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Section 1115 Waivers: Innovation Through Experimentation, or Stagnation Through Routine?

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SECTION 1115 WAIVERS: INNOVATION THROUGH EXPERIMENTATION, OR STAGNATION THROUGH ROUTINE?

ABSTRACT

The Medicaid program operates as a federal-state partnership, in which the states agree to meet certain federally mandated requirements in exchange for federal matching funds for program expenditures. These federal matching funds can be anywhere from 50–90% of health care expenses incurred through state Medicaid programs. As such, states have a substantial interest in continuing this partnership and ensuring that their state plans comply with federal requirements. There is a way, though, in which states can gain more freedom in building their individual state plans. Through section 1115 waivers, states can ask the Centers for Medicare and Medicaid Services ("CMS") to waive certain federal requirements, thereby allowing a state to implement an "experimental, pilot, or demonstration project" as its Medicaid program. Demonstration projects are intended to benefit health care by allowing states to try innovative ideas. These projects also benefit states and state Medicaid beneficiaries by allowing states to try different approaches to Medicaid that are better tailored to local needs. However, since their inception in the 1960s, section 1115 waivers have been abused. For example, the federal government has used these waivers to push political agendas on states, and states have used the waivers to cut corners purely in the interest of saving money. Many scholars have spoken to these issues and proposed novel solutions. This Comment specifically looks to one aspect of potential abuse: the duration of the operation of demonstration projects.

In 2017, CMS promulgated guidance that allowed for extensions of "routine, successful, non-complex" demonstration projects for up to ten years. However, section 1315, the governing statute of section 1115 waivers, only allows for extensions of up to three or five years. In fact, the statute explicitly limits waiver extensions to three or five years in two separate provisions, reinforcing Congress's intention. Therefore, Congress did not leave a gap for CMS to fill in regard to this precise issue and CMS's 2017 guidance is an impermissible construction of the statute. Additionally, the language "routine, successful, [and] non-complex" is in tension with the requirement that section 1115 waivers apply to "experimental, pilot, or demonstration project[s]." Experimental, pilot,

and demonstration describe projects that have experimental value in that the projects test or trial experimental procedures. Routine, successful, and non-complex describe projects that no longer have experimental value because these projects have already been evaluated and determined to be successful with well-established procedures. In 2022, CMS removed the 2017 guidance and replaced it with 2015 guidance that only allows for waiver extensions up to the statutory limits of three or five years. But before replacing the 2017 guidance, CMS approved waiver extensions ranging from seven to ten years in nine states. A tenth state received an extension of ten years and nearly four months. All but one of those excessive extensions still stand today, unchanged.

The original purpose of section 1115 waivers was to create meaningful innovations and improve outcomes for Medicaid beneficiaries. This Comment contends that ten-year extension periods obstruct this purpose. Long project durations like this hinder and delay innovation by allowing stagnant projects to continue to operate for extended periods of time under CMS's radar. More regular reviews conducted at intervals of five years or fewer provide more opportunities for external review and data examination so CMS and states can make any necessary adjustments. Additionally, ten-year extension periods block stakeholders from participating in the decision-making process for an inordinate amount of time. Stakeholders have shown that they value the opportunity to participate in public notice and comment periods regarding section 1115 waivers and that they do not want to wait ten years to do so. Finally, ten-year extensions effectively solidify the negotiations and agreements made between two administrations—one state and one federal—for an unreasonable amount of time. The effect of this is that future administrations and future voters will be bound by a contract negotiated by individuals who may no longer be in office. Future voters, and the agendas they vote for, should be protected by limiting demonstration project extensions to three or five years.

This Comment argues that, going forward, CMS should refrain from granting extensions in excess of the statutory three- or five-year limits. Further, while CMS has replaced the 2017 guidance, the agency must rescind or amend those extensions approved for periods in excess of five years under it. By revising the extensions to the statutorily prescribed operating periods, CMS would not only improve the functionality of the demonstration projects, but it would also address the invalidity of the 2017 guidance, thereby deterring administrations from reimplementing the ten-year extensions. Taking action by rescinding or amending these extensions is a critical step in ensuring that section 1115

waivers are able to fulfill their potential to create meaningful innovation and improved outcomes for Medicaid beneficiaries.

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INTRODUCTION

Each U.S. state administers its own Medicaid program.[1] However, the Medicaid program operates as a federal-state partnership in which states agree to meet certain federal requirements in exchange for federal matching funds for program expenditures.[2] A state can apply for a section 1115 waiver, though, and request that the Centers for Medicare and Medicaid Services ("CMS")[3] waive certain federal requirements, thereby allowing the state to implement an "experimental, pilot, or demonstration project[]" as its Medicaid program.[4] During the Trump Administration, nine states received approval for section 1115 waiver extensions with durations between seven and ten years.[5] One state, Georgia, received an extension of ten years and nearly four months.[6] However, section 1315, the federal statute governing these waivers, only provides for extension periods of up to three or five years.[7] It was agency guidance promulgated by CMS in 2017 that, at least in the agency's view, permitted the excessive extension periods.[8]

In 2022, CMS, operating under the Biden Administration, replaced the 2017 guidance on its website with guidance that was originally promulgated on July 24, 2015.[9] In conformity with the section 1115 waiver statute, the 2015 guidance only allows for extension periods of up to three or five years.[10] But, while the replacement effectively removed the option for ten-year extensions, most of the

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[1] *Program History*, MEDICAID.GOV, https://www.medicaid.gov/about-us/program-history/index.html (last visited Feb. 5, 2022).

[2] Katherine Rohde, Caitlin Kim & Taylor Ross, *Experimenting with Medicaid*, REGUL. REV. (Sept. 4, 2021), https://www.theregreview.org/2021/09/04/saturday-seminar-experimenting-with-medicaid/.

[3] This Comment refers to CMS when referencing the statutes, regulations, guidance, and responsibilities related to implementing Medicaid and section 1115 waivers. This Comment substitutes CMS where some statutes and regulations refer to the Secretary of the U.S. Department of Health and Human Services, because, in practice, it is CMS that fulfills these responsibilities through an authorization from the Secretary. Griffin Schoenbaum, *Predetermined? The Prospect of Social Determinant-Based Section 1115 Waivers After* Stewart v. Azar, 124 DICK. L. REV. 533, 543 (2020).

[4] *About Section 1115 Demonstrations*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html (last visited Aug. 13, 2022).

[5] *See infra* note 172.

[6] *See infra* note 173.

[7] 42 U.S.C. § 1315(e)(2), (f)(6).

[8] Press Release, Brian Neale, Ctr. For Medicaid & CHIP Servs., Dir., Section 1115 Demonstration Process Improvements (Nov. 6, 2017), https://www.medicaid.gov/federal-policy-guidance/downloads/cib110617.pdf.

[9] *See About Section 1115 Demonstrations*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html (last visited Aug. 13, 2022).

[10] Press Release, Vikki Wachino, Ctr. For Medicaid & CHIP Servs., Dir., Implementation of a "Fast Track" Federal Review Process for Section 1115 Medicaid and CHIP Demonstration Extensions (July 24, 2015), https://www.medicaid.gov/federal-policy-guidance/downloads/CIB07242015-Fast-Track.pdf.

extension periods granted under the 2017 guidance that exceeded the upper statutory limit of five years still stand today, unchanged.[11] The sole exception is Tennessee's section 1115 waiver extension.[12] On June 30, 2022, CMS sent a letter to Tennessee "ask[ing] the state to amend the most problematic parts" of its demonstration project ("TennCare") enacted via a section 1115 waiver.[13] CMS and Tennessee decided to work together to amend the state's demonstration project—a process that included initiating a public notice and comment period from July 19 to August 19, 2022.[14] The parts CMS asked the state to amend included a block grant and drug formulary components.[15] But, as health policy scholars and researchers have pointed out, "CMS's letter is troublingly silent on the ten-year approval."[16] As such, it seems likely that once TennCare is amended, it will be reinstated with the original ten-year operating period.

The act of administrations straying from the statutes and rules that govern section 1115 waivers is not unusual. In fact, abuse of these waivers has been

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[11] *See, e.g.*, *Georgia Planning for Healthy Babies*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81406 (last visited Feb. 5, 2023); *Florida Managed Medical Assistance (MMA)*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81311 (last visited Feb. 5, 2023); *Healthy Indiana Plan*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81641 (last visited Feb. 5, 2023); *Maine Section 1115 Demonstration for Individuals with HIV/AIDS*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81876 (last visited Feb. 5, 2023); *Mississippi Family Planning Waiver*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/82226 (last visited Feb. 5, 2023); *Montana Plan First*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/82401 (last visited Feb. 5, 2023); *Texas Healthcare Transformation and Quality Improvement Program*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/83231 (last visited Feb. 5, 2023); *Virginia FAMIS MOMS and FAMIS Select*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/83426 (last visited Feb. 5, 2023); *Wyoming Pregnant by Choice (Family Planning) Demonstration*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/83646 (last visited Feb. 5, 2023).

[12] *See TennCare III (subsumes TennCare II)*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/83206 (last visited Feb. 5, 2023). Tennessee's section 1115 waiver extension application is listed as pending following a rescission. *Id.* But the waiver's expiration date remains listed as December 31, 2030, which is nearly ten years after its listed effective date of January 8, 2021. *Id.*

[13] Leonardo Cuello, *Waiver Update: CMS May Have Found a Path Forward in Tennessee*, GEO. U. HEALTH POL'Y INST. (Aug. 1, 2022), https://ccf.georgetown.edu/2022/08/01/waiver-update-cms-may-have-found-a-path-forward-in-tennessee/.

[14] *TennCare Begins Amendment Process Building on Successful Administration of TennCare III*, DIV. OF TENNCARE (July 19, 2022), https://www.tn.gov/tenncare/news/2022/7/19/tenncare-begins-amendment-process-building-on-successful-administration-of-tenncare-iii.html.

[15] Cuello, *supra* note 13.

[16] *Id.*

documented for decades.[17] Some scholars, Congress, and the Government Accountability Office ("GAO") have spoken to the pitfalls of section 1115 waivers.[18] Though health care advocates and scholars have questioned and disputed the validity of the ten-year extensions,[19] to date, no legal scholarship nor case law has spoken on the issue. This Comment argues that ten-year extension periods stifle innovation, opportunity, and accountability by increasing the intervals between external review and public input periods from three or five years to ten years.

Although the issues here are technical and intricate, the stakes are large and all too human. One in five Americans depend on the Medicaid program for their health care needs[20] and states depend on federal matching dollars to run those programs.[21] Accordingly, it is important that the program operates uninterrupted, so no beneficiaries are at risk of losing health care coverage for any amount of time. It is also imperative that the program serves the needs of those who depend on it. This is where section 1115 waivers can be practical tools in the process of building Medicaid programs. Waiver negotiations between states and the federal government can help overcome legislative gridlock,[22] thereby ensuring that state Medicaid programs operate uninterrupted. This then ensures that state programs are not in danger of losing federal funds, and that beneficiaries are not in danger of losing coverage. Furthermore, section 1115 waivers delegate the task of reviewing a state's waiver request for approval to CMS at the time the waiver is submitted, and every three or five years after that.[23] This provides states an opportunity to implement programs that fall

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[17] *See* Anthony Albanese, *The Past, Present, and Future of Section 1115: Learning from History to Improve the Medicaid-Waiver Regime Today*, 128 YALE L.J. 827, 829–38 (2019).

[18] *See id.* at 829; Matthew B. Lawrence, *Fiscal Waivers and State "Innovation" in Health Care*, 62 WM. & MARY L. REV. 1477, 1482 (2021); Medicaid Program; Review and Approval Process for Section 1115 Demonstrations, 77 Fed. Reg. 11678, 11678 (Feb. 27, 2012) (to be codified at 42 C.F.R. pt. 431) [hereinafter Review and Approval Process for Section 1115 Demonstrations].

