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July 10, 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: West Virginia Creating a Continuum of Care for
Medicaid Enrollees with Substance Use Disorders (SUD)
Section 1115 Demonstration, Extension Request**

Dear Secretary Becerra:

The National Health Law Program (NHeLP) protects and advances the 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 West Virginia's requested extension to its section 1115 demonstration, "Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders (SUD)." For the reasons below, we ask HHS to reject West Virginia's request to continue waiving the IMD exclusion for individuals with SUD and its request to start waiving the Institution for Mental Disease (IMD) exclusion for individuals with serious mental illness (SMI).

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

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).



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 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 Waiver Request

West Virginia requests a renewal of its current waiver that allows the State to receive federal financial participation (FFP) for services provided to individuals with SUD who are residents of an IMD. While NHeLP supports efforts to improve access to treatment for Medicaid beneficiaries with SUD, we oppose the continuous reliance on Section 1115 waivers to funnel federal dollars to institutional care, including IMDs. First, we question whether West Virginia’s renewal 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

⁵ *Id.* § 1115(a)(2).

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).



they should continue to be considered experimental after all these years. Moreover, West Virginia 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.

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.

As the initial wave of SUD-specific IMD waivers approach expiration and states begin seeking renewals, CMS must scrutinize current these waivers and their corresponding hypotheses to ensure that states have incorporated available evaluation data into their request. It is encouraging to see that some of the evaluation data provided by West Virginia show improvements in certain areas regarding access to SUD services. However, we believe more information is needed to establish direct causation between the specific waiver activities and the improvements. The State acknowledges that there are different efforts underway to improve access to SUD services. For that reason, we are skeptical that the State can categorically say that the IMD exclusion waiver for SUD has been responsible for improvements in provider availability, members receiving SUD treatment, members receiving MAT, etc. West Virginia should provide information about how the State plans to test the specific effects of the IMD exclusion waiver on access to SUD treatment.

Moreover, even if causation was established, CMS does not have authority to approve a renewal request where the State has not put forward a specific hypothesis. If a State believes that a certain activity has been effective, the State should push for adoption of that policy through congressional action, instead of requesting continuous approval of Section 1115

⁷ 42 USC 1396n(l).



waivers. 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.

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) and 1396d(i)), approving such waivers exceeds the Secretary’s authority under Section 1115.

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

We are particularly troubled by CMS’ refusal to establish a maximum length-of-stay of 30 days in IMDs. 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. The lack of a maximum length

⁸ Sarah E. Wakeman et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorders*, 3 JAMA Network 2 (2020).



of stay is also specific to SUD 1115 waivers since the new temporary state option to provide SUD services for IMD residents is limited to 30 days in a calendar year.

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 communities and approval of IMD exclusion waivers for SUD has not changed this reality.⁹ 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 and initiation in these institutions.

Outside of the use of Section 1115 to waive the IMD exclusion, West Virginia requests Section 1115 authority to provide various new services for Medicaid beneficiaries with SUD. We are concerned with the use of a waiver to provide services that could either be covered through a state plan amendment or services that the Secretary has no authority to approve under Section 1115. In particular, West Virginia seeks to expand the existing demonstration to include peer support services through expenditure authority. We see no reason why peer support services would be covered under a waiver rather than a state plan amendment as those services have traditionally been covered, particularly absent a clear and reasonable experiment that would justify the use of a Section 1115 waiver.

III. SMI IMD Waiver Request

In addition to an SUD-specific IMD waiver, West Virginia requests new authority to receive FFP for residential and inpatient treatment services for individuals with SMI in IMDs. For the same reasons we object to West Virginia's request with regards to SUD, we oppose the State's request for an extension of this authority to SMI. First, as mentioned in the previous section

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>.



on SUD, because the IMD exclusion lies outside of 42 U.S.C. § 1396a, it cannot be waived. Second, West Virginia has not explained how obtaining FFP for services provided to beneficiaries with SMI at IMDs constitutes a valid experiment under the Medicaid Act. And finally, the waiver runs the serious risk of diverting funds from community-based mental health services and supports into institutional services, undermining community integration and the Olmstead mandate.

As noted above, a Section 1115 request must propose a genuine experiment of some kind. An experiment must have stated goals, a hypothesis, and a way to measure that hypothesis. According to Congress, “States can apply to HHS for a waiver of existing law to test a unique approach to the delivery and financing of services to Medicaid beneficiaries . . . contingent upon development of a detailed research methodology and comprehensive evaluation for the demonstration.”¹⁰ Providing FFP for mental health services in IMDs is not an experiment. CMS first permitted states to waive the IMD exclusion in 1993, and by the early 2000s, nine states had waivers to fund IMDs for psychiatric treatment: Arizona, Delaware, Maryland, Massachusetts, New York, Oregon, Rhode Island, Tennessee, and Vermont.¹¹ Some of these states only covered individuals at certain hospitals or for a set number of days; others offered broader coverage. As of 2009, CMS had phased out all but one of these projects, precisely because they were no longer “innovative or experimental.”¹²

Although CMS has recently encouraged states to apply for mental health-related Section 1115 waivers that would allow for FFP for services provided in IMDs, CMS has not provided any justification for its change in position.¹³ With almost 30 years of waivers, it is no longer plausible to claim that providing FFP for services to individuals residing in IMDs is a bona fide experiment, demonstration, or pilot. Section 1115 does not offer HHS a “back door” to provide funding for settings that Congress explicitly carved out of Medicaid.

¹⁰ H.R. Rep. No. 3892, pt. 2, at 307-08 (1981).

