Medicare and Medicaid Services (CMS) to take immediate action to address the significantly deficient data collection process used to establish new clinical laboratory payment rates, which resulted in unreliable and unsustainable rates that fall short of Congress' goal of establishing a market-based system. We urge CMS to suspend implementation of the draft payment rates until these deficiencies can be addressed.

The payment data collected by CMS for tests on the Clinical Laboratory Fee Schedule (CLFS) does not result in an accurate weighted median of private payer rates for most tests on the CLFS, as required by the *Protecting Access to Medicare Act (PAMA)*. We believe the data used to set the proposed rates would not stand up to statistical validity review. The data sources used to determine the preliminary rates do not appear to reflect the various market segments, which CMS has the authority to consider in order to validate the data submitted. It is also clear from our review that the overly burdensome regulatory requirements resulted in the submission of inaccurate and incomplete laboratory payment data that is not reliable for use in its current form. As a stakeholder community, we have repeatedly pointed out to CMS, HHS, and Congress in formal comments and in meetings our concerns with the final PAMA regulation, including the serious limitations and skewed process the regulation created.

The proposed CLFS rates will now result in significant harm to the nation's surveillance network for emergent public health issues, job losses across the United States, and significantly reduced access to clinical laboratory testing for Medicare beneficiaries, particularly those in rural geographic and post-acute care settings.

We stand together in our position that before CMS proceeds with making any revisions to the CLFS, the agency must first:

- Modify the PAMA regulation to address data integrity concerns and market exclusion through a statistically valid process that is least burdensome on providers;
- Ensure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market (national independent, community and rural independent, hospital outreach, and physician office laboratories); and
- Provide a transparent process to allow for the validation of the data collected by CMS.

In light of these significant concerns, we call on CMS to take swift action to engage in a constructive dialogue with stakeholders on ways to improve the PAMA data process and calculation, and establish a clear path forward for the clinical laboratory community and the Medicare beneficiaries who rely on its services. We urge CMS to suspend implementation of the revised payment rates while this path forward is determined.

Sincerely,

American Academy of Family Physicians
American Association for Clinical Chemistry
American Association of Bioanalysts
American Clinical Laboratory Association
AdvaMedDx
American Hospital Association
American Medical Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Association of American Medical Colleges
Association of Public Health Laboratories
Clinical Laboratory Management Association
COLA
College of American Pathologists
Medical Group Management Association
National Association for the Support of Long Term Care
National Independent Laboratory Association
New York State Clinical Laboratory Association
New York State Society of Pathologists
Point of Care Testing Association

Khani Declaration Exhibit 33

American
Clinical Laboratory
Association

PAMA Preliminary Rates

October 16, 2017

American Clinical Laboratory Association
1100 New York Avenue, NW
Suite 725 West
Washington, DC 20005
(202) 637-9466
www.acla.com

Overview

American Clinical Laboratory Association

- Before rates can go into effect:
  - Laboratory market has to be represented in the data
  - Substantial proportion of applicable labs must report data
  - Data errors must be corrected
- Issues with specific codes:
  - Codes with no CY 2017 NLA
  - General Health Panel
  - Definitive drug testing codes

Laboratory market not represented

American Clinical Laboratory Association

- OIG estimated **only 5% of labs** paid by Medicare for lab services in 2015 would report applicable information.
- In reality, **only 0.7 percent of labs** paid by Medicare for lab services in 2015 reported applicable information.
- OIG estimates compared to actual reporting labs:

	OIG Estimate	Actual # of labs	% of OIG Estimate	% of All Labs
Independent labs	1,398	658	47%	20%
Physician Office Labs	11,149	1,106	10%	0.5%
Hospitals	0	21	--	0.3%
TOTAL	12,547	1,942	**15%**	**0.7 %**

- **10,000 additional applicable labs** were expected to report.
- Congress did not make reporting applicable information optional – but CMS effectively has through insufficient outreach and education and lack of enforcement.

Obvious data problems

American Clinical Laboratory Association

- **Problematic data** that was reported
  - **$94,000** and **$0.01** reported for a lipid panel
  - **$65,000** and **$0.01** reported for a comprehensive metabolic panel
  - **$99,999.99 and $0.01** reported for a TSH
  - Price of **$0.00** reported for **2.4 million tests** – fully **1% of test volume**
  - One-fifth of HCPCS codes where 95th percentile is 10X the 5th percentile
  - Concern with these problems – and with data problems that are not as easy for CMS or the public to detect
- CMS's **inconsistent treatment** of the data
  - CMS has **no authority to allow labs to correct data** - or to decide that data is wrong when it would raise weighted medians "too much"
  - **Data thrown out** when labs did not correct data
  - **Accepted the attestation** of hospitals whose NPIs were not lab-specific; **did not accept the attestation** of labs whose data would increase weighted median to more than 150% of 2017 NLA
  - This is just what CMS self-reported in its summary – what else is there?

Rate reduction applied incorrectly to tests with $0 NLAs

American Clinical Laboratory Association

2017 Clinical Diagnostic Laboratory Fee Schedule

CPT codes, descriptions and other data only are copyright 2017 American Medical Association. All rights reserved. CPT is a registered trade

HCPCS	Modifier	National Limit	Mid Point	Floor	CA1 01112 LOC 00	CA2 01182 LOC 00	HI 01212 LOC 00	NV 01312 LOC 00	AK 02102 LOC 00	ID 02202 LOC 00	OR 02302 LOC 00
80061		0.00	0.00	0.00	18.37	18.37	18.37	18.37	18.37	15.57	18.37
80061	QW	0.00	0.00	0.00	18.37	18.37	18.37	18.37	18.37	15.57	18.37
80069		11.91	16.10	0.00	11.91	11.91	11.91	11.91	11.91	11.91	11.91
80069	QW	11.91	16.10	0.00	11.91	11.91	11.91	11.91	11.91	11.91	11.91
80074		0.00	0.00	0.00	65.34	65.34	65.34	65.34	65.34	65.34	65.34

- 26 HCPCS codes on the CY 2017 CLFS have local rates but show $0 in the NLA field
- Include codes such as lipid panel (80061) and acute hepatitis panel (80074)
- Rather than applying a maximum 10% reduction in CY 2018, CMS has proposed to apply the **entire reduction in 2018**:
  - Lipid panel would be cut by **39% in 2018**
  - Acute hepatitis panel would be cut by **40% in 2018**

Congress intended 10% reduction limit to apply to all tests priced via weighted median

American Clinical Laboratory Association

'(3) PHASE-IN OF REDUCTIONS FROM PRIVATE PAYOR RATE IMPLEMENTATION.—

"(A) IN GENERAL.—Payment amounts determined under this subsection for a clinical diagnostic laboratory test for each of 2017 through 2022 **shall not result in a reduction in payments** for a clinical diagnostic laboratory test for the year of **greater than the applicable percent** (as defined in subparagraph (B)) of the amount of payment for the test for the preceding year. "

(B) APPLICABLE PERCENT DEFINED.—In this paragraph, the term 'applicable percent' means— "(i) for each of 2017 through 2019, 10 percent; and "(ii) for each of 2020 through 2022, 15 percent.

42 U.S.C. § 1395m-1(b)(3)(A)

- Despite the mechanics of the CLFS – which has resulted in a $0 NLA for some tests – the payment amounts may not **result** in payment reductions greater than the applicable percentages of the **amount of payment in the previous year**.
- CMS must revise its calculations so that the CY 2018, 2019, and 2020 prices do not decrease by more than 10% of the amount of payment in CY 2017, 2018, and 2019, respectively.

Recommended approach for codes with no CY 2017 NLA

American Clinical Laboratory Association

- Recognize a *de facto* CY 2017 NLA for each test that does not have one:
  - For panel codes comprised of test codes that do have CY 2017 NLAs, the panel code's *de facto* NLA should be the sum of the component codes' NLAs.
  - Example: Lipid Panel

HCPCS Code	Component Codes	CY2017 NLA
83718	HDL	$11.24
ATP02	Triglycerides & Cholesterol	$7.15
	De facto CY 2017 NLA for 80061	$18.39
	CY 2018 rate (2017 *De facto* NLA – 10%)	**$16.55**

  - For other tests with a $0 NLA whose component codes do not have CY 2017 NLAs, the *de facto* NLA should be the highest local rate on the 2017 CLFS.
  - For gapfilled tests (listed on the 2017 CLFS with a $0 NLA and the local prices also are listed as $0), the *de facto* NLA should be the median gap-fill rate.

