AMERICAN CLINICAL LABORATORY ASSOCIATION

August 2, 2024

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

By email: Cures.RFI@mail.house.gov

Re: Comments on the Cures 2.0 Request for Information

Dear Representatives Bucshon and DeGette,

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to respond to your request for information (RFI) on Cures 2.0 and the policies therein that aim to ensure continued investment in innovation and modernization of coverage to broaden patient access to life-saving cures. ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

Innovation in Laboratory Diagnostics is Revolutionizing Health Care Delivery

Clinical laboratory services are foundational to the delivery of patient care as test results inform 70 percent of medical decisions.[1] The value of laboratory services is extraordinary, particularly considering that for Medicare, payments to clinical laboratories under the Clinical Laboratory Fee Schedule comprise only about one percent of total Medicare spending. Laboratories' investments in innovation are leading to extraordinary advancements, changing healthcare as we know it, and improving and saving lives. Laboratories are driving development of cutting-edge diagnostics essential for increasingly personalized medicine to screen for and help identify diseases, guide treatment determinations, and monitor care.

Innovations driven by clinical laboratories include:

- **Diagnosing common and complex neurological conditions**. Clinical laboratory testing helps inform Alzheimer's or other dementia diagnoses by measuring biomarkers in blood and cerebrospinal fluid indicative of disease. Blood-based testing has shown promise as a low-cost, less invasive means of diagnosing conditions and offers primary care physicians as well as specialists a way to identify patients at risk for Alzheimer's disease even before symptoms manifest.

- **Identifying cancers in their earliest and most treatable stages through more accessible screening tests**. Blood-based cancer screening can help improve screening rates and are particularly important for difficult-to-diagnose cancers that often do not present symptoms until late-and more deadly—stages of the disease.

- **Providing answers to families of infants and children with rare diseases** by using genetic technology such as multi-gene panels, exomes, and whole genome sequencing that can look for thousands of genetic mutations with a single blood or saliva sample. Genetic

[1] https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html

testing increases the potential for diagnosis as expeditiously as possible, which is crucial for timely and accurate medical interventions.

- **Creating companion diagnostics that use biomarkers to precisely match a patient with the right treatment option.** Biomarker testing performed by clinical laboratories allows providers to tailor treatments to patients based on their unique genetic makeup, molecular profiles, and disease characteristics.

- **Protecting public health by developing novel diagnostic approaches to emerging pathogens,** putting laboratories at the forefront of preparedness and saving lives.

With the goals of the 21st Century Cures Act in mind and as you consider additional policies, ACLA respectfully encourages enactment of policies impacting reimbursement, regulation, preparedness, and infrastructure to foster innovation in clinical laboratory diagnostics. ACLA is pleased to offer the recommendations that follow.

I. Innovation Depends on Sustainable Reimbursement for Clinical Laboratories

A. Enact PAMA reform through the Saving Access to Laboratory Services Act

Sustainable and predictable Medicare reimbursement is essential for clinical laboratories to continue to provide robust access to a broad range of testing services and to invest in innovative, novel diagnostic tests. ACLA thanks you for cosponsoring the bipartisan Saving Access to Laboratory Services Act (SALSA, H.R. 2377),[2] which is cosponsored by over 60 members in the House and Senate and supported by 70 leading organizations representing millions of patients and providers. SALSA is a reasonable legislative solution that would provide long-term relief from the flawed implementation of the *Protecting Access to Medicare Act* (PAMA) of 2014 by correcting flaws in how the Centers for Medicare and Medicaid Services (CMS) collects commercial market rates to set Medicare rates under the Clinical Laboratory Fee Schedule (CLFS), as required by (PAMA). Further, through application of limits on Medicare payment increases and decreases, SALSA would create a sustainable and balanced pathway forward for the Medicare program, clinical laboratories, and the patients they serve.

