UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

RONNIE MAURICE STEWART, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:18-cv-152 (JEB)
	)	
ALEX M. AZAR II, et al.,	)	
	)	
Defendants.	)	

PLAINTIFFS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

The Social Security Act grants the Secretary of Health and Human Services (the "Secretary") the authority to waive certain Medicaid Act requirements so that states may conduct experimental projects that are likely to further the Medicaid Act's objectives. Consistent with the current administration's antipathy for the Affordable Care Act (the "ACA"), the Secretary has relied upon this narrow authority to re-approve Kentucky HEALTH—a project that seeks to "comprehensively transform" Medicaid from a program designed to guarantee health coverage for low-income people to a program that makes health coverage available only on a conditional basis, allegedly in the name of promoting health and self-sufficiency. In doing so, the Secretary has sought to rewrite the Medicaid Act in a way that is contrary to the program's purpose: furnishing medical assistance to those who are unable to afford the costs of medically necessary care and services.

In June 2018, this Court vacated the first approval of Kentucky HEALTH. It found that the Secretary failed to adequately consider how the project advanced the Medicaid Act's central purpose. *Stewart v. Azar*, 313 F. Supp. 3d 237 (D.D.C. 2018), ECF 74. On November 20, 2018, after "further review," the Secretary re-approved Kentucky HEALTH, again conditioning Medicaid coverage on work requirements, premiums, and other restrictions that the State estimated will jettison approximately 95,000 people from the Medicaid program.

Try as he might, the Secretary has failed to remedy the shortcomings identified by the Court and Plaintiffs during the first round of this litigation. Once more, the Secretary has ignored an administrative record that makes plain that Kentucky HEALTH's requirements and benefits cuts are antithetical to Medicaid's core purpose. Again, the Secretary has sought to justify this transformation by distorting the purpose of the Medicaid statute, while resisting its text and history.

But the Secretary's limited authority to "waive" certain Medicaid provisions does not permit him to graft onto the statute broad, new requirements that drastically restrict coverage. Nor does it allow him to elevate the administration's policy objectives, such as reduced dependency on public assistance, at the expense of the central purpose of Medicaid, as defined by Congress. *Id*. at 268.

In short, the Secretary's approval is no more lawful now than it was before. The Secretary's actions do not reflect reasoned decision making but, instead, an effort to dismantle the Medicaid program Congress charged the Executive with administering. The Secretary's actions exceed his statutory authority. The Court should grant summary judgment on Plaintiffs' Administrative Procedure Act (the "APA") claims and vacate the waiver approval and related State Medicaid Director letter.

STANDARD OF REVIEW

The APA is the principal safeguard against irrational, incoherent, or unexplained agency decision making. Under the APA standard of review, *see* 5 U.S.C. § 706, the court must ensure that any agency action constitutes "reasoned decisionmaking." *Stewart*, 313 F. Supp. 3d at 259 (quoting *Michigan v. EPA*, 135 S. Ct. 2699, 2706 (2015)). The agency must "examine all relevant factors and record evidence," *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017) (internal quotation marks omitted), weigh "reasonably obvious alternative[s]" to its chosen course, *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 797 (D.C. Cir. 1984), and furnish "a satisfactory explanation for its action"—one that draws a "rational connection between the facts found and the choice made" and that supplies "a reasoned analysis for [any] change," *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 42-43 (1983) (internal quotation marks omitted). Courts "do not defer to the agency's conclusory or unsupported suppositions," *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d

557, 562-63 (D.C. Cir. 2010) (internal quotation marks and citation omitted), and merely "[s]tating that a factor was considered . . . is not a substitute for considering it," *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986). "Summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the [APA] standard of review." *Stewart*, 313 F. Supp. 3d at 249 (citations omitted).

STATEMENT OF FACTS

I. The Federal Medicaid Program.

The Social Security Act establishes a number of safety net programs to support low-income people. *See* 42 U.S.C. §§ 301-1397mm. The programs address a range of needs from cash and nutritional assistance to housing and health care. Title XIX of the Social Security Act addresses health care by establishing Medicaid. *See id.* §§ 1396-1396w-5. Congress enacted Medicaid "[f]or the purpose of enabling each State, as far as practicable . . . to furnish (1) medical assistance on behalf of families and individuals whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." *Id*. § 1396-1. States do not have to participate in Medicaid, but all do. To receive federal funding, a state must operate its program according to a state plan approved by the Secretary. *Id*. § 1396a. The plan must describe the state's program and affirm its commitment to comply with requirements imposed by the Medicaid Act and implementing regulations. *Id*. §§ 1396a, 1316(a)(1); 42 C.F.R. § 430.10. The federal government reimburses states for a portion of "the total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(1), (b) (establishing reimbursement formulas).

The Medicaid Act describes the population groups that are eligible to receive medical assistance. *See* 42 U.S.C. § 1396a(a)(10)(A), (C). States *must* cover individuals described in Section 1396a(a)(10)(A)(i) (the "mandatory categorically needy") and *may* cover individuals described in Sections 1396a(a)(10)(A)(ii) (the "optional categorically needy") and 1396a(a)(10)(C) (the "medically needy"). Prior to the ACA, covered population groups included children, pregnant women, parents and other caretaker relatives, and individuals who were aged, blind, or disabled. The ACA added a mandatory group to that list—adults who are under age 65, not eligible for Medicare, do not fall within another Medicaid eligibility category, and have household income below 133% of the federal poverty level ("FPL") (the "expansion population"). *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271 (2010) (adding 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII), (e)(14)) (eff. Jan. 1, 2014). By adding this new mandatory category of eligible individuals, Congress expanded Medicaid "into a program to meet the health care needs of the entire nonelderly population with income below 133 percent of the poverty level." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 583 (2012). And although the Supreme Court in *National Federation of Independent Business* prohibited the Secretary from terminating federal funding to states that do not implement the Medicaid expansion, *id*. at 585, the population group nevertheless continues to be described as a mandatory coverage group in the Medicaid Act itself. The majority of states, including Kentucky, have approved state plans to cover the expansion population. Kaiser Family Foundation, *Status of State Action on the Medicaid Expansion Decision*, Jan. 4, 2018, https://bit.ly/2RbKzYY.

The Medicaid Act requires states to cover all members of a covered population group, not just subsets of a group. *See* 42 U.S.C. § 1396a(a)(10)(B). States may not impose eligibility requirements that are not explicitly allowed. *Id*. § 1396a(a)(10)(A); *see, e.g.*, *Jones v. T.H.*, 425

U.S. 986 (1976) (affirming ruling that Utah regulation violated Title XIX by adding requirement for obtaining medical assistance).

While the statute allows states to impose premiums and cost sharing on certain enrollees up to specified amounts, *see* 42 U.S.C. §§ 1396o, 1396o-1, it prohibits states from charging premiums to most enrollees with incomes below 150% of FPL, *id*. §§ 1396o(a)(1), 1396o-1(b)(1)(A), (a)(2)(A). It also prohibits states from charging enrollees with incomes below 150% of FPL more than $8, adjusted for inflation, for non-emergency use of the emergency room. *Id.* §§ 1396o(a)(3), (b)(3), 1396o-1(e); 42 C.F.R. § 447.54(b); *cf.* 42 U.S.C. § 1396o(f) (describing tightly circumscribed conditions for the Secretary to waive cost sharing limits).

Since its enactment, the Medicaid Act requires states to determine eligibility and provide medical assistance to all eligible individuals with "reasonable promptness," 42 U.S.C. § 1396a(a)(8), and to provide retroactive eligibility for care provided in or after the third month before an enrollee's application if the enrollee would have been eligible for Medicaid at the time the services were received, *id.* §§ 1396a(a)(34), 1396a(a)(10)(A), 1396d(a). Finally, states must "provide such safeguards as may be necessary to assure" that eligibility and services "will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." *Id*. § 1396a(a)(19).

II. Section 1115 of the Social Security Act.

Section 1115 of the Social Security Act authorizes the Secretary to allow a state to implement an "experimental, pilot, or demonstration" project. *Id*. § 1315(a). In granting the Secretary that authority, Congress explicitly provided that the Secretary only can approve an experiment that is "likely to assist in promoting the objectives" of the Medicaid Act. 42 U.S.C. § 1315(a). In that narrow circumstance, the Secretary can waive a state's compliance with the

requirements of Section 1396a of the Medicaid Act. Additionally, such a waiver can extend *only* to the requirements of that section and *only* to the extent and for the period necessary to enable the state to carry out the experiment. *Id*. § 1315(a)(1). The costs of such an approved Section 1115 project are then regarded as Medicaid expenditures under the state plan. *Id*. § 1315(a)(2).

III. Medicaid Expansion in Kentucky and Kentucky HEALTH.

Kentucky implemented Medicaid expansion effective January 1, 2014. By year's end, over 375,000 individuals had enrolled through the expansion, Administrative Record ("AR") 4974, and the proportion of uninsured, low-income adults plummeted from 35% to under 11%. Joseph A. Benitez et al., *Kentucky's Medicaid Expansion Showing Early Promise on Coverage and Access to Care*, 35 Health Affairs 528 (2016). Enrollment has continued to grow, with over 428,000 individuals having access to medical assistance through the Medicaid expansion as of April 2016. AR 5437-38.

The Medicaid expansion furnishes critical medical assistance. In 2014 alone, over 232,000 enrollees had a non-annual office visit; almost 160,000 received medication monitoring; over 89,000 had their cholesterol tested; over 80,000 received preventive dental care; and 13,000 sought treatment for a substance use disorder. AR 5037, 5019. Additionally, 26,000 women received breast cancer screening and 34,000 received cervical cancer screening. AR 5037. The expansion has been associated with decreased reliance on emergency rooms, fewer skipped medications due to cost, lower out-of-pocket spending on medical services, and improved self-reported health. AR 13532-40. And it has enabled Plaintiffs to access valuable, lifesaving health care and to gain a measure of stability. *See generally* Pls.' Decls. (Exs. A-P, hereto). The expansion also has drastically lowered hospitals' uncompensated care costs, AR 5004, while creating tens of thousands of jobs in health and related fields. AR 4996-97 (more than 12,000 jobs created in 2014).

Upon taking office in December 2015, Governor Matt Bevin set out to "comprehensively transform Medicaid." AR 5447. Through the Kentucky HEALTH Section 1115 project, Kentucky sought to impose additional eligibility requirements on enrollees, terminate Medicaid coverage and prohibit reenrollment for up to six months when enrollees cannot meet those requirements, and eliminate critical Medicaid services. The Commonwealth estimates that Kentucky HEALTH would save it significant funds over five years, but those savings would largely result from 95,000 adults losing Medicaid coverage. AR 5419-23.

With the Kentucky HEALTH application pending, the Trump administration began its efforts to "explode" the ACA, including Medicaid expansion. Amy Goldstein & Juliet Eilperin, *Affordable Care Act Remains "Law of the Land," but Trump Vows to Explode It*, Wash. Post (Mar. 24, 2017), https://wapo.st/2DirehA. Upon taking office, President Trump signed an Executive Order calling on federal agencies to unravel the ACA. *See* Executive Order 13765, *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal*, 82 Fed. Reg. 8351 (Jan. 20, 2017).

Shortly thereafter, the Secretary issued a letter to state governors announcing the Centers for Medicare & Medicaid Services's ("CMS") disagreement with the ACA and labelling Medicaid expansion "a clear departure from the core, historical mission of the program." Tom Price, Sec'y of Dep't of Health & Human Servs., Dear Governor Letter, http://bit.ly/2zvx2zV, AR 115. Defendant Verma repeatedly criticized the expansion of Medicaid to "able-bodied individual[s]," advocating for lower Medicaid enrollment and outlining plans to "reform"

Medicaid through agency action. *See* Casey Ross, *Trump health official Seema Verma has a plan to slash Medicaid rolls. Here's how*, Stat (Oct. 26, 2017), https://bit.ly/2yUaQAL.[1]

On January 11, 2018, well after the required federal comment period for the Kentucky HEALTH application had closed, CMS issued a State Medicaid Director ("SMD") letter that announced a "new policy" to "Promote Work and Community Engagement Among Medicaid Beneficiaries." AR 90-99. The policy establishes guidelines for states wanting to impose work and "community engagement" requirements. *Id.* The next day, the Secretary applied the "new policy" and approved Kentucky HEALTH through September 30, 2023. AR 1-2. The approval authorized Kentucky to require work as a condition of Medicaid eligibility; charge monthly premiums of up to 4% of household income (with a six-month lockout for inability to pay); impose a six-month lockout on individuals who do not renew eligibility or report changes in income by the deadline; charge heightened cost sharing for non-emergency use of the emergency room; and eliminate retroactive coverage and non-emergency medical transportation ("NEMT") for most enrollees. AR 13-15, 85-89.