General Health Panel

American Clinical Laboratory Association

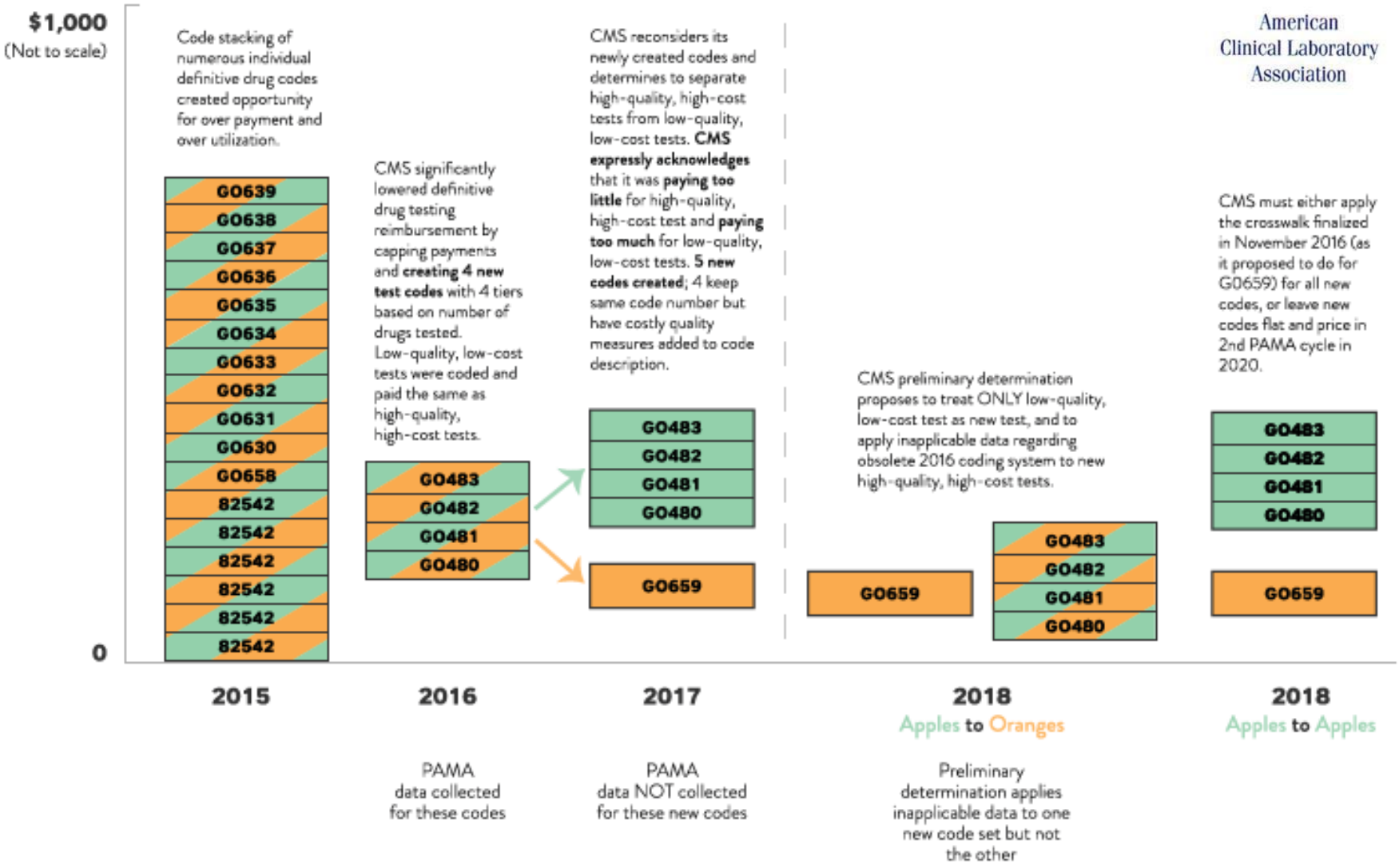
- CPT code 80050 – **not payable by Medicare** – consists of the following tests when they are ordered together:
  - Comprehensive metabolic panel (80053)
  - TSH (84443)
  - CBC (85025)
- Labs bill Medicare for the constituent codes separately, rather than bill the panel code
- Preliminary payment rate of $23.54 for 80050 – no CY 2017 NLA
  - Sum of CY 2017 NLAs for CMP, TSH, CBC = $48.20
- **Has CMS's policy changed** with respect to whether 80050 is payable?
- If 80050 is payable—
  - **Minimum CY 2018 price is $43.38**
  - Minimum CY 2019 price is $39.04
  - Minimum CY 2020 price is $35.14

Definitive Drug Testing Codes

American Clinical Laboratory Association

- **G0480 through G0483**
- Codes were "new or substantially revised" after the data collection period, and **applicable information reported about them cannot be used** because the data was reported about different codes
  - Data collection period: Jan. 1 – Jun. 30, 2016
  - Codes revised: Nov. 2016
  - Effective date of new codes: Jan. 1, 2017
- Codes revised to describe more sophisticated methodology and specific quality controls; fifth code added (G0659) to describe lower quality, cheaper test methods
- "New or substantially revised" codes must be crosswalked or gapfilled
- These codes should be **crosswalked to multiples of CPT code 82542**
  - Same crosswalks from late 2016 for Jan. 1, 2017
  - CMS has **done the work already** on the appropriate crosswalks

PAMA'S APPLICATION TO NEW AND REVISED DRUG TESTING CODES



ACLA
American Clinical Laboratory Association

American
Clinical Laboratory
Association

Thank You

Khani Declaration Exhibit 34

American
Clinical Laboratory
Association

October 23, 2017

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted electronically to CLFS_Annual_Public_Meeting@cms.hhs.gov

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) respectfully submits these comments on the CY 2018 Clinical Laboratory Fee Schedule (CLFS) Preliminary Payment Determinations and accompanying documents released on September 22, 2017.[1] ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, ESRD, and nursing home laboratories. The clinical laboratory industry is at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy annually. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing services are determined openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

We note at the outset that ACLA has objected to the Centers for Medicare & Medicaid Services' (CMS's) failure to implement the data reporting obligations that Congress included in Sec. 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA). Unless CMS corrects its implementation of the data reporting obligation, it cannot take the next step of establishing payment rates under Sec. 216(b) of PAMA. Although we hope that our comments will assist CMS with evaluating the preliminary payment rates, we continue to believe that CMS's definition of "applicable laboratory" does not comport with the definition of that term that Congress included in subsection (a) of Sec. 216 of PAMA.

ACLA remains committed to ensuring that all sectors of the laboratory market are represented adequately in the calculation of any new CLFS rates, consistent with Congressional intent. We have voiced our concerns to the agency repeatedly that the CY 2018 CLFS rates likely would not be market-based, that the rate-setting exercise would result in unsustainable cuts to Medicare rates for many tests, and that the integrity of the data used to calculate those rates was likely to be questionable. The preliminary rates that CMS released last month confirm that our concerns were not unfounded. Indeed, CMS calculated the preliminary rates using data from an extremely small number of labs that are not representative of the entire laboratory market serving Medicare beneficiaries. The quality of some of the data is poor, and aspects of CMS's administration of the data collection concern us.

[1] CY 2018 CLFS - Preliminary Payment Rates and Crosswalking/Gapfilling Determinations, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

In short, CMS's approach to collecting applicable information did not work. The deficiencies in the number and types of entities that reported data and in the data CMS used to develop weighted medians are far too significant for the agency to proceed according to its planned schedule. **CMS must delay implementation of any new CLFS rates until it has collected data and calculated rates that accurately reflect all segments of the laboratory market (independent labs, physician office labs, and hospital outreach labs), and until it addresses data integrity concerns.**

Among others, our comments address the following issues:

- The lack of representation of the full laboratory market in data reported to CMS and the miniscule number of laboratories that reported data;
- Obvious problems with some data that was reported;
- CMS's questionable treatment of certain reporting entities and data;
- The enormity of the cuts to many tests, going far beyond what Congress intended;
- CMS's treatment of codes without CY 2017 National Limitation Amounts (NLAs); and
- Problems with CMS's approach to pricing other specific codes.

I. The preliminary rates CMS released may not accurately reflect private payor rates paid in the full laboratory market serving Medicare beneficiaries.

The preliminary rates that CMS released do not include inputs from the full laboratory market serving Medicare beneficiaries. More than 99 percent of laboratories that were paid for laboratory services under Medicare Part B in 2015 reported no data to CMS – a mere 0.7 percent of all labs paid by Medicare reported applicable information to the agency.

