January 4, 2016

By Electronic Submission

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2328-FC
P.O. Box 8016
Baltimore, MD 21244-8016

Medicaid Program; Methods for Assuring Access to Covered Medicaid Services

CMS–2328-FC
RIN 0938–AQ54

Dear Sir or Madam:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to provide comments on HHS' proposed Medicaid regulation on Methods for Assuring Access to Covered Medicaid Services.

NHeLP thanks HHS for providing some guidance to states as it implements its duty under the Medicaid Act to enforce the requirements of the Social Security Act § 1902(a)(30)(A) ("(a)(30)(A)"). The absence of clear guidance has been a long-standing problem. Moreover, the need for standards and monitoring protocol is critical in the aftermath of *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378 (2015).

General Comments and the Need to Clarify the Armstrong Holding

While a regulation's preamble does not establish binding rules, statements in the preamble can carry great weight. We are quite concerned that the preamble includes critical overstatement and misstatement of the *Armstrong* holding. The preamble says that *Armstrong* decided that "the Medicaid statute does not provide a private right of action to providers to enforce state compliance in federal court. As a result, provider and beneficiary legal challenges are not available to supplement CMS review and enforcement to

ensure beneficiary access to covered services." 80 Fed. Reg. 67576, at 67577; *see also*, *e.g*., *id*. at 67579 (stating that the Medicaid statute does not provide a private right of action for providers and beneficiaries to challenge payment rates in federal court).

Those passages do not correctly state the *Armstrong* holding. As such, they could complicate beneficiaries' ability to bring enforcement actions in federal court that complement CMS oversight. (They are also at odds with positions announced by the federal government in court cases—the current Planned Parenthood cases, for example—where the government has expressly acknowledged that beneficiaries have rights to go to federal court to ensure access to covered services.)

Armstrong held that *providers* cannot enforce the *Supremacy Clause* or rely on the *equitable power of the federal court* to enforce the rate provisions of *(a)(30)(A)*. Thus, the quoted passages, above, are overly broad in at least three respects: First, *Armstrong* is about provider claims, contains analysis specific to providers, and never implicates beneficiaries. Second, *Armstrong* concerns only (a)(30)(A) of the Medicaid statute and, while including a test for reviewing equitable enforcement , it does not hold that other Medicaid provisions do not meet this test. Thus, *Armstrong* does not say that all of the Medicaid statute is "judicially unadministrable" (only four justices expressed doubt that providers could enforce the Medicaid Act while noting that Medicaid was enacted to benefit beneficiaries, not providers). Third, the quoted passages broadly state that beneficiaries cannot bring legal challenges to ensure access to covered services. This is incorrect. The federal courts of appeals have repeatedly and consistently recognized that beneficiaries can bring legal challenges when their access to covered services is allegedly being illegally denied by the state.

We strongly urge CMS to correct these statements by issuing a Federal Register notice or revised preamble that expressly withdraws the following sentence: "As a result, provider and beneficiary legal challenges are not available to supplement CMS review and enforcement to ensure beneficiary access to covered services." 80 Fed. Reg. 67578. The following sentence on the same page also needs to be revised to reflect *Armstrong's* actual holding, as follows: "In addition, because the proposed rule was issued several years prior to the *Armstrong* decision and therefore does not address CMS' or states' role in light of *Armstrong's* limits on providers' ~~and beneficiaries'~~ ability to take legal action regarding ***the equal*** access ***requirement of (30)(A).***" References on pages 67579 and 67581 also need to be corrected so as to accurately state the *Armstrong* holding.

That said, we agree with HHS that the lack of a private right of action for *providers* "underscores the need for stronger non-judicial processes to ensure access, including stronger processes at both the state and federal levels for developing data on beneficiary access and reviewing the effect on beneficiary access of changes to payment methodologies." We also support numerous features of the new regulation which we urge HHS to retain and develop further, including the general requirement for states to have Access Monitoring Review Plans, the requirement to trigger access reviews based on rate reductions, restructuring, and complaints received, and the application of the (a)(30)(A) requirement to rate policies implemented by state legislatures.