In calculating CLFS rates under PAMA, CMS relied on commercial rate data reported by fewer than 1% of laboratories across the country. ACLA challenged CMS's PAMA implementation in court, and in 2022, the U.S. Court of Appeals for the D.C. Circuit found the implementing regulation to be arbitrary and capricious, but the court was prohibited by statute from mandating a remedy. The three years of cuts totaled $3.8 billion, far surpassing CBO's estimate that PAMA would save $2.5 billion over 10 years. Enactment of SALSA will protect patient access to necessary testing and enable clinical labs to enhance investment in innovative diagnostic tests.

ACLA is grateful that Congress has delayed scheduled reimbursement cuts of up to 15% for the last four years and delayed data reporting for five years. The delays came after three consecutive years in 2018-2022 of reimbursement cuts of up to 10 percent under Sec. 216 of PAMA. ACLA appreciates the House Energy and Commerce and Ways and Means Committees' consideration this year of further short-term relief from pending Medicare reimbursement cuts of up to 15% that will take effect January 1, 2025 if Congress does not act. However, as the CLFS has failed to keep pace with inflation for many years such that in 18 of the last 25 years, including each of the last seven years, reimbursement rates on the CLFS either were cut or frozen, ACLA encourages Congress advance SALSA to achieve critically

[2] H.R. 2377/S. 1000.

needed PAMA reform. Inflation has significantly increased costs associated with maintaining a skilled workforce, transportation to move patient samples from all 50 states and territories to laboratories and purchasing testing supplies. Without both appropriate payment levels and payment stability, laboratories may have to reduce testing menus and increase result turnaround times, which could negatively impact patient care and access. Further, clinical laboratories must now comply with the costly Food and Drug Administration (FDA) rule that will regulate laboratory-developed testing services as medical devices. This combination of payment inadequacy and uncertainty and the most significant new regulatory obligations in decades could not only threaten patient access, but also reduce the ability of laboratories to invest in novel diagnostics.

Recommendation: Congress should advance long term PAMA reform through passage of the bipartisan Saving Access to Laboratory Services Act (SALSA) to ensure patient access to testing, enable clinical laboratories to invest in the next generation of clinical diagnostic tests, and support laboratory infrastructure.

B. Support Policies that Expand Coverage for Innovative Tests and Emerging Medical Technologies

ACLA encourages Congress to continue its work to promote innovation and meet the goals of the 21st Century Cures Act by advancing legislation that would expand coverage and access to innovative diagnostic tests.

The FDA Breakthrough Devices Program authorized by 21st Century Cures has resulted in innovative clinical diagnostic tests receiving breakthrough designation, including those supporting patient care in neurology, oncology and transplant medicine, which has expedited FDA clearance or approval of those tests. However, once a diagnostic laboratory test is cleared or approved by the FDA, the process of achieving coverage can be lengthy and may delay by years patient access to innovative technologies, even for those technologies that secured a breakthrough designation. Recognizing this challenge, CMS proposed a rule entitled, “Medicare Program; Transitional Coverage for Emerging Technologies (TCET),” to offer a pathway for swifter coverage. Regrettably, as ACLA conveyed to CMS in official comments, the TCET proposal fails to support innovation as diagnostic laboratory tests that otherwise would meet the eligibility requirements for TCET would be excluded from the program arbitrarily.[3] Such a test should be eligible on the same basis as other items and services if it meets the criteria of an “appropriate candidate” for the TCET pathway. ACLA urged CMS to include diagnostic laboratory tests, out of concern that it would hinder innovation and prevent developers from pursuing the TCET pathway.

ACLA supports the goals of H.R. 1691, the *Ensuring Patient Access to Critical Breakthrough Products Act of 2023,* which as originally introduced and as passed by the House Energy & Commerce Subcommittee on Health seeks to increase access to innovative technologies, including all diagnostics that achieve breakthrough designation, by providing four years of temporary Medicare coverage and payment and allowing a transitional period for CMS to make a permanent coverage decision. This legislation, which builds on provisions included in 21st Century Cures, would both spur continued innovation and speed patient access to transformative diagnostic technologies. However, we oppose the amendment to H.R. 1691 adopted by the House Ways and Means Committee which excludes coverage of clinical diagnostic laboratory tests. That amendment should not be adopted by the Energy & Commerce

[3] 88 Fed. Reg. 41633 (June 27, 2023)

Committee, and we urge you to not include the amendment if you choose to include the bill as a component of Cures 2.0.