Far fewer labs reported data than the Department of Health and Human Services Office of the Inspector General (OIG) estimated would be required to report their private payor data.[2] The OIG estimated that just five percent of all labs paid under Medicare Part B in 2015, or 12,547 labs, would qualify as applicable laboratories and would be required to report applicable information to CMS. In reality, only 0.7 percent of labs paid under Medicare Part B in 2015 – 1,942 out of 261,524 – reported applicable information to CMS.[3] Just 658 independent labs reported applicable information – only twenty percent of all independent labs paid under Medicare Part B and less than half of the labs the OIG estimated would report. Only 1,106 physician office labs (POLs) reported applicable information to CMS – only one tenth of the POLs the OIG estimated would

[2] Office of Inspector General, Medicare Payments for Lab Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040) at 7, *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf.
[3] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System ("Summary") at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.

report information and just one half of one percent of all POLs paid for lab services under Medicare Part B in 2015. And just 21 hospital outreach labs reported data – representing one percent of all reporting entities and less than one half of one percent of all hospital labs paid under Medicare Part B for lab services in 2015. Rural laboratories comprised just two percent of laboratories reporting applicable information.

Additionally, as shown below, the volume of applicable information CMS received from independent laboratories, POLs, and hospital laboratories is far out of proportion to their respective shares of CLFS volume.

	Proportion of CLFS Volume[4]	**Proportion of Applicable Information by Volume[5]**	**Potential Over- or Under-Representation**
Independent Labs	50 %	90.1 %	**40.1 % over**
POLs	23 %	7.5 %	**15.5 % under**
Hospitals	27 %	1.0 %	**26.0 % under**

Clearly, independent laboratories submitted a far larger proportion of applicable information than their share of CLFS volume. Hospital laboratories and POLs submitted significantly less applicable information by volume than their share of CLFS volume. Simply put, the preliminary rates cannot be characterized as "market-based" when the data does not reflect the market.

CMS reports that 1,074 TIN-level entities registered to submit applicable information, but only 994 TIN-level entities reported applicable information. The agency dismisses the fact that 80 registered TIN-level entities reported no applicable information by saying that the reporting entities "may have determined during the process that they do not have component laboratories that meet the definition of applicable laboratory and therefore, are not subject to reporting requirements."[6] The agency offered no support for its supposition. It is just as likely that some or all of these 80 missing TIN-level entities are or had component laboratories that meet the definition of applicable laboratory and were subject to the reporting requirement – yet failed to report.

Seemingly in order to avoid addressing the low number of applicable laboratories that reported data, CMS suggests that its modeling shows that more labs reporting would not make a material difference in the eventual payment rates. As a threshold issue, Congress did not require applicable laboratories to report applicable information only when that information would make a difference in payment rates; Congress required applicable labs to report applicable information, period. Regardless, CMS's modeling exercise was fatally flawed for two reasons. First, the agency simulated the difference in the weighted medians if twice as many POLs reported or ten times as many hospitals reported, but apparently it did not do any simulation to determine the

[4] 2016 Physician/Supplier Procedure Summary file; 2015 Outpatient Standard Analytic file.
[5] Summary at 3.
[6] *Id*. at 4.

impact if POLs or hospital laboratories reported in proportion to their share of CLFS payment volume. In 2016, hospital labs received about 26 percent of payments under the CLFS, but in CMS's model they would have only a 10 percent share.[7] Second, CMS's model also mistakenly assumed that all hospital labs would report the same prices, which is not the case. CMS's simulations significantly underrepresent the impact of additional laboratories reporting applicable information.

It is incumbent upon CMS to let the public know what enforcement actions it has taken against non-reporting laboratories. There is a large discrepancy between the number of applicable laboratories that the OIG estimated would be required to report applicable information to CMS and the number of laboratories that actually reported. CMS does not say if it investigated whether any of the 80 registered TIN-level entities that failed to report applicable information were under an obligation to do so, or if it made any efforts to identify the 10,000 laboratories that the OIG included in its estimate of applicable laboratories but that did not report information to CMS. CMS's receipt of applicable information from those 10,000 laboratories could have had a material impact on the weighted medians CMS calculated, especially for the highest-volume test codes.

The agency's data is woefully inadequate to calculate truly market-based rates, when such a miniscule portion of the market is represented and when some sectors of the laboratory market reported very little data to CMS. CMS should determine why so few applicable labs registered to report applicable information during the data reporting period, and why so many of those that registered to report failed to do so – and it must do so before finalizing the preliminary rates.

II. There are obvious problems with the data reported to CMS that call into question the integrity of the weighted medians.

The quality of the applicable information that CMS did receive from some reporting laboratories is questionable, as is CMS's treatment of some of the data. This raises serious concerns about the integrity of the weighted medians calculated from the data.

A. The quality of data reported by some laboratories raises serious concerns about the preliminary rates.

CMS published the final rule to implement Sec. 216 of PAMA on June 23, 2016.[8] In the Final Rule, CMS announced that the first data collection period would span January 1, 2016 to June 30, 2016, ending just one week after the Final Rule was published. Until the Final Rule was published and certain other subregulatory guidance was issued, laboratories were unable to build systems to extract information from their billing systems – not least because they did not know how long or when the first data collection period would be, what private payor rates would be included in applicable information, and whether manual remittances and secondary payor rates would be included. Each laboratory had to create a system for extracting data from its billing system, tailored to the specifics of the Final Rule. It was not until August 4, 2016 that CMS released the list of codes for which applicable laboratories were to report applicable information,

[7] Medicare Payments for Lab Tests in 2016: Year 3 of Baseline Data (OEI-09-17-00140) at 2.
[8] 81 Fed. Reg. 41035 (Jun. 23, 2016) ("Final Rule").

and it was in mid-September 2016 that CMS released the corrected template for reporting applicable information. CMS shared information with applicable laboratories in a variety of ways throughout the summer and fall of 2016, for a data reporting period that started on January 1, 2017.

We do not believe that laboratories reported inaccurate and incomplete data intentionally. But a review of the complete data file and statements that CMS included in its own summary underscore that many of the labs that did report applicable information did not understand what was to be included or excluded from the data, or found that it was impossible to access the information in their systems retroactively.

The weighted median distribution table that CMS released with the preliminary rates reveals truly bizarre data that some laboratories reported – and that CMS used to calculate weighted medians. A review of the table shows that laboratories reported that private payors paid:

- From **$.01** on the low end to **$27,356.01** on the high end for a metabolic panel (CPT code 80048)
- From **$.01** on the low end to **$92,702.94** on the high end for a general health panel (CPT code 80050)
- From **$.01** on the low end to **$65,081.33** on the high end for a comprehensive metabolic panel (CPT code 80053)
- From **$.01** on the low end to **$94,234.12** on the high end for a lipid panel (CPT code 80061)
- From **$.01** on the low end to **$51,061.49** on the high end for a renal function panel (CPT code 80069)

A lab also reported having received **$99,999.99** for a thyroid stimulating hormone assay (CPT code 84443) – which is the highest price that was possible to report for any test, and it also could be a place-holder value, but in either case, this data clearly is erroneous. Additionally, a price of **$0.00 was reported for 2.4 million tests**, which is fully one percent of the test volume reported by applicable laboratories.[9] CMS's guidance in the Final Rule was very clear: "Laboratories should not report zero dollars for CDLTs where a private payor has denied payment within a data collection period."[10] Despite this unequivocal statement by the agency, many laboratories apparently were not aware of this or mistakenly included these "zero payments."

The examples above are obvious and easily detectable errors in data reporting. Our concern lies not only with these examples, but also with all of the other data reporting errors that are not as easy to detect but that are just as likely to have occurred. We also are concerned about the impact

[9] We understand that these "zero payments" were not used in calculations of weighted medians but that the $.01 rates were used.
[10] 81 Fed. Reg. 41054.

these errors had on the preliminary payment rates that CMS released. When CMS relies on clearly erroneous information, it is not possible to have confidence in the data set as a whole.