[19] *See, e.g.*, CATHERINE MCKEE & JANE PERKINS, SECTION 1115 WAIVERS: STOP THE TEN-YEAR APPROVALS! (2022); Eli Kirshbaum, *Another 10 Years for Texas's 1115 Waiver? Experts Say It's Unlikely*, STATE OF REFORM (June 2, 2021), https://stateofreform.com/featured/2021/06/another-10-years-for-texass-1115-waiver-experts-say-its-unlikely/; Leonardo Cuello & Joan Alker, *Texas Medicaid Waiver Trilogy: The Final Installment*, GEO. U. HEALTH POL'Y INST. (May 3, 2022), https://ccf.georgetown.edu/2022/05/03/texas-medicaid-waiver-trilogy-the-final-installment/.

[20] Robin Rudowitz, Rachel Garfield & Elizabeth Hinton, *10 Things to Know About Medicaid: Setting the Facts Straight*, KAISER FAM. FOUND. (Mar. 6, 2019), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/.

[21] *See* Lawrence, *supra* note 18, at 1522.

[22] *Id.* at 1541.

[23] *Id.* at 1482; 42 U.S.C. § 1315e(2), f(6).

outside of the parameters that Congress may have drawn up many years before.[24] In turn, this can free state Medicaid programs from congressional "scorekeeping barriers," and allow states to test innovative ideas and apply different approaches that are better tailored to local needs.[25]

Unfortunately, though, the abuses of the approval process often overshadow the benefits of section 1115 waivers. Increased accountability and transparency in the approval process can revive the program's beneficial purpose. The extension periods prescribed by the section 1115 waiver statute provide for regular external reviews and data examination, thereby providing opportunities to make adjustments and to implement fresh innovative designs. Additionally, the limited extension periods provide stakeholders with more opportunities to be part of the decision-making process.

Accordingly, going forward, CMS should refrain from granting extensions in excess of the statutory three- or five-year limits. Further, CMS must rescind or amend those extensions approved for periods in excess of five years granted under the 2017 guidance. CMS should revise the operating periods of those extensions so that the durations comply with the three- or five-year limits set by statute. As shown with Tennessee's TennCare demonstration project, it is possible for CMS to work together with states to amend any problematic parts of already approved section 1115 waivers.[26] By revising the extensions to the statutorily prescribed operating periods, CMS would not only improve the functionality of the demonstration projects, but it would also address the invalidity of the 2017 guidance, thereby deterring administrations from reimplementing the 2017 guidance and ten-year extensions in the future. If CMS fails to challenge or amend the impermissible excessive extension periods, as it has done thus far, administrations will have no reason not to begin granting excessive extensions again. Further, the citizens of the states with existing excessive extensions will suffer the consequences of CMS's failure to act.

This Comment is divided into three parts. Part I of this Comment briefly introduces background information to put Medicaid and section 1115 waivers into context. Section A introduces the Medicaid program and explains how the federal-state partnership operates—reviewing federal funding and how those funds affect states and Medicaid beneficiaries. Section B introduces section

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[24] Lawrence, *supra* note 18, at 1482.

[25] *Id.* at 1482, 1501.

[26] *TennCare Begins Amendment Process Building on Successful Administration of TennCare III*, *supra* note 14.

1115 waivers and demonstration projects—explaining both their benefits and potential pitfalls. Section C then summarizes demonstration project criteria and section 1115 waiver procedures.

Part II then analyzes the legal issues surrounding CMS's 2017 guidance and the extensions granted under it. Part II discusses how CMS used this agency guidance to contravene the statutorily imposed time limits for section 1115 waivers. This Part contends that this action was impermissible in light of statutory interpretation and case law. Part II argues that CMS's 2017 guidance was unlawful, as were the excessive extension periods approved under it, because the guidance violated the governing statute: section 1315, "Demonstration projects." Part II begins by introducing demonstration project duration limits as mandated by section 1315. Section A reviews CMS's 2017 guidance which provided for approvals of project extensions in excess of the duration limits prescribed by section 1315. Section A then summarizes CMS's, under the Biden Administration, (now reversed) recission of Texas's waiver extension approval and the lawsuit that followed. Section B contends that Congress did not delegate authority to CMS to promulgate the 2017 guidance by looking at the governing statute and case law. Section C then argues that the language of the 2017 guidance—"routine, successful, [and] non-complex"[27]—is in tension with the language of the statute—"experimental, pilot, or demonstration project."[28]

Finally, Part III discusses the policy issues related to CMS's 2017 guidance and the extensions granted under it. Part III discusses how project duration impacts the original purpose of section 1115 waivers and demonstration projects: "creating meaningful innovations that improve outcomes for Medicaid recipients."[29] First, Section A looks to meaningful innovation and argues that longer durations, such as ten years, hinder and delay innovation. Section B then looks to improving outcomes for Medicaid recipients by exploring the recipients' interests as stakeholders in state Medicaid programs. Section B argues that the ten-year extension periods preclude local stakeholders from the opportunity to participate in program development for an inordinate length of time.

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[27] Neale, *supra* note 8, at 3.

[28] 42 U.S.C. § 1315(a).

[29] Albanese, *supra* note 17, at 847.

I. MEDICAID, WAIVERS, AND DEMONSTRATION PROJECTS

The statutes, rules, and guidelines that govern Medicaid can be technical, nitty-gritty, and, quite frankly, complicated. Section A of this part provides only a brief and condensed overview of the Medicaid program. It discusses how the program operates as a federal-state partnership, looking into how states receive federal funding for their Medicaid programs, and how that funding is calculated. Section A then explores the impact these funds have on states to demonstrate how important the funds are to state programs and their beneficiaries. The purpose of Section A is to provide context for the topic of Section B: section 1115 waivers. Section B introduces these waivers and discusses their benefits and potential pitfalls. Section B argues that section 1115 waivers are useful health care tools, but that a certain amount of agency transparency and accountability is necessary to ensure that both federal and state governments do not abuse the waivers. Because section 1115 waivers authorize states to implement demonstration projects, Section C summarizes the criteria that such projects must meet. Section C lists the steps that a state and CMS must take before CMS can approve a state's section 1115 waiver application.

A. Federal Requirements and Funding

The Medicaid program was established in 1965 under Title XIX of the Social Security Act.[30] Medicaid is a government-run health insurance program in which eligible low-income adults, children, pregnant women, elderly individuals, and individuals with disabilities may enroll.[31] The program is structured as a federal-state partnership.[32] Individual, state-administered Medicaid programs exist in all fifty states, the District of Columbia, and the U.S. territories.[33] While each state or territory administers its own program, the federal government shares in the costs of funding.[34] In exchange for federal funds, each state must come to an agreement with the federal government describing how that state will administer Medicaid.[35] These agreements are called "state plans."[36] CMS, within the Department of Health and Human Services ("HHS"), is the federal agency

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[30] *Program History*, *supra* note 1.

[31] *Medicaid*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/index.html (last visited Feb. 5, 2022).

[32] Rudowitz et al., *supra* note 20.

[33] *Program History*, *supra* note 1.

[34] *Medicaid*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/index.html (last visited Feb. 5, 2022).

[35] *Medicaid State Plan Amendments*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html (last visited Feb. 5, 2022).

[36] *Id.*

responsible for implementing Medicaid.[37] As such, the agency is responsible for approving state plans.[38] In order to receive federal funding, state plans must meet certain "core federal requirements."[39] For example, states are required to provide certain mandatory benefits—such as hospital, physician, and nursing home services—to certain core groups, such as children in low-income households and pregnant women.[40] However, plans vary from state to state because the federal government grants states a certain amount of flexibility to tailor their programs to fit their needs and goals.[41] A state may choose to customize its program's eligibility requirements, covered services, health care delivery, and methods for paying providers.[42] For example, a state may receive federal funds for nonmandatory services or groups that the state elects to cover under its state plan at its own discretion.[43]

Under current law, the federal government matches state spending made under a state's Medicaid program "for eligible beneficiaries and qualifying services without a limit."[44] The Federal Medical Assistance Percentage ("FMAP") determines the federal match rate for traditional Medicaid spending on most health care services.[45] The FMAP formula takes each state's financial ability to fund the costs of its own Medicaid health care services into consideration.[46] Therefore, the federal share of Medicaid health care services increases for states with per capita incomes lower than the national average and decreases for states with per capita incomes higher than the national average.[47] The federal statute mandates a minimum federal match rate of 50% and a

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[37] *Federal Policy Guidance*, MEDICAID.GOV, https://www.medicaid.gov/federal-policy-guidance/index.html (last visited Feb. 5, 2022).

[38] *See id.*

[39] Robin Rudowitz, Elizabeth Williams, Elizabeth Hinton & Rachel Garfield, *Medicaid Financing: The Basics*, KAISER FAM. FOUND. (May 7, 2021), https://www.kff.org/report-section/medicaid-financing-the-basics-issue-brief/.

[40] *Id.*

[41] *See* Rudowitz et al., *supra* note 20.

[42] Schoenbaum, *supra* note 3.

[43] Rudowitz et al., *supra* note 39.

[44] *Id.*

[45] *Matching Rates*, MACPAC.GOV, https://www.macpac.gov/subtopic/matching-rates/ (last visited Feb. 5, 2022). Traditional Medicaid spending includes health care costs incurred for children, the elderly, people with disabilities, and adults who are covered under Medicaid programs that were not expanded pursuant to the Affordable Care Act (or "non-ACA expansion adults"). Rudowitz et al., *supra* note 39.

[46] Rudowitz et al., *supra* note 39.

[47] *See id.*

maximum match rate of 83% for Medicaid health care services.[48] The federal match rate for Medicaid administrative expenses does not vary from state to state—it is generally 50%, but the rate may increase for certain types of administrative activities.[49] There are exceptions to the FMAP formula for certain beneficiaries, providers, and services.[50] One exception applies to Medicaid beneficiaries made newly eligible for the program under the Medicaid expansion provision of the Affordable Care Act ("ACA").[51] These "ACA expansion group[s]" receive special federal match rates that are higher than the standard FMAP match rates.[52] From 2014 to 2016, the ACA mandated a federal match rate of 100% for Medicaid expenditures for ACA expansion groups.[53] That percentage was set to decrease to 90% by 2020.[54]

Medicaid program funding has substantial impacts on states' governments, budgets, and economies.[55] The program is "the major source of financing for states to provide coverage of health and long-term care for low-income

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[48] 42 C.F.R. § 433.10(b) (2021). In fiscal year 2021, the federal contribution for the fifty U.S. states ranged from 77.76% in Mississippi to 50% in Alaska, California, Colorado, Connecticut, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Virginia, Washington, and Wyoming. MACPAC, MACSTATS: MEDICAID AND CHIP DATA BOOK 2019–2022, at 17–19 (2021). That same year, some U.S. territories, including American Samoa, Guam, the Northern Mariana Islands, and the Virgin Islands, were federally funded at the maximum FMAP rate of 83%—an increase from 55% in 2019. *Id.*

[49] Exceptions to the 50% limit include "activities that require medically trained personnel, the operation of information systems for eligibility and claims processing, fraud control activities, and administration of services that themselves have higher medical assistance match rates." *Matching Rates*, *supra* note 45.