IV. *Stewart* and Re-Approval of Kentucky HEALTH.

Sixteen Kentuckians challenged the Secretary's approval of Kentucky HEALTH under the APA and the U.S. Constitution. ECF 1. On June 29, 2018, the Court granted Plaintiffs' motion for summary judgment, denied Defendants' cross-motions for summary judgment, and vacated and remanded the Kentucky HEALTH approval. ECF 73, 74. The Court found the approval of

[1] *See also, e.g.*, Remarks by Adm'r Seema Verma at the Nat'l Ass'n of Medicaid Dirs. (NAMD) 2017 Fall Conference, CMS.Gov (Nov. 7, 2017), https://go.cms.gov/2AZDKNK (declaring that the ACA's decision to "move[] millions of working-age, non-disabled adults into" Medicaid "does not make sense," and announcing that CMS would resist that change through approval of state waivers that contain work requirements); *The Future Of: Healthcare*, Wall St. J. (Nov. 10, 2017), https://on.wsj.com/2AI1vMI (declaring Medicaid expansion a "major, fundamental flaw[]" and announcing CMS's efforts to "restructure the Medicaid program").

Kentucky HEALTH, as a whole, arbitrary and capricious because "[t]he Secretary never adequately considered whether Kentucky HEALTH would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid." *Stewart*, 313 F. Supp. 3d at 243. Specifically, the Secretary failed to consider, "[f]irst, whether the project would cause recipients to lose coverage," and, "[s]econd, whether the project would help promote coverage." *Id.* at 266 (citation omitted). The Court also found Defendants' focus on *possible* subsidiary objectives, such as promoting beneficiary health and financial independence, "[wa]s no substitute for considering Medicaid's central concern: covering health *costs*. . . ." *Id.* at 266 (emphasis in original; citation and quotation marks omitted).

In response, Defendant Verma reiterated to the public that CMS is "very committed" to work requirements and wants "to push ahead with our policy initiatives and goals." Dan Goldberg, *Verma: Court ruling won't close door on other Medicaid Work requests*, Politico, July 17, 2018, https://politi.co/2RsJhIF. Defendant Azar similarly declared that "[the Federal Defendants] are undeterred . . . [and a]re proceeding forward [with] . . . work requirements . . . in the Medicaid program." Colby Itkowitz, *The Health 202: Trump administration 'undeterred' by court ruling against Medicaid work requirements*, Wash. Post (July 25, 2018), https://wapo.st/2QUKyss; *see also* Alex M. Azar II, Sec'y, U.S. Dep't of Health & Human Servs., Remarks on State Healthcare Innovation at the Am. Legis. Exchange Council Annual Mtg. (Aug. 8, 2018) ("[Defendant Verma] is now overseeing the next great generation of transformation in Medicaid, through our efforts to encourage work and other forms of community engagement.").[2]

[2] The Secretary has approved similar work requirements in Michigan, Maine, New Hampshire, Wisconsin, Arkansas, and Indiana—each time directly invoking the SMD Letter or its policy prescriptions. Letter from Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs., to Kathy Stiffler, Acting Dir., Mich. Dep't of Health & Human Servs. (Dec. 21, 2018), https://bit.ly/2A9VoAo; Letter from Seema Verma to Stefanie Nadeau, Dir., Office of Me. Care

Consistent with these promises, CMS "re-opened" the public comment period, inviting comment on: "(1) Kentucky's original demonstration proposal from August 24, 2016, (2) Kentucky's revised proposal from July 3, 2017, and (3) the special terms and conditions ("STCs") that CMS approved on January 12, 2018." Medicaid.gov, Kentucky HEALTH-Application and CMS STCs, https://bit.ly/2LCLTya. Almost 12,000 comments were submitted through the CMS website during the comment period. *See id*. On November 20, 2018, the Secretary re-approved Kentucky HEALTH, effective April 1, 2019, for five years. *See* AR 6718-6843.

Aside from a few inconsequential changes discussed below,[3] the re-approved project is identical to the project halted by the Court's June 29 Order. Like the original Kentucky HEALTH, the re-approved project requires Medicaid enrollees to report, as a condition of eligibility, completion of 80 hours of "community engagement" activities every month, and enrollees will lose coverage if they fail to do so. AR 6773-80. Enrollees also must pay monthly premiums of up to 4% of their income (but no less than $1). AR 6769. Individuals who are unable to pay the premiums face a range of consequences, depending on their income and other characteristics—for instance, when most enrollees with income above 100% of FPL do not pay the premium, the Commonwealth will terminate their coverage, prohibit them from re-enrolling for up to six months, and deduct money from their *My Rewards* account. AR 6770-72. Enrollees in the

Servs., Me. Dep't of Health & Human Servs. (Dec. 21, 2018), https://bit.ly/2BYf5v5; Letter from Mary C. Mayhew, Deputy Adm'r & Dir., Ctrs. for Medicare & Medicaid Servs., to Henry D. Lipman, Medicaid Dir., N.H. Dep't of Health & Human Servs. (Nov. 30, 2018), https://bit.ly/2FSJ9NU; Letter from Seema Verma to Casey Himebauch, Deputy Medicaid Dir. & Adm'r, Div. of Medicaid Servs., Wis. Dep't of Health Servs. (Oct. 31, 2018), https://bit.ly/2COF7CB; Letter from Seema Verma to Cindy Gillespie, Dir., Ark. Dep't of Human Servs. (Mar. 5, 2018), https://bit.ly/2FFkcnT; Letter from Demetrios Kouzoukas, Principal Dep. Adm'r., Ctrs. for Medicare & Medicaid Servs., to Allison Taylor, Medicaid Dir., Ind. Family & Soc. Servs. Admin. (Feb. 1, 2018), http://bit.ly/2EZcMfO.

[3] *See* AR 6723. *See also* Section II.A.1, *infra*.

expansion population will no longer have coverage for vision or dental services or over-the-counter medications and instead must pay for those services by using money that accrues in their *My Rewards* account from completing extra community engagement activities and specified healthy behaviors. AR 6764. As before, the Secretary also authorized Kentucky to: (1) impose a six-month lockout penalty on enrollees who fail to complete the redetermination process or timely report changes in household circumstances that affect eligibility, AR 6756-60; (2) eliminate retroactive eligibility for most enrollees, AR 6756; (3) eliminate NEMT, AR 6762; and (4) charge heightened cost sharing for non-emergency use of the emergency room, AR 6764-65.

The new approval also did little to change the rationale of the original approval, which this Court vacated. Once more, the Secretary elevated the dubious claims of Kentucky to be seeking to "promote" health and help individuals attain financial independence over Congress's chosen purpose of assisting needy individuals by paying for health care costs. AR 6718 (stating that there is "little intrinsic value in paying for services"). Further, the Secretary again emphasized the goal of transitioning individuals to commercial coverage and reducing costs for the Commonwealth of Kentucky. AR 6725-26. The Secretary continued to refuse to analyze how many people will lose medical coverage as a result of Kentucky HEALTH.

This "restructuring" is of grave concern to Plaintiffs, who are at risk of losing their Medicaid coverage when they cannot find or maintain work, pay premiums, or timely submit required documentation, and who will lose access to previously covered services such as NEMT. Plaintiffs anticipate that, as before when they had no health insurance, they will incur medical bills they cannot pay and be forced to forego needed care or depend on relatives and friends to help them. *See* Pls.' Decls. (Exs. A-P, hereto).

ARGUMENT

I. The Secretary's Re-Approval of Kentucky HEALTH Promotes His Own Agenda at the Expense of the Medicaid Act's Objectives.

The Secretary may grant a Section 1115 waiver only for an experiment that is "likely to assist in promoting the objectives" of the Medicaid Act. 42 U.S.C. § 1315(a). As mentioned above, Congress appropriates funds for Medicaid "[f]or the purpose of enabling each State, as far as practicable . . . to furnish (1) medical assistance on behalf of [individuals] whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." *Id*. § 1396-1. Medical assistance is "payment of part or all of the cost of . . . care and services or the care and services themselves, or both . . . ." *Id*. § 1396d(a). Thus, as the Court has noted, Congress created Medicaid to enable states, as far as practicable, to furnish medical, rehabilitative, and other health care services to low-income people who are unable to meet the costs of medically necessary care. *Stewart*, 313 F. Supp. 3d at 260-61. The ACA "placed [the expansion population] group on equal footing with other 'vulnerable' populations, requiring that states afford them 'full benefits.'" *Id*. at 269.

In re-approving Kentucky HEALTH, the Secretary continues to tout that it advances a different slate of objectives: "promot[ing] beneficiary health and financial independence," AR 6723, transitioning low-income adults from Medicaid to commercial coverage, AR 6719, and improving the fiscal sustainability of the safety net, AR 6726. For the most part, these objectives restate those in the original approval. *See* AR 4 (objective to "familiarize beneficiaries with a benefit design that is typical of what they may encounter in the commercial market"), AR 90 ("help individuals and families rise out of poverty and attain independence"), AR 1029 ("lessen[] dependence on government assistance and promot[e] individual self-sufficiency"). But Congress

did not authorize these objectives and it is not for the Secretary to redefine Medicaid's very purpose. Moreover, the Secretary's stated objectives fail to provide a basis for his approval of Kentucky HEALTH.

First, the Secretary cannot avoid the express language of Section 1396-1 by proclaiming that Kentucky HEALTH may improve health outcomes and quality of life. "Promoting health" might be a desirable *result*, but the Secretary has no authority to "choose his own means to that end," *Stewart*, 313 F. Supp. 3d at 266-67 (citing *Waterkeeper Alliance v. EPA*, 853 F.3d 527, 535 (D.C. Cir. 2017)), especially where, as here, the project *conflicts* with Medicaid's stated objectives, *see* AR 6731 ("To create an effective incentive for beneficiaries to take measures that promote health and independence, it may be necessary for states to attach penalties" and "any loss of coverage as the result of noncompliance must be weighed against the benefits . . . of improved health and independence of the beneficiaries who comply."). "To the extent Congress sought to 'promote health' and 'well-being' . . . it chose a specific method: covering the *costs* of medical services." *Stewart*, 313 F. Supp. 3d at 267 (emphasis in original). That means the Secretary cannot approve a project just because it ostensibly "focus[es] on health"—he must account for "Medicaid's central concern: covering health *costs*." *Id.* at 266 (emphasis in original); *see also id.* at 267 (noting that Congress sought to "mak[e] healthcare more *affordable*" for low-income individuals (emphasis in original)).

Yet by the Secretary's logic, he may approve *any* policy he subjectively concludes might improve health outcomes. But if that were true, the Secretary could authorize states to require individuals to adopt a vegetarian, low-carb diet as a condition of eligibility because such diets

could improve health outcomes.[4] *See Stewart*, 313 F. Supp. 3d at 267-68. Or the Secretary could expand his authority to include areas governed by other statutes and other agencies (*e.g.*, housing, environmental regulations, or workplace safety standards—all of which are more likely correlated with improved "health outcomes" than the restrictive requirements at issue in this case). *Cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) ("[An] agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And in our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." (internal quotation marks and alterations omitted)). Surely that is not the law. "[T]he fact that [the Secretary] thinks [Medicaid] would work better if tweaked does not give [him] the right to amend the statute." *Am. for Clean Energy v. EPA*, 864 F.3d 691, 712 (D.C. Cir. 2017).

Second, the Secretary claims Kentucky HEALTH will promote individuals' "financial independence" and transition low-income adults from Medicaid to commercial coverage. *See* AR 6724-25, 6727. But nothing in the administrative record supports this proposition, *see* Section II.A.2, *infra*, and nothing in the Medicaid Act suggests that Congress enacted Medicaid to promote those goals. Medicaid exists to provide coverage to people "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1. While reducing the number of low-income people in general might be a laudable goal, it is external to Medicaid, which seeks to ensure that people have access to care when their incomes *are* too low, full stop. If Congress had wanted "reducing dependency on public assistance" to be a goal of Medicaid, it

[4] Here, the Secretary cites a study finding a relationship between health and social isolation and, on this basis, approves work requirements to force people to reduce their social isolation. AR 6733. But, as comments pointed out, many variables are similarly associated with improved health, including exercise, diet, and marital status. AR 17453-54.

would have said so. *Cf.* 42 U.S.C. § 601 (declaring that the purpose of the Temporary Assistance for Needy Families program ("TANF") is to "end the dependence of needy parents on government benefits by promoting job preparation, work, and marriage").