B. CMS selectively corrected or omitted data that would have resulted in higher than expected weighted medians.

CMS acknowledges that it made its own judgment about what would be an acceptable amount by which a weighted median could exceed a 2017 CLFS National Limitation Amount (NLA). In its Summary, it states:

> CMS identified four reporting entities that submitted data which resulted in weighted medians that were significantly high compared to the 2017 CLFS payment amounts (that is, greater than 150 percent of the 2017 CLFS national limitation amount (NLA)). All four reporting entities were contacted, 3 confirmed they misunderstood the "payment rate" and reported inaccurate data. Two of the reporting entities reported corrected data, which we included in calculating the weighted medians of the private payor rates; the third reporting entity stated that it would submit corrected data but did not (we removed the reporting entity's data from the calculation of the weighted medians of the private payor rate). The fourth reporting entity we contacted did not provide us feedback on the accuracy of its data; therefore, we removed this reporting entity's data from the calculation of the weighted medians of the private payor rates.[11]

In the same section of the summary, CMS states that it did not remove data associated with "statistical outliers" from the calculation of the weighted median of the private payor rates – when it assumed the impact on the weighted median would be minimal.[12]

CMS's selective editing of data does not comply with the law. Section 216 of PAMA does not prohibit the weighted median for a test from being higher than the 2017 NLA – by one percent or by 50 percent – and Congress did not give CMS the authority to decide that a 2018 rate that is 150 percent of a 2017 rate is "too much." Furthermore, the statute and the regulations do not allow CMS to "correct" data that have been submitted and certified by an officer of an applicable laboratory or his or her designee.[13] And nothing in the statute or the regulations allows CMS to pick and choose among the data it received, excluding certain data and including other data, based on how it would affect the weighted median.

While CMS did not accept at face value the questionable but certified data of some labs, it chose to accept at face value the attestations of other laboratories that reported questionable data.

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[11] Summary at 5-6.
[12] *Id*. at 6.
[13] *See* 42 U.S.C. § 1395m-1(b)(2) ("For each laboratory test with respect to which information is reported under subsection (a) for a data collection period, the Secretary shall calculate a weighted median for the test for the period, by arraying the distribution of *all* payment rates reported for the period for each test…") (emphasis added); 42 C.F.R. § 414.507(b).

For example, four of 21 hospital laboratories that reported applicable information "did not report applicable information with a distinct non-hospital NPI as required."[14] CMS's own current policy, as articulated in the Final Rule, is that a hospital enrolled in Medicare as an independent laboratory "or that obtains a unique NPI (separate from the hospital) and bills for its hospital outreach services (that is, services furnished to patients other than inpatients or outpatients of the hospital) using its unique NPI" can meet the definition of an applicable laboratory and report applicable information.[15] Regardless of its policy and its underpinnings, CMS inexplicably looked the other way, noting that "all laboratories are required to attest that they meet the definition of an applicable laboratory," and blindly accepted this attestation to include this data. These hospitals were not "applicable laboratories" under CMS's current regulations and were prohibited from reporting applicable information, unless they had an extremely unusual mix of Medicare CLFS and Physician Fee Schedule payments and bundled payments under the Inpatient Prospective Payment System and Outpatient Prospective Payment System.[16] CMS believed that these laboratories were not permitted to report applicable information, so the agency's acceptance of the hospitals' attestations is not reasonable. Furthermore, more hospital laboratories may have reported applicable information if they knew that CMS would accept their data, regardless of whether they met the definition of an "applicable laboratory" – even though the regulations are clear that "applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory."[17]

Given the low quality of much of the data that CMS received – and given that CMS has acted beyond its authority in selectively including and excluding certain data reported to it – it is not possible to have confidence in the accuracy of the weighted medians that the agency calculated and in the resulting preliminary rates.

III. The enormous cuts to tests commonly performed for Medicare beneficiaries would go far beyond what Congress and the Office of Management and Budget anticipated and would be unsustainable for many labs.

If CMS were to proceed with finalizing the preliminary rates, the resulting cuts would be unsustainable for many laboratories furnishing services to Medicare beneficiaries and would threaten access to laboratory services in some areas. The cuts go far beyond what Congress and the Office of Management and Budget anticipated, calling into question CMS's approach to implementing the law. Further, some of the cuts violate the statutory limit on how much a rate can be reduced from year to year.

A. The preliminary rates include enormous cuts to tests furnished to thousands of Medicare beneficiaries each day.

If the preliminary rates were to be implemented, nine of the top 10 laboratory tests (by CLFS spending) would be cut by more than 30 percent if fully phased-in. Moreover, 18 of the top

[14] Summary at 4.
[15] 81 Fed. Reg. 41046.
[16] 42 C.F.R. § 414.504(g).
[17] *See* 81 Fed. Reg. 41048.

25 lab tests (by CLFS spending) would be cut by more than 30 percent, and another three of the top 25 tests would be cut by between 20 and 30 percent. For example:

- Comprehensive metabolic panel would be cut by 35 percent (41.6 million tests performed in 2016)
- Complete blood count would be cut by 35 percent (42 million tests performed in 2016)
- Vitamin D test would be cut by 35 percent (9 million tests performed in 2016)
- Glycosylated hemoglobin A1c test would be cut by 36 percent (19.3 million tests performed in 2016)
- Thyroid stimulating hormone test would be cut by 35 percent (21.5 million tests performed in 2016)

Collectively, laboratories performed more than 133 million of the foregoing five tests for Medicare beneficiaries in 2016. The top 25 tests by CLFS spending represented fully 63 percent of all Medicare payments for lab tests in 2016, or $4.3 billion.[18] But the deep cuts are in no way limited to the highest volume test codes. The majority of test codes would be cut by more than 10 percent, if the preliminary rates were to be fully phased-in.[19]

Cuts of this magnitude would be unsustainable for many laboratories serving beneficiaries in rural areas, physician office labs in many locations, and nursing homes, and they would threaten beneficiary access to even basic laboratory testing. The costs of providing laboratory testing to Medicare beneficiaries in these labs is higher than costs in other types of labs. It is likely that the cost could exceed the return for some bread-and-butter tests, meaning some labs will close down and some physician offices no longer will offer routine lab testing to their patients to inform treatment and enable diagnosis at the time of a patient's visit. It is not at all the case that other laboratories will rush in and fill the void, once these laboratories stop operating.

B. The cuts go far beyond what Congress or the Office of Management and Budget anticipated.

The cuts that CMS has estimated would take place if the preliminary rates were to be finalized would go well beyond what the non-partisan Congressional Budget Office (CBO) or the Office of Management and Budget (OMB) anticipated. This indicates a fundamental disconnect between the way the law has been implemented and the way it was intended to be implemented. Following is a comparison of CBO's estimates of the effect of PAMA Sec. 216 on CLFS spending (when Congress passed the law), OMB's estimate of the Final Rule's effect on CLFS spending

[18] Medicare Payments for Lab Tests in 2016: Year 3 of Baseline Data (OEI-09-17-00140) at 3.
[19] Summary at 6. CMS itself said that "about 58 percent of HCPCS codes will receive a phased-in payment reduction in CYs 2018, 2019, and 2020, rather than a full private payor rate-based payment amount in CY 2018 because the total payment decrease" will exceed 10 percent.

(when the Final Rule was promulgated), and CMS's recently-released estimate of the effect of the preliminary rates on CLFS spending.

	Year 1	Year 2	Year 3	3-Year Total
CBO[20]	- $100 million	- $400 million	- $500 million	**- $1.0 billion**
OMB[21]	- $390 million	- $700 million	- $620 million	**- $1.7 billion**
CMS[22]	- $670 million	- $1.2 billion	- $1.7 billion	**- $3.6 billion**

The way CMS has implemented Sec. 216 of PAMA, the cuts to the CLFS in the first three years would be more than two and a half times what the CBO anticipated, and more than twice what OMB estimated when the Final Rule was promulgated in June of 2016. If the preliminary rates were implemented, the overall cut to the CLFS in the first three years would be a staggering $3.6 billion. The CY 2018 cut would be 10 percent in the aggregate, the CY 2019 rates would cut another 17 percent from the CLFS, and the CY 2020 rates would add another 23 percent cut on top of the previous years' cuts. We are not aware of another Medicare provider or supplier type that has been required to absorb such deep cuts in reimbursement in such a short period of time, and it is difficult to imagine a scenario in which Congress would legislate such a cut. Congress certainly did not do so in this instance.