ACLA also supports the goals of H.R. 2407, the *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection and Screening Coverage Act.* The bill would establish a new Medicare benefit category for multi-cancer early detection (MCED) screening tests. These blood-based technologies have been shown to help detect cancer earlier, allowing for the potential of better patient outcomes.

Recommendation: Congress should pass H.R. 1691 (without any diagnostics exclusion) and H.R. 2407 to expand more expeditious patient access to cutting edge screening and diagnostic tests.

C. Prior Authorization Reform is Essential to Ensuring Patients Have Access to Innovative Tests

Payor prior authorization policies increasingly have moved beyond limited efforts to ensure appropriate utilization of testing and instead have become tools to deny payment for medically necessary services, leaving patients and laboratories in an untenable position. Prior authorization policies target a wide array of necessary tests, including cutting edge genetic testing for mutations to determine cancer risk, prenatal screening tests, and biomarker testing to determine the most effective cancer treatment. These policies limit patient access to novel, diagnostics, standing in the way of delivering medically necessary, innovative laboratory testing services to the patients who need them.

Since Cures 2.0 was introduced, CMS has implemented reforms outlined in two final rules aimed at improving prior authorization the association considers important steps forward, yet, ACLA is encouraging both the Administration and Congress to advance further reforms .[4,5] ACLA supports H.R. 8702/S. 4532, *the Improving Seniors' Timely Access to Care Act of 2024,* yet is urging bill authors to include additional reforms to ensure patient access to covered laboratory services and appropriate reimbursement for laboratories for covered services that they provide. (See Enclosure) These additional needed reforms include requiring payors to accept prior authorization requests from clinical laboratories, allowing flexibility in the timeline that a payor must accept a prior authorization request for a clinical laboratory test, and requiring payors to request only medical documentation that is reasonably necessary to evaluate a prior authorization request.

Recommendation: Congress should advance H.R. 8702, augmenting it with ACLA-supported provisions that would better align prior authorization processes with laboratory order processes to alleviate challenges that aggressive payor policies pose to both patients and the laboratories that serve them.

D. Improve the Medicare Local Coverage Determination Process to Speed Patient Access

In recent years, Medicare Administrative Contractors (MACs) increasingly have shifted away from stand-alone Local Coverage Determinations (LCDs), which provide coverage for a specific test or test type, toward "foundational" LCDs, which can include coverage for a wide range of tests within a category. For example, tests originally covered under a "BRCA1 and

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[4] 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F), 88 Fed. Reg. 22120 (Apr. 12, 2023).

[5] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-F), 89 Fed. Reg. 8758 (Feb. 8, 2024).

BRCA2 Genetic Testing" LCD now might be included in the much broader "Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer" LCD, along with tests for many other gene alterations relevant to cancer care. The benefit to patients and the health care system of foundational LCDs is that there can be relatively quick updates to the list of covered tests through updated billing and coding articles, without formal reconsideration of the LCD as new evidence is developed. Quicker coverage determinations facilitate patient access.

However, a downside of the shift to foundational LCDs has been fewer opportunities for review of tests that do not fit clearly into one of the broad, foundational LCDs. Prior to the shift to the foundational LCD model, a laboratory could request that a MAC consider developing an LCD on a specific test and expect to receive a response in a timely manner. Now, when a laboratory or other stakeholder submits a request for consideration, the request will await review and processing by the MAC through a foundational LCD process that may take two years after submission. ACLA is concerned that this delay is preventing Medicare beneficiaries from gaining timely coverage and access to services and technologies.