[50] *Id.*

[51] As it was originally drafted, the ACA required all states to expand their Medicaid programs to cover all individuals with incomes up to 138% of the poverty level. Rudowitz et al., *supra* note 39. This meant that the federal government could—and would—withdraw federal matching funds from state programs that did not comply with this expansion because expansion became a "core federal requirement." *See id.* However, in a 2012 decision, the Supreme Court held that the federal government could not withdraw existing Medicaid funds from a state as a consequence of a state's failure to expand its current Medicaid program pursuant to the ACA. Nat'l Fed'n Indep. Bus. v. Sebelius, 567 U.S. 519, 523 (2012). As of January 10, 2022, twelve states had not adopted Medicaid expansion, including Alabama, Florida, Georgia, Kansas, Mississippi, North Carolina, South Carolina, South Dakota, Tennessee, Texas, Wisconsin, and Wyoming. *Status of State Medicaid Expansion Decisions: Interactive Map*, KAISER FAM. FOUND. (Jan. 10, 2022), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/. These twelve states are allowed to apply for section 1115 waivers, but they are not required to do so because expansion is now optional and not a core federal requirement. *See* Rudowitz et al., *supra* note 39. For instance, North Dakota is a non-expansion state which does not run its Medicaid program via a section 1115 waiver. *State Waivers List*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html (last visited Jan. 12, 2022). This indicates that North Dakota's state plan meets the core federal requirements of Medicaid even without expansion. *See* Rudowitz et al., *supra* note 39.

[52] Rudowitz et al., *supra* note 39.

[53] *Id.*

[54] *Id.*

[55] *Id.*

residents."[56] In 2018, the federal government paid $399 billion for medical costs incurred through Medicaid.[57] State costs for Medicaid health care services can be considerably high for individual enrollees. In 2019, the total spending for a Medicaid beneficiary ranged from $4,970 in South Carolina to $12,580 in North Dakota.[58] Considering these costs, states stand to receive substantial amounts of federal funds when the federal matching dollars are 50–83%—or 90% in expansion states—of these expenditures.[59] In fact, Medicaid accounts for 58% of all federal funding in states, making it the "largest single source of federal funds for states."[60]

State reliance on federal matching dollars for Medicaid is more relevant in light of the COVID-19 pandemic. Medicaid enrollment increases during recessions—as individuals suffer from decreased earnings and savings—and during periods of increased unemployment rates—as individuals lose access to employer-sponsored health insurance plans.[61] An increase in Medicaid spending naturally follows an increase in enrollment.[62] During economic downturns, like the one caused by the COVID-19 pandemic, "state Medicaid costs [increase] at the same time that state tax revenues are declining."[63] Because the FMAP formula takes into account each state's financial ability to fund the costs of its own Medicaid program, federal matching rates can increase when state revenues decrease, providing states with much needed relief.[64]

Today, the Medicaid program covers health care services for one in five Americans.[65] This includes low-income adults, children, the elderly, and individuals with disabilities.[66] The "vast majority of Medicaid enrollees lack access to other affordable health insurance."[67] Without the program, the majority of Medicaid beneficiaries would be unable to afford and access necessary, and oftentimes critical, health care services.[68] As of April 2021, over seventy-five

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56 *Id.*

57 Lawrence, *supra* note 18, at 1493.

58 Rudowitz et al., *supra* note 39.

59 42 C.F.R. § 433.10(b) (2021); Rudowitz et al., *supra* note 39.

60 Rudowitz et al., *supra* note 39.

61 *Id.*; Sarah Gantz, *Medicaid Enrollment Soars as Americans Lose Jobs to Pandemic: 'I Never Thought I'd Experience This'*, PHILA. INQUIRER (Feb. 9, 2021), https://www.inquirer.com/health/consumer/coronavirus-covid-19-medicaid-aca-unemployment-20210209.html.

62 *See* Rudowitz et al., *supra* note 39.

63 *Id.*

64 *See Matching Rates*, *supra* note 45.

65 Rudowitz et al., *supra* note 20.

66 *Id.*

67 *Id.*

68 *Id.*

million individuals were enrolled in Medicaid.[69] This total represents an increase of over 562,000 enrolled individuals since March 2021.[70] From February 2020 to April 2021, enrollment increased by over 11.5 million individuals.[71] These enrollment increases have likely been caused, at least partially, by the impacts of the COVID-19 pandemic.[72]

In 2021, as the Biden Administration settled in, it began reviewing and withdrawing state Medicaid plans that were approved via section 1115 waivers.[73] These withdrawn waivers allowed for demonstration projects that implemented Medicaid work experiments.[74] The administration also withdrew Texas's section 1115 waiver extension approval on procedural grounds.[75] In light of these rescissions, state policy- and law-makers were understandably concerned about losing federal funding and health care for their residents.[76] Withdrawing federal Medicaid funding at any time, but especially during a recession or pandemic, can have a devastating impact on a state's Medicaid program and the beneficiaries who rely on that program for health care services.[77] However, these withdrawals were not completely without merit.[78] As

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[69] CTRS. FOR MEDICARE & MEDICAID SERVS., APRIL 2021 MEDICAID AND CHIP ENROLLMENT TRENDS SNAPSHOT 3 (2021), https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/april-2021-medicaid-chip-enrollment-trend-snapshot.pdf.

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] Sara Rosenbaum, *Biden Administration Begins Process of Rolling Back Approval for Medicaid Work Experiments, but Supreme Court Hangs On*, COMMONWEALTH FUND (Apr. 8, 2021), https://www.commonwealthfund.org/blog/2021/biden-administration-begins-process-rolling-back-approval-medicaid-work-experiments.

[74] The affected states included Arkansas and New Hampshire. *Id.* Medicaid work experiments require beneficiaries to meet certain work-related requirements or risk losing Medicaid coverage. Benjamin D. Sommers, Anna L. Goldman, Robert J. Blendon, E. John Orav & Arnold M. Epstein, *Medicaid Work Requirements—Results from the First Year in Arkansas*, N. ENGL. J. MED. (2019), https://www.nejm.org/doi/full/10.1056/nejmsr1901772. For example, Arkansas's work requirement required beneficiaries aged thirty to forty-nine years of age "to work 80 hours per month, participate in another qualifying community engagement activity . . . or community service, or meet criteria for an exemption such as pregnancy or disability." *Id.*

[75] Letter from Elizabeth Richter, Ctrs. for Medicare & Medicaid Servs., Acting Adm'r, to Stephanie Stephens, Tex. Health & Hum. Servs. Comm'n, State Medicaid Dir. 1, 7 (Apr. 16, 2021) [hereinafter Letter of Withdrawal to Texas], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tx-healthcare-transformation-cms-ltr-st.pdf.

[76] *See* Jeremy Blackman, *Biden Administration Rescinds Billions in Medicaid Funding for Texas*, HOUS. CHRON. (Apr. 16, 2021), https://www.houstonchronicle.com/politics/texas/article/Biden-administration-rescinds-billions-in-16107275.php.

[77] *See* Rudowitz et al., *supra* note 39.

[78] *See infra* notes 108–10 and accompanying text (discussing the impacts of work requirements on Medicaid beneficiaries); *infra* notes 186–87 and accompanying text (discussing Texas's exemption from the federal-level notice and comment period).

some scholars point out, there is evidence that federal and state actors have abused the use of section 1115 waivers in Medicaid programs for decades.[79] The answer to this problem, though, is not a complete rejection of section 1115 waivers—which would put many states at risk of losing much needed federal funds—but, instead, more transparency and accountability in CMS's approval process.[80]

To better ensure that the section 1115 waiver approval process meets the transparency and accountability standards necessary for the waiver program's success, CMS must limit demonstration project durations and extension periods to the statutorily prescribed three or five years. Fortunately, in a move that brings CMS closer to this objective, the agency replaced the 2017 guidance and ten-year extension limit with 2015 guidance that reimplements the three- or five-year limits.[81] These shorter operation periods provide for CMS review more often, thereby encouraging more transparency and accountability, while not being so short as to become burdensome. But, in order to effectively curtail future section 1115 waiver abuse, CMS must take further action and formally challenge the validity of the 2017 guidance's ten-year extension limit. To do this, CMS must rescind or amend the waivers that were extended in excess of five years under the 2017 guidance. By requiring the revision of those extensions so they comply with the statutory three- or five-year limits, CMS will help to deter administrations from reimplementing the 2017 guidance and ten-year extensions in the future. Further, by reducing the existing excessive extensions to the permissible statutory limits, CMS will better protect the interests of the citizens and stakeholders of those states in the coming years.

Before diving into this argument, though, the remaining sections of Part I will provide background on how the section 1115 waiver program operates. Section B explains the waiver program generally, including an overview of the program's potential benefits and pitfalls. Section C details the criteria and approval process for demonstration projects enacted via section 1115 waivers.

B. Section 1115 Waivers

The federal requirements that each state Medicaid program must meet are defined in Title XIX of the Social Security Act, the ACA, and several federal

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79 *See* Albanese, *supra* note 17, at 829; *see also* Lawrence, *supra* note 18, at 1550.

80 *See* Albanese, *supra* note 17, at 829, 840; *see also* Lawrence, *supra* note 18, at 1550–51.

81 *About Section 1115 Demonstrations*, *supra* note 4; Wachino, *supra* note 10, at 1; Neale, *supra* note 8, at 4.

regulations.[82] CMS is tasked with issuing guidance on how to implement Medicaid laws and what states must do to comply.[83] In order to have its Medicaid program approved and receive federal matching funds for expenditures, each state must submit its plan to CMS to ensure compliance.[84] In addition to approving state plans that comply with federal requirements, CMS has the authority to approve "experimental, pilot, or demonstration project[s]."[85] These projects are implemented through section 1115 waivers which are codified under section 1115 of the Social Security Act.[86] These waivers allow a state to request that CMS waive certain federal Medicaid requirements.[87] The result is greater flexibility enabling a state to administer a proposed demonstration project as part of its Medicaid program.[88] By freeing a state to experiment with Medicaid outside of the parameters of the law, demonstration projects have the potential to inspire innovation and improve health care.[89] For approval, CMS performs case-by-case reviews of each demonstration project proposal.[90] The proposals must meet certain criteria and CMS must follow an approval process defined by federal regulation.[91]

So, why would the federal government agree to waive certain federal core requirements for state Medicaid programs and approve experimental, pilot, or demonstration projects? One reason is that section 1115 waivers allow CMS to authorize otherwise barred federal matching funds to states for expenditures that the agency thinks will improve health coverage.[92] Accordingly, in the past, states have used demonstration projects to expand coverage, including coverage for "substance abuse disorders and . . . public heath emergencies."[93] Other areas that could benefit from such expansions might include long-term care programs, comprehensive hospital transportation networks, and medical-legal partnerships.[94] Additionally, section 1115 waivers "can encourage the state to experiment (or free it financially to do so)."[95] These waivers can "inspire" and

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82 Rudowitz et al., *supra* note 20.
83 *Federal Policy Guidance*, *supra* note 37.
84 42 C.F.R. § 430.10 (2021).
85 42 U.S.C. § 1315(a); *accord* 42 C.F.R. § 431.416 (2021).
86 *About Section 1115 Demonstrations*, *supra* note 4.
87 Rohde et al., *supra* note 2.
88 *Id.*
89 Lawrence, *supra* note 18, at 1497–98, 1501.
90 *About Section 1115 Demonstrations*, *supra* note 4.
91 *Id.*; *See* 42 C.F.R. § 431.416 (2021) (providing the federal approval process).
92 Lawrence, *supra* note 18, at 1493–94.
93 Rohde et al., *supra* note 2.
94 Lawrence, *supra* note 18, at 1494.
95 *Id.* at 1498.