C. CMS must change its approach to payment for test codes with no CY 2017 National Limitation Amount.

In the event that CMS moves forward with implementation of the weighted median rates in CY 2018, it must change its approach to pricing test codes that had no CY 2017 NLA, because its current approach violates the statute. A section of the statute titled "Phase-in of Reductions from Private Payor Rate Implementation" states that "payment amounts determined [based on the weighted median of private payor rates] may not result in a reduction in payments for a clinical diagnostic laboratory test for a year of greater than the applicable percent…*of the amount of payment* for the test for the preceding year."[23] For 2018, the applicable percent is 10 percent. In the Final Rule, CMS limited a payment cut in 2018 to "10 percent of the national limitation amount

[20] CBO Cost Estimate for the Protecting Access to Medicare Act of 2014 (Mar. 26, 2014), *available at* https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf. The CBO estimate shows $1 billion in savings from 2014-2019, assuming the new rates would go into effect in 2017, as was called for in the law.
[21] 81 Fed. Reg. 41097.
[22] CY 2018 – Preliminary Private Payor Rate-Based CLFS Payment Rates and Analytics, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.
[23] 42 U.S.C. § 1395m-1(b)(3)(A) (emphasis added).

for the test in 2017," but it was silent on a cut for a code without an NLA.[24] A number of tests had no NLA for CY 2017. For example, the lipid panel (CPT code 80061) has not had an NLA because it includes two automated multi-channel chemistry (AMCC) tests that have been bundled and paid at the ATP02 price (triglycerides and cholesterol) and one test that is not a bundled AMCC test (HDL).

The document that CMS released entitled "Preliminary Payment Rates in 2018, 2019, and 2020 (with 10% Reduction Cap – where applicable)" shows a 2018 rate for the lipid panel of $11.23, a 39 percent cut from the most prevalent local fee schedule amount for the test. The chart also states that the entire reduction for this test would be taken in 2018. Applying a 39 percent reduction in payment for this test in 2018 would violate the plain language of the statute. The "10 percent reduction cap" is applicable to this test and to every other test that was paid for by Medicare in 2017 and whose rate is based on a weighted median of private payor rates, regardless of whether a test had an NLA, because the statute limits a reduction in payment in 2018 to 10 percent of "the amount of payment for the test for the preceding year." When establishing the phased-in reductions, Congress did not distinguish between tests that had an NLA in CY 2017 and those that did not – it limited the payment reduction for any test that had an "amount of payment" in the preceding year.

CMS can comply with the plain language of the statute by recognizing a *de facto* CY 2017 NLA for each test that does not have one. For panel codes comprised of tests represented by codes that do have CY 2017 NLAs, the *de facto* NLA should be the sum of those codes' NLAs. The maximum payment reduction in 2018 would be 10 percent of this *de facto* NLA. The 2019 payment reduction would be no more than 10 percent of the 2018 rate, and the 2020 payment reduction would be no more than 10 percent of the 2019 rate. Using this methodology, CMS would comply with the statutory limit on the year-to-year payment reduction without maintaining a system of different payment amounts in different localities. Using the lipid panel as an example, the CY 2017 NLA for HDL (CPT code 83718) is $11.24, and the CY 2017 NLA for ATP02 is $7.15. Their sum is $18.39. The 10 percent payment reduction limit would be applied as follows:

Lipid Panel (CPT code 80061)	
De facto CY 2017 NLA for lipid panel (sum of NLAs for 83718 and ATP02)	$18.39
Maximum 10 percent payment reduction (10 percent of *de facto* CY 2017 NLA)	$1.84
2018 rate (*De facto* CY 2017 NLA – maximum 10 percent payment reduction)	$16.55
2019 rate (2018 rate – 10 percent of 2018 rate)	$14.89
2020 rate (2019 rate – 10 percent of 2020 rate)	$13.40

The acute hepatitis panel (CPT code 80074) is another organ and disease panel without a CY 2017 NLA. CMS's preliminary 2018 rate for the acute hepatitis panel is $38.79. In 2017, it was paid most often at a price of $65.34, which is the sum of the CY 2017 NLAs for its constituent tests: Hepatitis A antibody (CPT code 86709), Hepatitis B core antibody (CPT code 86705),

[24] *See* 42 C.F.R. § 414.507(d); 81 Fed. Reg. 41079.

Hepatitis B surface antigen (CPT code 87340), and Hepatitis C antibody (CPT code 86803). The 10 percent payment reduction limit would be applied to the acute hepatitis panel this way:

Acute Hepatitis Panel (CPT code 80074)	
De facto CY 2017 NLA for acute hepatitis panel (sum of NLAs for 86709, 86705, 87340, 86803)	$65.34
Maximum 10 percent payment reduction (10 percent of *de facto* CY 2017 NLA)	$6.53
2018 rate (*De facto* CY 2017 NLA – maximum 10 percent payment reduction)	$58.81
2019 rate (2018 rate – 10 percent of 2018 rate)	$52.93
2020 rate (2019 rate – 10 percent of 2020 rate)	$47.64

Other test codes like this are:

- ACTH stimulation panels (CPT codes 80400 - 80406)
- Aldosterone suppression evaluation (CPT code 80408)
- Testosterone response panel (CPT code 80414)
- Estradiol response panel (CPT code 80415)
- Peripheral vein renin stimulation panel (CPT code 80417)
- Glucagon tolerance panel (insulinoma) (CPT code 80422)
- Glucagon tolerance panel (pheochromocytoma) (CPT code 80424)
- Gonadotrophin hormone panel (CPT code 80426)
- Growth hormone stimulation panel (CPT code 80428)
- Metyrapone panel (CPT code 80436)
- TRH simulation panels (CPT codes 80438 – 80439)

For other tests with a $0 NLA whose component codes do not have CY 2017 NLAs, the *de facto* NLA should be the highest local rate on the 2017 CLFS. CMS should apply the 10 percent payment reduction limit to this *de facto* NLA in CY 2018, as well.

In sum, for tests whose rates are calculated using the weighted median of private payor rates reported by applicable laboratories, as all of the above tests were, CMS cannot cut more than 10 percent from "the amount of payment for the test for the preceding year" (2017) without violating the statute. For each such test, CMS must determine "the amount of payment for the test for the preceding year" and limit any cuts to 10 percent of that amount.

IV. Other Issues

A. Automated Multi-channel Chemistry Tests

We wish to confirm that the 23 AMCC tests and the organ and disease panels that consist of AMCC tests will be paid based on the weighted medians of private payor rates received for each individual CPT code and that they will not be paid as bundles under the codes currently listed on the CLFS as "automated test panel" or "ATP" codes. These codes all are on the CLFS and CMS included them on its list of HCPCS codes about which applicable laboratories were required to submit applicable information. Consistent with this, reimbursement for each code is to be the weighted median of private payor rates reported by applicable laboratories.

The law sets forth clear instructions for when and how CMS is to develop new rates based on weighted medians of private payor rates. It does not permit CMS to determine which tests on the CLFS will be priced based on the weighted median of reported prices and which will be priced in some other fashion. Not paying for each of the AMCC codes individually would be contrary to both the letter and spirit of the law. CMS received private payor data from applicable laboratories for the AMCC tests and is required by Sec. 216 of PAMA and by CMS's own regulations to pay for the codes at the weighted medians of private payor rates.

B. Presumptive Drug Testing Codes

ACLA believes that the presumptive drug testing codes that first appeared on the CLFS in 2017 should maintain their current prices, as permitted under the statute. CMS did not receive any applicable information about CPT codes 80305, 80306, or 80307 during the first data reporting period under PAMA. This is because the codes did not exist on the CLFS during the first data collection period, which was the first six months of 2016. As a result, CMS could not calculate a weighted median for any of the codes for CY 2018. CMS has suggested re-crosswalking these codes to codes that no longer exist on the CLFS.[25] We do not believe that these codes may be crosswalked to non-existent G-codes. The crosswalking regulation says "Crosswalking is used if it is determined that a new CDLT is comparable to an *existing test, multiple existing test codes, or a portion of an existing test code.*"[26] The G-codes to which CMS has recommended re-crosswalking these codes no longer appear on the CLFS. However, we believe that the statute allows CMS to leave in place the current prices for these codes until after the next data reporting period.

As CMS acknowledged in the final rule implementing Sec. 216 of PAMA, the statute does not address how CMS is to price tests for which no applicable information was reported.[27] However, the statute does provide guidance to CMS on how it is to treat tests that received new codes on or after April 1, 2014. It says that in the case of a clinical diagnostic laboratory test that

[25] *See* Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule (CLFS) Final Determinations, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2017-CLFS-Codes-Final-Determinations.pdf.
[26] 42 C.F.R. § 414.508(b)(1) (emphasis added).
[27] 81 Fed. Reg. 41086

is assigned a new or substantially revised HCPCS code on or after the date of enactment of PAMA, "during an initial period until a payment rate under subsection (b) is established for the test, payment for the test shall be determined—(A) using crosswalking to the most appropriate existing test under the fee schedule under this section during that period" or through gapfilling.[28]

In late November 2016, CMS finalized its crosswalks for CPT codes 80305, 80306, and 80307 to then-existing test codes. Under the terms of the statute, "until a payment rate under subsection (b)[29] is established for the test," that crosswalked rate stays in place. The statute does not specify a minimum or a maximum number of years that a crosswalked rate may stay in effect—only that it is to remain in place until a weighted median of private payor rates can be calculated for that test. The "initial period" during which the crosswalked payment rate is to stay in effect is until after CMS calculates a weighted median for the new test, not the test to which it was crosswalked. Thus, the CY 2017 NLAs for these codes should remain in place until after the next data reporting period, when new payment rates will be calculated for them.