Additionally, prior to the shift away from stand-alone LCDs, stakeholders had greater insight into the position of their coverage determination requests in the queue and the progress of the MAC reviews through open meetings that included multiple stand-alone LCDs that were under consideration. While MACs continue to hold open meetings, they are generally focused on a single foundational LCD that is under consideration and do not provide the same level of information for all LCDs, including the backlog of stand-alone LCD requests, under consideration.

Recommendation: Congress should require CMS to develop a plan to ensure final decisions on stand-alone LCDs will be reached in no more than twelve months from the time an LCD request is submitted. Doing so will benefit patients by allowing quicker access to innovative tests. Additionally, ACLA recommends that Congress require CMS to require MACs to provide transparency into the LCD request queue and develop a system for requestors to monitor the status of their request.

II. Patient Access to Innovative Diagnostics Depends on Appropriate Regulation of Laboratory Developed Testing Services

ACLA acknowledges the significant work progress you have accomplished to develop legislation, the Verifying Accurate Leading-edge IVCT Development (VALID) Act (H.R. 2369), that would create a risk-based diagnostics-specific framework with a designated role for FDA in the regulation of all diagnostics. ACLA has worked collaboratively with Congress, the FDA, and other stakeholders throughout the discussion of VALID and is committed to constructive engagement on diagnostics legislation moving forward. ACLA strongly believes any new regulatory policies must ensure patient access to testing, foster continued innovation in diagnostics, recognize the critical role of laboratory services in our health care systems, and account for the unique features of laboratory diagnostics. ACLA maintains that only through legislation can the FDA have authority to regulate laboratory developed testing services.

Earlier this year the FDA issued a final rule that purports to regulate laboratory developed testing services as medical devices. Laboratory developed testing services are professional services, not medical devices. ACLA believes FDA's unilateral imposition of the ill-fitting medical device framework to laboratory developed testing services will reduce patient access to testing and slow innovation in diagnostics. The exorbitant costs that clinical laboratories will incur in complying with the final rule will divert resources away from innovations that the Cures Initiative endeavors to foster. Medical device authorities do not allow for the rapid innovation required to incorporate recognized scientific advancements and the standard of care into diagnostic

services. These barriers to innovation will add months or years to the development lifecycle for new laboratory developed testing services—months and years that can make a life-or-death difference to a patient. The result could be less investment in research and development and delayed development of the next generation of diagnostics for cancer, infectious disease, and numerous other diseases and conditions.

ACLA is challenging the FDA's final rule in federal court, as the FDA's actions exceed the agency's authority.

Recommendation: Congress should require FDA to halt implementation of the final rule that will regulate laboratory developed testing services as medical devices. ACLA encourages Congress to re-engage stakeholders on legislation to advance risk-based diagnostics-specific legislation that preserves the critical role of laboratory diagnostics and ensures that patients continue to have access to lifesaving testing services.

III. A Strong Workforce and Infrastructure is Critical to Realizing the Cures Goals

Greater investment in the clinical laboratory workforce is imperative to meet the current and future needs of our healthcare system. Patient access to testing depends on a strong and highly trained laboratory workforce. Laboratory operations also can benefit from investments in artificial intelligence (AI) tools, including machine learning models, which help address workforce shortages and manage the increasing demand for healthcare services.

Like for many other health care professions, the nation is facing a declining number of accredited laboratory professional education programs, making it difficult for clinical laboratories to meet state and federal regulatory requirements for personnel, as laboratory professionals exit the workforce through planned retirements, or, in part as a response to the lingering effects of the exceptional pressures of the COVID-19 public health emergency (PHE). Current workforce shortages are widespread and significant, with some clinical laboratories operating with a 10 to 25 percent staffing shortage. When laboratories are short-staffed, employees are more likely to suffer "burnout" as there is too much work for too few existing staff, further exacerbating personnel shortages. The most significant shortages are among highly specialized laboratory technicians and technologists, including cytotechnologists, histotechnologists, and microtechnologists, and molecular technologists and histotechnologists in esoteric laboratories. Genetic counselors and medical geneticists, critical to results interpretation and patient and provider engagement to inform the best care pathway for patients, are also in shortage, most acutely in rural areas and other underserved communities.