The Secretary continues to rationalize his emphasis on "financial independence" on the word "independence" in Section 1396-1. *See, e.g.*, AR 90, 6720, 6723-25. But this Court already has expressed "doubts [about] whether such an objective is proper," noting that this reading "excis[es]" the word independence from its context, which "limits its objectives to helping States furnish *rehabilitation and other services* that might promote self-care and independence. It does not follow that *limiting* access to medical assistance would further the same end." *Stewart*, 313 F. Supp. 3d at 271 (emphasis in original). Instead, in this context, "independence" refers to functional (not financial) independence—*i.e.*, the capacity to accomplish the activities of daily living, such as feeding, dressing, and bathing.[5] The Secretary cannot untether the term from its context and wring out meanings such as "enhance[d] . . . employability" AR 6724, which cannot be squared with the sentence in which "independence" is used. *See Yates v. United States*, 135 S. Ct. 1074, 1082 (2015) (noting "fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used" (citation omitted)).

Third, the Secretary argues that Kentucky HEALTH will advance the goal of fiscal sustainability. *See* AR 6719-20, 6726-27, 6732 (claiming his objective is to "improve the sustainability of the safety net" and enable states to "stretch" or "deploy" limited resources). But,

[5] *See, e.g.*, 42 U.S.C. § 1396d(a)(13)(C) (defining rehabilitation services as "any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or practitioner of the health arts . . . for maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level").

as other courts have held, if the "purpose of [a Section 1115] waiver application [i]s to save money," the application does not satisfy Section 1115. *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011). Section 1115 "was not enacted to enable states to save money or to evade federal requirements but to test out new ideas." *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994). Nevertheless, the Secretary asserts that financial sustainability is a uniquely valid rationale here because this approval promotes coverage due to the fact that the Commonwealth would not have the funds, absent Kentucky HEALTH, to continue the Medicaid expansion. *See, e.g.*, AR 6729. That claim, however, rests on a misreading of *National Federation of Independent Business*. Although that decision prohibits the federal government from withdrawing all Medicaid funding should a state refuse to cover the expansion population in the first place, the decision did not re-categorize the expansion population as an optional-coverage population for states that expand Medicaid. *Nat'l Fed. of Indep. Bus.*, 567 U.S. at 585. In other words, if a state has expanded Medicaid, the expansion population remains a mandatory-coverage population. *See* 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII). So once a state, like Kentucky, extends Medicaid to the expansion population, that state can no more choose to eliminate coverage for that group than it could for pregnant women, individuals with disabilities, or other mandatory-coverage populations.

Moreover, the Secretary's "fiscal sustainability" rationale stretches his waiver authority too far. The Medicaid Act contains its own fiscal controls: namely, states do not have to participate, but if they do, they have a great deal of flexibility to decide which optional eligibility groups and services to cover. More fundamentally, under the Secretary's rationale, he could approve *any* project that would save money on grounds that, without the project, the state may choose to terminate other optional populations or its Medicaid program entirely. Any project that cuts costs would be likely to promote the objectives of the Medicaid Act. *Cf. Stewart*, 313 F. Supp. 3d at

255-56 (asking "what's to stop" the Secretary from approving a waiver cutting all coverage for the blind, and concluding that the limitation comes from "[t]he statute's caveat that any such project must be likely to assist in promoting the statute's objectives."). Put another way, the Secretary seems to believe he can replace nearly every one of Congress's policy judgments about Medicaid—about who and what states must cover and how much they may charge enrollees—if a state wants to save money. Congress did not, and could not, grant the Secretary such unbridled authority. *See A.L.A. Schechter Poultry, Corp. v. United States*, 295 U.S. 495, 538-39 (1935) (finding delegation unconstitutional where President had authority to "impose his own conditions, adding to or taking from what is proposed, as 'in his discretion' he thinks necessary 'to effectuate the policy' declared by the act"); *Clinton v. City of New York*, 524 U.S. 417, 444 (1998).

Finally, the Secretary has converted saving money, which he previously described as a "happy side effect" of Kentucky HEALTH, into the primary rationale for its approval. But in doing so, he did not address any of the problems identified by the Court in *Stewart*. Nothing in the administrative record establishes that the Kentucky Medicaid program is "actually at risk." *Stewart*, 313 F. Supp. 3d at 271. There is no evidence about current state revenues or budget. *See id*. And even assuming Kentucky does need to curb its Medicaid costs, nothing in the record explains "why cuts to the expansion population would be the best remedy for any budget woes" given the enhanced federal matching rate for services provided to that population. *Id*.; *compare* 42 U.S.C. § 1396d(y) (setting the reimbursement for the expansion population at 94% in 2019 and 90% thereafter), *with* 42 U.S.C. § 1396b(a); 82 Fed. Reg, 55,383, 55,385 (Nov. 21, 2017) (setting reimbursement for Kentucky non-expansion populations, generally, at 71.67%).

In short, the Secretary's approval impermissibly prioritizes his own objectives, which are found nowhere in the statute, at the expense of the statute's "clear emphasis on promoting medical

. . . assistance." *Stewart*, 313 F. Supp. 3d at 268. Because the Secretary continues to "exercise[] discretion using the wrong legal standard, [his] action cannot survive." *Id.* at 272 (citing *SEC v. Chenery Corp*., 318 U.S. 80, 94 (1943)).

II. The Secretary's Re-approval of Kentucky HEALTH is Arbitrary and Capricious and Exceeds His Statutory Authority.

Given the administrative record, the Secretary could not reasonably conclude that his re-approval of Kentucky HEALTH is a valid experiment that is likely to promote the objectives of the Medicaid Act. 42 U.S.C. § 1315(a); *Stewart*, 313 F. Supp. 3d at 254 (citing *Newton-Nations*, 660 F.3d at 379-80). The expanded record, which now includes research added during the latest public comment period, confirms that Kentucky HEALTH will reduce Medicaid coverage and harm the health of low-income individuals.

The Secretary ignored or unreasonably dismissed that substantial evidence. *See Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978) (cautioning that where an agency reaches "precisely the same conclusion" after remand, the court "must recognize the danger that an agency, having reached a particular result, may become so committed to that result as to resist engaging in any genuine reconsideration of the issues" and must ensure that the agency action is "more than a barren exercise of supplying reasons to support a pre-ordained result"). And even if the Secretary adequately considered that evidence (which he did not), he lacked the statutory authority to approve key features of Kentucky HEALTH.

A. The Secretary Failed to Adequately Examine if Kentucky HEALTH Met the Section 1115 Conditions.

1. The Secretary Failed to Consider Whether the Project Would Cause Medicaid Coverage Loss or Promote Medicaid Coverage.

Given that the central objective of the Medicaid Act is to furnish medical assistance to low-income people, the Secretary needed to examine whether Kentucky HEALTH "would cause

recipients to *lose* coverage [and] whether the project would help *promote* coverage." *Stewart*, 313 F. Supp. 3d at 262. Once again, "[t]he Secretary . . . neglected both." *Id.*

Project as a whole. The record contains dozens of evidence-based comments warning that many people will lose Medicaid coverage due to Kentucky HEALTH. *See, e.g.*, AR 15482, 14664-65, 26308-11. The Secretary agrees that some individuals "may lose coverage," AR 06729, 06731, but this blithe acknowledgement does not show that he reasonably examined the problem or explained how the waiver would remedy that issue. *See Stewart*, 313 F. Supp. 3d at 259 (finding agency "must provide more than 'conclusory statements'" (citing *Getty*, 805 F.2d at 1057)).

Relying on an unsupported assertion that commenters misunderstood the data provided by Kentucky and inaccurately assumed "that 95,000 individuals will completely lose coverage and not regain it," the Secretary concluded—without any support from the record—that any coverage loss will not be significant. AR 6730-31. That is wrong. *See, e.g.*, AR 14044-45, 15486, 19388, 12967 (explaining that Kentucky HEALTH will cause *gaps* in coverage).[6] It is belied by the federal Defendants' own acknowledgment that the project was initially approved based on the 95,000 number. *See Stewart* Tr. 40-41. It also ignores credible evidence estimating much larger coverage losses. *See, e.g.*, AR 16708-10, 19954, 13175, 15482, 26309-10 (pointing to projections developed by health policy experts).[7] In the face of this evidence, the Secretary did not bother to provide a

[6] Commenters well understood the 95,000 estimate, even explaining the method used to arrive at the number—dividing the total decrease in member months (projected by Kentucky) by twelve. *See, e.g.*, AR 16707-08. What is more, the method undercounts the number of individuals who will lose coverage for some amount of time under Kentucky HEALTH, as it supposes that every person enrolled in Medicaid is enrolled for an entire year, which is not the case. So, a reduction in twelve member months could in fact reflect, for example, two people each losing coverage for six months.

[7] Commenters cited Aviva Aron-Dine, Ctr. on Budget & Policy Priorities, *Eligibility Restrictions in Recent Medicaid Waivers Would Cause Many Thousands of People to Become Uninsured* (2018), AR 19194-19205; Amicus Br. for Deans, Chair and Scholars, ECF No. 43-1, AR 13407-13447; Rachel Garfield et al., Kaiser Family Found., *Implications of a Medicaid Work*

"bottom-line estimate of how many people would lose Medicaid with Kentucky HEALTH in place." *Stewart*, 313 F. Supp. 3d at 262. Nor did he calculate how many of these individuals would, as he claims, transition to commercial coverage.[8] AR 6731. He thus "failed to consider an important aspect of the problem." *Id*. at 264 (citing *State Farm*, 463 U.S. at 43).

As he did in the initial approval, the Secretary contends that the exemptions to the eligibility requirements—the good cause exceptions and the "on-ramps" that allow individuals to re-enroll in Kentucky HEALTH before the end of the six-month penalty period—will minimize any coverage loss. AR 6725-26 (in general), 6727 (regarding administrative lockouts), 6733-34 (work requirements and premiums), 6735 (NEMT). However, with respect to the exemptions, the Secretary "cannot limit his review to only 'vulnerable individuals' . . . [h]e must consider coverage to all groups enrolled in the project."[9] *Stewart*, 313 F. Supp. 3d at 263-64. Equally important,

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Requirement: National Estimates of Potential Coverage Losses (2018), https://bit.ly/2VOnLgL, Letter from Allen Dobson and Joan E. DaVanzo, Dobson DaVanzo & Associates, LLC to CMS Administrator Seema Verma (Aug. 18, 2018), AR 14654-60.

[8] Commenters explained that due to the nature of the labor market, even individuals who fulfill the work requirement are not likely to access employer-sponsored or other commercial insurance. *See*, *e.g.*, AR 12823-24, 12858, 12973-75, 14044-45, 16715-18. Commenters included studies cited during the prior comment periods and new evidence, *e.g.*: Josh Bivens & Shawn Fremstad, Econ. Policy Inst., *Why Punitive Work-Hours Tests In SNAP And Medicaid Would Harm Workers And Do Nothing To Raise Employment* (2018), AR 17924-17940; Hannah Katch, et al., Ctr. on Budget & Pol. Priorities, *Taking Medicaid Coverage Away From People Not Meeting Work Requirements Will Reduce Low-Income Families' Access to Care and Worsen Health Outcomes* (Aug. 2018), https://www.cbpp.org/sites/default/files/atoms/files/2-8-18health2.pdf; Aviva Aron-Dine, *supra* n.7; Anuj Gangopadhyaya et al., Urban Inst., *Kentucky Medicaid Work Requirements: What Are the Coverage Risks for Working Enrollees?* (2018), AR 14046; Kids Forward, *The Wisconsin Approach to Medicaid Expansion* (2017), http://kidsforward.net/assets/Medicaid-Approach.pdf.

[9] The Secretary says only individuals who willfully ignore the work and other requirements will lose coverage. *See, e.g.*, AR 06726 (the project "may impact overall coverage levels if the individuals subject to these demonstration provisions choose not to comply with them"), 6729 (same). But commenters made clear that many individuals who are working or fall within an exemption will nonetheless lose coverage due to the added burden of reporting work hours or seeking an exemption. *See, e.g.*, AR 13558, 14908-14, 16709-10, 14915-16, 19960-63, 12794.

highlighting these so-called protections "is no answer at all" to the concerns commenters raised. *Id*. at 263. The prior project included almost identical features, meaning that commenters expressed their concerns about coverage loss despite those features.[10] *See, e.g.*, AR 15150-51, 19982-83, 20011, 20820, 26304-05, 12967 (all raising concerns about the exemptions and good cause exceptions); AR 14685, 13561-62, 16715 (warning that enrollees will not be able to use the "on-ramps"). In addition, with respect to the work requirement, commenters cited research from the Supplemental Nutrition Assistance Program ("SNAP") and TANF demonstrating that these kinds of safeguards do not avoid coverage loss. *See, e.g.*, AR 12749-50, 16709-10, 19958-60.

