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January 20, 2021

VIA ELECTRONIC SUBMISSION TO
Good.Guidance@hhs.gov

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

**Re: Petition to Withdraw Guidance Establishing
Procedures for Withdrawing or Terminating a Section 1115
Demonstration**

To whom it may concern:

The National Health Law Program (NHeLP) works on behalf of low-income and underserved individuals and families. NHeLP advocates, educates, and litigates at the federal and state levels to advance health and civil rights in the United States.

This petition is filed pursuant to 45 C.F.R. § 1.5, which establishes a process for interested parties to petition the Department of Health and Human Services to withdraw guidance documents.

NHeLP requests that the Department withdraw each of the "letters of agreement" and enclosures ("Letters") that the Centers for Medicare & Medicaid Services ("CMS") sent to states on or about January 4, 2021. The template of CMS's Letters is attached as Exhibit A. We have also attached a copy of the Letter CMS sent to the Department of Vermont Health Access, which is identical to the template (Exh. B).

NHeLP is an interested party for the purpose of filing this petition. We have clients who receive Medicaid coverage through Section 1115 demonstration projects and who, when harmed by CMS's Section 1115 demonstration decisions, have filed lawsuits in federal court to enforce their statutory and constitutional rights. As such, NHeLP has an interest in whether, how, and how long Medicaid beneficiaries can continue to be experimented upon, particularly in situations where CMS has determined that the demonstration project is no longer legally viable. The Letters purport to bind CMS and states to at least nine months (and as long as 19 months) of continued implementation of demonstration projects that CMS has determined are no longer legally viable. Of great concern, waivers that are being withdrawn are likely to be harming Medicaid beneficiaries. NHeLP also has an interest in transparent government—in the ability to receive advance notice and the opportunity to submit comments in response to proposed documents such as the Letters, which are intended to guide the conduct of regulated parties, such as state Medicaid agencies and Medicaid enrollees.

The Letters purport to establish the procedures that CMS “commits to applying” prior to the effective date of a suspension, termination, or withdrawal of a Section 1115 demonstration. Exh. A at 2; Exh. B at 2. Specifically, CMS “commits” to setting the effective date for its determination at least nine months after the date CMS determines a waiver is no longer legally viable and provides notice to the state of its determination. *Id.* The Letters purport to establish a specific hearing and briefing schedule that the parties “shall adhere to.” *Id.* And, the Letters purport to require states to complete this “preliminary appeals process” prior to filing an appeal with the Departmental Appeals Board (“DAB”). *Id.* at 3.

I. The Letters are “guidance documents” under 45 C.F.R. § 1.2.

Although styled as “letters of agreement” to individual states, the Letters constitute “guidance documents” under the recently promulgated definition adopted at 45 C.F.R. § 1.2. The regulation clarifies that “a document that on its face is directed to a particular party,” qualifies as guidance if the “content of the document is designed to guide the conduct of other regulated parties.” The Department, in the preamble, repeatedly states that it will adopt a “functional test” to determine whether a document is properly considered a “guidance document.” See 85 Fed. Reg. 78770, 78772, 76 (Dec. 7, 2020).

A “guidance document” is “any Department statement of general applicability intended to have future effect on the behavior of regulated parties and which sets forth a policy on a



statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation.” *Id.* That is exactly what the Letters do. *First*, the Letters are statements of general applicability. They state that CMS “commits” to follow the designated procedures prior to suspending or terminating a project or withdrawing demonstration projects based on a finding that a state has materially failed to comply with the Special Terms and Conditions (“STCs”) or the project is not likely to achieve the statutory purpose. Moreover, the content of the Letters is not specific to a particular demonstration but applies to all states with a demonstration project and to all approved demonstration projects in a state. Furthermore, as noted above, NHeLP understands that the same Letter was sent to every state with an approved Section 1115 demonstration project.