Recommendation: Congress should enact legislation that would incentivize states to institute licensure reciprocity; expand federal support for clinical laboratory educational programs; establish a federal loan repayment program for laboratory professionals; and require the Clinical Laboratory Improvement Advisory Committee (CLIAC) to update educational and training requirements for the abovementioned positions to maintain quality while easing staffing concerns.

IV. Recommendations to Build on Provisions Included in Cures 2.0

A. ACLA Supports Continued Efforts to Advance Diagnostic Stewardship to Combat AMR

Antimicrobial resistance (AMR) is a serious public health threat and exacts a devastating toll on human life and economies. ACLA thanks you for including provisions in Cures 2.0 that address the need for novel therapeutics, promote antibiotic stewardship in health care settings, and recognize the essential role diagnostics serve in diagnosis, detection of antimicrobial resistance and guiding appropriate antimicrobial prescribing.

ACLA is concerned that negative coverage policies for infectious disease diagnostic tests, including for antibiotic resistance markers, are preventing health care providers from moving towards the 21st Century Cures goal of appropriate antibiotic stewardship.

Recommendation: Congress should incentivize diagnostic stewardship, including through policies that will help prioritize and improve access to necessary tests by promoting reasonable coverage policies from payors.

B. ACLA Supports Cures 2.0 Provisions to Permanently Extend Telehealth Coverage under Medicare

Cures 2.0 includes policy that would permanently extend coverage of telehealth services, which was expanded during the COVID-19 pandemic and is due to expire at the end of this calendar year. ACLA supports this proposal and appreciates current Congressional efforts to extend telehealth flexibilities for two more years at the very least. Telehealth can improve patient access to health care services across the nation while easing burdens on providers. Through telehealth providers can meaningfully engage with patients, and, as appropriate, order laboratory testing services pursuant to the telehealth visit. Further, telehealth can be leveraged to relay laboratory testing results.

Recommendation: Congress should extend telehealth flexibilities, ensuring appropriate patient access to medically necessary testing services ordered pursuant to a telehealth visit, while avoiding unnecessary and inappropriate barriers such as requiring a prior in-person visit as a condition of payment for laboratory services ordered pursuant to a telehealth visit.

C. ACLA Supports Provisions Enacted to Bolster Public Health Emergency Preparedness and Response, But More Action is Needed

ACLA appreciates the inclusion in Cures 2.0 of policies focused on preparedness and response to public health emergencies, including a national strategy to prevent and respond to pandemics. ACLA was pleased to see important polices enacted in December 2022 in the PREVENT Pandemics Act, including establishing an Office of Pandemic Preparedness and Response Policy, allowing diagnostics to be included in the Strategic National Stockpile, and creating new authorities that would allow for warm base manufacturing and surge capacity capabilities for a subsequent public health emergency.

ACLA and the Johns Hopkins Center for Health Security have developed a set of actionable recommendations to improve the nation's testing preparedness and response for future health emergencies. The recommendations are included in our Proposal for a National Diagnostics Action Plan. Core to all the recommendations is the criticality of robust, ongoing, public-private collaboration and continuing engagement, not only in times of emergency.

Among the concrete recommendations set forth in the paper is for Congress to establish a

permanent public-private National Testing Coordination Forum[6]. Such a forum would meet regularly and be empowered to provide recommendations to the HHS Secretary, White House, and Congress on both preparedness and response matters. The Forum would be comprised of leaders from public health-sector agencies and departments with expertise on diagnostic testing (*e.g.*, CDC, CMS, FDA, NIH) and representatives of public-sector laboratories, hospital laboratories, commercial laboratories, private-sector organizations that represent diagnostic manufacturers, and healthcare product distributors. The entity also would serve as the primary coordinating hub for public- and private-sector stakeholders executing diagnostic testing plans to ensure real-time information sharing, swift development and scale-up of tests and testing capacity, and clear communications to the public on the state of testing. Importantly, the Action Plan urges that clinical laboratories be supported in timely delivery of data for public health through common sense establishment of an appropriately limited set of data elements provided to clinical laboratories through test orders or generated by test results. Clinical laboratories should not be required to collect and report public health data **not** in their possession such as demographic data typically available only through face-to-face encounters.

