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.	

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BRIEF FOR DEANS, CHAIRS AND SCHOLARS AS *AMICI CURIAE*
IN SUPPORT OF PLAINTIFFS

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CORPORATE DISCLOSURE STATEMENT

Amici are individuals and as such do not have a parent company and no publicly held company has a 10 percent or greater ownership interest in any *amici*.

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INTEREST OF *AMICI CURIAE*

Pursuant to Local Civil Rule 7(o), *amici* have sought leave for filing the instant brief. *Amici* are researchers and academics who are experts in the fields of health law, health policy, health services research, and national health reform. They seek to inform the Court about the history of Section 1115 of the Social Security Act, the essential elements of Medicaid demonstration evaluation, the validity of the assumptions on which Defendants' actions rest, and the likely effects of permitting Defendants' actions to continue to take effect in Kentucky. Given the scope of Defendants' actions upon vacatur and remand in this case, and that they have authorized or will authorize similar activities in other states, *amici* believe this case provides an appropriate vehicle for the Court to find that Defendants' actions are contrary to federal law.

No party or counsel for a party authored this brief in whole or in part. No party, counsel for a party or any other person contributed money that was intended to fund preparing or submitting the brief.

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STATEMENT

In *Stewart v. Azar*, this Court concluded that Defendants' approval of the Commonwealth of Kentucky's (the "Commonwealth") original demonstration project proposal pursuant to Section 1115 of the Social Security Act ("Kentucky HEALTH" or the "Demonstration Project") did not take into consideration "the project['s] impact on the individuals whom Medicaid was enacted to protect." 313 F.Supp.3d 237, 265 (D.D.C. 2018); *see also* 42 U.S.C. § 1315 (setting forth the Secretary's § 1115 waiver authority). Consequently, the Court vacated the Secretary's approval of Kentucky HEALTH, remanding the proposal to the agency. *See* Dkt. 73. On remand, the Centers for Medicare & Medicaid Services ("CMS") conducted a thirty-day public comment period addressing (i) the Commonwealth's original proposal dated August 24, 2016, (ii) the Commonwealth's revised proposal dated July 3, 2017, and (3) the special terms and conditions ("STCs") that Defendants approved on January 12, 2018. *See* CMS, KENTUCKY HEALTH – APPLICATION AND CMS STCS (last visited Jan. 11, 2019). The comment period closed on August 18, 2018. On November 20, 2018, Defendants reapproved Kentucky HEALTH, subject to certain minor adjustments. The basic contours of the Demonstration Project, however, remain untouched. *See* Joint Status Report, Dkt. 84, ¶¶ 1-3 (Dec. 14, 2018); Letter from Paul Mango, CMS Chief Principal Deputy Administrator and Chief of Staff to Carol H. Steckel, Commissioner, Kentucky Department for Medicaid Services (Nov. 20, 2018) (*attaching* Expenditure Authority, Waiver List *and* STCs), AR 6862-7137 (hereinafter the "Approval Letter").[1]

Once again, the Court is asked to review whether the Secretary has exceeded his authority in approving Kentucky HEALTH, an experiment that threatens to strip hundreds of

[1] Administrative record ("AR") citations refer to the record on remand unless otherwise noted.

thousands of beneficiaries of Medicaid coverage with no realistic alternative in sight. Moreover, contrary to the plain statutory terms, Defendants' approval of Kentucky HEALTH utterly lacks the necessary indicia of experimentation. *See* 42 U.S.C. § 1315(a). This is not what Congress envisioned when it permitted experiments under § 1115. *See id.* Congress authorized the Secretary to test improvements in Medicaid by waiving certain requirements for demonstration projects that "promote[] the objectives of the program," and by expending funds in ways not ordinarily permissible under federal law. *Id.* As discussed below, despite an additional public comment period and adjustments to the original STCs, the administrative record (the "Record") shows that, once again, the Secretary has not "adequately consider[ed] the effect of any demonstration project on the State's ability to help provide medical coverage." *Stewart*, 313 F.Supp.3d at 272 (emphasis in original). Consequently, the Court must again vacate the Defendants' approval of Kentucky HEALTH.

ARGUMENT

The purpose of Medicaid is to provide medical assistance to people whose income and resources are insufficient to pay for the cost of necessary care. *See* 42 U.S.C. § 1396-1. The Patient Protection and Affordable Care Act of 2010 (the "ACA"), Pub. L. 111-148, extended medical assistance to "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); *see* 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII) (extending Medicaid coverage effective January 1, 2014 to the "expansion population"). States may choose not to cover the ACA expansion population. *Nat'l Fed'n of Indep. Bus.*, 567 U.S. at 587. However, as this Court held, "if the state decides to provide coverage, those individuals become part of its mandatory population" and "the state must afford the expansion group 'full benefits' – i.e., it must provide 'medical assistance for all

services covered under the State plan that are substantially equivalent 'in amount, duration, or scope … to the medical assistance available for [other] individual[s] covered under the Act.'" *Stewart,* 313 F.Supp.3d at 244 (*citing* 42 U.S.C. § 1396d(y)(2)(B), 42 C.F.R. § 433.204(a)(2) and *Jones v. T.H.*, 425 U.S. 986 (1976)). There is no authority, demonstration or otherwise, that empowers Defendants to sidestep the purpose of Medicaid: to provide medical assistance.

