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Fulfilling States' Duty to Evaluate Medicaid Waivers

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exist but are not widely disseminated. For example, the Cleveland Clinic, Texas Children's Hospital, and other institutions have had every physician undergo formal training in communication skills.

The next step is measuring processes and outcomes, which requires agreement on metrics or appropriate surrogates. The research underpinning EBM suggests that "soft" outcomes are often the important ones and can be measured rigorously even when they're variable. If trust is the foundation on which clinician–patient relationships are built, for example, we have work to do in measuring it. Because improvement is important, measurement should be done in real time so that clinicians can respond nimbly, and the outcomes from multiple perspectives (such as patients, families, and other clinicians) should be captured.

The third step is enabling interpersonal medicine, which requires developing matchmaking protocols that predict stronger relationships, so we can pair clinicians and patients for success, creating environments that reduce anxiety and foster interaction. It also requires instituting service standards, best practices, and tools that encourage productive dialogue. For example, Dell Medical School's clinics have no waiting rooms. Patients are shown directly to a room that is designed primarily to accommodate conversation among the patient, family members, and the clinicians who will visit them. No exam table is in sight; a chair converts to an exam table when necessary.

The final step is creating incentives for interpersonal medicine, both financial and nonfinancial. This step is fraught with political hazards but could accelerate improvement. It requires rating and benchmarking clinicians on the basis of outcomes, relationships, and understanding and moving beyond productivity as a primary value indicator. It requires asking patients and caregivers to contribute to those ratings, and transparency in the form of their internal and external publication. Ultimately, transparency is the most effective way to celebrate and recognize humanistic skill in parity with scientific accomplishments.

None of these elements are unattainable: some solutions have already been proposed and (inconsistently) instituted, if not in medicine, then in adjacent or analogous fields. This effort is not about addressing lack of knowledge, but about building systemic capability at a scale that mirrors our scientific effort. We can pursue an empathetic version of medicine that embraces emotion and appreciates behavior if we value human nature as much as human biology.

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Fulfilling States' Duty to Evaluate Medicaid Waivers

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Nearly 75 million U.S. residents have health insurance coverage through Medicaid. Benefits and program designs vary from state to state. One source of state-based variation is Section 1115 projects, which are defined as "experimental, pilot, or demonstration" programs that are "likely to assist in promoting the objectives" of the Medicaid statute. States seeking to implement experimental policies in their Medicaid programs must apply to the Centers for Medicare and Medicaid Services (CMS) for a Section 1115 waiver, which lifts certain federal regulations for 5 years. Thirty-seven states had active Section 1115 waivers as of October 31, 2018 (see map),[1] and more than one third of Medicaid spending goes toward Section 1115 programming.[2]

Section 1115 waivers are becoming more consequential as CMS considers allowing states to implement policies that were disfavored by prior administrations. Foremost among these policies are community engagement requirements, which mandate that nondisabled, nonpregnant adults meet monthly quotas for time engaged in work, volunteer activities, or school to maintain their Medicaid coverage.[3] Other proposed waiver terms include beneficiary premiums with coverage lockouts

for people who do not pay, premium surcharges for tobacco use, elimination of retroactive eligibility, lifetime limits on coverage (which were rejected by CMS this year), drug screening and asset testing for beneficiaries, expansion of substance use treatment, elimination of nonemergency medical transportation services, and incentives or benefits tied to engagement in healthy behaviors.[1]

Many commentators have considered the legality of proposed waiver terms.[4] We believe that another important consideration is the legal, ethical, and practical imperative of conducting rigorous evaluations when CMS grants Section 1115 waivers for untested policies. Many proposed waiver terms have never previously been implemented in Medicaid programs, and their effects on beneficiaries' health are unknown. Every Section 1115 project is an experiment, and robust evaluations are essential in order for such experiments to yield useful lessons for Medicaid program design.

