May 21, 2018

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2406-P
P.O. Box 8016
Baltimore, Maryland 21244-8016

American Clinical Laboratory Association

RE: Medicaid Program; Methods for Assuring Access to Covered Medicaid Services—Exemptions for States with High Managed Care Penetration Rates and Rate Reduction Threshold (CMS-2406-P)

Dear Ms. Verma,

The American Clinical Laboratory Association (ACLA) submits these comments on the proposed rule entitled "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services—Exemptions for States with High Managed Care Penetration Rates and Rate Reduction Threshold." [1] ACLA is the leading trade association representing clinical laboratories throughout the country, including national, regional, and local laboratories that provide testing for thousands of Medicaid beneficiaries each day.

ACLA is deeply concerned that the proposed rule would curtail the already limited methods that the Centers for Medicare & Medicaid Services (CMS) has at its disposal to monitor the effects of payment rates on access to laboratory services and to require a state to take remedial action in the event of inadequate access. Even the current system that CMS and states use to monitor beneficiary access to services does not go far enough to require states to remediate access issues. If the proposed rule were to be implemented, cuts in payment for laboratory services would not be subject to any meaningful monitoring of payment adequacy or impacts on access for Medicaid beneficiaries. Implementation of the rule as proposed would be short-sighted in that inadequate access to laboratory testing has negative downstream effects on patients and on each state Medicaid program's bottom line.

If CMS is to finalize the proposed rule, it must take affirmative action of its own to ensure that Medicaid payment for laboratory testing and for other services is adequate to retain providers and preserve beneficiary access to the services.

A. Background

1. "Equal access" rule in fee-for-service Medicaid

States and the federal government have an obligation to ensure that Medicaid beneficiaries have sufficient access to services. Monitoring access to care is a requirement under both fee-for-service Medicaid and Medicaid managed care programs.

[1] 83 Fed. Reg. 12696 (Mar. 23, 2018).

A basic tenet of fee-for-service Medicaid is that a state Medicaid program's payments must be sufficient to ensure that Medicaid beneficiaries have access to services at least to the same extent as they are available to the general public. Section 1902(a)(30)(A) of the Social Security Act requires a state Medicaid plan to "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan…to assure that payments are consistent with efficiency, economy, and quality of care *and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area*."[2] Federal Medicaid regulations also reflect this so-called "equal access" provision.[3]

In 2015, CMS finalized regulations, effective Jan. 1, 2016, that purported to create a framework to guide states in meeting the statutory requirement in Sec. 1902(a)(30)(A). The rule was finalized after many years of concerns about CMS's hands-off approach to monitoring payment adequacy and resulting access problems, and after several court cases, including one that made its way to the U.S. Supreme Court.[4] The 2015 rule outlined a "data-driven process for states to document whether Medicaid payments are sufficient to enlist providers to ensure beneficiary access to covered care and services consistent with Sec. 1902(a)(30)(A) of the Act."[5] This is done through an "access monitoring review plan" (AMRP).

An AMRP must address and document the extent to which Medicaid beneficiary needs are fully met, the availability of care through enrolled providers, changes in beneficiary service utilization, characteristics of the beneficiary population, and actual and estimated levels of provider payment available from other payors, including other public and private payors.[6] Federal Medicaid regulations require a state to develop and submit to CMS an AMRP for fee-for-service payments, updated at least every three years, for the following services: (1) primary care; (2) physician specialist services; (3) behavioral health services; (4) pre- and post-natal obstetric services; (5) home health services; (6) any additional types of services for which review is required under § 447.203(b)(6) because of a proposed payment rate reduction or restructuring; (7) additional types of services for which the state or CMS has received a significantly higher than usual volume of beneficiary, provider, or other stakeholder access complaints for a geographic area; and (8) additional types of services selected by a state.[7] Under § 447.203(b)(6), a state has to add services to its AMRP when reducing payment rates could result in diminished access and implement a plan to monitor the effects of a rate reduction. The 2015 rule also included provisions for a public comment period for a state developing an AMRP, ongoing mechanisms for beneficiary and stakeholder input and state response to such input, and maintenance of records on public input.[8]

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[2] The italicized language was added to the Social Security Act in 1989 in the Omnibus Budget Reconciliation Act, Pub. L. 101-239, § 6402(a).

