December 29, 2021

VIA Electronic Mail to: cures2@mail.house.gov

The Honorable Diana DeGette
The Honorable Fred Upton
U.S. House of Representatives
Rayburn House Office Building
Washington, D.C. 20515

RE: Cures 2.0 Act (H.R. 6000) – Comments from the Point of Care Testing Association

Dear Ms. DeGette and Mr. Upton:

On behalf of the Point of Care Testing Association (POCTA), we appreciate the opportunity to respond to the request for stakeholder input regarding the updated, introduced text of the Cures 2.0 Act ("CURES 2.0"). We thank you both for your work on the original 21st Century Cures Act and your continued commitment to modernizing existing regulatory frameworks, including those affecting coverage and access to innovative technologies that can improve patient outcomes and achieve healthcare savings.

POCTA seeks to facilitate access to safe, effective, and cost-effective clinical diagnostic testing at the time of treatment. We work to achieve this goal by educating providers, payers, and patients about the benefits of point-of-care testing, and by advocating for public policies that foster innovation in and appropriate use of point-of-care testing. POCTA members are developers and manufacturers of point-of-care in vitro diagnostic tests.

We would like to share feedback on the Cures 2.0 introduced text, including comments related to sections 404, 405 (with section 301), 102, 103, and 203. In addition, we would also like to suggest additional reforms to improve access to patient testing at time of treatment, including efforts to facilitate development and commercialization of point of care diagnostics, payment for new clinical diagnostic laboratory tests under section 216 of the Protecting Access to Medicare Act of 2014, coverage pathways for emergency use authorization diagnostic devices, transitional pass-through payments for clinical diagnostic laboratory tests under the Medicare Hospital Outpatient Prospective Payment System, remote review of digitized clinical pathology slide images, pharmacist ordering of point-of-care testing, and expedited Medicare claims processing guidance for CLIA-waived tests. The need for reforms to address several of these issues has been highlighted by the current public health emergency (PHE).

We provide our comments on these key areas in the attached table by briefly describing each issue area and proposing a policy solution.

We would be happy to meet with you and your staff to discuss our comments and recommendations.

If you have any questions or comments, please contact me at 202-204-1457 or via e-mail at ezimmerman@mcdermottplus.com.

Sincerely,

Eric Zimmerman
Point of Care Testing Association

Issue Area	Brief Issue Description	Cures 2.0 Introduced Text Proposal	Comment
<u>Section 404(a) (enacting Section 1899C(b), (d), and (e))</u> **Coverage for breakthrough technologies**	In 2019, the Centers for Medicare & Medicaid Services (CMS) made several policy changes under the Medicare Hospital Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS) to improve access to breakthrough technologies. Under the IPPS, CMS deemed breakthrough technologies to have met the newness and substantial clinical improvement criteria, which are two of the three criteria necessary to qualify for a New Technology Add-on Payment (NTAP). Similarly, under the OPPS, CMS deemed breakthrough technologies to have met the substantial clinical improvement criterion for technologies seeking transitional pass-through payments. These changes significantly reduced barriers to payment for new technologies under the IPPS and OPPS. The same benefits do not exist for breakthrough technologies reimbursed under other Medicare payment systems such as the Clinical Laboratory Fee Schedule (CLFS). In addition, improvements in payment policy do not necessarily assure coverage for breakthrough technologies.	Section 404 essentially codifies the (now-repealed) Medicare Coverage of Innovative Technology pathway promulgated by CMS for breakthrough-designated devices that fall within a defined benefit category. Such devices that have received FDA marketing authorization under the breakthrough pathway within the 2-year period prior to the effective date of the legislation will be eligible to receive coverage for four years under Medicare. Section 404 automatically approves all breakthrough devices for additional payments under the relevant payment systems including the IPPS (NTAP), the OPPS (transitional pass-through payments), or under "other applicable systems" (or adjustments to such systems), including clinical diagnostic laboratory tests. A pathway for "specified breakthrough devices" that do not fall within a distinct benefit category is also identified. CMS is required to submit a report to Congress specifying how the device is classified (e.g., cancer screening test), the method of coverage and payment, impact on beneficiaries and Medicare program expenditures.	POCTA strongly supports the establishment of a pathway for FDA authorized devices with breakthrough designation that provides national coverage for a minimum of four years. Such a pathway will facilitate beneficiary access to life saving technologies. POCTA affirms the inclusion of clinical diagnostic laboratory tests in the coverage pathway for breakthrough devices and believes that any technology that has breakthrough status should be covered by Medicare regardless of payment system. POCTA members develop point of care clinical diagnostic laboratory tests including rapid tests for COVID-19 and other pathogens that may be eligible for coverage under this pathway (following FDA market authorization). POCTA supports a pathway to coverage for innovative technologies that do not fall within a defined benefit category. Such technologies may provide critical lifesaving and cost saving technologies, such as clinical laboratory tests to screen Medicare beneficiaries for treatable and life-threatening disease.