The Secretary points to other "guardrails" he contends will "protect beneficiaries," including requiring the State to: (1) provide reasonable modifications to the work requirement for people with disabilities; (2) prior to termination and lockout, determine eligibility for other Medicaid coverage categories and review eligibility for other insurance affordability programs; and (3) provide appeal rights prior to termination. AR 6729. Again, each of these features was included in the original STCs, meaning commenters were aware of them. In addition, existing federal law, not STCs, already requires these features. *See* 42 U.S.C. § 12312; 29 U.S.C. § 794; 42 U.S.C. § 18116 (prohibiting discrimination and requiring modifications for individuals with disabilities); *id.* § 1396w-3(b) (regarding eligibility determinations for other insurance programs);

[10] In re-approving the project, the Secretary moved being a survivor of domestic violence from a good cause exception to an exemption. He also altered the consequences for failure to pay monthly premiums for individuals in the transitional medical assistance (TMA) eligibility category to address an illegal aspect of his initial approval. *See* AR 7706. These narrow changes are insufficient to address coverage loss, and the Secretary made no effort to calculate the extent to which they could possibly minimize coverage loss. *See Stewart*, 313 F. Supp. 3d at 264.

Goldberg v Kelly, 397 U.S. 254 (1970) (holding that the Constitution's Due Process Clause requires opportunity for impartial review prior to termination of public benefits).[11]

The Secretary also appears to claim Kentucky HEALTH will promote *private health coverage* by preparing Medicaid enrollees who transition to commercial markets "to utilize [that] insurance successfully." AR 6725. This is both irrelevant and unsupported. Familiarizing Medicaid enrollees with commercial insurance is not an objective of the Medicaid Act, as described above. Even if it were, comments undercut the Secretary's statement by describing the distinctions between the project and a private plan. *See, e.g.*, AR 25694, 20871, 17460.

While the primary inquiry is whether the Secretary reasonably concluded that the project as a whole passes muster under Section 1115, as discussed below the components of the project are pertinent to that inquiry:

Work Requirements. Record evidence shows that the work requirement in Kentucky HEALTH will strip coverage from a massive number of Medicaid enrollees. Notably, commenters cited coverage loss estimates developed by health policy experts after the Secretary first approved Kentucky HEALTH. *See, e.g.*, AR 16708-10, 19954, 13175-79, 14043-63, 15482.[12] Comments also highlighted data from Arkansas, the first state to implement a Medicaid work requirement. During the first two months of Arkansas's program, more than a quarter of enrollees required to report work hours or seek an exemption did not. *See, e.g.*, AR 13558, 18317; *see also* AR 19568-84. There is nothing in the record to project a better result in Kentucky. Indeed, the record suggests rates of coverage loss in Kentucky will likely to be higher. *Cf.* AR 12826-27, 14664-65, 16712.

[11] The appeal process will only help individuals who were terminated erroneously or who belatedly realize they may qualify for a narrow good cause exceptions.

[12] For research commenters cited, s*ee supra* n.7 and Anuj Gangopadhyaya et al., *supra* n.8.

The Secretary argues that enrollees can satisfy their requirements through "an array of activities" other than work. AR 6730. As commenters carefully explained, however, extensive research shows that the requirement—however it is described—will still cause massive coverage loss. *See, e.g.*, AR 12967-70, 13558, 14034-35, 18404, 19955-58, 19961-62 (highlighting barriers preventing people from working, volunteering, or completing other activities, including nature of low-wage labor market and lack of internet access and affordable transportation). Simply put, the Secretary brushed aside the evidence showing significant coverage loss.

The Secretary also failed to reasonably explain how the work requirement would promote Medicaid coverage for low-income individuals. Although the Secretary noted that work requirements could promote private health insurance coverage if "individuals achieve financial independence and transition to commercial coverage," AR 6727, he ignored evidence showing that such a result is unlikely to occur, *see* Section II.A.2, *infra*. Even assuming that imposing a work requirement would cause Medicaid enrollees to transition to commercial coverage (and that such an objective is a goal of the statute and thus a proper objective for the project), the Secretary did nothing to balance the number of individuals who might gain commercial coverage against the number of individuals who will lose health coverage due to the work requirement. *Id*.

The Secretary had an obligation to consider the impact of Kentucky HEALTH on the individuals the Medicaid program was enacted to protect. *See Newton Nations*, 660 F. 3d at 381. Instead, unable to credibly address the mountain of record evidence showing Kentucky HEALTH would be disastrous to medical coverage, the Secretary attempts to justify his re-approval of the program by emphasizing that the work requirement is just an experiment, the exact outcome of which is uncertain. AR 6730, 6733. Again, Section 1115 does not allow him to approve any "experimental" project simply for the sake of experimentation. Rather, a project must be likely to

promote Medicaid's objectives.[13] The re-approval letter shows that the Secretary disregarded that obligation. AR 6730 ("*Regardless of the degree to which [the] project succeeds in achieving the desired results*, the information it yields will provide policymakers real-world data on the efficacy of such policies. That in itself promotes the objectives of the Medicaid statute." (emphasis added)).

Premiums and Associated Consequences. Once again, the record demonstrates that the monthly premiums and associated consequences will deter and reduce enrollment in Kentucky HEALTH, leaving many low-income individuals uninsured. During the most recent comment period, several dozen commenters cited the numerous studies, conducted over the course of almost two decades, that examine the effects of imposing premiums on low-income individuals enrolled in Medicaid and similar publicly funded insurance programs. *See, e.g.*, AR 19976, 15485, 26310-11 18613-14. That research has established that premiums—even in amounts that appear low—deter and reduce coverage.[14] Comments from Medicaid enrollees and health care providers in Kentucky echo that research. *See, e.g.*, AR 9238 (comment 319617), AR 9246 (comment 319705), AR 9406 (comment 323485), AR 9815 (comment 335277), AR 10519 (comment 341669), AR 10552 (comment 341969), AR 11813 (comment 353893), AR 12111 (comment 356329).

Despite that uncontroverted body of research, the Secretary maintains "there is not sufficient evidence to assert that premium requirements do not advance the objectives of Medicaid" and points to other states evaluating similar premium requirements on individuals in

[13] In any event, the work requirement is not actually "experimental." *See Beno*, 30 F.3d at 1069. Work requirements may not have been a condition of Medicaid eligibility, but they have been a condition of eligibility in other safety net programs (under those programs' governing statutes) and the subject of a large body of research with consistent findings regarding their effectiveness.

[14] Commenters pointed the Secretary to the studies they cited during the prior comment periods and to a new, comprehensive literature review. *See* Samantha Artiga et al., Kaiser Family Found., *The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings* (2017), AR 13139-49.

the expansion population. AR 6734. But the fact that other states may be conducting such investigations does not address the large volume of unrefuted research already establishing that premiums deter and reduce coverage among low-income individuals, like those in the expansion population. In any case, the data from those states, which commenters cited, reinforce what is already known: a significant portion of Medicaid enrollees who are subject to monthly premiums do not pay them, and in states that terminate coverage for failure to pay, significant numbers of enrollees have lost coverage. *See, e.g.*, AR 19977-78, 16713-14.[15] For example, in Indiana, which requires enrollees to pay monthly premiums of 2% of their household income (in Kentucky, this is 4%), 55% percent of enrollees subject to the requirement missed at least one monthly premium and were penalized with termination and lockout (for individuals above 100% of FPL) or loss of benefits and higher cost sharing (for individuals below 100% of FPL). *See* AR 13463-65.

The Secretary also contends that the imposition of premiums "merit[s] additional research" because none of the existing studies evaluated the effects of premiums as part of Kentucky HEALTH. AR 6735. That just means every time a state requests permission to implement a waiver to implement any new policy it would pass muster under Section 1115, as Medicaid varies by state. That makes no sense. An experiment to learn what will happen to an egg dropped from a building in Kentucky will produce the same results as that experiment in Oregon, Vermont, or Indiana, even if there are differences in building heights and weather conditions. And, in any event, this type of approval is not what Congress intended. *See* S. Rep. No. 87-1589, at 19-20 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961-62 (noting Section 1115 projects are "to be selectively approved").

[15] Commenters cited research from the prior comment periods, as well as updated data from Indiana's Section 1115 project. *See* State of Ind., Healthy Indiana Plan Demonstration, *Section 1115 Annual Report, Demonstration Year 3* (02/01/17 - 01/31/18) (2018), https://bit.ly/2slsDwc (finding that during the third year, 18% of enrollees with incomes above 100% of FPL lost Medicaid coverage for failing to pay premiums).

In addition, the fact that Kentucky HEALTH contains other "features which together, seek to encourage beneficiaries to engage in health-promoting behaviors," AR 6735, will only make it more difficult, if not impossible, to isolate and further examine the effects of premiums on coverage, access to care, and health. *See, e.g.*, AR 20871.

Finally, nothing in the record indicates that the premiums and associated consequences for inability to pay will actually promote Medicaid coverage. The Secretary did not offer any explanation, reasonable or otherwise, as to how that might occur.

Elimination of retroactive coverage. Once again, the administrative record is replete with well-founded comments stating the obvious—waiving retroactive coverage will create gaps in coverage and reduce access to Medicaid services by weakening the network of providers serving enrollees. *See, e.g.*, AR 12919, 13564, 13173-74, 14067, 15152, 16723-24, 20291-92, 17511, 18309, 19983-85.[16] The Secretary makes no meaningful attempt to contest that conclusion. As this Court previously observed, "restricting retroactive eligibility will, *by definition*, reduce coverage for those not currently on Medicaid rolls." *Stewart*, 313 F. Supp. 3d at 265. Indeed, the Secretary acknowledged that the projected decrease in enrollment "is likely attributable to a number of factors, including . . . the elimination of retroactive eligibility." AR 6731.

Instead, the Secretary suggests that eliminating retroactive eligibility will promote coverage by "encourag[ing] [beneficiaries] to obtain and maintain health coverage, even when healthy." AR 6724. But the Court already concluded that this "conclusory reference cannot suffice, especially when viewed in light of an obvious counterargument." *Stewart*, 313 F. Supp. 3d at 265

[16] A number of these comments cited an evaluation of a similar proposal to eliminate retroactive coverage in Ohio. That report estimated that ending retroactive coverage "could cost hospitals as much as $2.5 billion over the course of the five-year waiver." Virgil Dickson, *Ohio Medicaid waiver could cost hospitals $2.5 billion*, Modern Healthcare. (Apr. 22, 2016), http://www.modernhealthcare.com/article/20160422/NEWS/160429965.

(internal quotations omitted). Once again, there is no evidence in the record showing that low-income individuals decide not to enroll in Medicaid because they are healthy (thereby showing that eliminating retroactive coverage will promote coverage).[17] What the administrative record does contain are the evidence-based counterarguments noted above—waiving retroactive eligibility will create coverage gaps, harm providers, diminish enrollees' access to providers, and put low-income Kentuckians at risk of negative health outcomes and crushing medical debt. The idea that *withholding* coverage and services through eliminating retroactive coverage will somehow *promote* the furnishing of coverage and services remains nonsensical.