[3] 42 C.F.R. § 447.204 [previously enumerated at 45 C.F.R. § 250.30, 42 C.F.R. § 450.30(a)(7)]: "The agency's payment must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population."

[4] *Armstrong et al. v. Exceptional Child Center, Inc. et al*., 135 S. Ct. 1378 (2015).

[5] 80 Fed. Reg. 67576, 67577 (Nov. 2, 2015).

[6] 42 C.F.R. § 477.203(b)(1).

[7] 42 C.F.R. § 477.203(b)(5)(ii).

[8] 42 C.F.R. § 477.203(b)(2), (b)(7).

States submitted their first AMRPs in 2016, and CMS reviewed but did not formally approve the plans.[9] There are no federal standards that give structure to the Social Security Act's "equal access" provision; currently, CMS leaves it up to each state to determine whether payment is sufficient to enlist an adequate number of providers to guarantee that Medicaid beneficiaries have access to services that is equal to the general population. Further, AMRPs apply only to fee-for-service Medicaid—they do not address the adequacy of payments made by Medicaid Managed Care Organization (MMCO) plans for beneficiaries they cover. They also exclude from access measurement those populations covered by Medicaid waiver and demonstration programs.[10]

2. Medicaid managed care

Medicaid managed care quickly is becoming the default care delivery and payment system for Medicaid beneficiaries. Currently, about four-fifths of states have contracts with MMCOs, and more than half of all Medicaid beneficiaries are enrolled in an MMCO plan.[11] As of July 2017, 17 states already had more than 85 percent of Medicaid beneficiaries enrolled in an MMCO plan. Another 11 states had between 75 and 85 percent of Medicaid beneficiaries enrolled in an MMCO plan. Collectively, these states include six of the 10 most populous states: California, Florida, New York, Ohio, Pennsylvania, and Texas.[12]

The Medicaid managed care regulatory safeguards regarding payment adequacy and access are even more meager than those in fee-for-service Medicaid. While an MMCO is required to make services accessible to the same extent as such services are made accessible to fee-for-service beneficiaries, the Medicaid managed care regulations scheduled to go into effect on July 1, 2018 regarding access to services do not require payment sufficiency so that services are available to the same extent as they are to the general public.[13] Under the soon-to-be-implemented rules, services furnished pursuant to a Medicaid managed care plan simply must be "available and accessible in a timely manner," the MMCO's care delivery network must be sufficient to "provide adequate access to all services covered under the contract," and the plan must ensure physical access to services, reasonable accommodations, and accessible equipment.[14]

3. Proposed rule

The proposed rule purports to "amend the process for states to document whether Medicaid payments in fee-for-service systems are sufficient to enlist providers to ensure

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[9] Access Monitoring Review Plans, *available at* https://www.medicaid.gov/medicaid/access-to-care/review-plans/index.html.
[10] 80 Fed. Reg. 67582.
[11] Henry J. Kaiser Family Foundation, Medicaid Managed Care Market Tracker, *available at* https://www.kff.org/data-collection/medicaid-managed-care-market-tracker/.
[12] Henry J. Kaiser Family Foundation, Medicaid Managed Care Penetration Rates by Eligibility Group, *available at* https://www.kff.org/medicaid/state-indicator/managed-care-penetration-rates-by-eligibility-group/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.
[13] *See* 42 U.S.C. § 1396b(m)(1)(A)(i); 81 Fed. Reg. 27498 (May 6, 2016).
[14] 42 C.F.R. § 438.206.

beneficiary access to covered care and services consistent with the statute".[15] CMS said that in order to reduce the burden on states of complying with the AMRP requirements:

- A state with 85 percent or more of its Medicaid population enrolled in MMCO plans would be exempt from having to submit and update an AMRP—even for fee-for-service beneficiaries—and the state would be allowed to develop and implement an alternative approach to determining the effect of payments on access. States with less than 85 percent of their Medicaid populations enrolled in MMCO plans would follow the current AMRP process, as set forth in the 2015 rule.

- All states would be exempt from the special access monitoring requirements for payment reductions or restructuring, as set forth at 42 C.F.R. § 447.203(b)(6), when a rate change is less than four percent of overall spending on a "category of services" within a single state fiscal year, or less than six percent over two fiscal years for the "category of services".