Section (a)(30)(A) Should Apply to Managed Care (and Waiver Programs)

The preamble to the regulation says the (a)(30)(A) requirements are not applicable to Medicaid managed care. There is simply no legal basis for this statement and it is inconsistent with the agency's previously stated policy.

The § 1902(a)(30)(A) requirement is a broad Medicaid state plan requirement – like many others in § 1902(a). When Congress *intends* to exempt Medicaid managed care from foundational § 1902(a) requirements, Congress does so explicitly. For example, in § 1932(a)(1)(A), the statute explicitly authorizes state plans to include managed care "notwithstanding paragraph… (23)(A) of section 1902(a)" (the freedom of choice provision). No exemption like the explicit one for (a)(23)(A) exists anywhere in the statute for (a)(30)(A), and HHS has no authority to create such an exemption on behalf of Congress.

HHS may consider that the actuarial soundness requirement in § 1903(m)(2)(A)(iii) obviates the need for (a)(30)(A) in managed care. As a matter of law, we disagree. The mere addition of an actuarial soundness provision does not automatically invalidate a separate and very different rate provision. The basic principles of statutory construction hold that when two statutory provisions *might* be in conflict or redundant, they should be read in a way that renders both valid and operable if possible. In this case, it is clear that both requirements can apply with equal force, and neither needs to invalidate the other. We note that, in fact, both provisions are very different – (a)(30)(A) assuring fair rates to providers and § 1903(m)(2)(A)(iii) ensuring the financial viability of managed care organizations – and thus it is perfectly coherent to understand them working in tandem. In short, they are legally and factually independent criteria, and the only coherent way to apply the law is to comply with both criteria.

Other provisions of the Medicaid Act support this application of the traditional rules of statutory construction. For example. § 1903(m)(1)(A)(i) requires managed care organizations to make the services they provide accessible to Medicaid beneficiaries "to the same extent as such services are made accessible" to beneficiaries not enrolled. This provision clearly works alongside the (a)(30)(A) requirement that services be available to Medicaid beneficiaries at least to the extent such services are available to the general population. Indeed, (a)(30)(A) helps for the starting point for the § 1903(m) assessment. In short, the managed care provision cannot be enforced *(i.e*., it will be largely ignored) if the (a)(30)(A) provision is not also enforced.

The practical consequences of HHS' unlawful interpretation are enormous. About 70% of the Medicaid program operates in some form of managed care. This means that an overwhelming majority of Medicaid enrollees would not have one of the basic Medicaid protections guaranteed by § 1902(a). And with Medicaid managed care market share growing, HHS has essentially interpreted (a)(30)(A) into oblivion.

The optimal approach to assuring access in Medicaid managed care is a multi-faceted one which relies on actuarial soundness standards, network adequacy and access standards, *and* (a)(30)(A) compliance. Any one of these standards on its own is insufficient. For example, a plan with an "adequate network" that pays very low rates might result in network providers who resist seeing patients or providing treatments due

to the low rates. Under the Medicaid Act, HHS should use all three standards in combination to understand and guarantee access in managed care, and should use both of the latter two in fee-for-service.

The multi-pronged approach also makes sense because it helps achieve *alignment*, a very rational objective identified by HHS itself in the related RFI. We are baffled by the fact that in releasing the related RFI, HHS acknowledges the value of developing a universal and aligned standard for access, while, at the same time, avoiding an aligned standard for (a)(30)(A). We agree with HHS that there is value in alignment, but that alignment should apply to access standards *and* (a)(30)(A). That lack of alignment in the regulation is all the more confusing since fee-for-service Medicaid rates already form the backbone for many Medicaid managed care rate-setting processes and outcomes. As recently stated in the *Journal of Health Economics*:

> Medicaid free-for-service reimbursements remain a good proxy for Medicaid reimbursement generosity, since "fee-for-service physician reimbursement rates can affect what Medicaid managed care plans pay physicians, because these plans often receive monthly capitation payment based on what states would have paid for care on a fee-for-service basis."