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<u>Section 404(a) (enacting Section 1899C(d)(3)(D))</u> Additional payment system for clinical diagnostic laboratory tests	The currently pathways for determining payment for clinical diagnostic laboratory tests under the Protecting Access to Medicare Act of 2014 (PAMA) include: (1) gapfilling — local MACs assign a rate for new clinical diagnostic laboratory tests based on charges and routine discounts to charges, resources requirement to perform the test, payment amounts determined by other payors and other charges, payments or resources that may be relevant; (2) crosswalking — assign rate of a comparable laboratory test (or combination of tests) if one exists; (3) as an Advanced Diagnostic Laboratory Test — alternative pathway afforded single laboratories that are FDA cleared or approved or meet other criteria (e.g., algorithm-based test) A system created by CMS to provide additional payments for novel clinical diagnostic laboratory tests that qualify as breakthrough devices (analogous to transitional pass-through payments under OPPS and NTAP under IPPS) should be designed to provide incremental payment for breakthrough diagnostic tests (as compared to what would ordinarily be calculated under PAMA).	The statute identifies the following mechanisms for payment adjustment for clinical diagnostic laboratory tests with breakthrough designation: (1) Increase to the amount determined based on crosswalking to an existing code under 1834A; (2) Extension of the "initial period" of payment for Advanced Diagnostic Laboratory Tests; and (3) Other methods determined by CMS to reflect the cost associated with the test.	POCTA strongly supports the availability of additional payment for breakthrough devices that are clinical laboratory diagnostic tests. However, POCTA does not agree that methods for determining additional payment for clinical diagnostic laboratory tests should be limited to where ratesetting is established through crosswalk. CMS often assigns new, innovative technologies to gapfill instead of crosswalk because there are no similar tests. Therefore, limiting the opportunity for enhanced payment to in vitro diagnostic tests assigned new rates through crosswalk is inadequate for many in vitro diagnostics that are breakthrough technologies. POCTA requests that the language be modified to allow enhanced payment for tests where rates are established through gapfill as well as crosswalk.

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Section 404(a) (enacting Section 1899C(c)(1), (2), (3)) Coding for breakthrough devices	A CPT or HCPCS Level II code must be assigned to breakthrough devices to facilitate payment during the transitional coverage period.	CMS will assign devices with FDA breakthrough designation a unique temporary or permanent code to facilitate coverage and payment under the new pathway. The Clinical Laboratory Fee Schedule will be updated with the new codes on a semiannual or quarterly basis, and the code assignment process will be subject to public notice and comment.	POCTA supports a coding system for the transitional coverage period where the sponsor of the device believes that existing coding is not adequate. However, POCTA does not support a requirement that CMS assign a unique temporary or permanent code for breakthrough devices for the purposes of coverage during the transitional period if the sponsor believes existing coding is adequate. In vitro diagnostic (IVD) tests may be reported using existing Category I, Category III, or Proprietary Laboratory Analyses (PLA) codes issued by the AMA. Requiring issuance of a unique alternative code may produce confusion among providers in the market place insofar as such providers utilize existing code(s). In addition, there may be implications for reporting requirements under PAMA Section 216, including concerns that other payors may not recognize the codes issued by CMS under this provision and for other business reasons. Instead, manufacturers should be able to "opt in" to the establishment of a new code.