In January 2018, Defendants issued a State Medical Directors Letter (the "SMDL"), inviting states to submit Medicaid "community engagement" "demonstration" proposals. *See* Original AR 90-99. Defendants dramatically reversed their long-standing position that mandatory Medicaid work requirements do not promote Medicaid objectives without notice and comment and after states, such as Kentucky, had submitted demonstration project proposals to impose work requirements. The letter also promoted other coverage restrictions, such as premiums and punitive "lock-out" periods, that could bar coverage to beneficiaries for months at a time.

Kentucky HEALTH, along with a host of similar demonstration proposals approved by Defendants, will lead millions to lose Medicaid under untested conditions designed to drive people off the program – a blatantly political agenda that is directly counter to Medicaid's purpose.[2] To support its agenda, Defendants fabricated entirely new "purposes" of the Medicaid

[2] Defendants approved work requirements and other eligibility conditions in amendments to existing demonstrations in Arkansas, Indiana, Michigan, New Hampshire and Wisconsin. Defendants also approved a new demonstration in Maine. Some of these demonstrations may launch in 2019 or 2020. *See* Letter from Seema Verma, CMS Administrator to Stefanie Nadeau, Director, Office of MaineCare Services (Dec. 21, 2018); Letter from S. Verma to Kathy Stiffler, Acting Director, Michigan Department of Health and Human Services (Dec. 21, 2018); Letter from S. Verma to the Hon. Asa Hutchinson, Governor of Arkansas (March 5, 2018); Letter from Demetrios Kouzoukas, CMS Principal Deputy Administrator to Allison Taylor, Indiana Medicaid Director (Feb. 1, 2018); Letter from S. Verma to Henry D. Lipman, New Hampshire Medicaid Director (May 7, 2018); Letter from S. Verma to Casey Himebauch, Wisconsin Deputy Medicaid Director (Oct. 31, 2018). Other states have pending work "demonstration"

Act – to encourage work or "community engagement" and to prepare beneficiaries for the private health insurance market (regardless of whether they would actually obtain the financial resources to afford private coverage) – that have no bearing on Medicaid's legitimate purpose. To do so, Defendants ignored or mischaracterized both crucial research to support its unproven theory and comments in the Record addressing the health risks the Demonstration Project would create. Defendants' approval of Kentucky HEALTH is therefore arbitrary and capricious and contrary to law.

As discussed below, this reapproved iteration of Kentucky HEALTH still reflects the bizarre logic of Defendants' earlier SMDL letter: Medicaid's purpose is to improve health by denying people the very aid for which they qualify. For example, Defendants asserted, without explanation or evidence, that Medicaid work requirements, coupled with other eligibility barriers, create "appropriate" incentives for achieving gainful employment and a transition to private insurance. Along the way, Defendants also misrepresented Medicaid's other key goal of helping people with disabilities attain or retain capability for independence or self-care, using this distinct goal instead to justify experiments that will deny coverage to a large swath of the working-age beneficiary population. Defendants further asserted, without evidence, that the affected population will gain income and access to affordable private insurance coverage as a result. *See* Approval Letter at 8; AR 6869. However, Defendants cited no authority to support

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applications, including Alabama, Arizona, Kansas, Mississippi, Ohio, South Dakota, Utah and Virginia. *See* KAISER FAMILY FOUNDATION, *Medicaid Waiver Tracker: Which States Have Approved and Pending Section 1115 Medicaid Waivers*? (Sept. 28, 2018); *see also* James Romoser, *CMS Approves Medicaid Expansion in Virginia; Enrollment to Start Nov. 1*, IWP NEWS (Oct. 18, 2018). CMS denied North Carolina's attempt to implement a Medicaid workforce development program. Letter from S. Verma to Dave Richard, North Carolina Deputy Secretary for Medical Assistance (Oct. 19, 2018) at 5-6 (State legislature has not approved program).

their assertion that part time work, "community engagement," or other conditions to maintain Medicaid eligibility, raise personal income, provide access to employer insurance, or enhance health outcomes. In fact, all available data contradicts Defendants' assertion. For instance, in 2017, only four percent of Kentucky part-time employees in low-wage firms were eligible for employer-sponsored insurance (2.6 percent in small firms). Anuj Gangopadhyaya et al., *Kentucky Medicaid Work Requirements: What Are the Coverage Risks for Working Enrollees?*, Urban Institute (Aug. 2018). In short, Defendants failed to explain how a requirement to get a part-time job or perform volunteer activities would create opportunities to replace Medicaid coverage with affordable employer health insurance. Simply, Defendants' approval of Kentucky HEALTH does not meet the requisite standard.