"stimulat[e] state and local experimentation," as well as reward novel state Medicaid programs.[96] Therefore, demonstration projects may produce innovations and improvements in health care that otherwise would not have been realized without the aid of these waivers.[97]

However, section 1115 waivers and demonstration projects should be approached with caution. As mentioned previously, there is evidence of a history of abuse of these waivers as they are applied to Medicaid programs.[98] For example, the use of waivers can lead to increased federal government "steering" of state Medicaid programs.[99] If CMS "makes federal funds available only for particular reforms or subsets of reforms that it selects, the result is more compliance than innovation."[100] As a result, section 1115 waivers can reflect the "changing priorities from one presidential administration to another."[101] Additionally, section 1115 waivers can be used to cut benefits, a pitfall that President Kennedy recognized in 1962 when he endorsed the section 1115 bill.[102] In fact, these waivers were used to cut benefits during both the George H.W. Bush and Clinton Administrations.[103] Then, under George W. Bush's Administration, the expansion of coverage without additional funding prompted some states to cut benefits to certain populations.[104] More recently, the Trump Administration approved waivers that allowed demonstration projects to implement work requirements as a precondition for receiving Medicaid benefits.[105] In fact, the Trump Administration encouraged (or "steered"[106]) states to adopt these policies.[107] As a result of implementing these policies into demonstration projects, "[a] large fraction of people subject to the policies lost

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96 *Id.* at 1501.

97 *Id.*

98 *See* Albanese, *supra* note 17, at 829; *see also* Lawrence, *supra* note 18, at 1508–09.

99 Lawrence, *supra* note 18, at 1508.

100 *Id.*

101 Madeline Guth, Elizabeth Hinton, MaryBeth Musumeci & Robin Rudowitz, *The Landscape of Medicaid Demonstration Waivers Ahead of the 2020 Election*, KAISER FAM. FOUND. (Oct. 30, 2020), https://www.kff.org/medicaid/issue-brief/the-landscape-of-medicaid-demonstration-waivers-ahead-of-the-2020-election/.

102 Albanese, *supra* note 17, at 829.

103 *Id.* at 834.

104 *Id.* at 835.

105 *Id.* at 838.

106 Lawrence, *supra* note 18, at 1508.

107 Schoenbaum, *supra* note 3 at 547. In 2018, CMS (under the Trump Administration) sent letters to state governors suggesting that they experiment with work and community engagement requirements in their Medicaid programs. *Id.* However, prior to President Trump's election, CMS would not consider section 1115 waivers that included such requirements. *Id.*

coverage or were at risk of losing coverage."[108] In Arkansas, more than 18,000 people lost coverage, and in New Hampshire, almost 17,000 people would have lost coverage but the policy was put on hold.[109] The same policy in Michigan put 80,000 people in danger of losing coverage.[110] It is crucial that the approval process for demonstration projects adheres to certain levels of transparency and accountability, so that Medicaid programs are not vulnerable to administrative agendas and political bargaining. The ten-year extension limits provided for in CMS's 2017 guidance effectively allowed state and federal administration to solidify their Medicaid agendas and negotiations for up to ten years.

C. Demonstration Project Criteria & Procedures

Per statute, in order to approve a demonstration project, CMS and the proposed project must meet three requirements.[111] First, CMS must find that a proposed project is "likely to assist in promoting the objectives of [the Medicaid program]."[112] To evaluate this requirement, CMS performs case-by-case reviews to determine if the project's stated objectives are aligned with the objectives of Medicaid.[113] Second, CMS may only waive federal requirements for these projects "to the extent and for the period [CMS] finds necessary to enable such State or States to carry out such project[s]."[114] Third, demonstration projects must be budget neutral.[115] A project is "budget neutral" as long as it does not result in the federal government expending more than it would absent the project.[116]

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[108] Jennifer Wagner & Jessica Schubel, *States' Experiences Confirm Harmful Effects of Medicaid Work Requirements*, CTR. ON BUDGET & POL'Y PRIORITIES (Nov. 18, 2020), https://www.cbpp.org/research/health/states-experiences-confirm-harmful-effects-of-medicaid-work-requirements.

[109] *Id.*

[110] *Id.*

[111] 42 U.S.C. § 1315(a).

[112] *Id.*

[113] *About Section 1115 Demonstrations*, *supra* note 4. How these criteria are evaluated can change pursuant to current CMS guidelines. Guth et al., *supra* note 101. In November of 2017, CMS issued revised criteria for section 1115 waivers. *Id.* The revised criteria removed "expanding coverage" from the objectives and instead "focus[ed] on positive health outcomes, efficiencies to ensure program sustainability, coordinated strategies to promote upward mobility and independence, incentives that promote responsible beneficiary decision-making, alignment with commercial health plans, and 'innovative' payment and delivery system reforms." *Id.*

[114] 42 U.S.C. § 1315(a)(1).

[115] *Id.* § 1315(a)(2).

[116] *About Section 1115 Demonstrations*, *supra* note 4.

Transparency and public notice are key to the application and approval process for section 1115 waivers.[117] Section 10201(i) of the ACA ("Amendments to the Social Security Act and Title II of this Act") amended section 1115 of the Social Security Act by adding a new subsection, (d), requiring CMS "to issue regulations that would ensure the public has adequate opportunities to provide meaningful input into the development of State demonstration projects, as well as in the Federal review and approval of State demonstration applications and renewals."[118] CMS is required to promulgate these regulations for applications for both new demonstration projects and for extensions of existing demonstration projects if the proposed projects would impact Medicaid "eligibility, enrollment, benefits, cost-sharing, or financing."[119] These regulations must provide processes for: (1) state-level public notice and comment, including public hearings; (2) federal-level public notice and comment after the application is received by CMS; (3) submissions of periodic reports by the states to CMS concerning the demonstration project; and (4) periodic evaluations of the project by CMS.[120]

Subsections 1 through 4 of this section dive deeper into some approval procedures. Subsection 1 explains the various requirements of the state-level public notice and comment period. Subsection 2 details the steps a state must take to submit its section 1115 waiver application to CMS after completing the state-level public notice and comment period. Subsection 3 explains the various requirements of the federal-level public notice and comment period. Finally, subsection 4 discusses the circumstances in which a state may request, and CMS may grant, an exemption from the state-level or federal-level public notice and comment period.

1. State-Level Requirements: Public Notice and Comment Period

Before submitting a demonstration project application to CMS, the applying state must engage in a state-level public notice and comment period.[121] This requirement applies to applications for both new demonstration projects and

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[117] *See* U.S. DEP'T HEALTH & HUM. SERVS., REP. ON SECTION 1115(A) DEMONSTRATIONS: TRANSPARENCY IN THE REVIEW AND APPROVAL OF MEDICAID & CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP) SECTION 1115 DEMONSTRATIONS 3, https://www.medicaid.gov/medicaid/downloads/1115-transparency-rtc.pdf (last visited Jan. 27, 2023).

[118] Review and Approval Process for Section 1115 Demonstrations, 77 Fed. Reg. 11678, 11679 (Feb. 27, 2012).

[119] 42 U.S.C. § 1315(d)(1).

[120] *Id.* § 1315(d)(2).

[121] 42 C.F.R. § 431.408(a)(1) (2021).

extensions of existing demonstration projects.[122] Per federal regulation, the state must provide at least thirty days for the public notice and comment period.[123] The state-level public notice must include the following: (1) a comprehensive description of the application or extension "that contains a sufficient level of detail to ensure meaningful input from the public"; (2) "locations and Internet address where copies of the demonstration application are available for public review and comment"; (3) mail and email addresses where the public may send their written comments for review, and the thirty-day time period during which comments will be accepted; and (4) "[t]he location, date, and time of at least two public hearings convened by the State to seek public input on the demonstration application."[124]

The state must conduct at least two public hearings, to be held on separate dates and at separate locations, at least twenty days prior to submitting an application to CMS.[125] Members of the public throughout the state must have an opportunity to provide comments at these hearings.[126] During at least one of the two hearings, the state must provide telephonic or Web conference capabilities to ensure accessibility for anyone who wishes to participate and provide comment.[127]

Finally, federal regulation mandates certain responsibilities for states that are home to "[f]ederally-recognized Indian tribes, Indian health programs, and/or urban Indian health organizations."[128] These states must consult with the Indian tribes or seek advice from the Indian health organizations and programs prior to

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122 *Id.* § (a).

123 *Id.*

124 *Id.* § 431.408(a)(1). The state is required to "publish its public notice process, public input process, planned hearings, the demonstration application(s), and a link to the relevant Medicaid demonstration page(s)" from the CMS website on a public state website in a location and manner that is "prominent," and "readily identifiable." *Id.* § 431.408(a)(2)(i). This public website must be maintained and updated throughout the state-level notice and comment period. *Id.* Additionally, the state must publish an "abbreviated public notice" in the state's administrative record or in "the newspapers of widest circulation in each city with a population of 100,000, or more." *Id.* § 431.408(a)(2)(ii). Furthermore, the state is required to notify interested parties of the demonstration project application though electronic mailing lists or other reasonable mechanisms. *Id.* § 431.408(a)(2)(iii).

125 *Id.* § 431.408(a)(3).

126 *Id.*

127 *Id.* However, if the state can show that it successfully afforded members of the public throughout the state the opportunity to provide comment, such capabilities will not be required. *Id.* An example that would satisfy this requirement is if the state held its two public hearings in geographically distinct areas of the state, thus creating more accessibility. *Id.*

128 *Id.* § 431.408(b).

submitting their applications to CMS if the project would have a direct effect on those tribes or health organizations and programs.[129]

2. The Federal Application Process

To begin the federal application process for both new demonstration projects and for extensions of existing demonstration projects, a state must submit a proposal to CMS.[130] CMS will not consider an application complete unless it meets the requirements provided in federal regulation.[131] These requirements include, but are not limited to: a comprehensive project description; descriptions of the health care delivery system, eligibility requirements, benefits covered, and cost sharing; an estimate of expected costs of enrollment and expenditures; the current enrollment data; any research hypotheses that will be tested by the demonstration; and documentation of the state's compliance with public notice requirements.[132] Additionally, an application must be submitted in both printed and electronic formats, with the electronic format being accessible to individuals with disabilities.[133]

In addition to the above requirements, there are special procedures that a state must take when submitting applications for extensions of existing demonstration projects.[134] First, a state must submit their application to extend an existing project between twelve and eighteen months before the project is set to expire.[135] If an extension is granted, the state must submit a final report on the demonstration project by the date that is one year after the original demonstration project was set to expire.[136] After receiving this report, CMS must complete and release an evaluation of the project within one year.[137]

However, in 2015, CMS established a new "fast track" process for reviewing state applications to extend demonstration projects.[138] According to CMS's 2015 (and current) guidance, this process was designed for the extension of projects that meet the following requirements: (1) "have had at least one full extension cycle without substantial program changes"; (2) are "in compliance with

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129 *Id.*
130 *Id.* § 431.412(b).
131 *Id.* § 431.412(a).
132 *Id.*
133 *Id.* § 431.412(b).
134 42 U.S.C. § 1315(e).
135 *Id.* § 1315(e)(1).
136 *Id.* § 1315(e)(4).
137 *Id.* § 1315(e)(5).
138 U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 1176, at 3.

reporting deliverables and . . . have had positive monitoring and evaluation results that indicate the objectives of the demonstration and of the Medicaid/CHIP program have been achieved"; (3) "are not proposing major or complex changes"; and (4) "use the streamlined extension application templates."[139] CMS's 2017 guidance largely maintained these requirements, making only minor adjustments to the wording that did not appear to result in any substantial changes.[140] However, after listing the requirements, the 2017 guidance did provide a substantial change: it stated that CMS reserved the right to remove the first requirement—"that states must have had at least one full extension cycle without substantial program changes"—altogether, in appropriate circumstances.[141] This Comment is not about the impact of that particular change, but it is worth noting as another example of how the 2017 guidance expanded CMS's power in the granting of demonstration project extensions.