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Section 404(a) (enacting Section 1899C(b)(1)(B)(i), (ii)) **Definition of transitional coverage period**	Devices that have received FDA marketing authorization under the breakthrough pathway within the 2-year period prior to the effective date of the legislation will be eligible to receive coverage and payment for four years under Medicare. However, the current statute does not account for two factors: (1) the coverage period does not provide a process for manufacturers to "opt in," as not all manufacturers will desire transitional coverage under Medicare; and (2) as defined, the transitional coverage period does not clearly identify the start date for the four-year coverage period (e.g., if from the date of FDA marketing authorization, or the date unique coding becomes available).	The statutory definition of "transitional coverage period" in (b)(1)(B) provides a start date tied to FDA clearance/approval and an end-date tied to four years from the date CMS updates its payment systems and recognizes the newly established code. As written, it is unclear whether the four-year period starts with FDA approval/clearance, or if it begins with CMS' recognition of the (unique) code as payable.	POCTA believes that FDA clearance/approval should be required for a device to qualify for transitional coverage. POCTA encourages revisions to Section (b)(1)(B) to clarify that FDA clearance/approval is not the sole determining factor for the start date of the four-year coverage period. Rather, POCTA recommends the transitional coverage period be defined to extend four years from an "opt-in" date chosen by the manufacturer that: (i) cannot begin before receipt of FDA clearance/authorization/approval, (ii) falls within four years of receiving FDA clearance/authorization/approval, and (iii) ends no sooner than four years from the date the manufacturer opts in to coverage.
Section 404(a) (enacting Section 1899C(b)(2)(A)) **Identification of Additional Evidence**	Currently, most Medicare coverage decisions are made by the local Medicare Administrative Contractors. National Coverage Determinations are made through an evidence-based process that requires significant resources and can last for many years. National Coverage Analyses (resulting in National Coverage Determinations) are typically initiated upon CMS discretion or when a stakeholder submits a request.	Directs CMS to define what additional evidence, if any, will be needed for coverage in the post-transitional coverage period.	POCTA is concerned that the option to identify additional evidence will essentially create a de facto NCD process, which will add to the administrative burden on CMS and centralize coverage authority away from the local MACs. Provisions addressing evidence review should reflect the current process in which CAG makes determinations on an as needed basis for each product.

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Section 405 and Section 301 Digital health – developing a framework for establishing coding and payment for diagnostics that include digital health	Current perception is that anytime technology replaces human labor, payment for that service should be reduced or the software components may be considered indirect/overhead expenses.	Section 405 requires a report to Congress from CMS within one year that outlines a proposed definition and qualification determination process for therapeutic digital alternatives and establishes a coverage and payment system for digital therapeutics. Section 301 requires a report to Congress from FDA that aligns policies and definitions with respect to digital health technologies across the Agency. Recommendations are to address use and validation of digital health technology tools; qualification and validation of digital endpoints for regulatory review; use of digital health technologies in patient-focused development of products; and coordinating regulation and use of digital health technologies with foreign regulators. The sections outlining the CMS and FDA Reports to Congress do not specifically address digital diagnostic testing, including clinical diagnostic laboratory tests that comprise digital systems. In the section outlining the FDA report, digital health technologies are defined as "technologies in health care or society that help deliver or provide access to health care products and services such as hardware (for example, wearable sensors, virtual reality headsets, and digitally-enabled drug delivery devices), advanced analytics (for example, artificial intelligence, machine learning, and sophisticated computation), cloud services (for example, storage computing, and data processing), and software (for example, mobile medical applications, software as a medical device)."	POCTA encourages efforts to define clinical digital technologies and strongly supports harmonized regulatory pathways for product clearance/approval and the establishment of coverage and payment systems for these technologies. POCTA strongly recommends that the framework for establishing FDA clearance/approval as well as coding, coverage and payment for digital technologies specifically include diagnostic technologies, including clinical diagnostic laboratory tests, as well as therapeutic technologies.