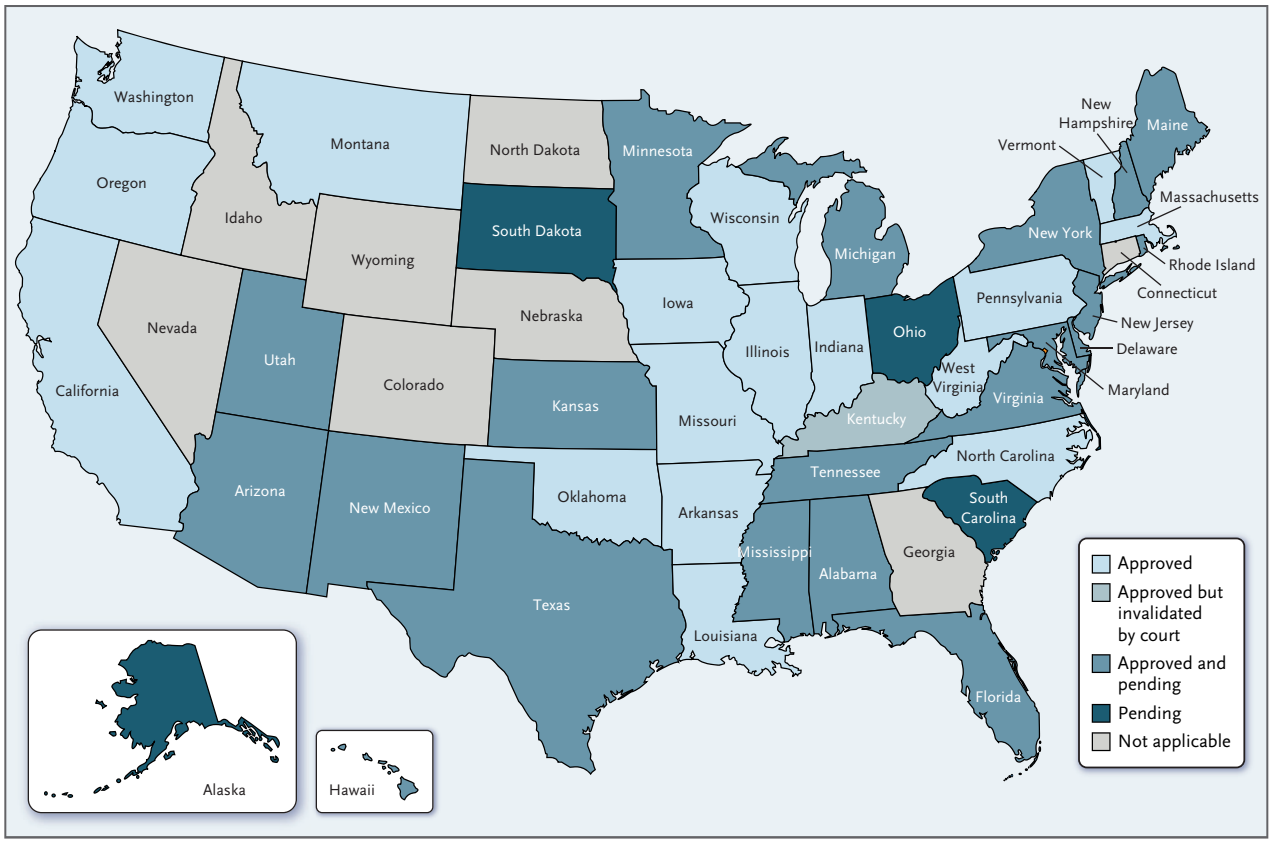
Although states have long studied their Section 1115 projects, in recent years federal requirements have changed the scope of those evaluations. States are now required to evaluate their demonstrations, and CMS mandates the use of independent evaluators.[2] Evaluators work with states to submit protocols to CMS, and research is jointly funded by states and CMS. The Affordable Care Act added to these requirements, mandating public posting of evaluation hypotheses, designs, timelines, and results. States applying for waiver renewals submit evaluation reports, which must include data on outcomes related to insurance coverage, access to care, quality of care, and beneficiary satisfaction.