Administrative lockouts. As before, the record overwhelmingly shows that administrative lockouts will "cause recipients to lose coverage." *Stewart*, 313 F. Supp. 3d at 262. Numerous commenters explained that lockouts, by definition, reduce coverage and interfere with enrollees' access to health services. *See, e.g.*, AR 15485-86, 16714-15, 17460-61. In light of this evidence, the Secretary did not articulate a "rational connection between the facts found and the choice made." *Foster v. Mabus*, 103 F. Supp. 3d 95, 105, 109 (D.D.C. 2015). Instead, he conceded that the lockouts "may impact overall coverage levels if the individuals subject to these demonstration provisions choose not to comply with them." AR 6726; *see also* AR 6731 (noting that

[17] Congress enacted retroactive coverage in part to protect individuals "who are eligible for Medicaid but do not apply for assistance until after they have received care, either because they did not know about the Medicaid eligibility requirements, or because the sudden nature of their illness prevented their applying." H. Rep. No. 92-231 (1971), *as reprinted in* 1972 U.S.C.C.A.N. 4989, 5099); S. Rep. No. 92-1230 at 209 (1972), http://bit.ly/2P9HU0O; *see also* Amends. to the Soc. Sec. Act 1969-1972: Hrg. on H.R. 17550 Before the S. Comm. on Fin., 91st Cong. 1262 (1970) (stmt. of Elliot L. Richardson, Sec'y, Dep't of Health, Edu., & Welfare) (indicating Congress also wanted to encourage providers to "furnish necessary medical assistance and ensure financial protection to otherwise eligible persons during the retroactive period"); *Blanchard v. Forrest*, 71 F.3d 1163, 1167 (5th Cir. 1996) (affirming purpose of retroactive eligibility provisions "is to make Medicaid coverage during this period just as effective as it would have been if the individual had already been certified for Medicaid"); *Cohen ex rel. Cohen v. Quern*, 608 F. Supp. 1324, 1332 (N.D. Ill. 1984) (quoting legislative history).

"beneficiaries who fail to comply [with the reporting and redetermination requirements] will lose Medicaid coverage, at least temporarily"). According to the Secretary, in 2017 only 37% of individuals who needed to submit redetermination paperwork did so. AR 6727. That data shows that many individuals will be subject to the lockout penalty. In addition, the Secretary gave no indication why the "additional incentive[]" of a lockout will be any more effective than the current "incentive" (coverage loss) at helping individuals navigate the obstacles that prevent them from meeting administrative deadlines. AR 6727; *see, e.g.*, AR 18209, 21885, 12956-57 (highlighting some of those obstacles).

What is more, the Secretary did not account for his shift in position on the redetermination lockout. In 2016, CMS rejected Indiana's request to implement a redetermination lockout, finding it inconsistent "with the objectives of the Medicaid program, which include ensuring access to affordable coverage." AR 239-40 (noting that completing redetermination can be "challenging" due to language access issues, frequent moves, and other barriers to receiving mail, as well as disabling health conditions, including mental illness). Although the Secretary acknowledged the previous position, he did not provide any reason for changing it. He asserted only that "CMS now believes that this policy should be evaluated, because it is likely to support the objectives of Medicaid to the extent that it prepares individuals for a smooth transition to commercial health insurance." AR 6725. Such "an [u]nexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (internal citation omitted). Moreover, the Secretary did not explain how administrative lockouts might promote Medicaid (as opposed to commercial market) coverage.

Elimination of NEMT. The record contains significant evidence demonstrating that eliminating NEMT will reduce access to medically necessary care, including preventive, mental health, and substance use disorder services. *See* AR 5478 (showing that, from June 2014 through June 2015, enrollees in the expansion population used around 140,000 NEMT trips); *see also* AR 13566, 15151-52, 19988-91, 16724-25, 17463-64, 20292, 13174. Once more, the Secretary's evaluation of these issues comes up short. The Secretary limited his assessment to vulnerable individuals, stating that the waiver will have minimal impact on "vulnerable beneficiaries" due to the exemptions. AR 6735. But commenters raised concerns about people the Secretary does not consider "vulnerable." *See, e.g.*, AR 13566, 14712, 16724, 9213 (comment 319281) (pointing to limited transportation options in rural areas and noting that low-income people often cannot afford transportation to and from health care appointments); *see also Stewart*, 313 F. Supp. 3d at 263-64 (noting "the Secretary cannot [] limit his review to only 'vulnerable individuals'").

The Secretary also claims the elimination of NEMT will promote the fiscal sustainability of the program, AR 6735-36, 6727, which fails for the reasons stated above. Furthermore, the record shows that Kentucky will actually *lose* money by eliminating NEMT. *See, e.g.*, AR 19991, 18602-03 (citing new study finding that NEMT results in "a total positive return on investment of over $40 million per month per 30,000 Medicaid beneficiaries," AR 20717-67), 16796. So the waiver of NEMT is nothing more than a "simple benefits cut." *Beno*, 30 F.3d at 1069.

2. The Secretary Could Not Have Reasonably Concluded that Kentucky HEALTH Would Further His Preferred Alternative Objectives for the Medicaid Program—Promoting Health and Financial Independence.

As discussed above, the Secretary's substituted objectives, including promoting beneficiary health and financial independence, are not appropriate objectives of the Medicaid Act. *See Stewart*, 313 F. Supp. 3d at 266 (pointing out that such a "focus on health is no substitute for considering Medicaid's central concern: covering health costs"); *id*. at 271 (expressing "doubts

whether such an objective [of promoting financial independence] is proper"). But even if the Secretary could have elevated these alternative objectives, he did not reasonably determine that Kentucky HEALTH was likely, on balance, to achieve them. The record shows that he, first, vastly overstated any health benefits that could possibly accrue, and, second, ignored the record evidence showing that the project will negatively impact the health and financial status of many people.

Overstated Possible Health and Financial Benefits. The Secretary did not reasonably conclude that Kentucky HEALTH will improve the health and financial status of individuals who satisfy the new eligibility requirements.

With respect to work requirements, the Secretary provides a simple causal argument: forcing people to work or volunteer will improve their health. *See* AR 6733. But the Secretary ignored the critical qualifications in the studies he cited to support this belief that commenters identified for him. *See, e.g.*, AR 12789-92, 14666-67, 16718-19, 17454-55, 19746-48, 19973-74, 20797-99. The research shows that job quality matters—unstable, low-wage work (often the only type of work Medicaid recipients can get) is associated with similar or even poorer health outcomes than no work at all. *See, e.g.*, AR 12790, 17454-545, 19746-47, 19973, 20805. Also, several studies discuss health selection effects—*i.e.*, healthier people are more likely to find work or volunteer. *See* AR 5052, 5392-409, 5054-58, 5386-91. Lastly, at least 15 commenters directed the Secretary to a new, comprehensive literature review noting these and other complications that undermine any claim of a simple causal relationship between work and health. *See, e.g.*, AR 11613 (comment 352145), 12918;[18] *see also* AR 25354. The Secretary did not acknowledge this evidence.[19]

[18] Citing Larisa Antonisse & Rachel Garfield, Kaiser Family Found., *The Relationship Between Work and Health: Findings from a Literature Review* (Aug. 2018), AR 19209-25.

[19] The Secretary cannot overcome his selective reading of the evidence by asserting that the literature is not "definitive[]" and therefore a "demonstration" is appropriate. AR 6733. The

But even if it were true that work always improves health outcomes, the Secretary could not rationally find that Kentucky HEALTH would meaningfully increase work and income. For instance, while commenters cited research showing that access to Medicaid helps people obtain and maintain work, rather than meaningfully address that research, the Secretary asserted that he "reviewed and considered the research cited." AR 6733. Of course, just "stating that a factor was considered is not a substitute for considering it." *Stewart,* 313 F. Supp. 3d at 259 (internal quote and alterations omitted). The Secretary also ignored substantial, longitudinal research from SNAP and TANF indicating that work requirements have failed to effectively promote work, while increasing poverty, financial insecurity, and even mortality. *See, e.g.*, AR 12791-93, 12961, 12970-71, 15484, 16720-23, 18181-82, 19349-50, 19963-68**,** 20002-03, 20169-70, 20265-66, 25354.[20] The Secretary likewise ignored evidence that voluntary employment support programs, which do not threaten coverage loss, have been effective at increasing employment for the small subset of Medicaid recipients who are not already working. *See, e.g.*, AR 12857, 14805, 17460, 19970-71, 20273.[21] The Secretary asserts that the various work "activities are . . . positive steps for

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presence of some uncertainty does not relieve the Secretary of his responsibility to examine the available evidence and adequately explain his decision.

[20] Commenters included the studies cited during the prior comment periods and new evidence directly refuting claims that work requirements are effective, including: Erin Brantley & Leighton Ku, *Work Requirements: SNAP Data Show Medicaid Losses Could Be Much Faster and Deeper Than Projected*, Health Affairs Blog (Apr. 12, 2018), AR 15496-505; Tazra Mitchell et al., Ctr. On Budget & Policy Priorities, *Life After TANF in Kansas: For Most, Unsteady Work and Earnings Below Half the Poverty Line* (2018), https://bit.ly/2Ft1K14; LaDonna Pavetti, Ctr. On Budget & Policy Priorities, *Work Requirements Don't Work* (2018), https://www.cbpp.org/blog/work-requirements-dont-work; LaDonna Pavetti, Ctr. On Budget & Policy Priorities, *Evidence Doesn't Support Claims of Success of TANF Work Requirements* (2018), https://bit.ly/2SRE4Hs; LaDonna Pavetti, *Evidence Counters CEA Claims on Work Requirements*, Ctr. on Budget & Policy Priorities Blog (July 30, 2018), AR 18742-43.

[21] Commenters included the studies cited during the prior comment periods and new evidence, including: Bureau of Business and Econ. Research, Univ. of Montana, *The Economic Impact of Medicaid Expansion in Montana* 3 (April 2018), https://bit.ly/2HtvBW9; Hannah Katch, Ctr. On

beneficiaries to take on their path to financial independence." AR 6733. This unsupported assertion alone, however, is insufficient. *See Beno*, 30 F.3d at 1075 (finding Section 1115 waiver arbitrary and capricious because there was no evidence "HHS gave any such thought to plaintiffs' objections or proposed alternatives").

With respect to premiums, the Secretary makes the implausible claim that requiring people to pay monthly premiums will improve their health outcomes. AR 6734. As support, the Secretary points to data from Indiana's Section 1115 project showing that individuals who paid premiums were "more likely to obtain primary care and preventive care, have better drug adherence, and rely less on the emergency room for treatment" than individuals who did not (but nevertheless remained enrolled in Medicaid). AR 6734-35 (citing The Lewin Group, *Indiana Health Indiana Plan 2.0: Interim Evaluation Report* (2016), AR 4850-961). However, the Secretary once again mistakes correlation for causation. *See Tex Tin Corp. v. U.S. E.P.A.*, 992 F.2d 353, 355-56 (D.C. Cir. 1993) (rejecting agency prediction where its reading of the studies "confuses correlation with causation"). Indiana's evaluation does not come close to suggesting that submitting premiums made enrollees healthier. Instead, it compares two disparate groups—enrollees who paid premiums and enrollees who did not—that differ in health status, income, and other demographic factors known to correlate with care utilization. *See, e.g.*, AR 4922. The evaluation does not control for these confounding factors, nor acknowledge that only the group that did not pay premiums was required to pay cost sharing for most services, which is known to reduce the use of services.

With regard to the redetermination and reporting lockouts, the Secretary declares that such lockouts "will strengthen beneficiary engagement in their personal health and provide an incentive

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Budget & Policy Priorities, *Promising Montana Program Offers Services to Help Medicaid Enrollees Succeed in the Workforce* (2018), AR 18851-55; Montana Dep't of Labor & Industry, *HELP-Link Program Update* (2018), https://bit.ly/2TRzKZd.

structure to support responsible consumer decision-making about maintaining health and accessing care and services" and, in support, points only to an evaluation of Indiana's Section 1115 project purportedly showing that "beneficiary engagement components . . . can have a positive impact on beneficiary behavior." AR 6724. But Indiana's project did not contain these kinds of administrative lockouts, so the evaluation cannot speak at all to their effectiveness in changing behavior or improving health outcomes. *See* AR 239-40, 4850-961. And there is no other substantial evidence in the record to suggest that these lockouts will in fact do that.

Finally, the Secretary suggests that the elimination of retroactive coverage will encourage people to enroll in Medicaid even when they are healthy, thereby encouraging them to seek preventive services and improving health outcomes. AR 06724. For the reasons discussed in Section II.A.1., *supra*, that implausible claim is simply not supported by the record. There is no conceivable way that making it more difficult for individuals to obtain necessary health services will promote health or financial independence.