3. Federal-Level Public Notice and Comment Period

Once a completed application has been submitted to CMS, the application enters the federal public notice and approval process.[142] Just as with the application procedures, this approval process applies to applications for both new demonstration projects or for extensions of existing demonstration projects.[143] Within fifteen days of receiving a state's completed application, CMS must provide written notice to the state and publish that notice on the CMS website.[144] Once the state has been notified in writing, CMS will begin to solicit public comment regarding the state's application for a total of thirty days.[145] This is the federal-level public notice and comment period.[146] To begin the federal public comment period, CMS must publish the following on its website: (1) the written notice of CMS's receipt of the application (as mentioned above); (2) the application (including supporting information submitted by the state); (3) the proposed effective date; and (4) mail or email addresses where the public may submit its inquiries and comments.[147] Second, CMS must "[n]otify[] interested parties through a mechanism, such [as] an electronic mailing list, that CMS will

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139 Wachino, *supra* note 10, at 1.
140 *See* Neale, *supra* note 8, at 4.
141 *Id.*
142 42 C.F.R. § 431.416 (2021).
143 *Id.* § 431.412(b)(1).
144 *Id.* § 431.416(a).
145 *Id.* § 431.416(b).
146 *See id.* § 431.416.
147 *Id.* § 431.416(b)(1).

create for this purpose."[148] During the federal-level public notice and comment period, CMS will publish additional appropriate information on its website at regular intervals.[149] CMS is required to publish written comments on its website.[150] While CMS is required to review and consider all comments received before the final deadline of the public notice and comment period, CMS will not provide written responses to public comments.[151] In order to ensure that CMS has ample time to receive and consider public comments, CMS must wait at least forty-five days after notifying the state of receipt of its completed application before rendering a final decision.[152] Finally, CMS is required to publish and maintain an administrative record detailing the application and approval process for each demonstration project application.[153]

4. Exemptions from Notice and Comment

Under the same federal regulation that requires CMS to complete a federal public notice and comment period, CMS is authorized to waive, in whole or in part, the federal- and state-level public notice and comment periods under certain circumstances.[154] In order to do so, the applying state must "demonstrate[] to CMS the existence of unforeseen circumstances resulting from a natural disaster, public health emergency, or other sudden emergency that directly threatens human lives that warrant an exception to the normal public notice process."[155] Additionally, CMS may "exempt a [s]tate from the normal public notice process or the required time constraints imposed in this section" when the state demonstrates such circumstances as a result of an emergency.[156] If a state seeks an exemption from the normally required public notice and comment period, the state must establish all of the following: (1) that "the State acted in good faith, and in a diligent, timely, and prudent manner"; (2) that the "circumstances constitute an emergency and could not have been reasonably foreseen"; and (3) that a "delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of [Medicaid] beneficiaries."[157] Pursuant to the

148 *Id.* § 431.416(b)(2).

149 *Id.* § 431.416(c). This information may include, but is not limited to, status updates and a list of issues raised during the public notice process. *Id.*

150 *Id.* § 431.416(d)(1).

151 *Id.* § 431.416(d)(2). Additionally, comments may be submitted after the deadline, but federal regulation does not guarantee that CMS will consider those. *Id.*

152 *Id.* § 431.416(e)(1).

153 *Id.* § 431.416(f).

154 *Id.* § 431.416.

155 *Id.* § 431.416(g)(1).

156 *Id.* § 431.416(g)(2).

157 *Id.* § 431.416(g)(3).

federal regulation—and presumably to continue to promote transparency—CMS must publish such applications and disaster exemptions on its website.[158] Additionally, CMS must publish any revised timelines it has established for the public notice and comment period.[159]

The statutory and regulatory procedures to approve section 1115 waivers and implement demonstration projects are specific and detailed.[160] The high level of detail is likely a result of Congress and CMS's initiative to improve transparency in the approval process.[161] The focus of these procedures is to help facilitate sufficient opportunity for meaningful public input and accessibility of program information.[162] To meet this goal of improving transparency in the approval process, and to better focus on facilitating public input, going forward, CMS should refrain from granting waiver extensions in excess of the statutory three- and five-year limits. These statutorily prescribed limits provide for more regular public notice and comment periods and CMS review every three or five years. This results in more opportunities for public input and transparency in the waiver process. And, as an additional step towards meeting these objectives, CMS must rescind or amend those extensions approved for periods in excess of five years granted under CMS's 2017 guidance. CMS must revise those extensions so their operating periods comply with the statutorily prescribed limits. Taking this action would decrease the intervals between the public notice and comment periods and CMS's external reviews of the demonstration projects, thereby providing more opportunities for public input and transparency.

II. SECTION 1115 WAIVER EXTENSION TIME LIMITS

Administrations prior to the Trump Administration typically granted section 1115 waiver extensions for three- or five-year periods.[163] These three- or five-year extensions conform with the language of the section 1115 waiver statute.[164] In fact, Congress doubled down on the three- or five-year extension limit rule

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158 *Id.* § 431.416(g)(4).

159 *Id.*

160 *See supra* Sections I.C.1–4 (outlining the procedures to approve section 1115 waivers).

161 U.S. DEP'T HEALTH & HUM. SERVS, *supra* note 117, at 5–7.

161 *Id.* at 6.

162 *Id.* at 5, 10.

163 AM. ACAD. OF FAM. PHYSICIANS, SECTION 1115 DEMONSTRATION WAIVERS 2, https://www.aafp.org/dam/AAFP/documents/advocacy/coverage/medicaid/BKG-Section1115Waivers.pdf (Feb. 2021) ("Under the Trump administration, CMS . . . granted waiver extensions for up to ten years instead of the typical three- or five-year extensions granted by previous administrations."); Guth et al., *supra* note 101 ("On December 28, 2017, CMS approved the first 10-year extension . . . .").

164 42 U.S.C. § 1315(e)(2), (f)(6).

by including it in two separate subsections of the statute.[165] First, under section 1315(e)(2), the statute reads "the State . . . may submit . . . written request for an extension, of up to 3 years (5 years, in the case of a waiver described in section 1396n(h)(2))."[166] Second, under section 1315(f)(6), the statute reads: "An approval of an application for an extension of a waiver project under this subsection shall be for a period not to exceed 3 years (5 years, in the case of a waiver described in section 1396n(h)(2) of this title)."[167] Section 1915(h)(2) allows for five-year extensions on waivers, including section 1115 waivers, which cover individuals who are dually enrolled in Medicare and Medicaid.[168]

This Part discusses how, in 2017, CMS used agency guidance to contravene these statutorily imposed time limits and argues that this action was not permissible in light of statutory interpretation and case law. This Part argues that this Trump-era CMS guidance was unlawful, as were the section 1115 waiver extensions granted in excess of five years under it, because the guidance violated section 1315 "Demonstration projects." As such, CMS must rescind or amend those extensions in order to revise their operating periods to comply with the statutorily prescribed three- or five-year limits.

Section A introduces the 2017 guidance and the state waivers that received extensions in excess of five years. Section A then discusses the recent court case in Texas that occurred after CMS, under the Biden Administration, rescinded Texas's waiver extension approval for failure to conduct a federal-level public notice and comment period. Section B argues that Congress did not delegate authority to CMS to promulgate the 2017 guidance through the governing statute. Section B contends that Congress spoke directly and clearly to the specific issue of waiver extension time limits, and Congress did not leave a gap in the statute which CMS was permitted to fill. Finally, Section C explains how the language of the 2017 guidance is in tension with the language of the statute. Section C looks to dictionaries and case law to define what qualifies as an "experimental, pilot, or demonstration project," and argues that such projects cannot also be considered "routine, successful, and non-complex," as required by CMS's 2017 guidance.

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165 *See id.* § 1315(e)(2), (f)(6).
166 *Id.* § 1315(e)(2).
167 *Id.* § 1315(f)(6).
168 *Waivers*, MACPAC.GOV, https://www.macpac.gov/medicaid-101/waivers/ (last visited Feb. 5, 2022).

A. Ten-Year Waiver Renewals

The typical practice of granting three- or five-year extensions changed after President Trump took office.[169] In November 2017, CMS announced that it "may approve the extension of routine, successful, non-complex section 1115(a) waiver and expenditure authorities in a state for a period of up to 10 years," rather than limiting extensions to the statutory limits of three or five years.[170] The next month, in December 2017, CMS approved the first ever ten-year demonstration project extension.[171] After CMS promulgated the guidance in 2017, the agency approved waiver extensions for periods ranging from seven to ten years for Florida, Indiana, Maine, Mississippi, Montana, Tennessee, Texas,

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169 AM. ACAD. OF FAM. PHYSICIANS, *supra* note 163, at 2.

170 Neale, *supra* note 8, at 3.

171 *CMS Approves First 10-Year Section 1115 Demonstration Extension*, CMS.GOV (Dec. 28, 2017), https://www.cms.gov/newsroom/press-releases/cms-approves-first-10-year-section-1115-demonstration-extension.

Virginia, and Wyoming.[172] Additionally, in 2019, CMS approved Georgia's application for a waiver extension with an effective period of September 1, 2019 through December 31, 2029.[173] Georgia's ten-year and nearly four-months-long

[172] Letter from Anne Marie Costello, Ctrs. for Medicare & Medicaid Servs., Acting Deputy Adm'r & Dir., to Beth Kidder, Fla. Agency for Health Care Admin., Deputy Sec'y for Medicaid 11 (Jan. 15, 2021) [hereinafter Waiver Approval Letter to Florida], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/fl-mma-ext-appvl-01152021.pdf (stating Florida's section 1115 waiver extension is approved from January 15, 2021 through June 30, 2030); Letter from Anne Marie Costello, Ctrs. for Medicare & Medicaid Servs., Acting Deputy Adm'r & Dir., to Allison Taylor, Ind. Fam. & Soc. Servs. Admin., Medicaid Dir. 22 (Oct. 26, 2020) [hereinafter Waiver Approval Letter to Indiana], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/in-healthy-indiana-plan-support-20-ca-01012021.pdf (stating Indiana's section 1115 waiver extension is approved from January 1, 2021 through December 31, 2030); Letter from Chris Traylor, Ctrs. for Medicare & Medicaid Servs., Deputy Adm'r & Dir., to Michelle Probert, Me. Dep't of Health & Hum. Servs., Dir. of Office of MaineCare Servs. 6 (April 19, 2019) [hereinafter Approval Letter to Maine], https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/me/Individuals-with-HIV-AIDS/me-hiv-cms-ext-appvl-04192019.pdf (stating Maine's section 1115 waiver extension is approved from April 19, 2019 through December 31, 2028); Letter from Danielle Daly, Div. of Demonstration Monitoring & Evaluation, Dir., & Andrea J. Casart, Div. of Eligibility & Coverage Demonstrations, Dir., to Drew Snyder, Miss. Dep't of Hum. Servs., Exec. Dir. of Div. of Medicaid 3 (Dec. 16, 2020) [hereinafter Waiver Approval Letter to Mississippi], https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ms/ms-family-planning-medicaid-expansion-project-ca.pdf (stating Mississippi's section 1115 waiver extension is approved from December 28, 2017 through December 31, 2027); Letter from Chris Traylor, Ctrs. for Medicare & Medicaid Servs., Deputy Adm'r & Dir., to Marie Matthews, Dep't of Pub. Health & Hum. Servs., Medicaid Dir. 6 (Mar. 29, 2019) [hereinafter Waiver Approval Letter to Montana], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/mt-plan-first-ext-appvl-03292019.pdf (stating that Montana's section 1115 waiver extension has been approved from April 1, 2019 through December 31, 2028); Letter from Seema Verma, Ctrs. for Medicare & Medicaid Servs., Adm'r, to Stephen Smith, Tenn. Dep't of Fin. & Admin., Dir. of TennCare 17 (Jan. 8, 2021) [hereinafter Waiver Approval Letter to Tennessee], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tn-tenncare-ii-cms-demo-appvl-01082021.pdf (stating Tennessee's section 1115 waiver extension is approved from January 8, 2021 through December 31, 2030); Letter from Seema Verma, Ctrs. for Medicare & Medicaid Servs., Adm'r, to Stephanie Stephens, Tex. Health & Hum. Servs. Comm'n, State Medicaid Dir. 12 (Jan. 15, 2021) [hereinafter Waiver Approval Letter to Texas], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tx-healthcare-transformation-cms-approval-01152021.pdf (stating Texas's section 1115 waiver extension is approved from January 15, 2021 through September 30, 2030); Letter from Calder Lynch, Ctrs. for Medicare & Medicaid Servs., Acting Dir., to Karen Kimsey, Va. Dep't of Med. Assistance Servs., Dir. 6 (Oct. 25, 2019) [hereinafter Waiver Approval Letter to Virginia], https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/va/va-famis-moms-famis-select-ca.pdf (stating Virginia's section 1115 waiver extension is approved from Oct. 25, 2019 through June 30, 2029); Letter from Calder Lynch, Ctrs. for Medicare & Medicaid Servs., Acting Dir., to Michael A. Ceballos, Wyo. Dep't of Health, Dir. 5 (Apr. 7, 2020) [hereinafter Waiver Approval Letter to Wyoming], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/wy-pregnant-by-choice-ca1.pdf (stating Wyoming's section 1115 waiver extension is approved from April 7, 2020 through December 31, 2027).