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Section 102(b) **Content of national strategy to prevent and respond to pandemics**	The COVID-19 pandemic demonstrates the importance of access to reliable, scalable, and accessible testing solutions, access to real-time information trends, projections, and areas of need, and modernization and expansion of diagnostics manufacturing.	Section 102(b) requires the national strategy to address strategies for testing, methods of data sharing to inform surveillance and other pandemic monitoring and response efforts, strategies to enable Americans to continue or return to work/school/childcare, modernizing and expanding domestic drug manufacturing, and developing and administering vaccines, therapies, and medical supplies, including to children, racial and ethnic minorities, and people with disabilities.	POCTA recommends that that national strategy be revised as follows: (a) so strategies for testing include consideration of high-throughput testing, point-of-care testing in non-traditional settings (e.g., long-term care facilities, retail pharmacies, ambulatory surgical centers), and over the counter testing (including at-home testing), (b) so methods of data sharing include providing test manufacturers access to real-time data on pandemic trends, areas of greatest need, and projections of future spread, (c) to establish a Master Testing Repository for the FDA and CDC to utilize during PHEs that provides a single interface for manufacturer and lab reporting to facilitate information sharing between industry and the federal government; and (d) so efforts to modernize/expand manufacturing and develop/administer certain products include efforts related to diagnostics.
Section 102 **Duration of PHEs**	Under section 319 of the Public Health Service Act, the Secretary of the Department of Health and Human Services may issue a PHE declaration that lasts for the duration of the emergency or 90 days. These declarations may be extended by the Secretary. To date, the Secretary has extended the COVID-19 PHE on several occasions. Recent PHEs (prior to COVID) also ran substantially beyond the initial 90-day period. For example, the PHE declaration for Influenza H1N1 ran from April 26th, 2009 – June 23rd, 2010 (423 days), and the PHE for Zika Virus from November 4th, 2016 – July 27th, 2017 (265 days.). During the PHE, providers and manufacturers have relied upon the continued availability of the PHE when making critical business decisions, and have expressed concerns regarding the ongoing need to extend the PHE beyond its (then-)current expiration point.	Not addressed	POCTA supports revising section 319 of the Public Health Service Act to give HHS the authority to declare a PHE for up to 365 days at a time. Increasing the length of time for which a PHE may be declared provides more predictability for manufacturer and provider planning purposes, and may help avoid disruptions to patient care or access to medical products and services.

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Section 103(a)(4) Pandemic Preparedness Plan	Shortages of diagnostic testing supplies will impair the country's ability to quickly and forcefully respond to future pandemics.	Section 103 requires the Secretary to award grants to eligible organizations to develop a pandemic preparedness plan addressing four components, including efforts to partner with local, state, and federal governments to promote a coordinated response to future pandemics and other PHEs.	POCTA supports clarifying that any plan funded by this section should include, as part of its efforts to partner with state and local governments, plans to establish future access to testing.
Section 203 Increasing diversity in clinical trials	Lack of diversity in clinical trial populations is a longstanding issue in clinical trials.	Section 203 takes several steps intended to increase diversity among clinical trial participants, including creating a task force that will provide recommendations on making clinicaltrials.gov more friendly.	As part of these efforts, POCTA recommends that the Secretary of HHS, in partnership with industry, create resources to ensure diversity within clinical trials, including creating a registry of eligible trial participants. POCTA also recommends that the task force convened by the Secretary to make clinicaltrials.gov more user-friendly include representatives from the diagnostics industry.
Development and commercialization of point-of-care diagnostic tests	Point-of-care (POC) testing – patient laboratory testing that is done at, or near, the patient – is important to inform immediate or near-term patient management across a range of settings including, but not limited to inpatient hospital, physician office and even in the home. Rapid test results can quickly help determine a course of action or treatment for a patient, and have been especially helpful during the COVID-19 PHE. However, POC testing is often undervalued and current policies may not be adequate to support the development and commercialization of POC diagnostic tests. Current policy should be reviewed and evaluated to identify policies to support better the development and commercialization of POC diagnostic tests.	Not addressed	POCTA supports establishing an interagency taskforce comprised of the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services and the Food and Drug Administration to evaluate how existing statutory and regulatory requirements impact the development and commercialization of point-of-care diagnostic tests and to develop recommendations that address identified barriers. The taskforce shall also include representatives from manufacturers of point-of-care diagnostic tests. A report with recommendations should be issued within one year of enactment.