Second, the Letters have a future effect on the behavior of other regulated parties, including states and Medicaid beneficiaries. They create a new “preliminary appeals process” that states signing the Letters must engage in before they can access the appeals process established in 45 C.F.R. part 16. They govern the future behavior of the states and CMS by establishing binding timelines for the appeals process. See Ex. A at 3 (“The hearing and associated briefing *shall* adhere to the following schedule...”) (emphasis added). Finally, they declare that a demonstration project determined to no longer promote the objectives of Medicaid or that is materially noncompliant with the STCs, will remain in effect for at least nine months following CMS’s decision to terminate, suspend, or withdraw. *Id.* This has a future effect not only on states but also the Medicaid enrollees who will remain subject to the approved demonstration during that time.¹

Third, the Letters set forth new policy. By requiring states to complete the preliminary appeals process prior to accessing an appeal to the DAB, the Letters create a new exhaustion requirement that states must follow. This is a new policy that is not required by any statute or regulation.

¹ *Cf.* 85 Fed. Reg. 78770, 78773 (Dec. 7, 2020) (noting that contractual obligations can be deemed guidance for purposes of the rule and acknowledging that materials sent from HHS to a third party (such as an agency contractor) are guidance if “the content is designed to guide the conduct of regulated parties”).



II. The Letters should be withdrawn under 45 C.F.R. § 1.5 because they violate the Administrative Procedure Act and attempt to impose binding legal obligations beyond what is required by the terms of applicable statutes and regulations.

Under the “good guidance” regulations, any interested party may petition the Department to withdraw a guidance document, including on the following bases: (1) the document, “no matter how styled, imposes binding obligations on parties beyond what is required by the terms of applicable statutes and/or regulations,” or (2) a “component of the Department is using a guidance document to create additional legal obligations beyond what is required by the terms of applicable statutes and regulations.” 45 C.F.R. § 1.5(a).

The Letters clearly satisfy these standards by violating the Administrative Procedure Act (“APA”) procedural requirements for notice and comment for substantive rules and establishing new obligations that exceed, and in some cases, conflict with the applicable regulations and statutes. The Letters therefore violate the Department’s “good guidance” rule and should be withdrawn immediately to “remedy the substance or use of any guidance documents that it determines in a petition response to be inconsistent with this part or otherwise unlawful.” *Id.* at § 1.5(e).

First, the requirements described in the Letters are unlawful because they exceed and conflict with existing regulations. *See Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000) (permitting agency statement that conflicts with plain meaning of regulation would permit the agency “under the guise of interpreting a regulation, to create *de facto* a new regulation”); *Itserve All., Inc. v. Cissna*, 443 F. Supp. 3d 14, 34 (D.D.C. 2020) (agency statement that “adopts a new position inconsistent with existing regulations,” is a substantive rule and also “substantively invalid”) (internal quotes and alterations omitted); *see also* 45 C.F.R. §§ 1.3(a)(2), 1.5(a)(1), (2). The existing regulations governing the DAB require exhaustion of a preliminary appeal process only if it is “required *by regulation*.” 45 C.F.R. § 16.3(c) (emphasis added); *see also* 45 C.F.R. Pt. 16, App. A(A) (describing “the types of disputes covered, and *any conditions for Board review ... resulting from those disputes*”). There is no such regulatory requirement for disputes regarding the termination of Section 1115 demonstration projects. In fact, it appears as though the DAB can have direct jurisdiction over Section 1115 termination disputes, without any conditions relating to a preliminary appeal process. *See* 42 C.F.R. § 430.3(c) (DAB has jurisdiction over “disputes pertaining to discretionary grants, such as grants for special demonstration



projects under sections 1110 and 1115 of the Act, which may be awarded to a Medicaid agency.”); 45 C.F.R. Pt. 16, App. A(C)(2), (4) (with respect to discretionary grants, DAB hears disputes regarding: “A termination for failure to comply with the terms of an award,” and “[a] voiding (a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).”). Thus, the Letters impermissibly create new, binding obligations on states and CMS beyond what is required by regulations. Moreover, the Letters conflict with the regulations by adding new conditions for DAB review, thereby restricting the jurisdiction granted to the DAB by regulation.