Sonchak, *Medicaid reimbursement, prenatal care and infant health*, 44 J. OF HEALTH ECON. 10 (2015) (quoting Zuckerman and Goin (2012)). The fee-for-service rate is also highly relevant because, while the managed care plan may itself be paid on a capitation basis, the plan's network of providers may be paid on a fee-for-service basis.

In addition, the proposed Medicaid managed care regulations require plans to report encounter data. These encounter data will allow us to know whether beneficiaries' are actually getting the care they need and that is required by law (*e.g*., children's preventive care under EPSDT). Once states begin collecting encounter data, the federal government, states and stakeholders will need to be able to pair it with payment rates to better understand why beneficiaries are getting the care they are getting. As recently stated, "Without access to payment data, however, it is not possible to determine how increases or decreases in Medicaid managed care plans' reimbursement policies affect the quality and accessibility of care." Rocco, Modernizing Medicaid Managed Care Can States Meet the Data Challenges", 314 JAMA 1559 (Oct. 20, 2015). Thus, enforcement of (a)(30)(A) in managed care settings is critical as a practical matter.

We also disagree with how the proposed regulation applies (a)(30)(A) to demonstration and home and community-based (HCBS) waivers programs. While HHS' intent is not entirely clear to us, it appears that HHS is proposing to distinguish between "state plan services" and "demonstration and waiver" services. HHS is proposing that the (a)(30)(A) regulations apply to the former and not the latter. We do not believe this policy is legal or practical.

First, (a)(30)(A) applies with equal force to demonstration and waiver programs. Any authority to waive *specific* Medicaid standards in § 1902 does not permit HHS to *generally* not apply requirements in § 1902, including the requirements of (a)(30)(A). For example, in a § 1115 demonstration program, the State must provide the agency with application and support for why a provision of § 1902 needs to be waived to accomplish

the proposed experiment and only § 1902 provisions *specifically* waived by HHS are non-applicable. Likewise, § 1915(c)(3) sets forth the specific provisions in § 1902 that can be waived by HHS (such as §§ 1902(a)(1) and 1902(a)(10)(B)), meaning the rest of § 1902 continues to apply. Section (a)(30)(A) is not included in that list, so HHS must apply (a)(30)(A) to programs under these demonstration and waiver provisions.

Second, nothing in (a)(30)(A) restricts application of (a)(30)(A) to a narrow set of "state plan services" defined to exclude special services provided through demonstrations or waivers. The plain language of (a)(30)(A) applies to "care and services available under the plan." HHS' interpretation that this excludes waiver and demonstration services is impermissibly narrow and stands in contrast to the interpretation of other provisions of § 1902 that apply to services "under the plan" and yet *are* interpreted to apply to all demonstration and waiver services. For example, both §§ 1902(a)(19) and 1902(a)(25) apply to services "under the plan" and yet these provisions should be and are in force with respect to demonstration and waiver program services. This is the correct interpretation as there is no legal basis for the distinction HHS makes in the proposed regulation. The HHS interpretation also ignores the words of the Medicaid Act stating that HCB waiver services *are* state plan services. *See* § 1915(c) (allowing Secretary to waive designated § 1902 provisions and "include [HCB waiver services] as 'medical assistance' under such [state] plan"). Moreover, the HHS preamble statement is inconsistent with its duly promulgated regulations, 42 C.F.R. § 430.25(d)(2), which list waivable provisions under § 1915(c) and do not include (a)(30)(A)); *see also ARC of California v. Douglas*, 757 F.3d 975, 987 (9th Cir. 2014) (noting that (a)(30)(A) is not among the waivable Medicaid provisions for an HCB waiver and rejecting argument that waiver approval equated to a conclusion that (a)(30)(A) had been met).