If CMS does not leave in place the CY 2017 NLAs for CPT codes 80305, 80306, and 80307, CMS must take into account the CY 2017 NLAs for each of these codes to calculate maximum rate reductions for CY 2018. For example, the CY 2018 rate reduction for CPT code 80307 should not be more than 10 percent of the CY 2017 NLA of $79.81, resulting in a CY 2018 rate of $71.83.

C. Definitive Drug Testing Codes

CMS cannot use the applicable information reported by applicable laboratories for HCPCS codes G0480 through G0483 to develop weighted medians for the CY 2018 rates because CMS materially revised the code descriptors for those codes as of January 1, 2017. As such, the applicable information that was reported for G0480 through G0483 is not relevant to the new codes. They must be treated as codes for which no applicable information was reported.

CMS substantially revised the code descriptors for the definitive drug tests represented by HCPCS codes G0480 through G0483 so that the codes could be used only by laboratories that employ highly complex mass spectrometry methods and several newly-added quality controls.[30] A new fifth code, G0659, was created to be used for lower quality and less expensive drug testing methodologies. In recognition of the material increase in resources required for the more complex methods and quality controls associated with the codes, reimbursement rates for these codes also were changed substantially. Reimbursement rates for codes G0480 through G0483 were increased by approximately 17 to 46 percent apiece. The lowest tier code (G0480) was priced about 50 percent higher than the lower quality test represented by G0659. These new codes and the new reimbursement rates became effective January 1, 2017. The old code descriptors that existed

[28] 42 U.S.C. § 1395m-1(c)(1).
[29] Subsection (b) of Sec. 216 of PAMA describes the methodology for calculating a weighted median from applicable information reported about a test.
[30] Under the Social Security Act, "a code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test)." 42 U.S.C. § 1395l(h)(8)(E)(ii).

during the data collection period are compared below to the code descriptors that were implemented on January 1, 2017 and that exist now:

HCPCS	Pre-2017 Code Descriptor	2017 Code Descriptor
G0480	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed	Drug test(s), definitive, utilizing: (1) drug identification methods able to identify individuals drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem), and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing; 1-7

		drug class(es), including metabolite(s) if performed
G0481	8-14 drug classes	8-14 drug classes
G0482	15-21 drug classes	15-21 drug classes
G0483	22 or more drug classes	22 or more drug classes
G0659	*Did not exist.*	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes)

HCPCS codes G0480 through G0483 were "assigned a new or substantially revised HCPCS code on or after the date of enactment" of Sec. 216 of PAMA. Accordingly, "payment for the test shall be determined…using cross-walking (as described in section 414.508(a) of title 42, Code of Federal Regulations, or any successor regulation) to the most appropriate existing test under the fee schedule under this section during that period."[31] These codes should be crosswalked to multiples of CPT code 82542, which remains on the CLFS and has a weighted median for CY 2018. CMS already has done the work and determined the proper crosswalks for these codes, given their methods and resources, and it should apply the same crosswalks as it did in November 2016 as follows:[32]

G0480	4 * 82542 + (3 * (.25 * 82542))
G0481	4 * 82542 + (10 * (.25 * 82542))
G0482	4 * 82542 + (17 * (.25 * 82542))
G0483	4 * 82542 + (25 * (.25 * 82542))

.

Alternatively, the CY 2017 NLAs for these codes could remain in place until after the next data reporting period, when new payment rate are calculated for them.

[31] 42 U.S.C. § 1395m-1(c)(1).
[32] *See* Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule (CLFS) Final Determinations.

D. General Health Panel

The general health panel (CPT code 80050) is a bundled code composed of a comprehensive metabolic panel (CPT code 80053), thyroid stimulating hormone test (CPT code 84443), and complete blood count (CPT code 85025), when ordered and performed together. It has not been listed on the CLFS historically or used for Medicare claims. We are not aware that CMS has changed its policy or that it has directed any laboratory to use CPT code 80050 going forward.

CMS released a preliminary rate for the general health panel of $23.54. Not having been on the CLFS in the past, the general health panel does not have a CY 2017 NLA. However, each of the constituent tests of the general health panel does have a CY 2017 NLA, which sum to $48.20.

We know of no reason why CMS would add CPT code 80050 to the CLFS now, when its policy for many years has been that the code is not payable by Medicare. Whether or not applicable information was reported for a code has no bearing on whether it appears on the CLFS or whether it is payable by Medicare. If CMS were to develop a policy justification for starting to pay for CPT code 80050 and were to include it on the CY 2018 CLFS, then like the lipid panel and the acute hepatic panel discussed above, the agency should develop a *de facto* CY 2017 NLA for the general health panel and limit any payment rate reduction to no more than 10 percent from the *de facto* CY 2017 NLA. Based on this, the CY 2018 rate would not be lower than $43.38. The CY 2019 rate would not be lower than $39.04, and the CY 2020 rate would not be lower than $35.14.

E. CLFS Codes v. Codes for which CMS Collected Applicable Information

We ask CMS to confirm that its collection of applicable information for a code that is not on the CLFS does not indicate that the code will be included on the CY 2018 CLFS or on future years' fee schedules. When CMS first released the list of codes on which applicable laboratories were to report applicable information, ACLA noted to the agency that the list included a number of codes that are not on the CLFS. They include codes that are not payable by Medicare for one reason or another (*e.g.*, general health panel), codes that were on the CLFS during the data collection period but that since have been removed from the CLFS (*e.g.*, G0479), and codes that do not describe a specific test (*e.g.*, Tier II molecular pathology procedure codes). In the Final Rule, CMS had said that for purposes of reporting applicable information, "only private payor rates for CDLTs paid for under the CLFS are considered private payor rates."[33]

If the agency seeks to add a code to the CLFS or change its policy on payment for a code, it should continue to do so through the public consultation process described in Sec. 1833(l)(8) of the Social Security Act or through rulemaking. CMS should not include a code on the CY 2018 CLFS or subsequent fee schedules simply because it received applicable information for the code and calculated a weighted median. Furthermore, for codes that never were on the CLFS, CMS had no basis to collect applicable information in the first place. The agency should remove from its

[33] 81 Fed. Reg. 41055.

website weighted medians it calculated for each of these codes, as well as the raw data files and weighted median distributions for the codes, and it should not distribute this information.

F. Codes Gapfilled in CY 2017

Like the presumptive drug testing codes, CMS did not collect any applicable information on the codes that were gapfilled by Medicare contractors in 2017. CMS should follow its normal procedure for these codes and determine the median gapfill rate for each of them, which will be the CY 2018 rate. Then, "during an initial period until a payment rate under subsection (b) is established" for the test codes, the median gapfill rate should stay in place until after the next data reporting period, because these codes are new after the date of enactment of PAMA, and because CMS has not yet collected any applicable information for them.[34]

G. New Codes Crosswalked for CY 2018

A test code that is new in CY 2018 does not have a CY 2017 NLA, but it may be crosswalked to a code that does have a CY 2017 NLA. In most instances, the code to which it is crosswalked will have had a weighted median calculated from private payor rates reported by applicable labs. Under the language of the statute and CMS's own regulations, the maximum reduction from the CY 2017 NLA for that existing code will be 10 percent. When CMS crosswalks a new CY 2018 code to an existing code, it also should apply the existing code's payment rate reduction limitation, if applicable, to the new code. The purpose of using the crosswalk payment determination ultimately is to arrive at a CLFS rate for the new code, and the weighted median in these cases is not a fee schedule value in the years when CMS is phasing in a payment reduction, so it is not available to use as the fee schedule value for the new code.

For example, an existing test code "A" has a CY 2017 NLA of $100, and the weighted median that CMS has calculated is $70. A test code that is new in CY 2018 - test code "B" – is crosswalked to test code A. In CY 2018, test code A would be paid at a rate of $90, taking into account the first year 10 percent reduction limit. In CY 2019, test code A would be paid at a rate of $81, and in CY 2020, it would be paid at $72.90. In CY 2018, 2019, and 2020, CMS should pay for test code B at the same rates as it pays for test code A (rather than apply the weighted median for three years beginning in CY 2018) and treat the payment rates for the two codes the same, as it has in the past with codes that are crosswalked.