Second, as described above, the Letters bind both CMS and states to utilizing a new “preliminary appeal process.” CMS has committed to delay the effective date of its determination by nine months, removing any discretion to impose an earlier effective date. Agency statements, such as this, qualify as a substantive rule because “the statement is a rule of present binding effect”—meaning that “the statement constrains the agency’s discretion.” *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320 (D.C. Cir. 1988). See also *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 99 (1995) (a substantive rule binds the agency to make decisions in a particular way); *Am. Bus Ass’n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980) (if a “purported policy statement genuinely [does not] leave[] the agency and its decision-makers free to exercise discretion,” it is a substantive rule). The states, for their part, are required to exhaust the preliminary but lengthy appeal process before appealing to the DAB. Such binding effect on regulated entities is the hallmark of a substantive rule. See *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 384 (D.C. Cir. 2002) (holding “Guidance Document” a substantive rule because it imposed “obligations upon applicants to submit applications that conform to the Document”). Substantive rules must go through notice-and-comment before taking effect. See 5 U.S.C. §§ 553(b), (c); *Chamber of Commerce of U.S. v. OSHA*, 636 F.2d 464, 470-71 (D.C. Cir. 1980). CMS did not follow those procedures here, so the Letters must be withdrawn.

Third, the timeline established for the preliminary appeal process severely restricts CMS’s ability to terminate, suspend, or withdraw a demonstration project that no longer meets the statutory requirements or complies with the approved STCs. The Letters require that CMS provide advance notice of its determination to terminate, suspend, or withdraw at least nine months before the action becomes effective. The newly established appeals and hearing process outlined in the Letters lasts at least nine months. The subsequent DAB process is generally expected to last six months if there is no hearing and nine months if the DAB determines a hearing is necessary. See 45 C.F.R. § 16.23. Generally, the agency is prevented from taking action until the DAB issues a final decision. See 45 C.F.R.



§ 16.22(a). Combined, this could lead to appeals processes lasting 16-19 months before CMS’s decision could become effective. This lengthy delay severely limits CMS’s ability to withdraw a waiver and functionally eliminates it for the last year and a half of the experimental project, which by law is supposed to be time-limited.² This conflicts with regulations which authorize the Secretary to “suspend or terminate a demonstration in whole or in part, *any time before the date of expiration, whenever* it determines that the State has materially failed to comply with the terms of the demonstration project.” 42 C.F.R. § 431.420(d)(1); *see also id.* § 431.420(d)(2) (“The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes.”).

Medicaid beneficiaries will continue to be experimented upon for this entire time, even when CMS has concluded that a state “has materially failed to comply with the terms of the demonstration project” or that the “demonstration project is not likely to achieve the statutory purposes.” Exh. A at 2; Exh. B at 2. *See* 42 U.S.C. § 1315(a) (demonstration projects must be likely to promote the objectives of the Medicaid Act). This could mean that Medicaid beneficiaries are being harmed because they are required to comply with the terms of a demonstration project that no longer meet the requirements of the statute—a possibility that even former Administrator Verma conceded. *See* Margot Sanger-Katz, *An 11th-Hour Approval for Major Changes to Medicaid in Tennessee*, N.Y. Times, Jan. 8, 2021, <https://www.nytimes.com/2021/01/08/upshot/medicaid-tennessee-trump-biden.html>. The Letters impose obligations well beyond the applicable statute. *See* 45 C.F.R. § 1.5.

Fourth, the guidance conflicts with the regulations mandating that the Section 1115 demonstration project’s approved STCs will themselves describe the notice and appeal rights that states have for a termination, suspension, or withdrawal of waiver authorities. *See* 42 C.F.R. § 431.420(d)(3); *see also* Medicaid Program; Review and Approval Process for Section 1115 Demonstrations, 77 Fed. Reg. 11,678, 11,688 (Feb. 27, 2012) (“The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.”). The Letters are not an amendment to the STCs governing the Section 1115 demonstrations. The Letters do not say they are amending the STCs or serving as an amendment to the STCs.