Practically, we believe that HHS' distinction makes little sense and represents bad policy. Although HHS references other HCBS regulations in the preamble, those regulations do *not* directly address access as does (a)(30)(A). We recognize that developing access standards for HCBS is daunting. However, the distinction makes little sense because even if HHS excluded demonstration and waiver programs from (a)(30)(A), HHS would *still* be required to develop metrics to measure the wide range of HCBS services that *can* be provided through the state plan (e.g., §§ 1905(a)(7), (a)(8), (a)(13)(C), (a)(15), (a)(22), (a)(23), etc.). Therefore, exclusion of waiver programs will not change the facts that HHS will have to develop metrics and states will have to use those metrics. The exclusion will only result in an inconsistent application of a required Medicaid standard based on what program an individual qualifies for services through. This in turn will reduce HHS' ability to compare performance and relative access across programs.

We note that it is unclear from the proposed regulation whether HHS is proposing to apply (a)(30)(A) to state plan HCBS, such as §§ 1915(i) and (k). A policy excluding these state plan options from (a)(30)(A) enforcement would stand in even greater contrast to the statutory structure and would contradict the fundamental trajectory of authority around HCBS services, which is evolving from an experimental option driven through waivers to (due to the success of HCBS waivers) permanent state plan authorities.

Exclusion of HCBS services is also a bad policy for two other practical reasons. First, access standards for HCBS are widely known to be underdeveloped. Therefore, it is all the more important for HHS to err on the side of multi-faceted review when it comes to monitoring HCBS. Second, whereas most non-HCBS services draw from a wide range of payers, therefore allowing "cost-shifting" when Medicaid payment rates are low, HCBS services are disproportionately financed through Medicaid, meaning providers have significantly smaller margins to absorb low payment rates, and thereby making adequate rates all the more important.

Finally, the exclusion of managed care and waiver programs from compliance with (a)(30)(A) would depart from HHS's previous consistently applied policy and—with no rationale given for such a dramatic departure—would represent questionable agency action under the Administrative Procedure Act. For example, in 1995, HHS informed the State of Tennessee that it explicitly refused to waiver (a)(30)(A) as part of the TennCare 1115 managed care waiver and that the State could not assume that (30)(A) was waived. *See* Letter from George Schieber, HHS Office of Research and Demonstrations, to H. Russell White, Tenn. Department of Health (Apr. 25, 1994). More recently, CMS approved the State of California's Bridge to Health Care Reform Waiver to incorporate Community Based Adult Services program, which includes a capitation payment component. That approval specifically assessed the waiver proposal against the requirements of (a)(30)(A). Letter from Cindy Mann, CMS, to Toby Douglas, California DHCS (Mar. 30, 2012).

Develop a Transparent Section (a)(30)(A) Standard

While we are supportive of the data HHS proposes to require states collect and many of the processes that HHS establishes in the regulation, we believe the regulation will not achieve its purpose – for consumers, providers, states, and HHS alike – until HHS develops a clear standard to evaluate the data and determine whether access is sufficient. The current methodology requires states to collect data and consult with stakeholders, but lacks objective criteria for interpreting the information collected. Without a yardstick, access decisions will ultimately amount to the opinion of state Medicaid agency staff, subject to a review by the opinions of HHS staff. Such a process would lead to uncertainty, the same predictable conflicts, and serves no stakeholder well. (We appreciate that HHS has issued an RFI to identify access standards which may play the role of a yardstick. We urge HHS to identify and apply such objective standards.)

The ideal approach would be a strong objective standard that ensures access. For example, HHS could develop a threshold-based requirement for rates to be at least 95% of a Medicare/commercial rate, and above actual costs, combined with broad network adequacy and/or access criteria (such as provider/patient ratios, wait times, metrics identified in the RFI, etc.). We believe that HHS should set this as the long-term goal to achieve the intent of (a)(30)(A). We are well aware that Medicare/commercial payment rates would not be a perfect match for Medicaid, which includes some services that are distinct, such as HCBS. However, Medicare/commercial standards would be an effective reference point for many Medicaid services, and HHS could develop other methods for reference prices for the gap services. Ultimately, clear standards for evaluating (a)(30)(A) compliance would reduce conflicts and promote access.

