Complaint Attachment B
Kolozsvary 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 JOHN KOLOZSVARY

I, John Kolozsvary, declare the following to be true and correct to the best of my knowledge:

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

2. I am the Chief Executive Officer of Joint Venture Hospital Laboratories, LLC ("JVHL"), where I have been employed for approximately 5 years. I have been the Chief Executive Officer throughout my tenure at JVHL.

3. Before joining JVHL, I served for nearly 4 years as the Chief Department Administrator of the Michigan State University College of Human Medicine Department of Surgery.

4. Before then, I served for approximately 3 years as the Chief Executive Officer of Southeast Michigan Surgical Hospital, an affiliate of National Surgical Hospitals, Inc.

5. I also serve on the Board of Directors for the American Clinical Laboratory Association in the role of Secretary Treasurer.

6. My job responsibilities at JVHL include overseeing our hospital laboratory network's administrative operations, member relations and development, strategic planning and development for the organization, and various other administrative support functions. In addition to these duties, I have primary responsibility for JVHL's relationships with third party payors and commercial health plans, a group that includes some of the largest health plans operating in all parts of the country. My responsibilities include negotiating with the health plans over clinical laboratory service agreements, which also includes rate negotiations.

7. As a result of my responsibilities at JVHL, I have significant knowledge of the clinical diagnostic laboratory market in Michigan. Because I am responsible for rate negotiations between the laboratory network and private health plan payers, I have a deep understanding of the ways in which clinical diagnostic laboratories are reimbursed by private payors, including the prevailing rates paid by commercial plans. For similar reasons, I have extensive knowledge of the ways in which government insurers, including Medicare, reimburse clinical diagnostic laboratories for providing laboratory services to their beneficiaries. I am also familiar with the manner in which the Secretary of the Department of Health and Human Services has implemented the reporting requirements of Section 216(a) of the Protecting Access to Medicare Act of 2014 ("PAMA").

8. Based on my experience with JVHL, I believe that the Secretary's failure to require hospital outreach laboratories to report commercial rate data, as Section 216(a) requires,

will have an irrevocable adverse impact on the outreach laboratory market in Michigan, on JVHL members in particular, and upon the millions of patients, including Medicare beneficiaries, who rely upon JVHL member laboratories and other Michigan hospitals for their outreach laboratory services.

Michigan Joint Venture Hospital Laboratories

9. JVHL is a Michigan-based laboratory network, formed in 1992 and jointly owned by several Michigan health care systems. JVHL consists of 123 participating hospitals across Michigan, northern Ohio, and northern Indiana and 40 professional pathology groups.

10. JVHL was established to create an organization that would help individual hospital laboratories to attract laboratory service agreements from major commercial health plans.

11. JVHL leverages the size and scale of a single entity made up of hundreds of members to attract, negotiate, and administer laboratory service agreements with commercial health plans. These are the types of agreements that are typically awarded only to large, independent commercial laboratories because of the volume of services they can provide.

12. A laboratory service agreement is an arrangement between a laboratory (or, in our case, a group of laboratories) and a health care insurer that sets forth the terms upon which the health care plan will cover clinical diagnostic services provided to the plan's members. JVHL has laboratory service agreements with several large health plans (including Medicare Advantage health plans), and through these plans, we provide outpatient and outreach laboratory services to more than 5.4 million people residing in Michigan. JVHL member laboratories perform 50 million clinical diagnostic laboratory tests annually for Medicare, Medicare Advantage, Medicaid, commercial payor, and other beneficiaries.

13. Medicare Conditions of Participation and Joint Commission standards require hospitals to have laboratories in order to provide diagnostic services to their inpatients and outpatients. But nearly every hospital also has a hospital outreach laboratory program that provides diagnostic laboratory services to individuals who are referred by their physicians for laboratory services, but who are not registered patients of the hospital. In this way, they provide a service similar to independent laboratories.

The Role that Hospital Laboratories Play in Rural Communities

14. Michigan has a small number of urban areas, such as Detroit, but most of the state is rural, which has a significant impact on how patients are able to access laboratory services throughout the state. Large independent laboratories far more frequently operate in urban and suburban markets than they do in rural areas.

15. Large numbers of individuals in Michigan rely heavily (some exclusively) on hospital outreach laboratories for laboratory services. This is especially true in rural areas where community physicians very often refer patients to hospitals for their laboratory services. It is my understanding that, in addition to providing services to their own patients, Michigan hospitals also provide over 70 percent of the state's non-hospital patient laboratory services with the Medicare, Medicaid, and commercial markets. As a result, in Michigan, the clinical laboratory services market for non-hospital patients is dominated by hospital outreach laboratory programs, not independent laboratories or physician office laboratories.