[173] Letter from Calder Lynch, Ctrs. for Medicare & Medicaid Servs., Acting Dir., to Lynette Rhodes, State of Ga. Dep't of Cmty. Health, Exec. Dir. of Med. Assistance Plans 8 (Aug. 29, 2019) [hereinafter Waiver Approval Letter to Georgia], https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ga-planning-for-healthy-babies-ext-appvl-08292019.pdf (stating Georgia's section 1115 waiver extension is approved from September 1, 2019 through December 31, 2029).

extension is not only in excess of the typical, statutorily prescribed, three- or five-year extension period, but it is also in excess of the ten-year limit provided for in CMS's 2017 guidance.[174] CMS approved each of these ten extensions from 2017 to 2021, while operating under the Trump administration.[175] Three states, Florida, Tennessee, and Texas, received their approvals in January of 2021, during the administration's final weeks.[176]

Texas's ten-year waiver extension has recently been the subject of debate. Opponents to the extension have pointed to Texas's failure to meet statutory public notice and comment requirements, the negative impact of the waiver on coverage, equity considerations, and the ten-year extension period as possible grounds for federal review and a rescission of the approval.[177] Ultimately, CMS, operating under the Biden administration, rescinded Texas's original waiver extension.[178] The issue was then taken up in the United States District Court for the Eastern District of Texas.[179]

In Texas's extension application submitted in November of 2020, Texas requested that CMS waive certain public notice and comment procedures to expedite the application process.[180] Title 42, Section 431.416 of the Code of Federal Regulations prescribes the process for federal public notice for section

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174 *See* AM. ACAD. OF FAM. PHYSICIANS, *supra* note 163, at 3; Neale, *supra* note 8, at 3.

175 *See* Waiver Approval Letter to Florida, *supra* note 172, at 1; Waiver Approval Letter to Indiana, *supra* note 172, at 1; Waiver Approval Letter to Maine, *supra* note 172, at 6; Waiver Approval Letter to Mississippi, *supra* note 172, at 3; Waiver Approval Letter to Montana, *supra* note 172, at 1; Waiver Approval Letter to Tennessee, *supra* note 172, at 1; Waiver Approval Letter to Texas, *supra* note 172, at 1; Waiver Approval Letter to Virginia, *supra* note 172, at 1; Waiver Approval Letter to Wyoming, *supra* note 172, at 1; Waiver Approval Letter to Georgia, *supra* note 173, at 1.

176 Waiver Approval Letter to Florida, *supra* note 172, at 1, 11 (showing the extension application approval date is January 15, 2021); Waiver Approval Letter to Tennessee, *supra* note 172, at 1, 17 (showing the extension application approval date is January 8, 2021); Waiver Approval Letter to Texas, *supra* note 172, at 1, 12 (showing the extension application approval date is January 15, 2021); Cindy Mann, *Uncompensated Care Pool Waivers Undermine Health Coverage for the Uninsured*, COMMONWEALTH FUND (Apr. 16, 2021), https://www.commonwealthfund.org/blog/2021/uncompensated-care-pool-waivers-undermine-health-coverage-uninsured.

177 Karen Brooks Harper, *Federal Judge Rules for Texas, Temporarily Restores Federal Health Care Funding Extension*, TEX. TRIB. (Aug. 20, 2021), https://www.texastribune.org/2021/08/20/exas-1115-waiver-judge-ruling-medicaid/; Mann, *supra* note 176.

178 Letter of Withdrawal to Texas, *supra* note 75, at 1, 7.

179 Brad Johnson, *Texas Wins Preliminary Victory Against Biden Administration in Medicaid Lawsuit*, TEXAN (Aug. 23, 2021), https://thetexan.news/texas-wins-preliminary-victory-against-biden-administration-in-medicaid-lawsuit/.

180 *Waiver Renewal*, TEX. HEALTH & HUM. SERVS., https://www.hhs.texas.gov/laws-regulations/policies-rules/waivers/waiver-renewal (click to expand the "November 2020 Extension Request" section on the webpage).

1115 waiver applications.[181] The statute allows CMS to grant states an exemption from the normal "Federal and State public notice procedures to expedite a decision on a proposed demonstration or demonstration extension request that addresses a . . . public health emergency, or other sudden emergency threats to human lives."[182] Texas cited this statute when it proposed the ongoing public health emergency—COVID-19—and the pressure this emergency put on the state's health care system as its rationale for an exemption request.[183] On December 15, 2020, one month prior to approving the waiver extension, CMS granted Texas's public health emergency exemption and confirmed that Texas was "exempt from the requirements for public notice and comment."[184]

On April 16, 2021, CMS, now under the Biden administration, formally rescinded Texas's original extension approval from three months prior.[185] CMS officially pointed to the absence of the required federal-level public notice and comment period as the agency's reason for rescinding the approval.[186] CMS explained that Texas's rationale for requesting an exemption from the normal public notice requirements "did not meaningfully explain why the extension requested addressed the COVID-19 public health emergency or any other sudden emergency threat to human lives" as required by statute.[187] As a result of the recission, Texas Attorney General Ken Paxton sued Chiquita Brooks-LaSure, Administrator of CMS.[188] Paxton claimed that the healthcare of Texas citizens would be "negatively and irreparably harmed absent the entry of a preliminary injunction" preventing HHS from implementing the April 2021 rescission letter.[189] On August 20, 2021, the district court granted Texas's motion for a preliminary injunction.[190] The court found, in part, that CMS's rescission based on the absence of public notice and comment requirements was arbitrary and capricious.[191]

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[181] 42 C.F.R. § 431.416 (2021).

[182] *Id.* § 431.416(g).

[183] *Waiver Renewal*, *supra* note 180.

[184] Letter from Angela Garner, Ctrs. for Medicare & Medicaid Servs., Dir. Div. Sys. Reform Demonstrations, to Stephanie Stephens, Tex. Health & Hum. Servs. Comm'n, State Medicaid Dir. 1 (Dec. 15, 2020), https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tx-healthcare-transformation-cmplt-ltr-state-phe-app-20201215.pdf; *see also* Waiver Approval Letter to Texas, *supra* note 172, at 9.

[185] Letter of Withdrawal to Texas, *supra* note 75, at 1, 7.

[186] *Id.* at 7.

[187] *Id.* at 3.

[188] Johnson, *supra* note 179.

[189] Plaintiffs' Motion for Preliminary Injunction at 32, 35, Texas v. Brooks-Lasure, No. 6:21-cv-00191 (E.D. Tex. Aug. 20, 2021).

[190] Texas v. Brooks-Lasure, No. 6:21-cv-00191, 2021 WL 5154219, at *15 (E.D. Tex. Aug. 20, 2021).

[191] *Id.* at *11.

On April 22, 2022, CMS announced that it was formally withdrawing its April 16, 2021 letter, in which the agency notified Texas that it was rescinding the state's extension approval dated January 15, 2021.[192] Despite the withdrawal, CMS's letter pointed out that the district court never "address[ed] the underlying legal issues" behind CMS's original rescission: Texas's "failure to comply with public notice and comment requirements."[193] CMS then explained that, while it "remains committed to working with states to conduct robust public notice and comment periods to receive feedback from Medicaid enrollees and other stakeholders," the agency "concluded that it is not the best use of the federal government's limited resources to continue to litigate [the] matter."[194] CMS concluded by stating it would not take any further action to rescind Texas's section 1115 waiver extension based upon the specific issue of the state's "failure to comply with public notice and comment requirements."[195] But, CMS did not rule out the option of taking action against Texas's waiver extension based upon other issues.[196] Accordingly, CMS's statement leaves the agency the option of rescinding or amending Texas's waiver extension in order to revise the extension operating period so it complies with the statutorily prescribed three- or five-year limits.

The following sections and Part III present this alternative argument for rescinding, or at least amending, Texas's section 1115 waiver extension, as well as the other waiver extensions granted in excess of five years. The following sections explore how CMS's 2017 guidance flouted section 1115's governing statute by allowing for ten-year extension periods. Part III further explores why three- or five-year extension limits are better suited to protect the interests of stakeholders and improve outcomes for Medicaid beneficiaries.

B. Authority, or Lack Thereof, to Promulgate the Guidance

In 1984, in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, the Supreme Court created a two-step test to be used when reviewing agency action with respect to a statute that the agency administers.[197] The focus of this

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[192] Letter from Chiquita Brooks-LaSure, Ctrs. for Medicare & Medicaid Servs., Adm'r, to Stephanie Stephens, Tex. Health & Hum. Servs. Comm'n, State Medicaid Dir. 1 (Apr. 22, 2022), https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tx-healthcare-transformation-cms-ltr-state-04222022.pdf.

[193] *Id.* at 2.

[194] *Id.*

[195] *Id.*

[196] *See id.*

[197] 467 U.S. 837, 842–43 (1984).

section will be the first step, which is "always" to ask "whether Congress has directly spoken to the precise question at issue."[198] In other words, it must be determined whether the statute is "silent or ambiguous with respect to the specific issue."[199] If Congress has directly spoken to the precise issue, and Congress's intent is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[200] However, if Congress has not spoken directly to the precise issue, administrative agencies are permitted to promulgate rules in order to fill any gaps left by Congress, so long as those rules are not arbitrary, capricious, or contrary to the statute.[201]

To evaluate if Congress's intent is clear and unambiguous, courts look to the "plain meaning rule" which considers the plain meaning of the statute.[202] The plain meaning rule calls on courts to first examine the text.[203] If a court finds that the language is clear and unambiguous on its face, the analysis ordinarily stops there and courts will not look beyond the words of the statute (such as to the legislative history or policy considerations[204]).[205] If the language of the statute is plain, the rule instructs courts "to enforce it according to its terms."[206]

To determine the plain meaning of section 1315 as it relates to demonstration project extension durations, Subsection 1 first examines the statute's text. Subsection 1 looks to the meanings of provisions sections 1315(e)(2) and 1315(f)(6), which speak directly to extension durations. Subsection 2 then analyzes the purpose of section 1315 as whole to further discern the statute's plain meaning as it relates to extension time periods. Finally, Subsection 3 analyzes subsection section 1315(a)(1) which allows CMS to approve waivers for the period the agency finds necessary to enable a state to carry out the project.