We understand that such a standard would not be feasible in the short-term, as many states might face a steep cost curve to come into compliance. In the short-term we believe that HHS such develop and implement such criteria as a presumption of compliance. In other words, states in compliance with the standards would be presumed to be in compliance with (a)(30)(A) and face a less burdensome process to demonstrate equal access. Meanwhile, states out of compliance with the presumption standards would have to follow a more thorough process of data collection and related reporting. Such an approach would reward high performing states and create an incentive for all states to become high performers. It would also create national standards allowing states and state innovations to be compared, including an objective assessment of which states are the farthest from meeting the presumption standards.

Other Concerns

We also have several additional concerns that we urge HHS to consider.

- Retroactive Approval. In the regulation, HHS reaffirms its policy allowing states to implement rate changes *prior* to the approval of the State Plan Amendment (SPA) requesting the change. We believe this policy is not legal and misinterprets the regulations. The law is clear, as determined by the United States Court of Appeals for the Ninth Circuit, that SPAs, including those proposing rate-setting adjustments, cannot be implemented until approved by CMS. *See Exeter Memorial Hosp. Ass'n v. Belshe*, 145 F.3d 1106 (9th Cir. 1998). While it is true that 42 C.F.R. § 447.256(c) currently permits implementation retroactive to the beginning of the quarter during which the SPA is submitted, that implementation is *retroactive* precisely because it is done *after* the approval. In other words, a payment rate change requested on February 15, and subsequently approved on April 15, could, *starting April 15*, be used to adjust payments retroactive to January 1. It does not follow, however, that the same state could, on February 15, begin adjusting payments prior to the eventual April 15 approval. Finally, we note that if HHS allows states to implement requests prior to their review, any delays in approving SPAs may result in noncompliant rates and reduced access for long periods of time, leading to significant harms for consumers. We recommend that HHS bring the retroactive approval policy into compliance with the law by only allowing retroactive implementation *after* approval.
- Granularity. HHS has stated in the regulation preamble that HHS "generally [does] not approve individual service rates unless a state presents a final rate, or a fee schedule." We recommend that HHS revisit this and not review rates in large aggregations. Such an approach may mask important trends that would otherwise be visible in the data (*i.e*., the average payment for a group of services may be acceptable, but some subset within that group may be far below normal), such as incentives for providers to avoid patients associated with low reimbursement treatments, based on their specific health conditions or expected treatment needs. Aggregation also presents complications for subspecialized areas (*e.g.*, pediatric dental) or areas that are often carved out (*e.g.*, behavioral health/substance abuse).

- Original HHS Analysis. We agree that states have an important role to play in gathering and evaluating data in the (a)(30)(A) compliance process. However, we do not believe that HHS can exclusively rely on state data and analysis in assessing (a)(30)(A) compliance. For example, a number of recent national reports have not included California in the results, after concluding that the Medi-Cal data is not accurate. We urge HHS to develop and clarify its data gathering, stakeholder feedback, and analytic responsibilities in the (a)(30)(A) compliance process and to ensure that states are accurately collecting data according to these conventions .
- 12-month Remediation. While we understand that remedying illegalities cannot be achieved overnight, we recommend that HHS shorten the 1-year remediation timeframe to at most 6 months. One year is a long time to risk consumers having inadequate access to care (or to expect providers to endure losses). We also suggest that HHS require, as part of the plan, outreach to consumers to meet their care needs during the 6-month remediation window.

Specific Comments

§ 447.203(b)(5) – Access Monitoring Review Timeframe

We are broadly supportive of HHS' proposal to require states to develop access monitoring review plans as well as the specific timelines established for reports in § 447.203(b)(5)(i).

We understand that HHS intended to strike a balance in § 447.203(b)(5)(ii)(A) to (E), by reducing the breadth of service areas subject to reporting but increasing the frequency of reports. We fully support the increase in frequency of reporting to at least every three years, as we believe a frequency of five years is too long and would allow for Medicaid rates to fall significantly behind the market. We urge HHS to preserve the three year review policy.