Ignored Health and Financial Harms. As established above, the record confirms that many thousands of individuals will lose Medicaid coverage due to Kentucky HEALTH. The record also includes substantial, unrefuted evidence that this coverage loss will significantly harm the health and financial security of those individuals. *See, e.g.*, AR 12821, 12916-17, 13547, 19985-87, 26311.[22] Relatedly, comments explain that eliminating retroactive coverage in particular will

[22] Commenters included the studies cited during the prior comment periods and additional evidence, including: Kenneth Brevoort et al., Nat'l Bureau of Econ. Research, *Medicaid and Financial Health* (2017), AR 19876-941; Steffie Woolhandler & David U. Himmelstein, *The Relationship of Health Insurance and Mortality: Is Lack of Insurance Deadly?*, 167 Annals Intern Med. 424 (2017), https://bit.ly/2RpVf6B; Aaron Sojourner & Ezra Golberstein, Health Affairs, *Medicaid Expansion Reduced Unpaid Medical Debt and Increased Financial Satisfaction* (2017), https://www.healthaffairs.org/do/10.1377/hblog20170724.061160/full; Leighton Ku & Erika Steinmetz, *Bridging the Gap: Continuity and Quality of Coverage in Medicaid*, Association for Community Affiliated Plans (2013), https://bit.ly/2sq1FU6, and additional studies not before

increase medical debt and bankruptcy, and damage the already tenuous financial situation of many low-income Kentuckians. *E.g.*, AR 16723-24, 17464-65, 14067, 13173-74, 14041, 18210.

Without estimating the number of individuals who would lose coverage for failure to comply with the new eligibility requirements, the Secretary could not have grappled with the magnitude of the health and financial harm those individuals would suffer. Nor could he have weighed that harm against health benefits. Further, the research the Secretary cited to support his claim that work improves health does not, and could not, account for the harms that stem from the *penalty* the Secretary approved. That research derives primarily from European countries and Australia, where access to health coverage is nearly universal and thus excludes consideration of the harm from health coverage loss. *See* AR 4824, 5112, 5386. In fact, one report the Secretary relied on, *see* AR 6733, cautions that "interventions which simply force claimants off benefits are more likely to harm their health and well-being," AR 5152. But while comments alerted the Secretary to these warnings, *see, e.g.*, AR 19744-48, he ignored them. "It was arbitrary and capricious for [the Secretary] to rely on portions of studies in the record that support [his] position, while ignoring [portions] in those studies that do not." *Genuine Parts Co. v. EPA*, 890 F.3d 304, 313 (D.C. Cir. 2018).

Moreover, the record reveals that many individuals who do not lose coverage will still suffer negative health effects. For example, individuals with household income at or below 100% of FPL who do not pay their monthly premiums will have money deducted from their *My Rewards* account and then lose access to the account for up to six months. This means they will have no coverage for needed vision and dental services and will have to pay cost sharing for covered

mentioned at AR 14533-34, 18328-59, 19476-522, 19795-802, 19803-13, 19864-75, 22016-58, 12716-18, 14353-54, 14355-56, 16266-67.

services. *See* AR 18175, 14662-63, 17462-63, 12889-91, 21510-16 (highlighting the importance of vision and dental care to overall health), 18320, 19978, 20686 (citing redundant research concluding that cost sharing limits access to medically necessary care). Likewise, commenters explained—with citation to research—that eliminating NEMT will reduce access to medically necessary services. *See* Section II.A.1, *supra*. Nothing in the record indicates that the Secretary adequately considered the health or financial consequences of this benefits cut.

In sum, the Secretary did not reasonably weigh the largely speculative health benefits of Kentucky HEALTH (for individuals who manage to remain enrolled) against the well-documented health costs associated with the project. *See Am. Wild Horse*, 873 F.3d at 932 (agency must "adequately analyze . . . the consequences" of its action). Even assuming the Secretary properly determined the objectives of the Medicaid Act (and he did not), his decision was arbitrary and capricious because he ignored, oversimplified, or misconstrued the evidence in the record to reach a conclusion that, especially given the absence of any material difference between this approval and the approval this Court vacated, was evidently predetermined.

B. The Secretary Lacks the Authority to Approve Kentucky HEALTH.

Work Requirements. In allowing Kentucky to attach work requirements to Medicaid, the Secretary exceeded his authority under Section 1115. In Section 1115, Congress gave the Secretary only the narrow authority to "waive compliance" with certain provisions of the Medicaid Act. 42 U.S.C. § 1315(a). The term "waive" is unambiguous. It means "[t]o refrain from insisting on (a strict rule, formality, etc.); to forgo." *Black's Law Dictionary* (10th ed. 2014). It does not confer the authority to fundamentally modify, amend, or change statutory provisions. Yet as this Court previously has recognized, "Kentucky HEALTH . . . promise[s] to 'comprehensively transform' [Kentucky's] Medicaid program." *Stewart*, 313 F. Supp. 3d at 243. Authorizing a state to

comprehensively transform Medicaid by *creating* new, mandatory work requirements cannot be understood as a *waiver* of compliance with an existing condition or requirement of coverage under the Medicaid Act. *See Syed v. M-I, LLC*, 853 F.3d 492, 502 (9th Cir. 2017) ("To authorize is to 'grant authority or power to.' *American Heritage Dictionary* 120. To waive is to 'give up . . . voluntarily' or 'relinquish.' *Id.* at 1947. Authorization bestows, whereas waiver abdicates."), *cert. denied*, 138 S. Ct. 447 (2017).

Further, Section 1115 permits the Secretary only to "waive compliance" for a time-limited experiment that is "likely to assist in promoting the objectives" of the Medicaid Act. 42 U.S.C. § 1315(a). Again, as described in detail above, the central purpose of the statute is to provide medical assistance to low-income individuals; it does not encompass withholding that assistance from otherwise eligible people who do not meet a work requirement. The difference between the statutes governing the various safety net programs illustrates this point. TANF (which also is part of the Social Security Act) and SNAP expressly authorize work requirements; the Medicaid Act does not. *Compare* 42 U.S.C. § 607 (requiring states to ensure that most TANF recipients engage in "work activities" and that TANF benefits will be reduced or terminated if an individual does not) *and* 7 U.S.C. § 2015(d), (o) (requiring individuals to meet work requirements as a condition of participation in SNAP), *with* 42 U.S.C. § 1396a(a)(10) (requiring states to provide medical assistance to individuals who meet the criteria listed); *see also* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, 110 Stat. 2105 (amending eligibility criteria for SNAP, TANF, and Medicaid, but including work requirements in only SNAP and TANF). This difference shows that Congress knows how to include work requirements when it wants to, and it chose not to include them in Medicaid. *See Digital Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 777 (2018) ("When Congress includes particular language in one section of a statute

but omits it in another," it is "presume[d] that Congress intended a difference in meaning." (internal quotation marks omitted and alterations adopted)).

Moreover, Congress did not just include work requirements in SNAP and TANF—it prescribed detailed regimes outlining the nature of the requirements, including how they would balance against other congressional policy priorities, such as minimum wage and nondiscrimination protections. *See, e.g.*, 42 U.S.C. § 607 (detailing TANF work requirements, exemptions, and penalties for beneficiaries, and creating non-displacement protections for other workers); *id.* § 604a (addressing role of religious organizations and establishing nondiscrimination protections for contracting organizations and beneficiaries); 7 U.S.C. § 2029(a)(1) (directing SNAP benefit amounts to account for minimum wage laws). These detailed regimes demonstrate that the nature and scope of any work requirement is a decision left to Congress in the first instance.

Congress has had several opportunities to import the work requirements from Aid to Families with Dependent Children ("AFDC") and TANF into the Medicaid program, but has not done so. For example, the recently-adjourned 115th Congress unsuccessfully attempted to authorize states to implement work requirements. *See* American Health Care Act, H.R. 1628, 115th Cong., § 117 (2017) (failed proposal to amend § 1396a with the following: "a State may elect to condition medical assistance to a nondisabled, nonelderly, non-pregnant individual under this title upon such an individual's satisfaction of a work requirement"); Medicaid Reform and Personal Responsibility Act of 2017, S. 1150, 115th Cong. (2017) (failed proposal to amend § 1396a to require states to "condition medical assistance . . . upon . . . an individual's satisfaction of a work requirement."). In addition, when Congress repealed AFDC in favor of TANF in 1996, it amended Medicaid's Section 1396u to maintain consistency for certain joint TANF/Medicaid recipients, including by allowing states to terminate the Medicaid benefits of individuals—and only those

individuals—who had their TANF benefits terminated for failure to comply with TANF's work requirements. *See* 42 U.S.C. § 1396u-1(b)(3)(A). At that time, Congress could have amended the Medicaid Act to permit work requirements generally, but it did not. That is revealing. Where a statute "expressly describes a particular situation to which it shall apply, what was omitted or excluded was intended to be omitted or excluded." *Teles AG v. Kappos*, 846 F. Supp. 2d 102, 111 (D.D.C. 2012) (citation omitted); *see also Leatherman v. Tarrant Cty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993).

In sum, Section 1115 does not permit the Secretary to circumvent the will of Congress and transform Medicaid into a program designed to "incentivize" work. Nothing in Section 1115 suggests a broad agency authority for such a rewrite of Medicaid. "[H]ad Congress wished to assign that [authority] to [the] agency, it surely would have done so expressly." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (quoting *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014)). Congress does not implicitly, or in ancillary provisions, give agencies the authority to transform statutes. *See MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 231 (1994) (finding that "[i]t is highly unlikely that Congress would leave" an "essential characteristic" of the statutory scheme "to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' [statutory] requirements"); *Cyan, Inc. v. Beaver Cty. Emps. Ret. Fund.*, 138 S. Ct. 1061, 1071 (2018) ("Congress does not hide elephants in mouseholes." (internal quotation marks and citations omitted)).

The Secretary cannot change this basic fact by asking this Court for deference. As the Court has recognized, "during the 50-plus years of Medicaid," CMS has *never* "approved a community-engagement or work requirement as a condition of Medicaid eligibility. Instead, the agency has consistently denied these requests, finding that work requirements could undermine access to care

and were thus inconsistent with the purposes of Medicaid." *Stewart*, 313 F. Supp. 3d at 245 (internal quotation marks omitted).[23] The agency's prior interpretation of work requirements as outside its own Section 1115 waiver authority weakens any plea for deference here. *See United States v. Nat'l Ass'n of Sec. Dealers, Inc.*, 422 U.S. 694, 717 (1975). For these reasons, the Secretary lacks statutory authority to allow Kentucky to condition eligibility for Medicaid on work or the completion of work-related activities.

Premiums. The Medicaid Act contains two provisions—Section 1396o and Section 1396o-1—that prohibit states from imposing premiums on individuals described in Section 1396a(a)(10)(A) (*i.e.*, categorically needy groups) with incomes below 150% of FPL. The first, Section 1396o, prohibits states from charging enrollees an "enrollment fee, premium, or similar charge," except as permitted under Section 1396o(c). 42 U.S.C. § 1396o(a)(1). Subsection (c), in turn, allows states to impose premiums on specific categories of enrollees whose household incomes are above 150% of FPL. *Id.* § 1396o(c). The second, Section 1396o-1, also prohibits states from imposing premiums on enrollees with income below 150% of FPL. *See id*. § 1396o-1(b)(1)(A), (a)(2)(A). The Section 1115 waiver authority, however, extends only to waivers of Section 1396a, not Sections 1396o or 1396o-1. *See id.* § 1315(a)(1). As such, Section 1115 does

[23] *See* Letter from Sylvia M. Burwell, Sec'y U.S. Dep't Health & Human Servs. to Asa Hutchinson, Gov. Ark. (Apr. 5, 2016), *Gresham v. Azar*, No. 1:18-cv-00152 (D.D.C. Nov. 5, 2018); Letter from Andrew M. Slavitt, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs., HHS to Thomas Betlach, Dir. Az. Health Care Cost Containment Sys. (Sept. 30, 2016), http://bit.ly/2PHb0Ek; *see also* Letter from Vikki Wachino, Dir., Ctrs. for Medicare & Medicaid Servs., to Jeffrey A. Meyers, Comm'r, N.H. Dep't of Health & Human Servs., at 1 (Nov. 1, 2016), https://bit.ly/2f5lkRt. HHS also previously denied a work requirement request from Indiana. *See* CMS.Gov, *CMS and Indiana Agree on Medicaid Expansion* (Jan. 27, 2015), https://go.cms.gov/2QJt5hq (not approving work requirements). Other states withdrew their requests after HHS indicated that it would not grant them. *See* Kaiser Fam. Found., *Medicaid Expansion in Pennsylvania: Transition from Waiver to Traditional Coverage* (Aug. 3, 2015), https://www.kff.org/medicaid/fact-sheet/medicaid-expansion-in-pennsylvania.

not allow the Secretary to waive the premium and cost sharing limits. *See Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001) (Section 1115 "does not authorize [the Secretary] to waive . . . [§ 1396o's] requirement that Medicaid beneficiaries contribute no more than a 'nominal' amount to the cost of medical benefits they receive.").