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198 *Id.* at 842.

199 *See id.* at 843.

200 *Id.* at 842–43.

201 *Id.* at 843 (citing Morton v. Ruiz, 415 U.S. 199, 231 (1974)).

202 *See* Bethesda Hosp. Ass'n v. Bowen, 485 U.S. 399, 403 (1998).

203 LARRY M. EIG, CONG. RSCH. SERV., 7-5700, STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS 47 (2014), https://sgp.fas.org/crs/misc/97-589.pdf.

204 William Baude & Ryan D. Doerfler, *The (Not So) Plain Meaning Rule*, 84 U. CHI. L. REV. 539, 543 (2017).

205 Tenn. Valley Auth. v. Hill, 437 U.S. 153, 184 n.29 (1978).

206 EIG, *supra* note 203, at 47.

1. Section 1315 Unambiguously Sets Three- or Five-Year Limits

The language used by Congress in section 1315 clearly and unambiguously sets the maximum permissible section 1115 waiver extension time periods. The statute speaks to first-time extensions of current demonstration projects in section 1315(e)(2).[207] When prescribing first-time extension durations, section 1315(e)(2) provides that states may request extensions "of up to 3 years (5 years, in the case of a waiver described in section 1396n(h)(2) of this title)."[208] The Merriam-Webster Dictionary defines "up to" as "a function word to indicate a limit or boundary."[209] Therefore, the language in section 1315(e)(2) sets the "limit or boundary" on extension time periods by clearly prescribing that waivers may be extended for a maximum of three years, or five years in certain situations.[210] The statute then reiterates this same extension time limit in section 1315(f)(6) when it is speaking to subsequent extensions of projects already extended pursuant to section 1315(e)(2).[211] When prescribing subsequent extension durations, section 1315(f)(6) states that "[a]n approval . . . for an extension of a waiver project under this subsection shall be for a period not to exceed 3 years (5 years, in the case of a waiver described in section 1396n(h)(2) of this title)."[212] The Merriam-Webster Dictionary defines "exceed" as "to go beyond a limit set by."[213] Therefore, the language in section 1315(f)(6) states that the waiver extension period shall not go beyond the limit of three years, or five years in certain situations.[214] Not once but twice the statute clearly and unambiguously speaks directly to time limits for section 1115 waiver extensions.[215] The statute prescribes specific extension limits, with five years being the longest possible extension available.[216] These two provisions of section 1315 set firm limits on extension time periods, thus invalidating CMS's 2017 guidance allowing for extensions beyond these limits.

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[207] 42 U.S.C. § 1315(e)(2).

[208] *Id.*

[209] *Up to*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/up%20to (last visited Nov. 18, 2021).

[210] *See* 42 U.S.C. § 1315(e)(2).

[211] *Id.* § 1315(f)(6).

[212] *Id.*

[213] *Exceed*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/exceed (last visited Nov. 18, 2021).

[214] *See* 42 U.S.C. § 1315(e)(2).

[215] *Id.* § 1315.

[216] *Id.*

2. The Purpose of Section 1315 as a Whole

The purpose of section 1315 further supports the reading that Congress intended to impose time limits on waiver extensions. In section 430.25 (titled "Waivers of State plan requirements"), Congress expressly described the purpose of all waivers granted by CMS, which includes section 1115 waivers.[217] Under section 430.25(b) (titled "Purpose of waivers"), the statute reads: "Waivers . . . permit a State to implement innovative programs or activities on a time-limited basis . . . ."[218] The phrase, "on a time-limited basis"[219] supports reading section 1315 to conclude that Congress intended to impose time limits and not simply allow CMS unlimited and unfettered discretion to decide waiver durations.

As described above, per section 430.25(b), Congress's express purpose for all Medicaid waivers issued by CMS supports the conclusion that Congress intended to impose time limits on section 1115 waivers.[220] Congress then set those time limits in text when it drafted and passed section 1315.[221] In reading section 1315 as a whole, Congress clearly and unambiguously set section 1115 waiver extension time limits.[222] The text of the statute supports this conclusion.[223] Congress spoke directly to the precise issue of waiver extension time limits by setting a single time limit: "3 years (5 years, in the case of a waiver described in section 1396n(h)(2) . . . ."[224] Congress included this phrase, verbatim, in two different subsections of section 1315.[225] By including the exact same time limit in two separate subsections, Congress reinforced its intent to impose this limit, leaving no gap for CMS to fill in regard to this precise issue.

3. For the Period CMS Finds Necessary

However, there is one more subsection of section 1315 that speaks to waiver time periods. Subsection 1315(a)(1) states that CMS "may waive compliance with any requirements . . . to the extent and for the period [CMS] finds necessary to enable such State . . . to carry out such project."[226] In fact, CMS included this

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217 42 C.F.R. § 430.25(a)–(b) (2021).
218 *Id.* § 430.25(b).
219 *Id.*
220 *Id.*
221 42 U.S.C. § 1315e(2), f(6).
222 *Id.* § 1315.
223 *See id.* § 1315e(2), f(6).
224 *Id.* § 1315e(2), f(6).
225 *Id.* § 1315e(2), f(6).
226 *Id.* § 1315e(a)(1).

statutory language in nine of its approval letters that granted waiver extensions in excess of five years.[227] Subsection 1315(a)(1) does not specify if it is to be applied to new waiver approvals, waiver extensions, or both.[228] However, for the sake of argument, this Comment will take the position that CMS took on the matter and presume the subsection applies to waiver extensions. The phrase "for the period [CMS] finds necessary" is certainly ambiguous and it appears to be a gap that Congress expressly permitted CMS to fill.[229] However, a single sentence in a statute should not be read in "complete isolation."[230] When ascertaining a statute's meaning, a court should not be "guided by a single sentence or member of a sentence, but look to the provisions of the whole law."[231]

The Ninth Circuit echoed this idea that courts should look to the whole law in *Beno v. Shalala*.[232] In *Beno*, the Ninth Circuit sought to interpret section 1315 and stated: "In interpreting § 1315, we must, of course, 'follow the cardinal rule that a statute is to be read as a whole.'"[233] The court elaborated: "[T]he meaning of statutory language, plain or not, depends on context."[234] During its analysis of the whole statute, the court began analyzing the "extent and period necessary" language from section 1315(a)(1).[235] In its analysis, the court stated that it would not be appropriate to give CMS complete deference when interpreting "for the 'extent and period she finds necessary'" if the "agency's interpretation . . . conflicts with the statute's plain meaning."[236] When section 1315(a)(1) is read in context with section 1315 as a whole, it appears that Congress granted CMS the authority to grant section 1115 waivers for the period that the agency found

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[227] Waiver Approval Letter to Florida, *supra* note 172, at 1; Waiver Approval Letter to Indiana, *supra* note 172, at 1; Waiver Approval Letter to Maine, *supra* note 172, at 1; Waiver Approval Letter to Montana, *supra* note 172, at 1; Waiver Approval Letter to Tennessee, *supra* note 172, at 1; Waiver Approval Letter to Texas, *supra* note 172, at 1; Waiver Approval Letter to Virginia, *supra* note 172, at 1; Waiver Approval Letter to Wyoming, *supra* note 172, at 1; Waiver Approval Letter to Georgia, *supra* note 173, at 1. Notably, these same letters make no mention of the three- or five-year limits prescribed in sections 1315(e)(2) and 1315(f)(6) of the statute. *See* sources cited *supra* note 172.

[228] *See* 42 U.S.C. § 1315(a)(1).

[229] *Id.*

[230] Mastro Plastics Corp. v. NLRB, 350 U.S. 270, 285 (1956).

[231] *Id.* (quoting U.S. v. Boisdore's Heirs, 49 U.S. (8 How.) 113, 122 (1849)).

[232] 30 F.3d 1057, 1068 (9th Cir. 1994).

[233] *Id.* (quoting Conroy v. Aniskoff, 507 U.S. 511, 515 (1993)).

[234] *Id.* (alteration in original) (quoting *Conroy*, 507 U.S. at 515).

[235] *Id.* at 1071.

[236] *Id.* (first citing Sullivan v. Everhart, 494 U.S. 83, 88–89 (1990); and then citing Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984)).

necessary, as long as waiver extensions did not exceed the three- or five-year limits prescribed in section 1315(e)(2) and section 1315(f)(6).[237]

In 2015, the Supreme Court also examined this relationship between plain meaning and context.[238] In *King v. Burwell*, the Court stated that a phrase must be "read in context, 'with a view to [its] place in the overall statutory scheme.'"[239] The Court further explained that even where a phrase "may seem plain 'when viewed in isolation,'" such reading may "turn[] out to be 'untenable in light of [the statute] as a whole.'"[240] The Court held that the context and structure of the statute at issue compelled the Court to depart from the most natural reading of the phrase.[241] Here, reading section 1315(a)(1) to mean that CMS could grant waiver extensions in excess of five years would contradict the statute's overall context and structure. Specifically, this reading would contradict the text of sections 1315(e)(2) and 1315(f)(6).[242] Additionally, if Congress did intend for CMS to extend waivers for an unlimited amount of time as the agency saw fit, then adding extension time limits to the two final subsections of section 1315 would contradict that intent.

However, this provision—that CMS has the discretion to grant waivers for the period the agency sees fit—is not surplusage. Congress prescribed three- or five-year limits as a ceiling. CMS has the discretion to grant section 1115 waivers for the time period the agency sees fit, up to this set ceiling. The phrases "up to," from section 1315(e)(2),[243] and "not to exceed," from section 1315(f)(6),[244] support such a reading. In using these phrases, Congress set a firm extension time limit, while simultaneously leaving CMS with some discretion regarding time periods.[245]

C. An Impermissible Construction of the Statute

Even if there remains a question as to the agency's authority to promulgate the 2017 guidance, the guidance is still contrary to the meaning and purpose of

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237 *See* 42 U.S.C. § 1315(a)(1), (e)(2), (f)(6).

238 576 U.S. 473, 497 (2015).

239 *Id.* at 487 (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000)).

240 *Id.* at 497 (quoting Dep't of Revenue of Or. v. ACF Indus., Inc., 510 U.S. 332, 343 (1994)).

241 *Id.*

242 *See* 42 U.S.C. § 1315(a)(1), (e)(2), (f)(6).

243 *Id.* § 1315(e)(2).

244 *Id.* § 1315(f)(6).

245 *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 147, 155 (2000) (relying on, in part, Congress's consideration and rejection of several amendments that would have given the FDA the authority to regulate tobacco when holding that the FDA did not have such authority).

the governing statute. In *Chevron*, the Supreme Court stated that "if the statute is silent or ambiguous with respect to the specific issue"—thereby giving an agency the authority to fill such a gap—"the question for the court is whether the agency's answer is based on a permissible construction of the statute."[246] The statute governing section 1115 waivers, section 1315, states that the programs receiving these waivers are to be "experimental, pilot, or demonstration project[s]."[247] The 2017 CMS guidance states that, in order to qualify for an extension "for a period up to 10 years," a demonstration project under a section 1115 waiver must be "routine, successful, [and] non-complex."[248] Even if the agency had the authority to grant extensions in excess of five years (but it does not, as described above), the 2017 guidance would still be unlawful because the "routine, successful, [and] non-complex" demonstration projects it makes eligible for extensions are by definition inconsistent with the statute's limitation of waiver grants to "experiment[s]," "pilots," and "demonstration[s]."

Subsection 1 discusses the meaning of "routine, successful, [and] non-complex," while Subsection 2 discusses the meaning of "experimental, pilot, [and] demonstration." Subsection 2 contends that the two descriptions are in tension with one another. The subsection argues that demonstration projects cannot be "routine, successful, [and] non-complex" while also being "experimental, pilot, or demonstration."