16. In my experience, hospital outreach laboratories often incur higher costs to provide diagnostic services than large, independent laboratories, and these costs are typically reflected in higher negotiated private payor rates. There are many reasons for the higher costs. By way of example, any single hospital laboratory will have a lower testing volume than an

independent laboratory, and therefore the hospital laboratory is not able to negotiate the type of discounts on supplies and equipment that larger volume laboratories can negotiate. Hospital laboratories also tend to have higher labor costs than independent laboratories because, for example, they are required to make their services available 24 hours a day, seven days a week for inpatient and emergency care and must staff the laboratory accordingly. Hospitals are also obligated to have blood banking capabilities, including acquiring, storing, and managing blood products.

17. The prices that I am able to negotiate for JVHL members with commercial health plans allows JVHL members to continue to provide laboratory services in rural, small, and underserved communities, such as those in the Upper Peninsula of the state.

18. Approximately 60 percent of JVHL members provide laboratory outreach services in rural markets. Twenty-four JVHL members, and 35 hospitals total in Michigan, are critical access hospitals, which, by definition, means that they are small hospitals in a rural area of the country and located at least 35 miles from any other hospital. *See* 42 C.F.R. § 485.610(b)-(c). These and other rural hospitals are often the only option for individuals who need laboratory services in these report areas.

19. It is my understanding that other states have similar experiences to that of Michigan in that they rely upon hospital outreach laboratories to provide laboratories services in rural and remote parts of the State. That is, in other states with rural areas, hospital outreach laboratories, which typically have higher cost structures, are one of the few if not only available laboratory services for these residents.

The Effect of Excluding Hospital Laboratories from the Reporting Requirements of PAMA Section 216(a)

20. Congress enacted PAMA Section 216 to modernize the Medicare Clinical Laboratory Fee Schedule so that it reflected the market forces at work in the commercial payor market. To accomplish that goal, the statute imposes an obligation on certain laboratories, defined in the statute as "applicable laboratories," to report private payor information to the Secretary. It then requires the Secretary to take that information and establish new Medicare reimbursement rates based upon the weighted mean of the reported data.

21. The reporting obligations reflected in the Secretary's final rule are deeply flawed and contrary to PAMA's requirements. Instead of requiring that all "applicable laboratories" report private payor information, as Congress directed, CMS's regulations carve out thousands of laboratories from the statutory requirement and exclude virtually all hospital outreach laboratories, including the hospital outreach laboratories in Michigan.

22. These failures are most evident by looking at the data collected by the Secretary. Out of approximately 261,500 unique National Provider Identification numbers ("NPIs") that billed the Medicare program for laboratory services in 2015, only 1,942 NPIs identified themselves as "applicable laboratories" under the Secretary's definition; that is, less than one percent of all laboratories reported data. *Compare* Office of Inspector General, Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data, OEI-09-16-0004 (Sept. 2016) at 8, *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.

23. The flawed data collection is even more stark when looking at hospital outreach laboratories. During the data reporting period, there were an estimated 7,000 hospital laboratories that billed the Medicare program for diagnostic services to non-patients under the Clinical Laboratory Fee Schedule. But only 21 of those hospital laboratories reported private payor information under the Secretary's definition of "applicable laboratory." *Id.* This figure represents less than one half of one percent of all hospital laboratories in the country. In other words, the Secretary virtually eliminated all hospital laboratories from the commercial payor data reporting requirement.

24. The elimination of thousands of hospitals laboratories from the reporting requirement skews the data that Congress required the Secretary to use to determine the weighted median of commercial payor rates. As explained above, hospital laboratories typically receive higher commercial rates than other types of laboratories. The Secretary has excluded that data. Furthermore, the sample size of 21 hospital laboratories — less than one half of one percent — cannot adequately or reliably represent the full spectrum of the commercial rates that hospital laboratories receive.

25. Although the underlying data is not public, based on my communication with JVHL's membership, I believe that 2 of those 21 hospital laboratories were JVHL members. This means that, of JVHL's hospital membership of 123 hospitals, just 1.6 percent reported private payor data. Because JVHL members make up approximately 70 percent of the hospital laboratory entities in Michigan, it follows that the majority of Michigan hospital laboratory entities were excluded.

26. Based on my knowledge of the hospital outreach laboratory market and the rates that such laboratories negotiate through JVHL, excluding commercial data from hospital

laboratories private payor data will significantly depress the weighted median payment rates that PAMA requires CMS to use in generating the new Clinical Laboratory Fee Schedule. This is the case because there are a significant number of hospital outreach laboratories in the country that are typically paid higher commercial rates than independent laboratories. By excluding the private payor data from these laboratories, the Secretary has eliminated a significant amount of data that would be expected to affect the weighted median of these rates.