As noted, Defendants presented no evidence that there would be substantial gains in private health insurance coverage to offset the loss of Medicaid coverage. Data from the U.S. Census Bureau's American Community Survey permits a comparison of Kentucky's health insurance coverage rates between 2013, before its Medicaid expansion, and 2017 (the most recent year available). U.S. CENSUS BUREAU, AMERICAN COMMUNITY SURVEY (TABLES HI05, 2013 AND 2017). Between 2013 and 2017, the percent of Kentuckians under age 65 with Medicaid coverage rose from 19.0 percent to 29.4 percent. By contrast, there was virtually no change in private health insurance coverage: 64.1 percent in 2013 to 65.1 percent in 2017. Even though Kentucky's unemployment rate fell from eight percent in 2013 to 4.9 percent in 2017, there was almost no improvement in private insurance coverage that might offset the loss of Medicaid coverage. *See* U.S. Bureau of Labor Statistics, *Annual Average Statewide Unemployment Data*.

The inquiry before the Court requires a review of the Record to assess whether the Secretary fulfilled his legal responsibility to examine "'the impact of the state's project' on the individuals whom Medicaid 'was enacted to protect.'" *Stewart*, 313 F.Supp.3d at 265 (internal citation omitted). Once more, "'the record contains rather a stunning lack' of discussion about the effect of Kentucky HEALTH on health coverage." *Id*. at 263 (*quoting Beno v. Shalala*, 30 F.3d 1057, 1074 (9th Cir. 1994)). Again, for the reasons discussed below, vacatur is warranted.

I. The Secretary's reapproval of Kentucky HEALTH failed to provide any evidence that the Demonstration Project can fulfill its stated goals.

Defendants offer no new evidence that imposing multiple barriers to Medicaid will promote access to private insurance, foster more stable and continuous enrollment, or bolster the use of preventive care. Like the administrative record that Defendants relied upon in approving the original Kentucky HEALTH project, the new Record contains no empirical evidence to support these assertions. Indeed, Defendants appear to be unfamiliar even with readily available evidence regarding the effects of work requirements on income over time or the dramatically limited extent to which employers offer insurance to part-time, low-wage workers.

Defendants claimed repeatedly that the Demonstration Project will allow the Commonwealth to experiment with ways to improve "beneficiary health and financial independence" by requiring beneficiaries to "work, look for work, or engage in activities that enhance their employability." Approval Letter at 2, 6-7; AR 6863, 6867-6868. Defendants offered no empirical evidence to support the notion that imposing a community engagement or work requirement on Medicaid participation (i) assists beneficiaries in finding and keeping work, (ii) raises personal incomes sufficiently to make private coverage affordable, or (iii) promotes access to employer coverage. Notably, Defendants also do not offer evidence that they considered less punishing alternatives than suspending or terminating Medicaid coverage to

those beneficiaries who are unable to meet the work and reporting requirements or who could not otherwise comply with the Demonstration Project's other restrictions.

In the Approval Letter, Defendants repeat their claims that many elements of the experiment will prepare people for the commercial insurance market and reduce gaps in coverage. Approval Letter at 5; AR 6866. However, Defendants failed to provide any support for the assertion that charging premiums, reaching as high as four percent of family income (which exceeds what is permitted for the poorest Marketplace enrollees); eliminating non-emergency transportation; eliminating retroactive eligibility; and imposing disqualification periods (lockouts) for failing to report changes in status, sufficient work hours, or engage in timely redeterminations will "encourage more individuals to seek preventive care," will test whether "beneficiaries will be encouraged to obtain and maintain health coverage" or will achieve a "reduction in gaps in coverage." Approval Letter at 7; AR 6868. Further, Defendants approved the Demonstration Project without ensuring that their claims will be properly tested by an objective, robust, and high-quality evaluation with the ability to collect and analyze evidence from a representative population sample, as is required by the Medicaid Act. *See, e.g., Beno*, 30 F.3d, *supra* at 1069 (noting that Secretary must assess whether the experiment is "likely to yield useful information").

Defendants claimed that the adjusted STCs include separate "on-ramp" opportunities to overcome disqualification by paying catch-up premiums or permitting beneficiaries to provide information they previously failed to furnish. Approval Letter at 8; AR 6869. Defendants also asserted that these "on-ramps" will help mitigate harm to the experimental population. But the Demonstration Project's "on-ramps" are narrowly constructed and Defendants clarified that recovery of benefits due to non-payment of premiums can happen only once during a twelve-

month period. Approval Letter at 8; AR 6869. Defendants offered no evidence regarding how frequently beneficiaries whose incomes are tied to part-time, hourly jobs with fluctuating wages could experience income loss serious enough to put premium payments at risk in a given year, or why a single annual "on-ramp" is sufficient. *But see* Anuj Gangopadhyaya et al., *Kentucky Medicaid Work Requirements: What Are the Coverage Risks for Working Enrollees?*, Urban Institute (Aug. 2018). Nor did Defendants offer evidence as to how many beneficiaries will be able to resume payments and pay back amounts owed.