Many evaluations of Section 1115 projects, however, have had little impact on policy. The Government Accountability Office has noted striking methodologic deficiencies in prior evaluations — including lack of comparison groups, insufficient sample sizes, failure to test key hypotheses, and selective reporting of outcomes — in part because of insufficient funding for this research.[2] Reports have been delayed for years after waiver cycles, which limits their usefulness to CMS, as well as to other states considering similar projects. CMS has revised expectations regarding evaluation independence and methods,[2] but often past Section 1115 waivers have taught policymakers little about what works.

New evaluations should break from these precedents. In states where waivers have already been approved, we believe that evaluators should identify and test states' health promotion goals. And when new waiver policies are proposed, CMS should urge states to incorporate randomized, controlled trials into their evaluations. Although health policy trials are rare, past examples — such as the RAND cost-sharing study and the Oregon Health Insurance Experiment, which evaluated a Section 1115 project — have contributed substantially to public understanding of the effectiveness of the policy innovations tested.[5] Section 1115 projects already expose Medicaid beneficiaries to risks and benefits in the name of experimentalism, and they spend public funds with the promise of advancing Medicaid's goals over the long term. Using rigorous study designs to evaluate these projects will ensure that they yield useful lessons.

Designs used in prior evaluations of Section 1115 projects, such as before-and-after comparisons and difference-in-differences analyses incorporating data from multiple states, have had many limitations. Medicaid and the individual insurance market both undergo frequent legislative and regulatory changes that confound before-and-after comparisons. As Section 1115 waivers proliferate, there is also no guarantee of having a stable, appropriate comparison group. For example, Kentucky was the first state to receive approval for a Section 1115 waiver permitting community engagement requirements, although the waiver is currently blocked by a federal court decision. Neighboring states that expanded Medicaid — including Indiana, Ohio, Illinois, and West Virginia — could theoretically serve as controls in an evaluation of Kentucky's demonstration if it moves forward. But Indiana recently received approval for a similar waiver, and Ohio's waiver application is pending, making use of these states as comparators problematic. States that incorporate randomization into the rollout of their Section 1115 projects will have rigorous evaluations regardless of other states' choices.

Incorporating randomization into Section 1115 projects may prompt several concerns. One is related to administrative capacity: states using a randomized trial to evaluate a new program must implement a different version of Medicaid for each study arm. But in fact states already provide different benefits to different statutory classes of beneficiaries. For example, recent Section 1115 waivers focus on people covered under Medicaid expansion but exempt other beneficiaries, such as those who are pregnant, elderly, or medically frail. States implementing these waivers already have the necessary infrastructure to facilitate



Section 1115 Medicaid Waiver Status, by State.

Adapted from the Kaiser Family Foundation.[1] Waiver status shown was current as of October 31, 2018.

exemptions. A randomized, controlled trial would use this existing capacity and extend exemptions to a randomly selected control group.

A second concern involves the ethical issue of equipoise: is there sufficient uncertainty regarding how the waiver will affect beneficiaries as compared with the existing program? Under federal regulations, research that is subject to approval by a federal agency head, and that is "designed to study, evaluate, improve, or otherwise examine public benefit . . . programs," is exempt from the requirements for review by an institutional review board. When CMS reviews a Section 1115 waiver application, the Medicaid statute asks the agency to consider the potential benefits and to approve only waivers that are likely to advance program goals. Once CMS grants approval for a new waiver policy, all eligible beneficiaries in the state are exposed to the terms of the waiver. This approach has no ethical advantage over randomization; instead, it exposes a larger number of beneficiaries to the risks and benefits of an untested policy and it strips waivers of their intended purpose — testing the effects of new Medicaid terms.