The Secretary *acknowledges* that his Section 1115 authority is limited to waiving requirements in Section 1396a—a provision that contains no substantive limits on premiums. Nonetheless, he claims the authority to ignore Congress's crafted scheme for premiums and cost sharing by arguing that 42 U.S.C. § 1396a(a)(14) "incorporates Sections 1916 [1396o] and 1916A [1396o-1]." AR 06741. That is both textually wrong and wholly inconsistent with Congress's enactment of Sections 1396o and 1396o-1.

To begin, Section 1396a(a)(14) does not even reference Section 1396o-1, so it clearly cannot incorporate it. And while Section 1396a(a)(14) does refer to Section 1396o, the text, structure, and history of the Medicaid Act show that this reference does not incorporate Section 1396o into Section 1396a(a)(14) such that it can be waived pursuant to Section 1115.

As for the text, Section 1396o has its own separate demonstration waiver provision, Section 1396o(f), which is even more restrictive than Section 1115. *See* 42 U.S.C. § 1396o(f) (permitting waiver of cost sharing (*e.g.*, copayment) requirements only if, after public notice and comment, the Secretary finds that the proposed project will meet five tightly circumscribed criteria). What is more, Section 1396o(f) *explicitly provides* that "[n]o deduction, cost sharing, or similar charge may be imposed under any waiver authority of the Secretary," except as provided in Section 1396o and Section 1396o-1. *Id.* Congress did not include a provision in Section 1396o allowing the Secretary to waive the premium requirements. Thus, under the well-established interpretive canon, *expressio unius est exclusio alterius*, they are not waivable. *See Sebelius v. Cloer*, 569 U.S. 369,

378 (2013) (explaining and applying canon). Further, if the Secretary could use Section 1115 to waive the requirements in Section 1396o, then Section 1396o(f) would be superfluous.[24] *See, e.g.*, *Laurel Baye Healthcare of Lake Lanier, Inc. v. NLRB*, 564 F.3d 469, 472 (D.C. Cir. 2009) (noting that interpretations creating superfluity are disfavored). Moreover, Section 1396a(a)(14) states that premiums and cost sharing may be imposed "only as provided in section 1396o." 42 U.S.C. § 1396a(a)(14). This is the only place in Section 1396a where Congress uses the phrase "only as provided in." That unique language, combined with the more precise waiver authority of 1396o, indicates that Congress intended to place premiums and cost sharing outside the Secretary's Section 1115 authority.

The history and structure of Sections 1396a(a)(14) and 1396o make this intention clear. When Congress passed Medicaid in 1965, it allowed states to impose premiums and cost sharing on enrollees, as long as the amount was "reasonably related" to their financial situation. Social Security Act Amendments of 1965, Pub. L. No. 89-97, § 1902(a)(14), 79 Stat. 286, 346 (1965). In 1972, Congress amended Section 1396a(a)(14) to ensure that Medicaid remained affordable. It allowed states to impose premiums on enrollees who qualified through the optional "medically needy" category (but not the categorically needy). Cost sharing was prohibited for mandatory services provided to the categorically needy and limited to "nominal" amounts for optional services. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 208(a)(14)(A), 86 Stat. 1329, 1381 (1973) (codified at 42 U.S.C. § 1396a(a)(14) (1974)).

[24] Reading the statute to allow the Secretary to waive the requirements of Section 1396o would also produce an absurd result. The Secretary could conceivably permit states to impose premiums on individuals with household income below 100% of FPL (through a waiver of Section 1396o), but not on individuals between 100 and 150% of FPL (as independently prohibited by Section 1396o-1, which is not referenced in Section 1396a). Congress could not have intended such a bizarre and unjust outcome.

During the 1970s, two courts upheld the Secretary's Section 1115 authority to waive Section 1396a(a)(14) and allow states to impose heightened cost sharing. *See Crane v. Mathews*, 417 F. Supp. 532, 538-40, 543 (N.D. Ga. 1976); *Cal. Welfare Rights Org. v. Richardson*, 348 F. Supp. 491 (N.D. Cal. 1972). Congress responded in 1982 by removing the substantive provisions on premiums and cost sharing from Section 1396a(a)(14) and creating a new Section 1396o—outside of Section 1396a—to address premiums and cost sharing. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, 96 Stat. 324, 367. Significantly, Section 1396o imposes independent requirements on states.[25] *See* 42 U.S.C. § 1396o(a), (b) (stating "the State plan shall provide . . . .").

The legislative history of Section 1396o also confirms that Congress did not intend to incorporate Section 1396o into Section 1396a(a)(14); rather, Congress expressly intended for Section 1396o to insulate premiums and cost sharing from the Secretary's Section 1115 waiver authority. *See* H.R. Rep. No. 97-757, pt. 1, at 6 (1982) (noting that States have sought Section 1115 waivers for cost sharing and finding that "this bill gives the States sufficient flexibility in this regard to make further exercise of the Secretary's demonstration authority unnecessary").

Further, in the decades since 1982, Congress has consistently confirmed that the flexibility available to states with respect to premiums and cost sharing must come from Congress. Congress has amended the provisions on numerous occasions—each time establishing the substantive boundaries. *See* Omnibus Reconciliation Act of 1987, Pub. L. No. 100-203, § 4101(d)(1), 101 Stat. 1330, 1330-141 to -142 (authorizing premiums on pregnant women and infants with incomes over

[25] If Congress intended for Section 1396o to have no independent legal significance, but to flesh out Section 1396a, it would have at least referenced Section 1396a in Section 1396o. It was logical for Congress to keep Section 1396a(a)(14) as a cross-reference to Section 1396o—that ensured that Section 1396a remained an exhaustive list of all required state plan elements.

150% of FPL); Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6408(d)(3)(B), (C), 103 Stat. 2106, 2269 (codified at 42 U.S.C. § 1396o(d)) (authorizing premiums for certain working individuals with disabilities with incomes over 150% of FPL).[26]

As a result, Section 1396o painstakingly delineates the premiums and cost sharing states may charge to different groups of Medicaid recipients. It is hard to believe that Congress would go to the trouble of spelling out in detail exactly who can be charged and how much—all with an eye to "mak[ing] further exercise of the Secretary's demonstration authority unnecessary"—if the Secretary could come along and waive these carefully delineated restrictions altogether. *See* H.R. Rep. No. 97-757, pt. 1, at 6 (1982)*; see also Ross v. Blake*, 136 S. Ct. 1850, 1858 (2016) ("When Congress amends legislation, courts must presume it intends [the change] to have real and substantial effect." (internal quotations and citations omitted)); *Beno*, 30 F.3d at 1068-69 (noting that a legislative scheme with mandatory language and detailed requirements evidences congressional intent to take certain decisions away from states).

Heightened Cost Sharing for Non-Emergency Use of the ER. The Medicaid Act allows states to impose cost sharing on certain enrollees subject to clear limitations. *See* 42 U.S.C. §§ 1396o, 1396o-1; *see also* 42 C.F.R. § 447.51. For non-emergency use of the emergency room, states may charge individuals with household income below 150% of FPL twice the "nominal" amount, as set by regulation. 42 U.S.C. §§ 1396o-1(e), 1396o(a)(3), (b)(3); *see id.* § 1396o-1(e)(4)(A) (defining non-emergency services). The Secretary has set this amount at $8, subject to increases for inflation. 42 C.F.R. § 447.54(b).

[26] *See also* Ticket to Work and Work Incentives Act of 1999, Pub. L. No. 106-170, § 201(a)(3)(B), 113 Stat. 1860, 1893 (codified at 42 U.S.C. § 1396o(g)) (authorizing premiums or cost sharing on people with disabilities in ticket to work programs); American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 5006(a)(1)(B), 123 Stat. 111, 505 (codified at 42 U.S.C. § 1396o(j) (2012)) (prohibiting premiums for Native Americans).

The Kentucky HEALTH charge for non-emergency services violates these limits. The amounts Kentucky proposed—$20 for the first visit, $50 for the second, and $75 for subsequent visits—range from over two times to over nine times the amount allowed by law. AR 5463. Kentucky will assess these charges by deducting funds from enrollees' *My Rewards* accounts. The Secretary allowed the Commonwealth to do so without obtaining a waiver, stating "the *My Rewards* account deduction is not cost-sharing." AR 6736, 6765. But that is wrong.

The Medicaid Act broadly defines cost sharing to include "any deduction, copayment, or similar charge." 42 U.S.C. § 1396o-1(a)(3)(B), (e); *id.* § 1396o(a)(3). Thus, the text makes clear that Congress intended for the term cost sharing to capture various mechanisms states might use to impose financial consequences on enrollees for using services.

Although the Secretary contends that the *My Rewards* account contains "non-monetary credits" and "virtual credits," AR 6736, he cannot seriously contest that reducing the account balance has real, financial consequences for enrollees.[27] Under Kentucky HEALTH, the Commonwealth will no longer cover vision services, dental services, or over-the-counter medications for enrollees in the expansion population. Rather, enrollees are to use the "credits" in their *My Rewards* account to pay for these services. AR 6762, 6763-65. Any deduction from the *My Rewards* account leaves the enrollee with fewer funds available to pay for other necessary services, which means that many enrollees will be forced to pay out-of-pocket or forego them entirely. Consequently, while the Kentucky HEALTH charge is different from a traditional copayment (a payment to a health care provider that leaves the payer with less money available to him), the effect of the charge is identical.

[27] The Secretary is adamant that the *My Rewards* account does not contain money, but the "credits" in the account have a dollar-value equivalent, as enrollees may transfer money remaining in their deductible account at the end of the year directly into their *My Rewards* account. AR 6722, 6763.

Because the Kentucky HEALTH charge unquestionably constitutes a "deduction, copayment, or similar charge" under the Medicaid Act, the Secretary exceeded his authority in approving the policy.[28] To hold otherwise would permit states to skirt the limits on cost sharing by simply devising a novel way to indirectly charge enrollees for the use of services.

III. The Dear State Medicaid Director Letter Violates the Administrative Procedure Act.

On January 11, 2018—one day before CMS issued its first approval of Kentucky HEALTH—the agency released a Dear State Medicaid Director Letter (the "SMD Letter") that announced a new policy of allowing states to condition Medicaid coverage on work or community engagement. AR 90-99. Not only is the new policy arbitrary and capricious, CMS failed to follow the notice-and-comment procedures required under the APA for a substantive rule, which is what the SMD Letter implements. *See* 5 U.S.C. § 553(b), (c). Thus, the SMD Letter separately violates the APA and must be vacated.

A. The SMD Letter's Authorization of Work Requirements is Arbitrary and Capricious and Exceeds Statutory Authority.

The SMD Letter violates the APA's ban on arbitrary and capricious action. In the Letter, CMS did not provide any logical reasoning to conclude that work requirements advance the objectives of Medicaid, failed to discuss alternatives to work requirements for achieving its objectives, and insufficiently explained the agency's about-face from its longstanding stance against work requirements.

[28] The Secretary could waive the cost sharing requirements only by meeting the detailed conditions in Section 1396o(f)(1)-(5). Even if the Secretary had attempted to do so, he could not have approved the request under the first factor (requiring a unique and previously untested use of cost sharing) or the third factor (requiring a benefit to recipients that is reasonably expected to be equivalent its risks). *See, e.g.*, AR 19996-97, 3747-48, 3832 (citing studies finding that cost sharing for non-emergency use of the emergency room does not reduce visits among Medicaid enrollees).

First, the SMD Letter ignores the central purpose of Medicaid—the provision of medical assistance to low-income people—in pursuit of the administration's preferred goals of promoting health and financial independence. *See* Section I, *supra*. What is more, the Letter provides inadequate support for the conclusion that work requirements promote those alternative objectives. Like the Kentucky HEALTH re-approval letter, the SMD Letter focuses on the possible health benefits of work, while ignoring the obvious health and financial consequences associated with withholding or terminating health insurance coverage for individuals who do not work. AR 91-92. Indeed, for the reasons described in Section II.A.2, *supra*, none of the "authorities" cited in the SMD Letter (which are the same as those cited in the re-approval letter) addresses work *requirements* or come close to supporting them.