Finally, Defendants asserted that the experiment is "designed to lead to higher quality care at a sustainable cost" because its terms will promote "health and wellness." Approval Letter at 9; AR 6870. However, the record does not support this claim. In fact, Defendants' claim flies in the face of extensive, readily available evidence regarding Medicaid's positive impact on access to, and use of, high-value, cost-effective care such as cancer screening or immunizations. Larisa Antonisse *et al.*, *The Effects of Medicaid Expansion Under the ACA: Updated Findings from a Literature Review* (March 2018).

II. The Secretary's reapproval of Kentucky HEALTH did not adequately consider properly conducted research contradicting the Demonstration Project's hypotheses.

Past experience with work requirements in assistance programs shows that such requirements should be voluntary, focused on a younger and healthier population, and adequately resourced to offer proper education, training, and employment supports in order to succeed. *See* Leighton Ku et al., *Medicaid Work Requirements; Will They Help the Unemployed Gain Jobs or Improve Health,* Commonwealth Fund (Nov. 6, 2018). The Demonstration Project's work requirements ignored these considerations. Further, comparisons between work requirements in the Supplemental Nutrition Assistance Program ("SNAP") and those Defendants approved in

Medicaid are inapposite for two reasons. First, SNAP typically includes funding to support job training and other employment assistance. However, Defendants bar the use of Medicaid funds for work or job supports, presumably because such expenditures are contrary to program purposes. *See* SMDL at 7 ("[T]his demonstration opportunity will not provide states with the authority to use Medicaid funding to finance these services [(i.e., job training or other employment services, child care assistance, transportation or other work supports)] for individuals."); Original AR at 96. Second, by placing the burden on the states to implement such job training and employment services, § 1115 waivers, such as the Demonstration Project, will likely overwhelm state resources, leaving Medicaid beneficiaries (as well as those who will be removed from the program) without sufficient support to find and maintain work.

Further, SNAP work requirements are imposed only on a limited population – adults ages 18-49 years old without dependent children. Kentucky HEALTH's work and community engagement requirement, on the other hand, covers all adults ages 18-64 except for very narrow exemptions. The Demonstration Project permits the Commonwealth to reach deep into the near-elderly population despite readily-available evidence that, by the age of fifty-five, seventy-percent of low income people report being in fair to poor health compared to half of the non-low income population. *See* Sara Rosenbaum et al., *Medicaid Work Demonstrations: What Is at Stake for Older Adults?*, Commonwealth Fund (Mar. 19, 2018). How can work improve health for an impoverished 60-year-old affected by multiple health conditions?

Paradoxically, evaluations of Medicaid expansion, including a survey conducted by the University of Michigan, demonstrated that the Medicaid expansion is associated with better use of health care and employment growth. Specifically, the Michigan study found that the Medicaid expansion more than doubled the use of preventive care rates (eighty-five percent post-

expansion compared to forty percent pre-expansion), halved foregone needed care – a major leap in access to care in the right place (i.e., a doctor's office rather than an emergency department) – and led to a growing number of beneficiaries reporting physical and mental health improvement. Most strikingly, this evaluation reported that, among the twenty-eight percent of respondents who were out of work, more than half reported that having Medicaid made it more possible to look for work. *See* University of Michigan, Institute for Healthcare Policy and Innovation, *Healthy Michigan Voices*, *Findings from a survey of Healthy Michigan Plan enrollees* (June 2018). Furthermore, among employed beneficiaries, sixty-nine percent reported that Medicaid helps them work better. *See* Renuka Tipirneni et al., *Changes in Health and Ability to Work Among Medicaid Expansion Enrollees: A Mixed Methods Study*, Journal of General Internal Medicine (Dec. 5, 2018). Defendants chose to ignore the Michigan study and ample research evidence showing Medicaid's positive impact on work, health care, and health outcomes, preferring instead to pursue experiments to test the baseless claim that threat of Medicaid coverage loss could improve work prospects.

III. The Secretary's reapproval of Kentucky HEALTH willfully ignored the harm that will befall Kentucky's Medicaid beneficiaries.