² *See* 42 U.S.C. § 1315(a) (Secretary may grant a waiver only “for the period he finds necessary to enable such State or States to carry out such project.”); *see also id.* § 1315(e)(2), (f)(6) (generally limiting extensions of statewide, comprehensive projects to three years).



They are separate guidance describing the process CMS “commits to applying.”³ Moreover, the Letters could not serve as amendments to the STCs because CMS did not follow the required procedures for such an amendment. Generally, to amend the STCs, states must submit an amendment application to CMS. For amendments to the STCs initiated by CMS, most STCs require CMS to provide 30-days advance notice of such changes. See, e.g., Letter from Anne Marie Costello, Acting Deputy Adm’r & Dir., Ctrs. for Medicare & Medicaid Servs., to Mike Smith, Secretary, Vt. Agency of Human Servs., Special Terms & Conditions for Global Commitment to Health Section 1115 Demonstration ¶ 3 (Dec. 3, 2020), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/vt/vt-global-commitment-to-health-ca.pdf>. CMS did not do so here. Thus, the Letters create additional obligations beyond those outlined in the terms of the regulation.

In summary, without APA notice and the opportunity for comment, and without following its own “good guidance” regulations, CMS amended the rules on how it withdraws or modifies experimental waivers. CMS’s approach would give states the right to continue to operate waivers for months and months, even though CMS has found they no longer comply with the STCs and/or the objectives of the Medicaid program. The Letters violate the APA and impose obligations beyond existing regulations and statutory requirements. We ask that they be withdrawn immediately pursuant to 45. C.F.R. § 1.5.

Sincerely,



Jane Perkins
Legal Director

³ Additional verification that the Letters are guidance, not an STC amendment, came when CMS approved waivers after January 4th (e.g., Tennessee and Texas) that did not include the new procedures in the STCs.



Exhibit A



January 4, 2021

State Medicaid Director
Agency
Address

Dear State Medicaid Director:

Your state currently operates at least one Medicaid section 1115 demonstration. These demonstrations have proven to be a cornerstone of state innovation from which new best practices can emerge and next generation program design be fostered. They represent one of the most critical elements of our commitment to state flexibility and building a state and federal partnership centered on accountability and results.

By their nature, section 1115 demonstrations represent a contract between the state and federal government, governed by established terms and conditions and only approved after a determination by the Secretary of the Department of Health and Human Services (HHS) that such a demonstration would advance the objectives of the Medicaid program. In the rare event that CMS makes a determination that it must terminate, amend, or withdraw waiver authority, the standard terms and conditions in each demonstration generally provide for a process in which CMS will notify the state in writing and afford the state an opportunity to request a hearing prior to the effective date.

Your terms and conditions describe this process at only a high level, without describing the advance notice or the specific timeline in which such an opportunity to be heard would occur. While a decision to terminate or withdraw waiver authority would likely only be made as a last measure, states have the right to due process over that decision as well as adequate notice to prepare to transition their programs to a new state of authority. That is why I am sending to you today a letter of agreement outlining additional details of the process which CMS commits to applying prior to the effective date of any amendment or withdrawal of a demonstration.

By signing this letter of agreement, you are agreeing to abide by this process should CMS in the future take any such relevant action against an existing 1115 demonstration operating in your state. If you would like to commit to adhering to this process, I ask that you return this agreement, signed by the state Medicaid director or appropriate authority, as soon as possible. Please send to me directly or email the signed agreement to 1115demorequests@cms.hhs.gov.