We do not support the limitation of regular reporting to the five service areas identified in the regulation. There is no clear reason to exempt other services, and we ask HHS to include all covered services in the reporting requirement. In the alternative, HHS could require review in the five identified service areas at least every three years (as per the proposed regulation), and require review in all other service areas at least every five years (as per the 2011 proposed regulation). It is important that *all* services be reviewed periodically because otherwise the only system to identify deficient rates is the complaint-driven process established in §§ 447.203(b)(5)(G) and (b)(7). While these provisions are *necessary* components of HHS' regulatory approach, they are not *sufficient* to enforce (a)(30)(A) for services outside the five regulatory service review areas. We note that due to inflation it is simply unavoidable that all payment rates will eventually become inadequate unless adjusted upwards. Therefore, the lack of a regular review process for all services guarantees that some service payment rates will violate (a)(30)(A), and they will do so in perpetuity or, at best, perhaps for years or decades until enough complaints pile up to trigger a review.

Additionally, we recommend that HHS should:

- Add Early and Periodic Screening (medical, vision, hearing, and dental) to the list of service for regular review;
- Add transportation to the list of service for regular review; and
- Develop standards for evaluation of payment rates with respect to subspecialists and subpopulations. For example, while payment rates might be enough to generally retain providers in general a given service area, they might not be enough to retain pediatric specialists or disability accessible providers.

We support HHS' proposal at § 447.203(b)(5)(ii)(F) to require states to submit an "access review" with every proposal to reduce or restructure rates. This is a critical component of the regulation, since many past conflicts have stemmed from state efforts to address budget shortfalls through provider rate reductions. Specific to this provision, we recommend that HHS:

- Develop a strong standard for reductions or restructuring that "could result in diminished access." If diminished access is interpreted too narrowly, the exception could eviscerate the rule, or piecemeal changes could be combined for larger impacts. For example, a state could implement a 1% rate cut every year over a 10-year period, thereby never making a cut that in and of itself signals "diminished access," yet the aggregate reduction of 10% after 10 years clearly might impact access. We also note that in areas outside of the five regular monitoring areas listed in § 447.203(b)(5)(ii), the rates may *already* be inadequate prior to reduction or restructuring, meaning HHS should err on the side of reviewing changes.
- Develop more prescriptive standards for monitoring impacts of approved reductions or restructuring. While we support the requirement for public review and annual monitoring for three years, we believe that HHS should do more than require the state to "establish procedures" to monitor access impacts.

We strongly support HHS' proposal at § 447.203(b)(5)(ii)(G) to require a process for states to review rates for services when there are complaints. However, we think that the phrase "significantly higher than usual volume of beneficiary, provider or other stakeholder access complaints" is vague and will take on vastly different meaning from state to state. For example, if in 2015 the level of complaints about the lack of in-home services in Illinois is quite high, what does it take for the level to become significantly higher than usual? While we agree that this measure is a critical component of HHS' system to enforce (a)(30)(A), we ask that it be amended and retained to require the review process to apply when "the state or CMS has received a significant volume of beneficiary, provider or other stakeholder access complaints." Review of services based on complaints is also essential because this is one of the few parts of the regulation that will trigger review by outsiders and not the states themselves (which, as noted above, are documented to have inadequate data collection capabilities).

We recommend that HHS be more prescriptive about minimum standards for a consumer complaint process. This should include at a minimum:

- Establishment of a specific contact point for access-related complaints for consumers and rate-related complaints by providers (and notice of this contact point provided in Medicaid materials);
- Reports from state hotlines;

- A process to collect access concerns from the state Medicaid Care Advisory Committee;
- A process to compile and review complaints/grievances filed by beneficiaries in the state's Medicaid program; and
- Reports from managed care plan member services (assuming HHS heeds our recommendation to apply this regulation to managed care).

HHS has also requested comment on whether to allow exemptions based on state program characteristics, such as high managed care enrollment. We do not believe HHS should implement exemptions from (a)(30)(A) requirements. We believe cost-benefit analysis clearly favors retaining the requirements with few or no exemptions.

Conclusion

Thank you for consideration of these comments. If you have any questions or need any further information, please feel free to contact me (perkins@healthlaw.org) or Leonardo Cuello (cuello@healthlaw.org) at the National Health Law Program.

Sincerely,

Jane Perkins
Legal Director