Defendants attempted to undercut the number of beneficiaries who stand to lose coverage (data that already is part of the record, *see Stewart*, 313 F. Supp. 3d at 265), failed to independently assess the Commonwealth's estimates of the number of beneficiaries who will lose Medicaid coverage, and portrayed a vast loss of coverage as something that merits no particular consideration. Approval Letter at 13-15; AR 6874-6876. First, Defendants tried to dispute the estimate that 95,000 people stand to lose coverage by the fifth year of the Demonstration Project, which figured into the Court's decision. *See* Dkt. 74. Defendants claimed that commenters "appear to misunderstand" Kentucky HEALTH. Approval Letter at

13; AR 6874. To illustrate this claim, Defendants offered an absurd explanation, stating that the Commonwealth's estimate simply showed "5 percent fewer member months than would have been covered without the demonstration project," even though the number of member months projected to be lost under the waiver is equivalent to 95,000 members losing coverage over the span of the five-year demonstration. Approval Letter at 13-14; AR 6874-6875. Defendants then asserted that even if the loss of 95,000 beneficiaries is technically accurate, it does not mean that "95,000 will completely lose coverage" since this figure does not include beneficiaries "transitioning to commercial coverage." Approval Letter at 14; AR 6875. Defendants go so far as to suggest that people losing coverage simply may be choosing not to continue with Medicaid. Defendants make this statement with no evidence and without an objective evaluation to accompany implementation.

Moreover, Defendants also tried to justify the number by stating that the loss represents total loss from all of Kentucky HEALTH's components. This, of course, is beside the point, since Defendants argued, and the Court agreed, that the Secretary's approval needs to be considered as a whole, and not in its component parts. *Stewart*, 313 F.Supp.3d at 270 (the Secretary "must thus evaluate the effect of Kentucky HEALTH on all Medicaid recipients…and he must do so without prioritizing certain groups over others…." (emphasis in original)). Plaintiffs are not challenging only the work requirement, but the total effects of Kentucky HEALTH, which, as Defendants concede, will drive enrollment down. Approval Letter at 14; AR 6875. Researchers at the George Washington University estimate that the Demonstration Project, as approved, could lead to Medicaid coverage losses ranging between twenty-six and forty-one percent of those required to comply with the work requirements, or between 86,000 and 136,000 of the roughly 331,000 Medicaid-eligible adults that could be affected by the new

work requirements, in the first year, rather than gradually over five years, as the Commonwealth estimated. It also notes that this is the number expected to lose coverage because of the work requirements, rather than for reasons such as moving away, changes in age or income, or simply failing to reapply. *See* Leighton Ku and Erin Brantley, *Updated Estimates of the Effects of Medicaid Work Requirements in Kentucky,* GW Health Policy Matters, The George Washington University (Revised Jan. 8, 2019).

As noted above, Defendants offered no fact-based estimates of how many beneficiaries will attain commercial coverage through work, job training, or volunteer services, nor did Defendants estimate how many beneficiaries might avoid loss of coverage by enrolling in substance abuse treatment, which may help their health but offers no pathway to commercial insurance. This Court already pointed out the lack of any nexus between commercial insurance and such activities, *Stewart*, 313 F. Supp. 3d at 264, and Defendants have cited no new studies that would establish such a nexus. In fact, research shows that low wage jobs at twenty hours per week are unlikely to yield either commercial coverage or income sufficient to afford private marketplace coverage. *See, e.g.,* Medicaid and CHIP Payment and Access Commission, *Work as a Condition of Medicaid Eligibility: Key Take-Aways from TANF* (Oct. 2017); *see also* MaryBeth Musumeci and Julia Zur, *Medicaid Enrollees and Work Requirements: Lessons from the TANF Experience,* Kaiser Family Foundation (Aug. 2017).

Defendants further tried to undercut the effect of Kentucky HEALTH's downward impact on enrollment by stating that the Commonwealth's initial estimates did not include the "guardrails" (or "on ramps") included in the adjusted STCs. Defendants appear to have forgotten that they described these "on ramps" narrowly. Approval Letter at 14; AR 6875.

Further Defendants did not judge these "guardrails" independently, nor did they evaluate whether there was basis to claim that the "guardrails" would mitigate harm.

Finally, Defendant attempted to reframe the loss of nearly 95,000 beneficiaries. Rather than a loss, following their logic, the reduction in beneficiaries is simply a slightly lesser version of the ACA adult Medicaid expansion, similar to other states such as Indiana or Michigan, that initially expanded under more limited experimental conditions sanctioned by § 1115 waivers. In this version of reality, Kentucky simply is being allowed to test the Medicaid expansion under alternative terms and it should be permitted since the Medicaid expansion is optional. The Demonstration Project simply offers a means of preserving at least a limited expansion. Approval Letter at 12, 15 (claiming that 95,000 lost beneficiaries is outweighed by 454,000 adults who stand to lose coverage if the Commonwealth terminates the optional expansion); AR 6873, 6876.

These claims have no basis in law or fact. First, as the Court pointed out in this action, Kentucky HEALTH extends at least to some "traditional" adult recipients, not just the Medicaid expansion population. *Stewart,* 313 F. Supp. 3d at 268-269. Any assertion that this is simply a modified Medicaid expansion is false on its face. Second, tying the Medicaid expansion to work requirements was not an experimental option in 2014, nor did the Commonwealth have any interest in doing so then. Five years later, Defendants cannot simply reinvent the history of Kentucky's Medicaid expansion and the enormous, positive impact it has had on access to essential health care; nor can they simply declare that these 95,000 people are some sort of nullity – that they do not exist because this is simply a modified Medicaid expansion. These are real people who will suffer real consequences. By the Commonwealth's own estimates, 95,000

Medicaid beneficiaries will lose coverage over five years – a figure *amici* believe substantially understates the true impact and the time period over which this loss will occur.