ACLA was pleased to have provided to the Congress a detailed set of recommendations of proposals that should be included in the reauthorization of the Pandemic All Hazards Preparedness Act (PAHPA), specifically to improve the nation's testing preparedness and response for future emergencies. These recommendations, including those described above, are included in ACLA's March 2023 correspondence to Congress, available here.

Recommendation: Congress should finalize and advance reauthorization of the Pandemic All Hazards Preparedness Act (PAHPA), including the addition of ACLA recommended policies to strengthen testing preparedness and response, outlined here.

Thank you for your consideration of ACLA's comments and for your continued leadership on 21st Century Cures. ACLA and its members stand ready to work with you to continue to advance the goals of the Initiative to promote policies that support innovation and expand patient access to diagnostics, treatments, and medical technologies that improve and save lives. Please contact Mary Lee Watts, ACLA Vice President of Government Affairs and Policy at mlwatts@acla.com with any questions.

Sincerely,

Susan Van Meter
President
American Clinical Laboratory Association

Enclosure:
ACLA May 21, 2024 Letter re *Improving Seniors Timely Access to Care Act 2024*

[6] Gronvall, GK; Rao, SB; Van Meter, S; Borden, A and T Inglesby. Proposal for a national diagnostics action plan for the United States. *Health Policy OPEN*. 2023, *available at* https://doi.org/10.1016/j.hpopen.2023.100099.

AMERICAN CLINICAL LABORATORY ASSOCIATION

May 21, 2024

The Honorable Mike Kelly
U.S. House of Representatives
1707 Longworth House Office Building
Washington, DC 20515

The Honorable Suzan DelBene
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The Honorable Ami Bera
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The Honorable Roger Marshall
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479A Russell Senate Office Building
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The Honorable Kyrsten Sinema
U.S. Senate
317 Hart Senate Office Building
Washington, DC 20510

The Honorable John Thune
U.S. Senate
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Washington, DC 20510

Dear Representatives Bera, Bucshon, DelBene and Kelly, Senators Brown, Marshall, Sinema and Thune:

The American Clinical Laboratory Association (ACLA), the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers, commends you for your leadership to reform prior authorization practices through the *Improving Seniors' Timely Access to Care Act of 2024.* ACLA strongly supports your efforts to codify and build upon the CMS Interoperability and Prior Authorization final rule. As you work to advance the legislation this year, ACLA respectfully requests that you consider the inclusion of modest adjustments that would ensure that patient access to timely, medically necessary laboratory testing is not impeded by aggressive prior authorization policies.

Timely access to laboratory testing for patients and the providers who care for them is essential because clinical laboratory test results inform approximately 70% of health care decisions, from diagnosis to treatment determination and monitoring of care.[1] Unfortunately, many payers' prior authorization policies have moved beyond limited efforts to ensure appropriate utilization of testing and instead have become tools to deny medically necessary services, leaving patients and laboratories in an untenable position.

Aggressive prior authorization policies are now targeting a wide array of necessary tests, including metabolic panels, genetic testing for mutations to determine cancer risk, prenatal

[1] https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html

screening tests, infectious disease testing, and biomarker testing to determine the most effective cancer treatment. These policies can limit patient access to necessary testing.

For clinical laboratories, aggressive prior authorization policies often result in denials of reimbursement for medically necessary testing services already performed. This is because in practice, a physician or other clinician orders a laboratory service and sends a patient's blood or tissue sample to a clinical laboratory along with an order for specific testing. In general, a patient sample must be analyzed promptly for clinical decision making, so a laboratory runs the test in good faith only to experience a payment denial when it discovers the order and sample arrived without already-secured prior authorization. Sometimes an order arrives without documentation sufficient for the laboratory to seek prior authorization on behalf of a patient and in some cases, the plan has a restrictive policy that prohibits a laboratory from securing prior authorization, even for services it performs.