- Currently, when a state plan amendment is submitted with a rate change or a change in payment methodology that could affect access, the state has to submit an analysis of its effect. Under the proposed rule, a state would have to provide only an assurance that the rate change or restructuring would not make it fall out of compliance with the payment adequacy requirement, and baseline data to support that assertion. The data would be used to monitor the effect of the rate reduction for three years following implementation – but only if the change remains subject to the requirements of 42 C.F.R. § 447.203(b)(6).

B. Comments on the Proposed Rule

ACLA does not support finalization of the proposed rule because it would weaken an already ineffective system for monitoring Medicaid payment rate adequacy, and it would not address unsustainable cuts to Medicaid reimbursement for laboratory services. In effect, the proposed rule would return payment adequacy monitoring to the pre-2015 era, when there was neither a meaningful "carrot" nor a "stick" to incentivize states to monitor payment adequacy and effects on access to services.

1. Exempting states with high MMCO plan enrollment from AMRP requirements would be a step backwards from the current system.

a) High MMCO plan enrollment state exemption

Despite the shortcomings of the current system for payment adequacy and access monitoring, a widely-applied whole state exemption for states with high MMCO plan enrollment would deprive Medicaid beneficiaries of the benefits of the basic access monitoring structure that was set forth in the 2015 rule. Under the proposed rule, an exempted state "would be permitted to submit alternate information and analysis, as determined by the state, when proposing

[15] 83 Fed. Reg. 12696.

payment rate reductions."[16] The rule includes no other guidance from CMS, and there are no requirements for a data-driven process, the types of services that require payment adequacy monitoring, a public comment period, or documentation. A state's analysis, if it has one, would be completely open-ended. This would be equivalent to what each state was free to do – or not do – before implementation of the 2015 rule: make an empty promise to comply with the "equal access provision." Indeed, CMS said that the reason it proposed the AMRP requirements in 2011 was because states had been left "without clear and consistent guidelines and have subjected them to considerable uncertainty as they move forward in designing service delivery systems and payment methodologies."[17]

As proposed, the rule immediately would exempt at least 17 states from existing AMRP requirements, and it could exempt another dozen states whose MMCO plan enrollment is growing and who are close to the threshold now. Yet even in states with high MMCO plan enrollment, certain classes of Medicaid beneficiaries and certain types of services still are paid for on a fee-for-service basis (*e.g.*, long-term services and supports, behavioral health).[18] In these states, Medicaid beneficiaries would lack even meager protections of the current AMRP standards and process, because the exemption would apply to the entire state—not merely to payments for services furnished to MMCO plan enrollees. Under fee-for-service Medicaid, the state bears the burden of demonstrating that payments are sufficient to support access to services for Medicaid beneficiaries that is equal to that of the general population, but it is not clear under the proposed rule whether or how a state would do so.

b) Exemption from special access monitoring requirements under 42 C.F.R. § 447.203(b)(6)

Under the proposed rule, all states would be exempt from the special access monitoring requirements for payment reductions or restructuring, as set forth at 42 C.F.R. § 447.203(b)(6), when a rate change is less than four percent of overall spending on the "category of services" within a single state fiscal year, or less than six percent over two fiscal years for the "category of services". Nor would states have to consider data collected through the AMRP and undertake a public process that solicits input on the potential impact of such cuts or restructuring.[19] A "category of services" is one that is defined at 42 U.S.C. § 1396d(a)(1)-(29), including "other laboratory and x-ray services."[20]

CMS describes these as "nominal payment rate changes" that are "unlikely to diminish access to care". ACLA vehemently disagrees. Cuts of this size can have a material impact on whether a laboratory can continue to serve Medicaid patients in a state, especially for laboratories that operate on razor-thin margins, like laboratories serving nursing homes. We challenge the agency to support its assertion that cuts of four percent, or successive year cuts totaling six percent, "would be unlikely to have adverse impacts on Medicaid beneficiaries'

[16] 83 Fed. Reg. 12697.
[17] 76 Fed. Reg. 26342, 26343 (May 6, 2011).
[18] Medicaid and CHIP Payment Advisory Commission, March 2017 Report to Congress on Medicaid and Chip, Ch. 4 at 135, *available at* https://www.macpac.gov/publication/monitoring-access-to-care-in-medicaid.
[19] 83 Fed. Reg. 12699; 42 C.F.R. § 447.204(a)-(c).
[20] 42 U.S.C. § 1396d(a)(3).

access to care."[21] A laboratory's costs go far beyond the cost of performing a test, extending to maintenance of electronic interfaces, results reporting, and following up with clinicians. As we discuss below, clinical laboratories already are in the midst of massive cuts to reimbursement for their services, so payment reductions of any size must be viewed in the context of other unsustainable cuts that are being implemented.