Third, Defendants seek to evade the legal limits of § 1115 by speculating about the future. In fact, there will be no automatic coverage rollback if Kentucky HEALTH does not proceed because the terms set forth in the Commonwealth's "New Adult Group" Medicaid State Plan Amendment would continue to control as a matter of federal law. *See* Letter from Jackie Glaze, Associate Regional Administrator, CMS Div. of Medicaid & Children's Health Operations to Lawrence Kissner, Commissioner, Kentucky Dept. for Medicaid Services (Jan. 10, 2014) (*attaching* Kentucky State Plan Amendment 13-020). As this Court pointed out, rather than eliminate coverage for some half million people, the Commonwealth might look to alternative savings strategies that preserve Kentucky's access to substantial federal financial participation in Medicaid through the ACA. *See* Stewart, 313 F.Supp.3d at 271 (noting the federal government's ninety percent share of expansion costs starting in 2020). Threatening to hold hundreds of thousands of people hostage unless nearly twenty percent can be pushed off the program is not merely inhumane, but it ignores the legal safeguards that apply when the government attempts experiments that threaten assistance essential to health.

Defendants also argued that this is a low-burden demonstration that is easily achievable and, at worst, may result in some short-term losses until people grow accustomed to the new requirements or simply opt out of maintaining Medicaid coverage. Approval Letter at 12-14; AR 6873-6875. Having resorted to § 1115 to justify approval of Kentucky HEALTH, the Secretary must satisfy the applicable statutory terms and require a reasonably considered experiment. To claim that the new burdens on eligibility are somehow *de minimis* because their impact may be

"temporary" does not cut it, especially since the Record is devoid of any evidence from which the Secretary could reasonably infer the loss of coverage in fact will be "temporary."

Moreover, Defendants minimized evidence of the potential for serious error, without offering any explanation or evidence to show why the Demonstration Project's requirements are easy to comply with or that the Commonwealth will implement Kentucky HEALTH in a way that eliminates errors. Defendants' tack is to simply point out that there is always the potential for "clerical errors" in removing people who are still eligible, but that this is no reason to deny approval. Approval Letter at 15; AR 6876. This argument fails because § 1115 waivers are based on experimental authority and are not simply state plan administration as usual. If the design cannot be implemented without significant error, there is a compelling reason not to test it in a program with the objective to provide medical assistance to qualified individuals.

Finally, Defendants asserted that it is normal for people to cycle on and off Medicaid and that this experiment simply is more of the same. Approval Letter at 12-13; AR 6873-6874. But Defendants offered no evidence to the effect that enrollment losses will stay within ordinary bounds. Furthermore, Defendants did not dispute that, under its impact requirements, a state must present estimates of impact *as a result of its experiment*. That is, the estimates required of Defendants are of additional losses beyond the normal fluctuation owing to Medicaid "churn." That, indeed, is the entire point of the impact estimate rules – to gauge the effect of the experiment and anticipate its impact on conditions as they would exist in the absence of the experiment.

IV. The Secretary's reapproval of Kentucky HEALTH violated the Medicaid Act because the Secretary failed to ensure that an objective, thorough evaluation of the Demonstration Project was in place.

The reapproval of Kentucky HEALTH cannot pass muster given that Defendants have not acted consistent with the experimental authority set forth in § 1115. In the new STCs, the Commonwealth is given 180 calendar days after approval of the Demonstration Project to submit a draft evaluation design for Defendants' comment and approval. In other words, the initial design of the Demonstration Project's evaluation will be presented for Defendants' consideration only after the demonstration begins, when it would be impossible to develop essential baseline data. Approval Letter, STC 82 at 57; AR 7078. As discussed below, even the Medicaid and CHIP Payment and Access Commission ("MACPAC"), the advisory body charged with advising Congress on all aspects of the Medicaid program, cautioned the Secretary of the perils of launching implementation of work and reporting requirements without an evaluation design in place. This substantive and procedural flaw will leave the agency, the Commonwealth, and all stakeholders without objective evidence of the underlying causes for enrollment decline. This will not do.

