June 24, 2022

VIA ELECTRONIC SUBMISSION

The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Healthy Louisiana OUD/SUD Section 1115 Demonstration, Extension Request

Dear Secretary Becerra:

The National Health Law Program (NHeLP) protects and advances health rights of low-income and underserved individuals and families. We advocate, educate, and litigate at the federal and state levels to advance health and civil rights in the U.S. We appreciate the opportunity to comment on Louisiana's requested extension to its section 1115 demonstration, "Healthy Louisiana Substance Use Disorder 1115 Demonstration." For the reasons below, we ask HHS to reject Louisiana's request for waiver-based SUD services.

I. HHS Authority Under Section 1115

For the Secretary to approve a project pursuant to section 1115, the project must:

- be an "experimental, pilot or demonstration" project;
- be likely to promote the objectives of the Medicaid Act;

- waive compliance only with requirements in 42 U.S.C. § 1396a; and
- be approved only "to the extent and for the period necessary" to carry out the experiment.

Discussing each of these limitations a bit further:

First, the state must propose to conduct an "experimental, pilot, or demonstration" project. This demands a "novel approach" to program administration.[1] To evaluate whether a proposed project is a valid experiment, the Secretary needs to know what will be tested and how, at the point in time when the project is being approved.

Second, the project must promote the Medicaid Act's objectives. Congress has made clear that the purpose of Medicaid is to enable states "to furnish[] medical assistance" to individuals "whose income and resources are insufficient to meet the costs of necessary medical services" and to provide "rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care."[2] Thus, the "central objective" of the Medicaid Act is "to provide medical assistance."[3]

Third, the Secretary can only waive provisions set forth in section 1396a of the Medicaid Act. The Secretary cannot waive requirements contained in sections 1396b-1396w-5.[4]

Once the Secretary has acted under section 1115(a)(1) to waive compliance with designated provisions in section 1396a, section 1115(a)(2) provides that the costs of "such project" are "regarded as expenditures under the State plan" and, thus, paid for under the same statutory formula that applies for a state's expenditures under its State plan.[5] Section 1115(a)(2) does

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[1] *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).
[2] 42 U.S.C. § 1396-1; 1396d(a) (defining "medical assistance" as provision of, or payment for, specified health care and services).
[3] *Stewart v. Azar*, 366 F. Supp. 3d 125, 138 (D.D.C. 2019); *id.* at 144 (rejecting "promoting health" as an independent objective because the Medicaid Act is "designed … to address not health generally but the provision of care to needy populations" through a health insurance program).
[4] *See* Social Security Act, § 1115(a)(1).
[5] *Id.* § 1115(a)(2).

not create an independent "expenditure authority" for the Secretary to allow a state to ignore provisions of the Medicaid Act outside of section 1396a or to rewrite the provisions in section 1396a or any other provision outside of section 1396a. To the contrary, it is a "clean-up" provision that merely provides the authorization necessary for federal reimbursement of expenditures for a project that has been approved under section 1115(a)(1).

Fourth, section 1115 allows approvals only "to the extent and for the period . . . necessary" to carry out the experiment.[6] Congress did not enact section 1115 to permit the Secretary to make long-term policy changes.

II. SUD-Specific IMD Exclusion 1115 Waiver Request

While NHeLP supports efforts to improve access to treatment for Medicaid beneficiaries with substance use disorders (SUD), we oppose the continuous reliance on section 1115 waivers to funnel federal dollars to institutional care, including IMDs. First, we question whether Louisiana's proposal meets the experimental requirement of section 1115. A section 1115 demonstration request must propose a genuine experiment of some kind. While these SUD-specific IMD exclusion waivers (now in place in over thirty states) may have represented a novel approach to addressing SUDs when they were first approved, we see no reason why they should continue to be considered experimental after all these years. Moreover, Louisiana has not presented a valid hypothesis that would justify approval of the waiver for the purpose of testing such hypothesis, other than a general assumption that the waiver will improve access to SUD care.