Sincerely,

Seema Verma

Enclosure

CENTERS FOR MEDICARE & MEDICAID SERVICES

PROCEDURES FOR WITHDRAWING OR MODIFYING A SECTION 1115 DEMONSTRATION

CMS regulations state that each Section 1115 demonstration's Terms and Conditions "will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities." 42 CFR § 431.420(d)(3). While the precise language in each demonstration's Terms and Conditions varies slightly, these documents set forth only a general outline of the procedure to apply, for example: "CMS will promptly notify the State in writing of the determination and the reasons for the amendment and withdrawal, together with the effective date, and afford the State an opportunity to request a hearing to challenge CMS' determination prior to the effective date." This letter agreement sets forth the procedures that CMS commits to applying prior to the effective date of any amendment or withdrawal of a demonstration.

If CMS determines that it will either (1) suspend or terminate a demonstration in whole or in part because the State has materially failed to comply with the terms of the demonstration project, or (2) withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes, see 42 CFR § 431.420(d)(1)–(2), CMS will promptly notify the affected State in writing of its determination and the reasons for the suspension, termination, amendment, or withdrawal. CMS will also provide an effective date for its determination and a schedule for a hearing to challenge CMS' determination.

In order to ensure that affected states have adequate notice and opportunity to be heard, CMS shall make the effective date for its determination no sooner than 9 months after the date on which CMS transmits its determination to the affected State. The hearing and associated briefing shall adhere to the following schedule:

- Within 15 days of the date of CMS' determination, the affected State shall provide notice in writing to CMS that it disagrees with CMS' determination and plans to invoke its right to a hearing as part of a preliminary appeal.
- Within 90 days of the date of CMS' determination, the affected State shall submit a written brief to CMS outlining the bases for its disagreement.
- Within 90 days of the date the State submits its written brief, CMS shall send a written response to the affected State responding to the major arguments raised by the State.
- Within 60 days of the date that CMS sends its written response, the State shall submit a written rebuttal responding to the major arguments raised by CMS.
- Within 45 days of the date that the State sends its written rebuttal, CMS shall hold a hearing and provide the State with an opportunity to be heard regarding its disagreement with CMS' determination.
- Following the hearing, CMS shall issue a written decision either modifying or finalizing its initial determination.

The decision resulting from this preliminary appeals process shall be appealable to the Departmental Appeals Board using the procedures at 45 CFR Part 16. *See* Appendix A to 45 CFR Part 16, C.(b). Monetary damages cannot remedy a breach of this preliminary appeals process. Any breach constitutes irreparable harm and final agency action.

The preliminary appeals process set forth above applies to the following demonstrations:

State Demonstration Plan

State Medicaid Director

Agency

State

Date: _____

Seema Verma

Administrator

Centers for Medicare & Medicaid Services

U.S. Department of Health & Human Services

Date: _____

Exhibit B

January 4, 2021

Cory Gustafson
Commissioner
Department of Vermont Health Access
280 State Drive
Waterbury, VT 05671

Dear Mr. Gustafson:

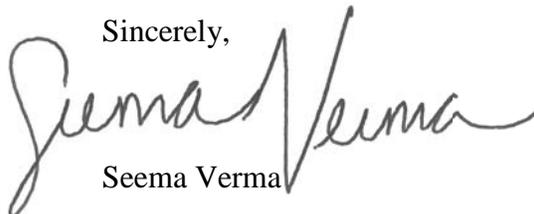
Your state currently operates at least one Medicaid section 1115 demonstration. These demonstrations have proven to be a cornerstone of state innovation from which new best practices can emerge and next generation program design be fostered. They represent one of the most critical elements of our commitment to state flexibility and building a state and federal partnership centered on accountability and results.

By their nature, section 1115 demonstrations represent a contract between the state and federal government, governed by established terms and conditions and only approved after a determination by the Secretary of the Department of Health and Human Services (HHS) that such a demonstration would advance the objectives of the Medicaid program. In the rare event that CMS makes a determination that it must terminate, amend, or withdraw waiver authority, the standard terms and conditions in each demonstration generally provide for a process in which CMS will notify the state in writing and afford the state an opportunity to request a hearing prior to effective date.