Consistent with applicable decisions, the Record must show the basic methodological soundness of the experiment. *See, e.g.*, *Newton-Nations v. Betlach*, 660 F.3d 370 (9th Cir. 2011) (Medicaid) *and Beno*, 30 F.3d 1057 (Aid to Families with Dependent Children). The Demonstration Project must produce valuable information that could lead to program improvements, facilitate "true research data[,] and serve interests beyond state fiscal concerns." *Recent Case: Ninth Circuit Holds Statutory Waivers for Welfare Experiments Subject to Judicial Review,* 108 HARV. L. REV. 1208, 1212 (1995). "[T]he Secretary must make at least some inquiry into the merits of the experiment-she must determine that the project is likely to yield

useful information or demonstrate a novel approach to program administration." *Beno*, 30 F.3d at 1069. Moreover, "[t]he Secretary's second obligation under *Beno* is to 'consider the impact of the state's project on the' persons the Medicaid Act 'was enacted to protect.'" *Newton-Nations*, 660 F.3d at 381. In the absence of a true experimental design, the risks are confusion, contamination of research findings, and additional hardship to people who depend on the program. Like all sound experimentation, the Demonstration Project must yield new knowledge, be methodologically sound, and benefits should outweigh risks.

Defendants did not require Kentucky to submit even a proposed evaluation design before allowing the Commonwealth to launch requirements that will affect coverage for tens of thousands of beneficiaries. Their Approval Letter required Kentucky to perform an evaluation by an independent party and to submit an evaluation plan. *See* Approval Letter, STCs 81 and 82 at 56-57; AR 7077-7078. However, waiver authority under § 1115 is not a license to run alternative Medicaid programs. It is a special grant of authority to conduct an experiment. As a result, allowing a massive reduction in enrollment without an operating evaluation that can capture baseline data renders the approval arbitrary, capricious, and contrary to law. *Generally, see* Gov't Accountability Office, GAO-18-220, MEDICAID DEMONSTRATIONS: EVALUATIONS YIELDED LIMITED RESULTS, UNDERSCORING NEED FOR CHANGES TO FEDERAL POLICIES AND PROCEDURES (Feb. 20, 2018) (citing Defendants' poor record of Section 1115 research oversight and failure to produce evaluation results).

V. The Secretary's reapproval of Kentucky HEALTH ignored readily available evidence from the State of Arkansas that imposing work requirements causes significant harm to Medicaid beneficiaries.

It is striking that the Secretary approved the Demonstration Project despite considerable evidence that the reporting requirements approved Arkansas's demonstration, which are similar

to those that the Secretary approved in Kentucky HEALTH, have caused substantial Medicaid coverage loss in Arkansas. Notably, numerous studies estimated that the losses in Arkansas's Medicaid enrollment would be significantly lower than the losses that are actually occurring in the State. *See* Leighton Ku and Erin Brantley, *Medicaid Work Requirements, Who's At Risk?*, Health Affairs Blog (Apr. 12, 2017); Rachel Garfield and Robin Rudowitz, *Understanding the Intersection of Medicaid and Work*, Kaiser Family Foundation (Jan. 5, 2018). In fact, through January 7, 2019, a total of 18,164 beneficiaries have lost Medicaid coverage due to failing to meet work and reporting requirements since they were implemented in Arkansas in June 2018. *See* Robin Rudowitz et al., *Year End Review: December State Data for Medicaid Work Requirements in Arkansas*, Kaiser Family Foundation (Jan. 17, 2019). The Secretary simply opted to ignore these warnings in approving the Arkansas demonstration and in reapproving Kentucky HEALTH.

The actual experience of Arkansas enrollees and providers under that State's demonstration project also underscores the unreasonableness of approving these types of demonstrations. The Kaiser Family Foundation recently conducted a focus group survey of Medicaid enrollees and providers in Arkansas to gauge their experience with the new program, which, despite being anecdotal, provides significant insight into the on-the-ground effects of Arkansas's on-going § 1115 demonstration. MaryBeth Musumeci *et al.*, *Medicaid Work Requirements in Arkansas: Experience and Perspectives of Enrollees*, Kaiser Family Foundation (Dec. 2018). As expected from a demonstration launched without either an evidentiary basis or sufficient safeguards, the focus group participants reported administrative obstacles navigating the compliance and reporting process. Furthermore, participants reported that the new requirements did not provide any additional incentive to work beyond mere economic pressures

which already existed prior to program implementation. Many of the participants were already employed but worked uncertain and unpredictable hours that made it difficult to comply with the program's eighty-hour monthly requirements. Those who were working reported being in jobs that either did not offer health insurance or that offered health insurance that was prohibitively expensive.

The provider-participants reported that Arkansas's demonstration would have the most significant effect on the most vulnerable of Arkansas's enrollees, those suffering from mental and physical limitations and possibly even homelessness, who nonetheless do not qualify for a medical frailty or other exemption. According to the providers, these enrollees were the most likely to face barriers complying with the new requirements and thus the most likely to lose Medicaid coverage.

These findings corroborate the projections of readily available studies and articles that warned of the inevitable detrimental effects of such a program. Several months into Arkansas's demonstration, it is clear that these concerns expressed prior to implementation are unfortunately coming to fruition. There is nothing inherent in Kentucky HEALTH to suggest that enrollee experience in the Commonwealth would differ in any significant way from the experience of enrollees in Arkansas.