H. Calculation Errors

There are six HCPCS codes in the preliminary rate file whose CY 2020 rates are lower than the indicated weighted median rate. These CY 2020 rates should be corrected as follows before CMS finalizes the 2018-2020 rates:

- 82274 (Assay test for blood fecal): The weighted median rate is $15.92, but the CY 2020 preliminary rate is listed erroneously as $15.91. This should be $15.92.

[34] *See* 42 U.S.C. § 1395m-1(c)(1).

- 83630 (Lactoferrin fecal (qual)): The weighted median rate is $19.70, but the CY 2020 preliminary rate is listed erroneously as $19.63. This should be $19.70.

- 85347 (Coagulation time activated): The weighted median rate is $4.28, but the CY 2020 preliminary rate is listed erroneously as $4.26. This should be $4.28.

- 87169 (Macroscopic exam parasite): The weighted median rate is $4.31, but the CY 2020 preliminary rate is listed erroneously as $4.27. This should be $4.31.

- 88175 (Cytopath c/v auto fluid redo): The weighted median rate is $26.61, but the CY 2020 preliminary rate is listed erroneously as $26.49. This should be $26.61.

- 88262 (Chromosome analysis 15-20): The weighted median rate is $125.49, but the CY 2020 preliminary rate is listed erroneously as $124.64. This should be $125.49.

V. Conclusion

We very much appreciate that along with the preliminary rates, CMS released its raw data file and a summary of its approach to calculating new CLFS rates. The information has been extremely helpful to ACLA and other stakeholders reviewing the preliminary rates in order to provide feedback to the agency. We also appreciate your willingness to meet with ACLA representatives in person to discuss our concerns.

ACLA's position is that CMS must not implement any final rates until it has collected private payor data from all sectors of the laboratory market in proportion to their share of the laboratory market and in a manner that is not burdensome to laboratories, until there is reasonable certainty about the quality and integrity of the data used to develop those rates, and until those rates fairly reflect the significant private payor pricing differentials among different sectors of the laboratory market.

Thank you for your consideration of ACLA's comments.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association

Khani Declaration Exhibit 35

CMS Stakeholder Meeting: PAMA

November 16, 2017

AdvaMedDx
American Clinical Laboratory Association
College of American Pathologists
National Independent Laboratory Association
Navicent Health

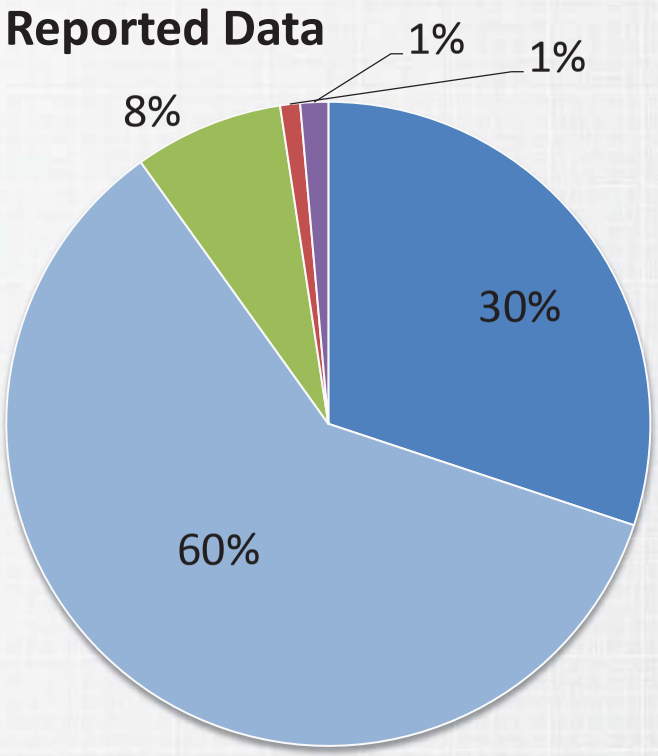
Stakeholder Requests

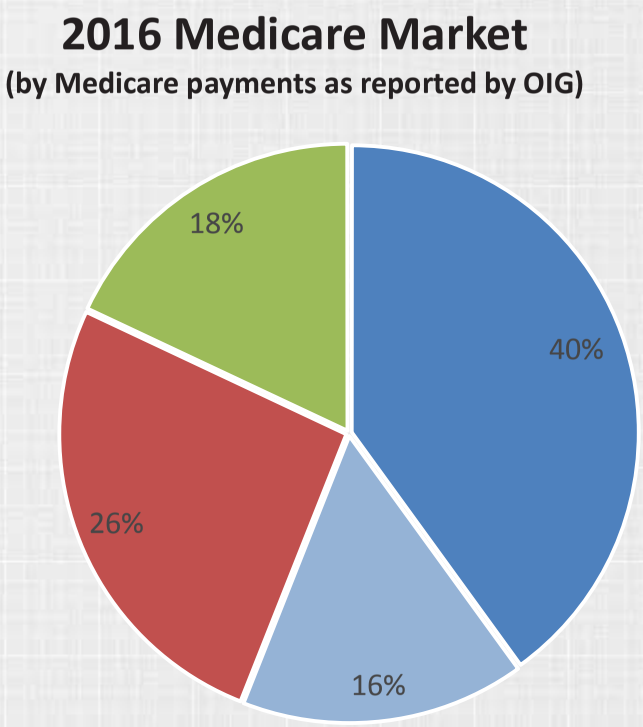
- **Suspend implementation of the new CLFS payment rates to allow time to work with the stakeholder community to address key flaws in PAMA implementation**
  - Address data integrity concerns and market exclusion through a statistically valid process that is least burdensome on providers;
  - Ensure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market (national independent, community and rural independent, hospital outreach, and physician office laboratories); and
  - Allow for a transparent process for the validation of the data collected by CMS

Flaws in PAMA Data

- Data set excludes 99.3% of the laboratory market as identified by OIG
- Hospital labs only contributed 1% of the data compared to 26% share of Medicare CLFS spending
- Physician Office Labs (POLs) only contributed 7.5% of data compared to 18% share of Medicare CLFS spending
- 2.4 million $0.00 prices were submitted as compared to 2.3 million data points from all reporting hospital NPIs
- 3.7 million data points are likely inaccurate outliers, creating questions of pricing errors which are not obvious as outliers (outliers defined as less than $1.00 and greater than $10,000)
- Alternative CMS simulations incorrectly assume additional hospital labs and physician office labs would report pricing volume and distribution identical to data already captured
- CMS selectively corrected or omitted data that would have resulted in higher than expected weighted medians

The Big Labs Are Not Representative of the Market





Other Independents | Big 3 Labs | Physician Office Labs | Hospital Labs | Other

PAMA Data Inadequate

- **Hospital laboratories are significant providers in the Medicare CLFS**
  - 3,043: number of hospital laboratories provided more than $12,500 in *just* CLFS billed services in the first two quarters of CY 2016 (the period used to qualify as an applicable laboratory), without including PFS billed services
  - 1,300: 1,300 more mid-sized hospital labs service the CLFS than mid-sized independent labs
    ("mid-sized" defined as between $568,937 and $12,500 billed in Q1 and Q2 of 2016; 2,627 hospitals and 1,327 independent labs were found to be mid-sized)
  - 26%: Hospital laboratories accounted for 26% of Medicare CLFS payments as reported by the HHS OIG, but were only 1% of data submitted
  - 21: Only 21 hospital NPIs reported data and the actual number of reporting hospital TIN entities is likely even fewer

- **Physician office laboratories significantly expand patient access points**
  - 60,000: Approximately 60,000 physician office laboratories provide services under the CLFS
  - 5,962: Number of physician office labs that exceeded $12,500 in CFLS claims in Q1 and Q2 of 2016
  - 18%: Percentage of Medicare CLFS payments paid to physician offices in 2016
  - 8%: Actual percentage of data reported by physician office labs under PAMA

Independent Analysis of CMS data and summary by Braid-Forbes Health Research

CMS received data on an extremely small proportion of private sector laboratory payments.
CMS reported receiving 4.9 million records representing 248 million laboratory tests from 1,942 laboratory reporting entities. In the Medicare claims data alone there are over 78,000 laboratories who billed Medicare in 2016 for lab tests. The 1,942 labs in the CMS data are less than 3% of the total number of labs that currently serve Medicare patients. Private insurance covers 157 million people. Medicare covers 44 million. Medicare paid for over 430 million tests in 2016.