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[6] *Id.* § 1115(a); *see also id.* §§ 1115(e)(2), (f)(6) (limiting the extension of "state-wide, comprehensive demonstration projects" to one initial extension of up to 3 years (5 years, for a waiver involving Medicare-Medicaid eligible individuals) and one subsequent extension not to exceed to 3 years (5 years, for Medicare-Medicaid waivers). In 2017, a CMS Informational Bulletin announced the intent "[w]here possible, . . . [to] approve the extension of *routine, successful, non-complex*" section 1115(a) waivers for a period up to 10 years. Ctr. for Medicaid & CHIP Servs., CMS, CMCS Informational Bulletin 3 (Nov. 6, 2017) (emphasis added). The Bulletin should be disregarded because it conflicts with, among other things, section 1115's limitation of approvals to experimental, pilot, or demonstration projects (not for "routine" projects) and only for the period necessary to carry out the experiment (not to maintain a successful experiment as an ongoing policy).

Section 1115 is not intended to provide opportunities to states to waive Medicaid requirements in perpetuity and, in so doing, bypass congressional intent and/or approval. Rather, Congress envisioned section 1115 waivers as a tool for states to test novel approaches to health coverage that would then presumably inform congressional action. After seven years of SUD-specific IMD exclusion waivers, Congress could have amended the Medicaid statute to permanently allow states to use federal dollars for SUD treatment in IMDs. In fact, Congress has spoken on this very question as it has specifically enacted a more limited Medicaid state plan option to treat SUD conditions in IMDs that is set to expire in 2023.[7] Failure to extend this state plan option or otherwise amend the IMD exclusion provision indicates that Congress intends the IMD exclusion to remain the law of the land.

In addition to considerations regarding the requirement that a state present an actual experiment or demonstration, the IMD exclusion is not waivable under section 1115. By its terms, section 1115 authorizes the Secretary to waive only those Medicaid requirements contained in 42 U.S.C. § 1396a. And, as explained above, section 1115 does not give the Secretary an independent "expenditure authority" to allow a state to ignore requirements outside of § 1396a. Because the IMD exclusion is found outside of § 1396a (in § 1396d(a)(31)(B)), the Secretary does not have the authority to allow states to receive federal Medicaid funding for services provided in IMDs.

There are also several policy reasons why we oppose waiving the IMD exclusion for SUD services. First, because of the risks that institutionalization presents, residential treatment in IMDs should be used only for patients with more serious SUDs, and only on a short-term basis. Community-based services are more effective, less restrictive and less coercive alternatives for SUD treatment.[8] Regardless of where individuals start their treatment—in the community or in a facility—there must be sufficient resources in the community to support individuals upon discharge and ensure continuity of care. Thus, it is important that states continue to invest and build their community-based systems. Unfortunately, the way current IMD exclusion waivers are designed provides no guarantee or commitment that states will continue investing in and reinforcing availability of community-based services. This reality contrasts with the state plan option that Congress authorized, which contains an explicit

[7] 42 U.S.C. § 1396n(l).
[8] Sarah E. Wakeman et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorders*, 3 JAMA Network 2 (2020).

maintenance of effort requirement to ensure resources are not diverted from community-based services.

On top of that, Louisiana's request makes no reference whatsoever to either maximum or average length-of-stay, which is in line with CMS' recent refusal to establish a maximum length-of-stay in IMDs when approving these waivers. Lack of a maximum length-of-stay risks longer average stays in the institution even for beneficiaries who do not need that level of care for such an extended period of time. While the early IMD exclusion waivers incorporated requirements regarding assessments of a statewide maximum average length-of-stay of 30 days, this language has been omitted from more recent CMS guidelines and approvals. Notably, in the state plan option to treat SUDs in IMDs, Congress imposed a maximum average length-of-stay of 30 days. Similarly, CMS has included maximum lengths-of-stay of 30 days in its approval of IMD exclusion waivers for mental health services. There is no reason why that limit should not apply to SUD services.

In addition, while we commend CMS for implementing a requirement that IMDs connect individuals to medication-assisted treatment (MAT), we caution that IMD patients are less likely to receive MAT, the gold standard of care, than patients in the community and approval of IMD exclusion waivers for SUD has not changed this reality.[9] Until CMS properly enforces this requirement, the treatment Medicaid beneficiaries receive in these institutions remains questionable at best and harmful at worst. Importantly, the requirement should not be limited to the availability of MAT or referral to MAT, but should ensure increased MAT intake among IMD residents with SUD. No evidence to date demonstrates that IMD waivers specific to SUD have resulted in increased MAT availability in these institutions, much less MAT initiation, which should be the key measurement of effectiveness.