ACLA believes that aligning prior authorization processes with laboratory order processes would alleviate many of the challenges that payer policies pose to both patients and the laboratories who serve them. Respectfully, we request the inclusion of modest improvements to the bill, specified in the enclosed redline, that would:

- Require payers to accept prior authorization requests from clinical laboratories, as suppliers of services.

- Require payers to accept a prior authorization request either before specimen collection or at any time between specimen collection and the date a timely claim for reimbursement is submitted to the plan.

- Require payers to request only medical documentation that is reasonably necessary to evaluate a prior authorization request.

ACLA appreciates that the *Improving Seniors' Timely Access to Care Act of 2024* would require more granular data reporting than the CMS final rule does about Medicare Advantage plans' prior authorization practices for items or services identified by the Secretary. The information that Medicare Advantage plans would be required to report is critical to improving the prior authorization experience for patients and providers and to understanding its impact on access to health care services.

In addition, ACLA strongly supports shorter timeframes for prior authorization decisions, including 24 hours for expedited requests. The association appreciates that the current bill gives authority to the Secretary to establish a shorter timeframe for expedited requests, such as 24 hours, and are hopeful that this language would facilitate implementation of shorter timeframes by CMS in the future. Holding patient samples for several days or even a week until prior authorization is secured is not in the best interest of patients and may in fact cause real patient harm. While laboratories perform tests promptly and in good faith, they frequently experience payment denials for tests if prior authorization is not obtained before testing.

ACLA commends your work to reform prior authorization to ensure patients timely access to necessary services. Clinical laboratory tests are foundational to informed clinical decision making and we appreciate your consideration of the recommendations outlined above ACLA

believes would improve patient access to testing services. We look forward to continuing to work with you as you seek to enact prior authorization reform for the benefit of patients.

If you have any questions or would like to discuss our recommendations, please reach out to Mary Lee Watts, ACLA Vice President of Government Affairs and Policy at mlwatts@acla.com.

Sincerely,

Susan Van Meter
President
American Clinical Laboratory Association

Enclosure

AMERICAN CLINICAL LABORATORY ASSOCIATION

Suggested Redline for the *Improving Seniors' Access to Timely Care Act of 2024*

SEC 2. ESTABLISHING REQUIREMENTS WITH RESPECT TO

THE USE OF PRIOR AUTHORIZATION UNDER MEDICARE

ADVANTAGE PLANS

(a) IN GENERAL.-Section 1852 of the Social Security Act (42 U.S.C. 1395w-22) is amended by adding at the end the following new subsection:

"(o) PRIOR AUTHORIZATION REQUIREMENTS.-

"(1) IN GENERAL.-In the case of a Medicare Advantage plan that imposes any prior authorization requirement with respect to any applicable item or service (as defined in paragraph (5)) during a plan year, such plan shall-

"(A) beginning with plan years beginning on or after January 1, 2027-

"(i) establish the electronic prior authorization program described paragraph (2); ~~and~~

"(ii) meet the enrollee protection standards specified pursuant to paragraph (4); ~~and~~

"(iii) accept a prior authorization request from any provider of services or supplier involved in an enrollee's care, including a provider or supplier to which the enrollee has been referred for services;

"(iv) in the case of a prior authorization request for a clinical diagnostic laboratory test, accept a prior authorization request prior to the date of specimen collection or at any time between the date of specimen collection and the date on which a timely claim for reimbursement is submitted to the plan; and

"(v) request from a provider or supplier only medical or other documentation that is reasonably necessary to evaluate a prior authorization request; and

"(B) beginning with plan years beginning on or after January 1, 2025, meet the transparency requirements specified in paragraph (3).

. . .