A third concern relates to the many methodologic choices involved in designing randomized, controlled trials. States and their evaluators must decide whether to study the effects of a waiver as a whole or individual waiver terms, how to define units of randomization (e.g., counties, households, or individual beneficiaries), how to address participant consent and compensation for new data collection, and how to conduct analyses. These choices may be daunting, but they are surmountable with evaluation expertise.[5] They are also less formidable than the analytic challenges involved in identifying appropriate control groups for nonrandomized evaluations. If states establish robust study designs at the outset, evaluations will have payoffs for the duration of Section 1115 demonstrations and for other states considering similar waiver terms.

States and CMS can also strengthen evaluation designs by using mixed methods to assess untested policies. Quantitative analyses should include prespecified hypotheses and sample sizes that provide enough statistical power for two-tailed tests, whereas qualitative methods can help researchers understand beneficiaries' and providers' experiences with new

programs. Combining these insights can help explain key findings, illuminate unanticipated effects, and clarify self-reported outcomes such as quality of life.

Many new Section 1115 waiver policies are controversial, which raises the stakes for postapproval evaluations. Waiver policies are also diffusing rapidly; as states exchange ideas, their evaluations should establish a knowledge base for Medicaid policy choices. Section 1115 waivers rely on experimentalism, and the model of states as laboratories can best fulfill this commitment by producing meaningful evidence of the effects of experimental programs. For untested waiver policies, we believe that CMS and states should take "experimentalism" literally and harness the rigor of randomized, controlled trials.

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Doctor Sahib

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Many of my father's patients, Pakistanis who migrated to Britain to save dying manufacturing industries (which were starved for laborers), did not take their medications. His most memorable patient was Mr. Khan, a good-natured Pathan (Pashtun) who hailed from the border zone between Pakistan and Afghanistan. Mr. Khan feared no one except Allah, doctors, and his wife. That he feared my father struck me as endearingly comical, since he towered nearly a foot above him.

Mr. Khan, with hypertension, diabetes, and a lipid profile suggestive of a silent uprising — a sort of Metabolic Spring against a tyranny of red meat — would play hooky from his medications. On one occasion, my father recalls, Mr. Khan's wife accompanied him to a consultation. She begged my father to reproach her husband for failing to bring his medications on a recent visit to Pakistan. Mr. Khan said, cheekily, that the weight limit for checked baggage had been exceeded, so he'd had to leave the medications behind.

Neither Mr. Khan nor his wife spoke a word of English, but my father understood them not just because he was fluent in Urdu: as a migrant himself, he understood that most people from the Indian subcontinent — Muslims, Hindus, and Sikhs alike — don't see doctors unless they're ill and don't take their medications unless they have symptoms. Mr. Khan's blood pressure was climbing perilously high, and my father's challenge was getting him to take his medication. So my father indulged in a subcontinent variant of shared decision making, a variant not taught in medical school.

My father: "*Khan Sahib, aapko dawaii lai nee paregi*." (You must take your medication.)

Mr. Khan: "*Doctor Sahib, agar nahi, to kya hoga*?" (What will happen if I don't?)

My father: "*Tab aapka haath or pare nahi chalega*." (You will become paralyzed.)

Mr. Khan: "*Tab kya hoga, doctor sahib*?" (What will happen next?)

My father: "*Tab aapka beta aapka zyadaad lega aura aapko ghar se nikaal dega*." (Then your son will take your property and throw you out of the house.)

Mr. Khan (laughing): "*Tab to mujhe dawaii lainee paregi*." (Then I must take my medication.)

My father never asked Mr. Khan what his values and preferences were — he knew such an approach would be pointless, because Mr. Khan saw the job of the doctor as telling him what to do, not asking what outcomes he wanted. If my father used decision aids to explain the trade-offs between various anticoagulants in order to arrive at a shared decision, Mr. Khan would probably have been befuddled.