Although Louisiana's evaluation of the original waiver shows increased intake and initiation of MAT during the initial waiver period, it is unclear from the evaluation whether this increase is due to the use of IMDs. We caution that such results should not be interpreted as proof that unlimited use of IMDs for SUD treatment automatically leads to higher MAT intake, as it is

[9] Tamara Beetham et al., Therapies Offered at Residential Addiction Treatment Programs in the United States, 324 JAMA 804 (2020), https://jamanetwork.com/journals/jama/article-abstract/2769709; Johanna Catherine Maclean et al., Institutions for Mental Diseases Medicaid Waivers: Impact on Payments for Substance Use Treatment Facilities, 40 HEALTH AFF. 326 (2021), https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00404.

likely that increased MAT is incidental to the use of IMDs. We caution CMS and Louisiana not to confound higher MAT intake and IMD use and ask that, at a minimum, the State evaluate whether in fact there is a correlation between higher MAT intake and IMD use before using the data to justify extension of the IMD exclusion waiver. We reiterate that Louisiana must clearly lay out an experiment and provide evidence that the current demonstration has been effective and should be extended. Absent those determinations, CMS has no option other than to reject the request.

Finally, we are concerned that Louisiana's proposal does not address the specific applicability of this request to children and adolescents under age 21. IMD waivers are an improper avenue to provide residential behavioral health services to children and adolescents. As CMS has explained, Congress created a state Medicaid plan option to provide inpatient behavioral health care, including SUD, under the inpatient psychiatric services for beneficiaries under 21 benefit. As part of this benefit, states have the option of providing limited residential SUD services to minors in Psychiatric Residential Treatment Facilities (PRTFs). By seeking approval of a section 1115 IMD waiver that extends to beneficiaries under 21, Louisiana is effectively seeking to circumvent the avenue that Congress established for these service settings. As long recognized by CMS, children and adolescents are not small adults.[10]

III. Original Waiver Goals

We are deeply concerned with the fact that Louisiana's renewal application acknowledges the lack of positive outcomes as a result of the first five years of the demonstration. For all of the goals of the original demonstration, except availability of MAT, Louisiana states that either no data is available or that evidence demonstrates mixed results pointing towards the demonstration having no significant impact. For example, one of the goals of the original waiver was to "ensure sufficient provider capacity at each level of care for OUD/SUD." In the current application, however, the State explicitly acknowledges that the rate of increase in provider availability has slowed since the approval of the demonstration, concluding that "the demonstration is not yet having a positive impact on provider capacity."

[10] CMS, EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents (2014), https://www.medicaid.gov/sites/default/files/2019-12/epsdt_coverage_guide.pdf.

As discussed before, section 1115 demonstrations are not intended to be long-term projects to implement specific policy changes without an experiment. Even assuming Louisiana's initial project was a valid experiment, which as described above, it was not, the evidence provided by the State shows that the test has failed. As the provider availability example shows, most of the hypotheses laid out in Louisiana's original application have not been proven and there is no reason for HHS to believe, nor has Louisiana made a compelling argument, that the project will have different results during the renewal period. Moreover, in its renewal application, Louisiana has not argued for more time to evaluate the results of the original experiment, and it would be improper for CMS to ascribe a purpose to the new demonstration that Louisiana has not put forward.

As the original SUD-IMD waivers wrap up and states begin submitting applications for renewal, CMS must be careful not to renew projects that do not propose a clear, reasonable experiment that is likely to promote the objectives of Medicaid.

IV. Conclusion

For the above legal and policy reasons, we ask the Secretary to reject Louisiana's request to waive the IMD exclusion for SUD services. We appreciate your consideration of our comments. If you have questions about these comments, please contact Héctor Hernández-Delgado (hernandez-delgado@healthlaw.org).

Sincerely,

Héctor Hernández-Delgado
Staff Attorney