Furthermore, and perhaps the best evidence that Defendants had ample warning of expected harm, is a letter sent to the Secretary by the MACPAC. The letter, dated November 8, 2018, asked the Secretary to pause disenrollment in Arkansas due to evidence that the recent large coverage losses in the State resulted from a failure in the reporting system and not to enrollee failure to work or seek work. Letter from Penny Thompson, MACPAC Chair to Alex Azar II, Secretary, U.S. Department of Health and Human Services (Nov. 8, 2018).

MACPAC states that "the low level of reporting is a strong warning signal that the current process may not be structured in a way that provides individuals with an opportunity to succeed with high stakes for beneficiaries who fail." *Id*. at 1. As a result, a pause in disenrollment is needed "in order to make program adjustments to promote awareness, reporting, and compliance." *Id*. MACPAC explicitly calls attention to the fact that "there was not an approved evaluation design in place at the time of implementation." *Id*. at 2. MACPAC "is concerned whether the state and [CMS] will be able to interpret early experience and evaluate progress.. . ." *Id*. The Commission goes on to note the absence of time for people to learn the new system, the absence of job supports, and the reliance on online reporting increase the likelihood of erroneous disenrollment.

If MACPAC has gone on the record calling for a freeze in an existing demonstration, it is not a stretch to argue that it is not sound decision making to launch a second demonstration affecting about twice as many people in the target population. The Secretary owed a legal obligation to act in a reasoned fashion pursuant to the Administrative Procedure Act. *See* 5 U.S.C. § 706(2); *Stewart*, 313 F.Supp.3d at 249. Acting in a reasoned fashion in this context would mean not pursuing more experiments in yet more states and thereby risk harm to tens of thousands, if not hundreds of thousands, more beneficiaries before understanding why the losses are of such a greater magnitude than projected at the initial site.

Proof enough that Defendants see the harms that await those losing coverage under Kentucky HEALTH appears in STC 47(k) at 42 (AR 7063), which explicitly instructs the Commonwealth to give people losing their Medicaid coverage information on how they may obtain free or low-cost medical care at federally qualified health centers that operate pursuant to Section 330 of the Public Health Service Act, 42 U.S.C. § 254b. Defendants rely on health

centers to cushion the impact of this demonstration without pausing to understand how disenrollment losses due to implementation of Kentucky HEALTH will impact health centers.

In 2017, Kentucky health centers provided medical services to 461,552 persons, including 215,773 Medicaid beneficiaries. This Demonstration Project may cause between fourteen and twenty-three percent of total Medicaid-enrolled health center patients to lose coverage, with an estimated revenue loss between $24 and $37 million, a six to ten percent total revenue loss. Moreover, this could in turn lead to as much as a ten percent staffing loss, or 196 to 309 less health center employees, and a reduced service capacity of 28,842 to 45,481 patients (a six to ten percent reduction in patient capacity). *See* Peter Shin et al., *Updated Impact Estimates Show that Kentucky's Medicaid Work Experiment Could Cause as Many as Four in Ten Adult Medicaid Patients Served by Health Centers to Lose Coverage – and Up to a Ten Percent Decline in Total Patient Care Capacity*, GW Health Policy Matters (Jan. 10, 2019). Defendants' addition of this explicit duty of the Commonwealth to warn tens of thousands of beneficiaries about how they can obtain health care when they lose their Medicaid benefits underscores Defendants' awareness that this demonstration threatens public health and that it will cause significant disruptions in medical coverage with no ready pathway to commercial insurance and no roadmap out of poverty and hardship.

CONCLUSION

This Court vacated Defendants' original approval of Kentucky HEALTH due to the Defendants' "sleight of hand" in proclaiming a new purpose of Medicaid yet turning a "blind eye" to Medicaid's principal purpose of providing medical assistance. Some months later, and fresh out of an additional public comment period, the Secretary still has not made a considered decision about the coverage impact of the Demonstration Project. He has never determined how

much of the coverage impact would be mitigated through safeguards or through access to alternative coverage (e.g., marketplace individual plans or employer coverage). He has never made a considered judgment regarding how improvements in health would offset the loss of health insurance. "At bottom the record shows that 95,000 people would lose Medicaid coverage, and yet the Secretary paid no attention to that deprivation." *Stewart* at 265. In short, the Secretary still has not conducted the analysis necessary for proper exercise of § 1115 authority. Therefore, the Defendants' reapproval of the Commonwealth's Demonstration Project is arbitrary, capricious, and contrary to law.

For the foregoing reasons, this Court should vacate the Defendants' reapproval of Kentucky HEALTH.

Respectfully submitted,

Dated: January 18, 2019

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Local Civil Rule 7(o). This brief consists of twenty-two (22) pages of text, exclusive of the Table of Contents, Table of Authorities, Attorney identification and Certificate of Compliance, and contains two (2) footnotes containing twenty (20) aggregate lines of text.

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CERTIFICATE OF SERVICE

I hereby certify that on January 18, 2019 I caused the foregoing document to be served on the parties' counsel of record electronically by means of the Court's CM/ECF system.

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