Your terms and conditions describe this process at only a high level, without describing the advance notice or the specific timeline in which such an opportunity to be heard would occur. While a decision to terminate or withdraw waiver authority would likely only be made as a last measure, states have the right to due process over that decision as well as adequate notice to prepare to transition their programs to a new state of authority. That is why I am sending to you today a letter of agreement outlining additional details of the process, which CMS commits to applying prior to the effective date of any amendment or withdrawal of a demonstration.

By signing the letter of agreement, you are agreeing to abide by this process should CMS in the future take any such relevant action against an existing 1115 demonstration operating in your state. If you would like to commit to adhering to this process, I ask that you return this agreement, signed by the state Medicaid director or appropriate authority, as soon as possible. Please send to me directly or email the signed agreement to 1115demorequests@cms.hhs.gov.

Sincerely,



Seema Verma

Enclosure

CENTERS FOR MEDICARE & MEDICAID SERVICES

PROCEDURES FOR WITHDRAWING OR MODIFYING A SECTION 1115 DEMONSTRATION

CMS regulations state that each Section 1115 demonstration's Terms and Conditions "will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities." 42 CFR § 431.420(d) (3). While the precise language in each demonstration's Terms and Conditions varies slightly, these documents set forth only a general outline of the procedure to apply, for example: "CMS will promptly notify the State in writing of the determination and the reasons for the amendment and withdrawal, together with the effective date, and afford the State an opportunity to request a hearing to challenge CMS' determination prior to the effective date." This letter agreement sets forth the procedures that CMS commits to applying prior to the effective date of any amendment or withdrawal of a demonstration.

If CMS determines that it will either (1) suspend or terminate a demonstration in whole or in part because the State has materially failed to comply with the terms of the demonstration project, or (2) withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes, see 42 CFR § 431.420(d)(1)–(2), CMS will promptly notify the affected State in writing of its determination and the reasons for the suspension, termination, amendment, or withdrawal. CMS will also provide an effective date for its determination and a schedule for a hearing to challenge CMS' determination.

In order to ensure that affected states have adequate notice and opportunity to be heard, CMS shall make the effective date for its determination no sooner than 9 months after the date on which CMS transmits its determination to the affected State. The hearing and associated briefing shall adhere to the following schedule:

- Within 15 days of the date of CMS' determination, the affected State shall provide notice in writing to CMS that it disagrees with CMS' determination and plans to invoke its right to a hearing as part of a preliminary appeal.
- Within 90 days of the date of CMS' determination, the affected State shall submit a written brief to CMS outlining the bases for its disagreement.
- Within 90 days of the date the State submits its written brief, CMS shall send a written response to the affected State responding to the major arguments raised by the State.
- Within 60 days of the date that CMS sends its written response, the State shall submit a written rebuttal responding to the major arguments raised by CMS.
- Within 45 days of the date that the State sends its written rebuttal, CMS shall hold a hearing and provide the State with an opportunity to be heard regarding its disagreement with CMS' determination.
- Following the hearing, CMS shall issue a written decision either modifying or finalizing its initial determination.

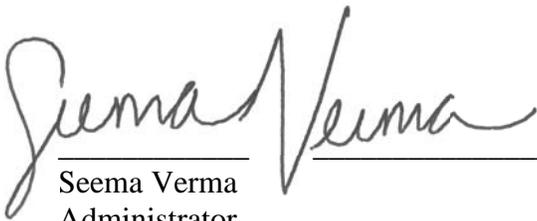
The decision resulting from this preliminary appeals process shall be appealable to the Departmental Appeals Board using the procedures at 45 CFR Part 16. *See* Appendix A to 45 CFR Part 16, C. (b). Monetary damages cannot remedy a breach of this preliminary appeals process. Any breach constitutes irreparable harm and final agency action.

The preliminary appeals process set forth above applies to the following demonstration:

Vermont Global Commitment to Health

Cory Gustafson
Commissioner
Department of Vermont Health Access
State of Vermont

Date: _____



Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services

Date: January 4, 2021