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New laboratory test payment under PAMA section 216	CMS establishes payment rates for new laboratory tests using "crosswalking" or "gapfilling" methodologies. Under the "crosswalking" methodology, the payment rate for a new laboratory service is established based on the payment rate of a similar laboratory test or combination of tests. Under the "gapfilling" methodology, the payment rate is based on information such as charges and routine discounts to charges, resources required to perform the laboratory test, negotiated payer rates, and payment amounts for other tests that may be comparable. Under the Protecting Access to Medicare Act of 2014 (PAMA), if the payment rate for a new laboratory test is set based on crosswalk and payment for the "crosswalk" test declines, those payment reductions apply to the new test's payment as well. However, those payment reductions are based solely on reported data for the crosswalk test and do not include any payment data for the new test.	Not addressed	For new laboratory tests for which payment rates are established via crosswalk, POCTA recommends that payment rates established by crosswalk shall be held constant at the rate in effect at the time the crosswalk was assigned until the next cycle of laboratory reporting and ratesetting under PAMA. Modifying this practice would provide consistency and stability to initial rate setting consistent with crosswalking principles until test-specific private payor payment data are collected and reported under current requirements.
Coverage and payment pathway for medical products with Emergency Use Authorizations	During the COVID-19 public health emergency, CMS has acted quickly to establish coverage for medical products granted EUAs. However, there has been limited transparency regarding any conditions for coverage for these products. Moreover, although CMS released payment information for certain medical products with EUAs, it has not provided such information for others. CMS should implement an expedited, systematic approach for both establishing coverage and setting payment rates for medical products with EUAs during the PHE that is applicable to future PHEs. The process should include notifying the public of the conditions for coverage and payment rate not later than 10 days after an EUA is issued and providing a minimum of 30 days for public comment.	Not addressed	POCTA recommends requiring Medicare to cover and establish payment for any medical product authorized under an Emergency Use Authorization (EUA) by the US Food and Drug Administration. In so doing, CMS must notify the public of the conditions for coverage and a payment rate not later than 10 days after an EUA is issued and provide a minimum of 30 days for comment. Furthermore, POCTA recommends the implementation of an expedited appeals process for the coverage and rate-setting determinations (e.g., in the event that stakeholders believe that comments submitted above have not been adequately addressed).