The Impact of the Secretary's Final Action on JVHL Members, Medicare Beneficiaries and Other Individuals

27. The Secretary's decision to exclude hospital outreach laboratories from PAMA's reporting requirements poses a significant threat to JVHL's members. It will also lead to a lack of access to necessary clinical laboratory services for Medicare beneficiaries and other individuals. The final rates under PAMA will be phased in over 3 years. I have been informed by some JVHL members that the reimbursement rates under PAMA will ultimately be lower than the cost of providing laboratory services in some cases, particularly for laboratories affiliated with critical access hospitals. This would likely not be the case if the Secretary had collected commercial payor data from all sectors of the hospital laboratory market, including hospital outreach laboratories, which typically have higher laboratory costs and reimbursement rates. As a direct result of the Secretary's decision to exclude hospital laboratories from the reporting requirement, some of JVHL's members will be forced to discontinue offering their outreach laboratory services. If some of JVHL's members discontinue their outreach services, then physicians in rural communities will have very few, if any, laboratories to which they can refer their patients, including Medicare beneficiaries, for essential laboratory testing. Hospital outreach laboratories in these areas provide essential healthcare services to this population, many of whom are elderly and economically disadvantaged. These individuals rely on outreach

laboratory services to obtain the routine and specialized testing that they need to help diagnose, manage, and treat their illnesses. If JVHL members discontinue their laboratory outreach programs, patients in these areas will either delay or go without essential clinical diagnostic laboratory services, putting their health at risk.

28. It is unlikely that large independent laboratories will add services in rural markets to fill the void. Independent laboratories largely operate in densely populated urban and suburban areas and collect samples at patient service centers. Among other things, this model enables them to maximize the number of samples they collect and manage their per patient collection costs. It is difficult to deploy this model in rural, less densely populated areas, and it cannot be taken for granted that independent laboratories will replace all the services that hospital outreach laboratories provide.

29. It is also unlikely that physician office laboratories will be able to fill this void. Typically, physician office laboratories do basic and routine laboratory services, not the full range of testing done in the hospital outreach setting. Broadening the types of testing performed would require physician offices to go through a more stringent accreditation process and purchase new equipment. It is therefore unlikely that such laboratories would make up for the loss of hospital outreach laboratories exiting the market.

30. The effects of the Secretary's unauthorized implementation of PAMA Section 216(a)'s reporting requirements are not limited to patient access and health problems; they include widespread economic impact for individuals who provide these healthcare services. If hospital outreach laboratories scale back their services, there will be a significant impact on jobs throughout the state of Michigan. Hospital laboratories will be forced to reduce staffing based on lost testing volume. In certain rural markets, the hospital laboratory may be the only potential

employer of laboratory technicians. Those technicians will be forced to relocate or chose another line of work to stay gainfully employed.

31. Based on my understanding of the hospital outreach laboratory markets in other states with significant rural populations, I believe that the Secretary's unauthorized implementation of PAMA Section 216(a)'s reporting requirements will lead to similar healthcare access, healthcare outcomes, and job dislocation problems in these states as well. Just as in Michigan, there are other states with large rural populations that rely on hospital outreach laboratories to provide essential diagnostic laboratory services. Because these laboratories were prohibited from reporting commercial payor information to the Secretary, the rates they will receive under the revised Clinical Laboratory Fee Schedule for tests will, in many instances, be below the cost of performing those tests. Hospitals in those states will all be forced to consider discontinuing their outreach programs, and patients, including Medicare beneficiaries, will be left with a gap in access to essential clinical diagnostic laboratory services.

32. The Secretary's unauthorized implementation of Section 216(a)'s reporting requirements will likely drive down Medicaid and commercial payor rates in Michigan. The rates established under PAMA Section 216(a) are artificially low because they do not include a true representative sample of all sectors of the diagnostic laboratory market, particularly the hospital outreach market. Medicaid and commercial payors, however, may use the fact that the rates purportedly represent the median of commercial rates for these laboratory services as leverage, and the rates they pay can be expected to trend eventually toward the Clinical Laboratory Fee Schedule rates. This outcome will be precisely the opposite of what Congress intended when it passed PAMA. Congress enacted PAMA's reporting requirements in order to

ensure that Medicare payments reflect market data and, therefore, market forces. It did not intend PAMA to interrupt and skew these market forces.

33. In conclusion, the Secretary's failure to capture market data from across a broad spectrum of hospital laboratories will have a significant and deleterious impact on most JVHL members and the patients that they serve with their hospital laboratory outreach programs. By failing to capture fully representative market data, the Secretary has skewed the Clinical Laboratory Fee Schedule in the direction of data supplied by large independent laboratories that typically receive lower commercial reimbursement for their services as compared to hospital outreach laboratories. This skewed data will lead to rates that are not reflective of the commercial market. Many hospital outreach laboratories will be paid below costs for their services, which will in turn force many of these laboratories out of the outreach market and leave individuals without clinical diagnostic services that are essential to their healthcare.

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

John Kolozsvary
Chief Executive Officer
JVHL

12/9/2017
Date