Second, CMS failed to mention even a single alternative course of action the agency considered. "[F]ail[ure] to provide any explanation for [the agency's] implicit rejection of alternatives . . . or to consider such alternatives" is arbitrary and capricious. *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 815 (D.C. Cir. 1983). Although the SMD Letter acknowledges that, in the past, the agency sought to capture any salutary effects from work and community engagement by supporting state programs like "job training and work referral," it does not explain why that approach was ineffective. AR 91. To be sure, an agency need not consider and explain "every alternative device and thought conceivable by the mind of man." *State Farm*, 463 U.S. at 51 (internal quotation marks omitted). But nowhere in the SMD Letter does CMS weigh any of the many obvious and compelling alternatives to the authorization of work requirements. *See Donovan*, 722 F.2d at 817 (finding agency action arbitrary and capricious where agency failed to consider options "specifically mentioned" to the agency or that were "an obvious

response"). "[S]uch an artificial narrowing of options is antithetical to reasoned decisionmaking and cannot be upheld." *Id.* (internal quotation marks omitted).

Third, CMS failed to discharge its "duty to explain why it deemed it necessary to overrule its previous position" on work requirements. *Navarro*, 136 S. Ct. at 2126. The SMD Letter reverses HHS's prior position that "the Secretary does not have the authority to permit a state to require Medicaid beneficiaries to work." Sylvia Burwell, Sec'y of Health & Human Servs., Hearing on The President's Fiscal Year 2017 Budget, Attachment—Additional Questions for the Record, U.S. House of Rep. Energy & Commerce Health Subcomm. at 13 (Feb. 24, 2016), http://bit.ly/2QcKnEi.; *see also* n. 23, *supra*. Although the APA does not bar an agency from reversing course, *see Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1043 (D.C. Cir. 2012), when an agency does so it must candidly weigh the relevant factors, including the "facts and circumstances that underlay or were engendered by the prior policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009). The agency must also "set forth with such clarity as to be understandable" why it is changing course. *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). That is true even when the White House changes hands. *See, e.g.*, *Clean Air Council v. Pruitt*, 862 F.3d 1, 8-9 (D.C. Cir. 2017).

Here, CMS did not adequately explain its about-face. The Letter offers only the vague and unsupported claim that imposing work requirements "is anchored in historic CMS principles that emphasize work to promote health and well-being." AR 92. Yet Defendants do not identify those principles or explain why they support *conditioning* health coverage on satisfying work requirements. Moreover, the studies cited in the SMD Letter all predate agency decisions to reject work requirements as fundamentally incompatible with the Medicaid Act, so Defendants cannot contend that new information supported the change in position. *Compare* AR 91 nn.3-9, *with supra*

n.23 (noting prior CMS decisions). Likewise, the fact that CMS "has long assisted state efforts to promote work and community engagement and provide incentives" for individuals to work does not explain the agency's decision to convert policies that support and incentivize Medicaid enrollees to work into policies that withhold Medicaid coverage if individuals are not working sufficient hours. AR 91. Defendants' decision to "simply disregard" the agency's earlier, long-held rationale confirms they did not undertake a reasoned analysis of the complex issues at stake or consider the impact of the policy reversal. *Fox*, 556 U.S. at 515. Thus, CMS's decision to authorize work requirements in the SMD Letter, was arbitrary and capricious.

B. The SMD Letter Imposes a Substantive Rule Without the Requisite Notice and Comment Procedures.

The SMD Letter also violates the APA's procedural requirements of notice and comment. The APA mandates notice-and-comment rulemaking before any substantive rule (also known as a legislative rule) can take 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). There is no dispute Defendants did not go through notice-and-comment procedures before issuing the SMD Letter. Because the Letter announces a substantive rule that cabins CMS's discretion, drives its outcomes, and alters the regulatory framework, the lack of notice and comment independently invalidates the Letter.

An agency's statement qualifies as a substantive rule, and thereby requires notice-and-comment rulemaking, if 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). To make this determination, courts look at whether the "language" in the agency's statement "strongly suggests that [the agency] will treat the [statement] as a binding norm," and, even "[m]ore critically," whether the agency's "later conduct applying [the statement] confirms its binding character." *Id.* at 1320-21. The key inquiry is "whether the substantive effect

is sufficiently grave so that notice and comment are needed to safeguard the policies underlying the APA." *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec. (EPIC)*, 653 F.3d 1, 5-6 (D.C. Cir. 2011). The SMD Letter clearly meets this test.

First, the language of the Letter shows that it "constrains the agency's discretion" and is thus a rule of present, binding effect. *McLouth*, 838 F.2d at 1320. The Letter "announc[es] a new policy"—"support [for] state efforts" to add work requirements to their Medicaid programs—and sets out numerous conditions that states must meet to obtain CMS approval. AR 90. The Letter phrases these conditions in binding terms, stating that state applicants "will be required" to make various showings to win agency approval and "will not be permitted" approval unless they meet certain standards. AR 93, 96-98. For example, the SMD Letter says "States must also create exemptions for individuals determined by the state to be medically frail[.]" AR 94. This kind of "mandatory, definitive language" is a "powerful, even potentially dispositive, factor" in identifying a substantive rule. *Community Nutrition Instit. v. Young*, 818 F.2d 947 (D.C. Cir.1987); *see also 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"); *McLouth*, 838 F.2d at 1320-21 ("The use of the word 'will' suggests the rigor of a rule, not the pliancy of a policy.")

Second, the agency has confirmed in its application of the SMD Letter that the Letter has binding effect. *See McLouth*, 838 F.2d at 1320-21; *see also Texas v. United States*, 809 F.3d 134, 173 (5th Cir. 2015) ("[A] rule can be binding if it is 'applied by the agency in a way that indicates it is binding.'" (quoting *Gen Elec.*, 290 F.3d at 383)), *aff'd by an equally divided court*, 136 S. Ct. 2271 (2016). In CMS's initial approval of Kentucky HEALTH, the January 12, 2018 approval letter expressly relied on "the parameters set out in the [SMD] letter," and used this reliance on the

Letter to avoid providing any meaningful response to the public comments that "questioned the efficacy of work requirements." AR 8-9. The re-approval letter again relies on the parameters set out in the SMD Letter, simply choosing not to explicitly refer to the Letter this time around. As reasons for its re-approval of Kentucky HEALTH, CMS discusses various components of the project that the agency deems mandatory in the SMD Letter. For example, the re-approval letter notes that Kentucky HEALTH "provides exemptions" for certain "vulnerable beneficiaries," AR 6734, as is required in the Letter. AR 94-95. Thus, Defendants have deemed the SMD Letter controlling by invoking it or its requirements in their decisions to approve.

Moreover, Defendants' implicit reliance on the SMD Letter in this case is not an isolated occurrence. Since its issuance, the policies established in the Letter have driven each outcome the agency has reached on a request to impose work requirements. In approving an Arkansas program with work requirements, the agency explained, "CMS is approving the community engagement program based on our determination that it is likely to assist in promoting the objectives of the Medicaid program" because its terms and conditions "are consistent with the guidance provided to states through [the SMD Letter]." *See* Letter from Seema Verma to Asa Hutchinson, Governor of Arkansas (Mar. 5, 2018), https://bit.ly/2FFkcnT. The agency's approval of Indiana's application was even more explicit. It justified approval of work requirements based on the fact that the "terms and conditions of Indiana's community engagement requirement that accompany this approval are aligned with the guidance provided to states through [the SMD Letter]." Letter from Demetrios Kouzoukas, Principal Dep. Admin., Ctrs. For Medicare & Medicaid Servs., HHS, to Allison Taylor, Medicaid Dir., Ind. Family & Soc. Servs. Admin. (Feb. 1, 2018), http://bit.ly/2EZcMfO.

As this Court has explained, the SMD Letter replaces a decades-old policy against work requirements with "a new commitment" to support state efforts to implement work requirements

and promulgates criteria to reach that result. *Stewart*, 313 F. Supp. 3d at 245-46. Through the SMD Letter, and under the guise of "guidance," the Secretary has transformed Medicaid from medical coverage for the poorest among us to a work program with health coverage on the side—all without Congressional action or authorization. This action has undermined the very purposes of the Medicaid program, affecting hundreds of thousands of Kentuckians and millions of Medicaid recipients across the nation. The SMD Letter plainly does more than "clarify a statutory or regulatory term, remind parties of existing statutory or regulatory duties, or 'merely track[]' preexisting requirements and explain something the statute or regulation already required." *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (citation omitted). It "effects a substantive regulatory change to the statutory or regulatory regime." *EPIC*, 653 F.3d at 6 (internal quotation marks omitted). Because the APA requires notice and comment before promulgating such substantive changes, the SMD Letter must be vacated.

IV. The Secretary's Approval of the Kentucky HEALTH Waiver and the SMD Letter Should Be Vacated.

Because the Secretary's action violates the APA, the Kentucky HEALTH re-approval and SMD Letter should be vacated. "When a court concludes the agency action violates the APA, 'the practice of the court is ordinarily to vacate the rule.'" *Stewart*, 313 F. Supp. 3d at 272 (quoting *Ill. Pub. Telecomms. Ass'n v. FCC*, 123 F.3d 693, 693 (D.C. Cir. 1997)); *see also Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) ("[V]acatur is the normal remedy."). In the first round of this litigation, the Secretary nonetheless argued that any remand should be without vacatur. But, as this Court already has recognized, nothing about this case warrants a departure from the default rule favoring vacatur. *Stewart*, 313 F. Supp. 3d at 273-74. For remand without vacatur to be justified, the Court must consider "the seriousness of the deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim

change that may itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). Here, neither of those factors weighs against vacatur.

With respect to the first factor, courts "have not hesitated to vacate a rule when the agency has not responded to empirical data or to an argument inconsistent with its conclusion." *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009). As explained above, the Secretary's approval of Kentucky HEALTH suffers from "major shortcomings," including his failure to address the important effects of the program and his decision to "turn[his] back on the implications" of the program. *Humane Soc'y of the U.S. v. Zinke*, 865 F.3d 585, 614-15 (D.C. Cir. 2017). The deficiencies in the Secretary's approval thus are serious, substantive, and cannot be explained away. Moreover, the deficiencies in the Secretary's waiver approval are "not merely procedural; rather . . . the agency acted outside of the scope of its statutory authority." *Children's Hosp. Ass'n of Tex. v. Azar*, 300 F. Supp. 3d 190, 211 (D.D.C. 2018). Where the Secretary has misinterpreted the statute, including the scope of his waiver authority, or "neglected to consider one of Medicaid's central objectives," "vacatur [is] appropriate." *Stewart*, 313 F. Supp. 3d at 273.

As for the second factor—the disruptive consequences of vacatur—that consideration is "weighty only insofar as the agency may be able to rehabilitate its rationale for the regulation." *Comcast*, 579 F.3d at 9. For reasons Plaintiffs have described, the re-approval cannot be rehabilitated and, therefore, the Court need not reach the second factor. *See Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs*, 282 F. Supp. 3d 91, 97 (D.D.C. 2017). But even if the Court were to consider this factor, it plainly weighs in favor of vacatur. Previously, Defendants have suggested that Medicaid recipients in Kentucky might have their coverage terminated altogether if the waiver is invalidated, but the prospect that Kentucky would terminate the expansion at this point is highly speculative and legally questionable. "[F]orcasted harms [that] are imprecise or

speculative" do not warrant "departure from the presumptive remedy of vacatur." *Pub. Emps. for Envtl. Responsibility v. U.S. Fish & Wildlife Serv.*, 189 F. Supp. 3d 1, 3 (D.D.C. 2016); *see also Standing Rock*, 282 F. Supp. 3d at 107. By contrast, allowing the approval to remain in effect will indisputably disrupt access to health insurance coverage and medically necessary care for tens of thousands of Medicaid enrollees. Vacatur will leave the status quo in place.

Finally, the SMD Letter should be vacated because the agency failed to comply with the APA's notice-and-comment requirements. "[D]eficient notice is a 'fundamental flaw' that almost always requires a vacatur." *Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 20 (D.D.C. 2017); *id.* ("When notice-and-comment is absent, the Circuit has regularly opted for vacatur."); *see also Daimler Trucks N. Am. LLC v. EPA*, 737 F.3d 95, 103 (D.C. Cir. 2013). Nothing about the circumstances of this case warrants departure from that established practice.

CONCLUSION

For the reasons above, Plaintiffs respectfully ask the Court to vacate the approval or, in the alternative, sever and vacate the aspects of the waiver approval that exceeded the Secretary's authority and/or vacate and remand the aspects of the waiver approval that lacked evidentiary support. Plaintiffs also ask the Court to enjoin the SMD Letter as a rule that was not properly promulgated under the APA.

Dated: January 14, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2019, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send an electronic notice to all authorized CM/ECF filers.

By: /s/ Jane Perkins
Jane Perkins