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Medicare Hospital Outpatient Prospective Payment System transitional pass-through payment	Both the IPPS and the OPPS include payment pathways to facilitate adoption of new technologies. Under the IPPS, NTAP provides additional payments for certain new technologies. Under the OPPS, additional payments are made for new technologies via Transitional Pass-Through Payments. Although both prospective payment systems have mechanisms for facilitating adoption of new technology, criteria are inconsistent between the IPPS and OPPS. Current policy limits OPPS transitional pass-through payments to those devices that are "surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion." This requirement excludes novel diagnostic tests from consideration for transitional pass-through payments despite their being packaged under the OPPS. This requirement does not exist under the IPPS and, as recently as FY 2020, novel diagnostic tests have been granted NTAP status.	Section 404 (Cures 2.0) approves all breakthrough devices for additional payments under the relevant payment systems including the IPPS (new technology add on payments), the OPPS (transitional pass-through payments), or under "other applicable systems" (or adjustments to such systems), including clinical diagnostic laboratory tests. Broader criteria for qualifying for NTAP, pass-through payment or other payment systems are not addressed.	POCTA supports the eligibility of breakthrough devices to receive NTAP or transitional pass-through payment under OPPS but believes that payments to facilitate adoption of new technologies should not be limited to breakthrough designated devices. POCTA also recommends that the transitional pass-through payment program under OPPS be extended to allow all clinical diagnostic laboratory tests to be eligible if such tests meet the newness, substantial clinical improvement, and costs not insignificant criteria that apply to all other devices. This change would put clinical diagnostic laboratory tests on an equal footing with devices that are "implanted or inserted…"

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Remote review of digital slides and images	The Clinical Laboratory Improvement Amendments (CLIA) originally became law in October 1988. As such, its detailed regulations were formulated well before the digital era and its requirements are out of touch with current technology and practice. For example, in the United States pathologists must make primary diagnostic interpretations while viewing slides in a CLIA-certified location regardless of the diagnostic modality used (*i.e.*, glass slides or digital whole slide imaging (WSI)). CLIA does not permit remote review of digital slides and images unless the pathologist has a CLIA license for the pathologist's home or remote WSI workstation. Current CLIA requirements are also inconsistent with requirements in other clinical areas such as radiology. In the U.S. radiologists are able to report digital studies from home. Although CMS/CLIA currently exercises enforcement discretion with respect to this requirement as part of its response to the COVID-19 PHE, these flexibilities will disappear once the PHE ends. Pathologists and laboratory professionals should be permitted to read digital slides and images and interpret data in locations other than a CLIA certified lab and without the need for a separate CLIA certificate.	Not addressed	POCTA recommends the inclusion of language that would explicitly allow for remote review of digital slides and images and interpretation of data in locations other than a CLIA certified lab without the need for a separate CLIA certificate as long as standards are met to assure adequate clinical quality.

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Permanent flexibility to allow pharmacist involvement in testing	In general, a diagnostic test is only eligible for Medicare reimbursement if it is ordered by the physician who is treating the beneficiary. Pharmacists are not included in the list of nonphysician practitioners (NPPs) who are treated as physicians for purposes of this requirement if operating within the scope of their authority under state law. During the COVID-19 PHE, a physician (or other HCP) order is not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis when performed in conjunction with COVID-19 diagnostic laboratory test in order to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID-19 and related tests are reasonable and necessary when ordered by a physician or NPP in accordance with the usual Medicare requirements, or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. The flexibility that currently allows pharmacists to order tests will end when the PHE ends.	Not addressed	POCTA supports the inclusion of statutory language that would make permanent the recognition of pharmacist's authority to order diagnostic tests, subject to state law.

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Expedited publication of Medicare guidance on CLIA-waived tests	Point-of-care labs can lawfully offer CLIA-waived tests as soon as a test receives FDA clearance/approval and "waived" designation from FDA. However, point-of-care labs cannot bill Medicare for claims for CLIA-waived tests until CMS updates its list of "waived tests" to include the test and its associated CPT code. CMS recommends that providers hold claims until it is able to update this list and the local Medicare Administrative Contractors (MACs) implement the change. Normally, the above-described process takes CMS and the local MACs 4-6 months to complete. However, during the COVID-19 PHE, CMS has substantially expedited its usual process, and issued instructions quickly enough that waived laboratories must only hold claims for 1-2 months.	Not addressed.	POCTA supports the inclusion of statutory language that would require CMS to update its claims processing instructions – and for the MACs to update their claims processing systems – to account for new CLIA-waived tests within one calendar quarter from FDA's decision to authorize a test for use in a CLIA-waived setting.