If states are not required to adhere to the special provisions for rate reductions or restructuring at 42 C.F.R. § 447.203(b)(6), then Medicaid beneficiaries are left with no real protections under the proposed rule or the 2015 rule against inadequate access because of reduced rates. Their only protection would be toothless pronouncements about "equal access" in the Social Security Act and implementing regulations, which were not effective before 2015 and will not be effective going forward.

2. States would not have to address already-inadequate Medicaid reimbursement for laboratory services.

ACLA is concerned that many states' Medicaid rates already are woefully inadequate as result of reductions in the Medicare Clinical Laboratory Fee Schedule (CLFS) and that access will be threatened because laboratories cannot continue to provide services at such low reimbursement rates. More than one-third of all states peg their Medicaid reimbursement for laboratory services to the Medicare CLFS, rather than developing their own fee schedules. For example, in California, reimbursement rates for clinical laboratory services may not exceed 80 percent of the lowest maximum allowance established by the federal Medicare program for the same or similar services.[22] In Mississippi, payment for laboratory services is made from a statewide uniform fee schedule based on 90 percent of the then-current Medicare fee schedule and is updated each year.[23] Many other states have similar provisions in their statutes, regulations, state Medicaid plans, or guidance.

Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) changed the way that rates on the CLFS are established, for the first time in thirty years.[24] In 2017, laboratories reported the rates paid to them by private payors for tests on the CLFS, along with the associated volume at each rate. Beginning on January 1, 2018, rates on the CLFS reflect the weighted median of private payor rates for each test, as reported by laboratories. As a result of the changes made by PAMA, reimbursement rates for nine of the top 10 Medicare codes by CLFS spending were cut more than 30 percent, and reimbursement rates for 21 of the top 25 were cut more than 20 percent.[25]

States that tie their Medicaid rates to the current CLFS reduced Medicaid reimbursement for laboratory services by virtue of rate reductions under PAMA that were effective January 1, 2018, even if they did not affirmatively reduce or "restructure" their rates. But since the new

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[21] 83 Fed. Reg. 12699.
[22] Cal. Welfare & Inst. Code § 14105.22.
[23] Mississippi Medical Assistance Program State Plan, Attachment 4.19-B, p. 3.
[24] Pub. L. 113-193.
[25] CY 2018 Final Private Payor Rate-Based CLFS Payment Rates, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-Rates.zip.

CLFS rates went into effect in January, a number of states have reduced Medicaid reimbursement for laboratory services even further, beyond the already-deep cuts effectuated by PAMA. For example, Missouri finalized a proposal to reduce reimbursement rates for laboratory services from 100 percent of the current Medicare rate to 80 percent of the current Medicare rate effective January 1, 2018 despite a comment period that closed February 9, 2018.[26] Ohio implemented a five percent across-the-board reduction in payment for laboratory services starting January 1, 2018, which currently is schedule to be in effect for two years. In addition to the temporary five percent cut, Medicaid payment for laboratory services (clinical laboratory, molecular pathology, and anatomic pathology services) in Ohio were reduced further to 75 percent of the applicable Medicare allowed amount.[27] Yet these Medicaid cuts could go virtually unnoticed by the public, since public notice of changes in statewide methods and standards for setting payment rates is not required if the change is being made to conform to Medicare methods or levels of reimbursement.[28] Additionally, based on guidance from CMS to states contained in a Medicaid Director letter, these drastic cuts may not be rate reductions or restructuring under 42 C.F.R. § 447.203(b)(6) that have to be noticed in a state plan amendment, along with demonstration of sufficient access to services:

> In the absence of information to the contrary…CMS has determined that the following circumstances are unlikely to diminish access and, as such, would not invoke the requirements of § 477.203(b)(6):…Reductions that result from changes implemented through the Medicare program, where a state's service payment methodology adheres to the Medicare methodology.[29]

CMS did not discuss laboratory fee schedules specifically its letter, nor did it offer any support for its categorical conclusion that a rate reduction tied to a Medicare payment methodology is "unlikely to diminish access." It remains unclear whether a change in Medicaid laboratory reimbursement rates as a result of reductions to the CLFS would require a state to file a state plan amendment notice. State Medicaid reimbursement cuts for laboratory services that are derivative of CLFS cuts, and other perennial cuts to laboratory rates, may fall outside of existing payment adequacy monitoring structures, and the proposed rule would do nothing to ensure that states are monitoring access for the services.