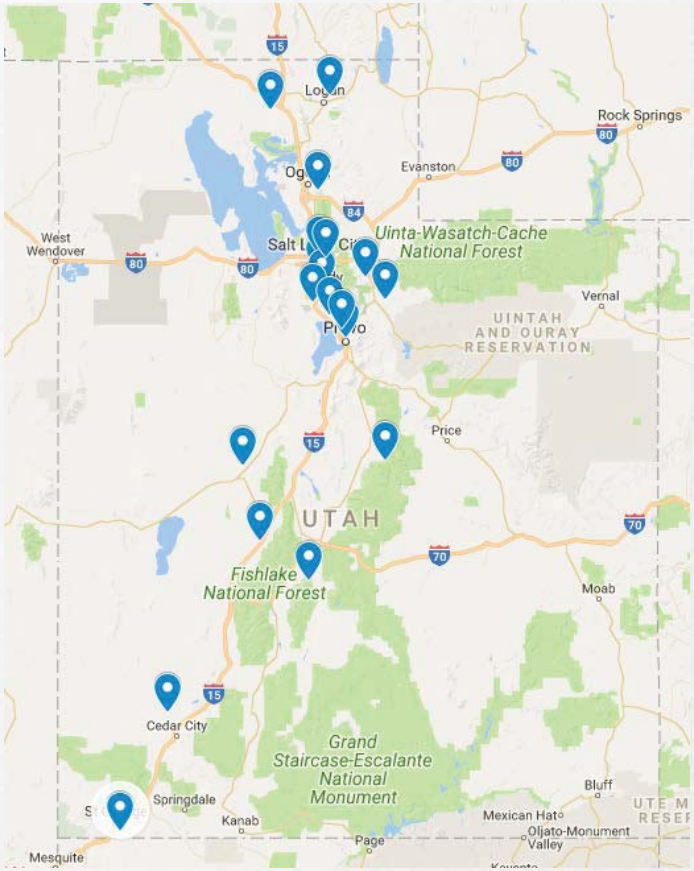
CMS is missing data from an entire important sector of laboratory providers - hospitals.
Over 7,000 hospital labs billed Medicare in 2016. CMS reported collecting information from only 21 hospital NPIs, but since NPIs were bundled under TIN entities, the number of actual hospitals is likely fewer than 21. This leaves hospitals essentially unrepresented in the dataset. Further, it appears that the handful of hospitals that did report are large academic hospitals, which will not be representative of the preponderance of hospital laboratories.

The sample of laboratories that reported is unrepresentative, and cannot be used for unbiased estimation of national payment rates. The sample of laboratories that reported data is extremely small, and entirely excludes important market segments – almost all hospitals, and all non-academic hospitals, and likely other critical laboratory types whose payment rates may differ from others'. Given this, it is not possible to calculate statistically unbiased estimates of the true national payment rates. CMS explored the possibility of reweighting the sample to match nationally representative laboratory characteristics, however even this would not suffice given the complete absence of key laboratory types; this is likely the reason CMS found no significant impact on CLFS spending when it performed its sensitivity analyses.

There is no transparency on the analysis of the sample that CMS performed. CMS stated that the agency performed additional modeling to "determine whether increased participation would significantly affect the payment rates." (p.7) CMS concluded based on its analysis that additional data reporting would not have made significant impact on the payment rates. (p.7) While the data and information released was a positive step in transparency, the agency did not present adequate information on the analyses performed to reach the conclusions presented nor did it make available sufficient data for outside stakeholders to replicate the analysis.

See https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Intermountain Health Utah Labs Excluded From Reporting



Hospital Name	Zip	CLFS CY2016
DIXIE REGIONAL MEDICAL CENTER	84790	$2,555,238
MCKAY DEE HOSPITAL	84403	$738,465
LOGAN REGIONAL HOSPITAL	84341	$598,407
INTERMOUNTAIN MEDICAL CENTER	84107	$549,589
CEDAR CITY HOSPITAL	84721	$539,199
SANPETE VALLEY HOSPITAL - CAH	84647	$320,160
HEBER VALLEY HOSPITAL	84032	$306,889
FILLMORE COMMUNITY HOSPITAL	84631	$281,905
DELTA COMMUNITY HOSPITAL	84624	$249,839
SEVIER VALLEY HOSPITAL	84701	$229,983
LDS HOSPITAL	84143	$216,162
UTAH VALLEY HOSPITAL	84604	$214,849
ALTA VIEW HOSPITAL	84094	$162,323
RIVERTON HOSPITAL	84065	$149,511
AMERICAN FORK HOSPITAL	84003	$138,943
PARK CITY HOSPITAL	84060	$135,712
BEAR RIVER VALLEY HOSPITAL	84337	$55,889
PRIMARY CHILDRENS HOSPITAL	84113	$49,103
OREM COMMUNITY HOSPITAL	84057	$48,523

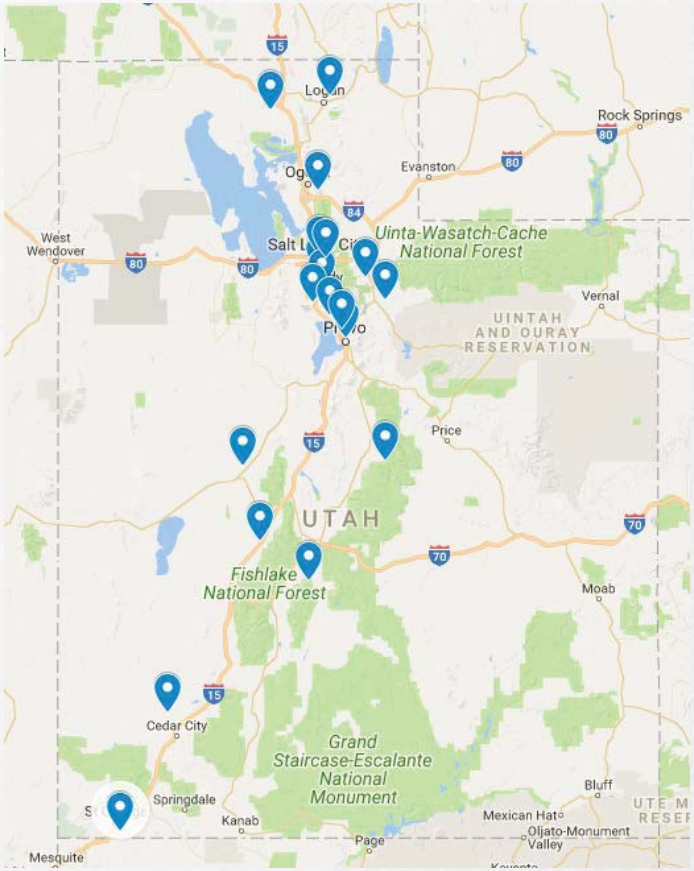
JVHL and Northshore Labs Excluded From Reporting

Michigan	Zip	CLFS CY2016
St John Providence Hospital & Medical Center	48236	$ 8,087,221
Beaumont Laboratories	48073	$ 7,626,544
Sparrow Regional Laboratories	48912	$ 5,650,309
Beaumont Hospital Dearborn	48124	$ 5,182,993
University of Michigan Hospital - MLabs	48109	$ 3,973,105
Covenant HealthCare System	48602	$ 2,747,236
OSF St Francis Hospital	49829	$ 2,581,805
Mercy Health Hackley Campus	49442	$ 2,417,672
Beaumont Hospital Troy	48085	$ 2,283,970
Munson Medical Center	49684	$ 2,099,908
Aspirus Iron River Hospital	49935	$ 2,092,165
Illinois	**Zip**	**CLFS CY2016**
NORTHSHORE UNIVERSITY HEALTHSYSTEM	60201	$ 5,135,867
NORTHSHORE UNIVERSITY HEALTHSYSTEM	60201	$ 818,101

Geisinger Labs
Excluded From Reporting

Hospital Name	Zip	CLFS CY2016
GEISINGER MEDICAL CENTER	17822	$ 3,660,515
GEISINGER WYOMING VALLEY MEDICAL CENTER	18711	$ 1,922,884
GEISINGER-COMMUNITY MEDICAL CENTER	18510	$ 1,498,199
GEISINGER-LEWISTOWN HOSPITAL	17044	$ 720,992
GEISINGER MEDICAL CENTER	17822	$ 367,424
GEISINGER-BLOOMSBURG HOSPITAL	17815	$ 320,165
GEISINGER WYOMING VALLEY MEDICAL CENTER	18711	$ 196,463

Intermountain Health Utah Labs Excluded From Reporting



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Comments and Questions