¹¹ U.S. Gov. Accounting Office, *States Fund Services for Adults in Institutions for Mental Disease Using a Variety of Strategies* 29 (2017), <https://www.gao.gov/assets/690/686456.pdf>.

¹² *Id.*

¹³ CMS, *Dear State Medicaid Director Letter* (Nov. 13, 2018) (SMD #18-011) (Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance), <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf> [hereinafter “SMD #18-011”].



Furthermore, West Virginia fails to clearly lay out a specific hypothesis to be tested through the use of this new funding stream for SMI patients at IMDs nor has the State offered enough detail to allow for meaningful comment on the hypothesis related to SMI. While the application states that “additional evaluation questions and hypothesis for new demonstration features” will be forthcoming, this information is essential and must be provided prior to demonstration approval in order for stakeholders to provide meaningful input. In fact, the application seems to continue to heavily rely on the SUD metrics without explicitly incorporating SMI-specific goals.

One of the SUD-specific hypotheses is that the waiver will “decrease ED visits, inpatient admissions, and readmissions to the same level of care or higher.” In the context of SMI, this hypothesis was already explicitly tested and found to be unsupported by the federally authorized Medicaid Emergency Psychiatric Demonstration (MEPD) program, a three-year IMD demonstration authorized by the Section 2707 of the Affordable Care Act.¹⁴ The MEPD evaluation found that in those states that had sufficient data to draw conclusions, “[t]he results do not support our hypothesis that ER visits would decrease as a result of MEPD.”¹⁵ The MEPD evaluation also found that the MEPD did not reduce psychiatric admissions to non-psychiatric beds, often called “scatter-bed” admissions.¹⁶ So, this has been studied – through legal demonstrations – and the answers are known. There is no need for a Section 1115 waiver in this context.

West Virginia’s demonstration also risks exacerbating current gaps in services by creating more incentives to increase institutional capacity instead of developing community-based resources. This in turn could worsen shortages and continue a negative cycle of viewing institutional settings as the solution to SMI treatment needs. This is particularly concerning given the evidence of the risk of “bed elasticity,” a phenomenon where supply drives demand.¹⁷ That is, if beds are available, they are filled, siphoning resources from community-based services, but

¹⁴ Crystal Blyer et al., Mathematica Policy Research, *Medicaid Emergency Psychiatric Services Demonstration Evaluation, Final Report*, (Aug. 18, 2016), <https://innovation.cms.gov/Files/reports/mepd-finalrpt.pdf> [hereinafter “MEPD Evaluation”].

¹⁵ MEPD Evaluation at 49.

¹⁶ *Id.* at 41.

¹⁷ Martha Shumway et al., *Impact of Capacity Reductions in Acute Public-Sector Inpatient Psychiatric Services*, 63 PSYCH. SERVS. 135 (2012), <https://ps.psychiatryonline.org/doi/pdf/10.1176/appi.ps.201000145>.



when beds are not available, other options adequately meet individuals' needs. When states have limited resources, spending money on costlier institutional settings results in less available funding for more cost-effective community-based programs, making community-based services harder to access. Historically, the IMD exclusion has provided important incentives to states to develop community-based alternatives and to rebalance spending towards more integrated settings. Community-based treatment is often more effective and frequently more cost-effective than inpatient or residential care.¹⁸

We are also worried about the lack of specifics regarding actions West Virginia commits to taking to ensure appropriate funding and availability of community-based services. The renewal application states that the demonstration is meant to complement and not supplant other efforts to improve community-based services. Nonetheless, more concrete steps are needed to ensure approval of the IMD exclusion waiver for SMI does not divert funding away from community-based services. While CMS has traditionally required States to increase crisis and community-based services as a condition for approval of SMI-specific IMD waivers, this requirement typically does not specify the size of the increase, nor does it require a rate of growth in investment in community-based services sufficient to ensure that FFP for IMDs does not incentivize overuse of institutional settings. We firmly believe CMS should, at a minimum, add more specificity to this requirement to properly fund and expand community-based mental health services.

Finally, providing FFP for services provided in IMDs could undermine hard-won civil rights for people with disabilities and decades of federal policy initiatives stressing the importance of increasing community integration.¹⁹ IMDs are by definition institutional settings where individuals with disabilities receive services, and decisions regarding funding for services in IMDs will inevitably have an impact on where people with disabilities receive services. In passing the Americans with Disabilities Act, Congress found that "historically, society has tended to isolate and segregate individuals with disabilities, and, despite some improvements, such forms of discrimination against individuals with disabilities continue to be a serious and

¹⁸ See Barbara Dickey et al., *The Cost and Outcomes of Community-Based Care for the Seriously Mentally Ill*, 32 HEALTH SERV. RES. 599 (1997), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1070217/>.

¹⁹ President's New Freedom Comm'n on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America* (2003), <https://govinfo.library.unt.edu/mentalhealthcommission/reports/FinalReport/FullReport.htm>.



pervasive social problem.”²⁰ Providing FFP for large institutional settings could reify discriminatory presumptions about the ability of individuals with disabilities to receive services in community-based settings, and undermining the integration mandate articulated by the Supreme Court in *Olmstead v. LC*. In short, this request promotes the segregation of people with mental illnesses.

Because West Virginia’s request with regards to SMI risks diverting resources from community-based services and undermining the civil rights of people with disabilities, the Secretary should not approve this demonstration request.

IV. Conclusion

For the above legal and policy reasons, we ask the Secretary to reject West Virginia’s request to continue waiving the IMD exclusion for SUD services and the request to waive the IMD exclusion for individuals with SMI. 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

²⁰ 42 U.S.C. § 12101(a)(2).