3. Having inadequate safeguards against deep cuts to reimbursement for laboratory services is short-sighted.

Allowing cuts to Medicaid reimbursement for laboratory services to proceed without a thorough analysis of the impact on beneficiary access is short-sighted. Laboratory testing is a critical, high-value component of disease prevention, diagnosis, and management for Medicaid beneficiaries. Laboratory tests guide more than 70 percent of all medical decisions made by health care providers. Clinical laboratory tests provide objective information on the functioning

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[26] Missouri Department of Social Services, Public Notice Regarding Reduction in Rates for Laboratory Services, *available at* https://dss.mo.gov/mhd/files/public-notice-lab-reimbursement-180111.pdf.
[27] Ohio Admin. Code R. 5160-11-09, Laboratory related services: claim payment.
[28] 42 C.F.R. § 447.205(b)(1).
[29] State Medicaid Director Letter 17-004 (Nov. 16, 2017), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/smd17004.pdf.

of the human body so that patients can be diagnosed, treated, and monitored as precisely and quickly as possible. The information furnished by these tests provides the necessary data for physicians and other health care professionals to make clinically informed decisions. More than seven billion laboratory tests are performed in the United States each year, providing critical data for a relatively small expenditure.

Reduced access to such services is tantamount to a reduced ability to guide the right treatment for the right patient at the right time. For example, it is far less costly when a Medicaid beneficiary with a chronic disease receives regular laboratory tests to monitor disease and receives proper ongoing treatment than when the same beneficiary does not have access to laboratory testing and is hospitalized for expensive interventions. A pregnant woman whose gestational diabetes can be detected through an easily accessible glucose test and who has access to adequate pre-natal services has a far better chance of delivering a healthy-weight baby than a woman whose gestational diabetes goes undetected. Without adequate access to laboratory testing, or a way to redress inadequate access, Medicaid beneficiaries likely will have worse health outcomes and the overall costs to the program will rise.

C. If CMS does finalize the proposed rule, it should be modified.

If CMS does finalize the proposed rule, it should modify the rule and take affirmative steps to ensure that Medicaid payment for laboratory testing and other services is adequate to retain providers and preserve beneficiary access. CMS's role is particularly important in light of the holding in *Armstrong et al. v. Exceptional Child Center, Inc.* that there is no private right of action to enforce the "equal access" provision. In *Armstrong*, the Court said unequivocally that the "sole remedy Congress provided for a state's failure to comply with Medicaid's requirements…is the withholding of Medicaid funds by the Secretary of Health and Human Services." In other words, CMS is obligated to shoulder the burden of enforcing the "equal access" provision on behalf of Medicaid beneficiaries, and only it has the tools at its disposal to do so.

If CMS proceeds with exempting from the AMRP process those states with 85 percent or more of their Medicaid population enrolled in MMCO plans, it should require more of an exempted state than a mere assurance that a rate change or a change in payment methodology will not cause it to fall out of compliance with payment adequacy requirements. Also, CMS needs to give more guidance to states exempted from the AMRP process about what would be considered an acceptable "alternative approach to determining the effect of payments on access".

Given the large number of states that in some way tie their Medicaid reimbursement rates for laboratory services to the rates paid by Medicare, we believe that it is critical that any rate changes be made known to the public and be subject to an open review. CMS has proposed that states making "nominal" rate changes would not be required to consider data collected through an AMRP or undertake a public process soliciting input on the potential rate reduction.[30] ACLA believes that these rate reductions, too, should be subject to state plan amendment notice and public notice and comment.

[30] *Id.*

We are heartened to know that CMS remains "interested in developing and adopting meaningful access measures that could apply consistently, regardless of the service delivery approach used by the state.[31] This would be far preferable to allowing states to develop and implement their own measures, leading to inconsistency in access to services among states, and even within states.

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Thank you for your consideration of ACLA's comments on the proposed rule.

Sincerely,

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Vice President, Legal and Regulatory Affairs
American Clinical Laboratory Association

[31] *Id*. at 12698.