1. Routine, Successful, Non-Complex

CMS's 2017 guidance reads: "Where possible, and subject to the public notice and transparency requirements, CMS may approve the extension of routine, successful, non-complex section 1115(a) waiver and expenditure authorities in a state for a period up to 10 years . . . ."[249] There is no "or" separating the list of traits. And the list's placement immediately before "section 1115(a) waiver" suggests that, in order to extend a waiver for up to ten years, the project must be routine, successful, *and* non-complex.

The Merriam-Webster Dictionary defines "routine" as "of a commonplace or repetitious character" and "of, relating to, or being in accordance with

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246 Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843 (1984).
247 42 U.S.C. § 1315(a).
248 Neale, *supra* note 8, at 3.
248 42 U.S.C. § 1396n(h)(2)(A).
249 Neale, *supra* note 8, at 3.

established procedure."[250] "Successful" is defined as a "resulting or terminating in success."[251] And "success" is defined as a "favorable or desired outcome."[252] The Merriam-Webster Dictionary defines "non-complex" as "not hard to separate, analyze, or solve."[253] Based on these definitions, the types of projects CMS seemed to be referring to in the 2017 guidance were projects that: (1) had established procedures, (2) resulted in a favorable or desired outcome, and (3) were not difficult to analyze and implement. Therefore, these types of projects would be programs that were fully developed and established after a trial period resulted in a favorable outcome.

CMS's 2017 guidance does not offer any insight into how CMS defines "routine," "successful," and "non-complex."[254] CMS's approval letters to states for extensions in excess of the three- or five-year statutory limits also do not offer any express explanations as to how CMS might define "routine," "successful," and "non-complex."[255] However, CMS's "Developing the Evaluation Design" document does provide some explanatory context for successful projects.[256] The document makes a reference to projects that have "previously been rigorously evaluated and found to be successful."[257] This context further clarifies that a successful project can only be deemed as such *after* it has been previously evaluated. This suggests that a trial or test was conducted prior to such evaluation.

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[250] *Routine*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/routine (last visited Nov. 20, 2021).

[251] *Successful*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/successful (last visited Nov. 18, 2022).

[252] *Success*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/success (last visited Nov. 20, 2021).

[253] *Noncomplex*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/noncomplex (last visited Nov. 20, 2021).

[254] *See* Neale, *supra* note 8 at 3.

[255] *See* Waiver Approval Letter to Florida, *supra* note 172; Waiver Approval Letter to Indiana, *supra* note 172; Waiver Approval Letter to Maine, *supra* note 172; Waiver Approval Letter to Mississippi, *supra* note 172; Waiver Approval Letter to Montana, *supra* note 172; Waiver Approval Letter to Tennessee, *supra* note 172; Waiver Approval Letter to Texas, *supra* note 172; Waiver Approval Letter to Virginia, *supra* note 172; Waiver Approval Letter to Wyoming, *supra* note 172; Waiver Approval Letter to Georgia, *supra* note 173.

[256] *See* MEDICAID.GOV, SECTION 1115 DEMONSTRATIONS: DEVELOPING THE EVALUATION DESIGN 5, https://www.medicaid.gov/medicaid/downloads/developing-the-evaluation-design.pdf (last visited Nov. 21, 2021).

[257] *Id.*

2. Experimental, Pilot, or Demonstration

Now, this section seeks to define what qualifies as an "experimental, pilot, or demonstration" project and explore how those qualities compare with the meanings of "routine, successful, [and] non-complex." This analysis will begin with the dictionary. One dictionary defines "experimental" as "pertaining to, derived from, or founded on experiment."[258] "Experiment" is defined as "a test, trial, or tentative procedure."[259] One dictionary defines "pilot" as "serving as an experimental or trial undertaking prior to full-scale operation or use."[260] Various dictionaries define "demonstration" only as a noun,[261] not as an adjective as it is used throughout section 1315.[262] However, CMS itself states that a demonstration project "test[s] and measure[s] the effect of potential program changes."[263] Many organizations and entities define demonstration projects in a similar way. For example, the CDC states that "[d]emonstration projects test and measure the effects of program changes in real-world situations."[264] Each of these definitions reference the same words: "experiment," "test," and "trial."[265] When comparing these definitions with the meanings of "routine," "successful," and "non-complex," the tension is apparent. The statutory descriptions—"experimental, pilot, [and] demonstration"—describe projects that have experimental value in that the projects test or trial experimental procedures.[266] In contrast, CMS's 2017 guidance descriptions—"routine, successful, [and] non-complex"—describe projects that would no longer serve any experimental, testing, or trial purpose because these projects have already been evaluated and determined to be successful with well-established procedures.[267]

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[258] *Experimental*, DICTIONARY.COM, https://www.dictionary.com/browse/experimental (last visited Nov. 19, 2021).

[259] *Experiment*, DICTIONARY.COM, https://www.dictionary.com/browse/experiment (last visited Nov. 19, 2021).

[260] *Pilot*, DICTIONARY.COM, https://www.dictionary.com/browse/pilot (last visited Nov. 19, 2021).

[261] *Demonstration*, DICTIONARY.COM, https://www.dictionary.com/browse/demonstration (last visited Nov. 19, 2021); *Demonstration*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/demonstration (last visited Feb. 6, 2022); *Demonstration*, CAMBRIDGE DICTIONARY, https://dictionary.cambridge.org/us/dictionary/english/demonstration (last visited Feb. 6, 2022).

[262] *See* 42 U.S.C. § 1315.

[263] *Medicare Demonstration Projects & Evaluation Reports*, CMS.GOV, https://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts (last visited Nov. 19, 2021).

[264] *Demonstration Projects*, CDC.COM, https://www.cdc.gov/hiv/research/demonstration/index.html (last visited Nov. 19, 2021).

[265] *See supra* notes 259–60, 263–64 and accompanying text.

[266] *See supra* notes 259–60, 263–64 and accompanying text.

[267] *See supra* notes 250–53, 256–57 and accompanying text.

Additionally, each definition of the statutory descriptions—"experimental, pilot, or demonstration"—indicates a lack of permanence and full development. Per one dictionary, an "experiment" is tentative.[268] And "tentative" is defined as "unsure, uncertain," as well as "done as a trial, experiment, or attempt."[269] Notably, once again, the words "experiment" and "trial" are mentioned. Importantly, though, "tentative" describes a project that is uncertain, indicating it is not meant to be implemented on a permanent basis yet.[270] Once fully adopted and implemented, a program becomes certain, and it no longer meets the definition of "tentative." A pilot occurs "prior to full-scale operation or use."[271] Similar to a tentative project, once adopted and implemented into full-scale operation or use, a pilot project no longer meets the definition of "pilot." Finally, a demonstration project tests "potential program changes."[272] Once these changes are adopted and implemented, the project becomes actual and not potential, thereby effectively ending the demonstration.

What each of these descriptions have in common is that they indicate a project that is occurring *prior* to the (possible) implementation of a fully developed program.[273] Once a fully developed program is adopted and implemented, by definition each of these projects necessarily ends.[274] The statutory descriptions—"experimental, pilot, [and] demonstration"—describe temporary projects that *precede* the eventual implementation of a fully-developed program.[275] In contrast, CMS's 2017 guidance descriptions—"routine, successful, [and] non-complex"—refer to programs that are established, not temporary, and that occur *after* a successful trial or test.[276]

Case law also offers insight as to what an "experimental, pilot, or demonstration" project is. As mentioned previously in this Comment, the Ninth Circuit sought to interpret section 1315 in *Beno*.[277] The court analyzed the statute during its review of a California section 1115 waiver that CMS had granted.[278] The first requirement of section 1315 that the court analyzed was the "experimental, pilot, or demonstration project" requirement noted in provision

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268 *Experiment*, *supra* note 259.
269 *Tentative*, DICTIONARY.COM, https://www.dictionary.com/browse/tentative (last visited Nov. 19, 2021).
270 *Id.*
271 *Pilot*, *supra* note 260.
272 *Medicare Demonstration Projects & Evaluation Reports*, *supra* note 263.
273 *See supra* notes 268–72 and accompanying text.
274 *See supra* notes 268–72 and accompanying text.
275 *See supra* notes 268–72 and accompanying text.
276 *See supra* notes 250–53, 256–57 and accompanying text.
277 Beno v. Shalala, 30 F.3d 1057, 1068–72 (9th Cir. 1994).
278 *Id.* at 1060.

section 1315(a).[279] The court first confirmed that this provision was indeed a requirement for section 1115 waivers.[280] The Ninth Circuit then briefly explained how it interpreted this requirement.[281] The court quoted the Senate Report of the Committee on Finance from 1962 stating that section 1315 "was not enacted to enable states to save money or to evade federal requirements, but to 'test out new ideas and ways of dealing with the problems of public welfare recipients.'"[282] Therefore, a benefits cut without any research or experimental goal, would not meet this primary requirement.[283] The court concluded that the "experimental, pilot, or demonstration project" provision required that CMS determine that the proposed project "has a research or a demonstration value" and that it is "likely to yield useful information or demonstrate a novel approach to program administration."[284]

The project descriptions from CMS's 2017 guidance—"routine, successful, [and] non-complex"—are in tension with the Ninth Circuit's interpretation in *Beno*.[285] If a project has been deemed successful after achieving a "favorable or desired outcome,"[286] and its procedures are established and made routine,[287] it is difficult to ascertain what kind of further "useful information or . . . novel approach" that project might deliver.[288] Therefore, it is unlikely that a "routine, successful, [and] non-complex" project would have a research or demonstrative value as required.[289]

In *Newton-Nations v. Betlach*, the Ninth Circuit reviewed a demonstration project approved via a section 1115 waiver in Arizona.[290] In its opinion, the court cited to the requirements that *Beno* listed for demonstration projects, including that the project must have a "research or demonstration value."[291] In *Newton-Nations*, Arizona's demonstration project included increased copayments and this was the reason for the court's review.[292] The court quoted a public health

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279 *Id.* at 1069.
280 *Id.*
281 *Id.*
282 *Id.* (quoting S. REP. NO. 87-1589 at 19, *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1962).
283 *Id.*
284 *Beno*, 30 F.3d at 1069.
285 *See id.*
286 *Success*, *supra* note 252.
287 *Routine*, *supra* note 250.
288 *See Beno*, 30 F.3d at 1069.
289 *See id.*
290 660 F.3d 370, 374 (9th Cir. 2011).
291 *Id.* at 381 (quoting *Beno*, 30 F.3d at 1069).
292 *Id.* at 374.

expert who stated that "[o]ver the last 35 years, a number of studies have looked at the effects of cost sharing on the poor. Of all forms of cost sharing, copayments are the most heavily studied."[293] The question before the court in regard to this particular issue was whether Arizona's project would "actually demonstrate something different than the last 35-years' worth of health policy research."[294] This standard the court applied to its question meant that a project's research or demonstration value could be diminished not only by a prior demonstration project, but also by prior health policy research in general.[295] This raised the standard for what kind of data might be found to be different, new, or novel by expanding the amount of existing data that any new data must be compared to.[296] Ultimately, the Ninth Circuit reversed the district court's decision that CMS's approval of Arizona's cost sharing met the requirements of section 1315.[297] The court then remanded the issue back to CMS for further consideration.[298] This heightened standard for what qualifies as different, new, or novel data makes it that much more difficult to ascertain how a "routine, successful, non-complex" demonstration project would deliver "useful information or . . . novel approach."[299] Further, the Ninth Circuit's decision partially relied upon the fact that there was already "35-years' worth" of information on the subject of Arizona's demonstration project.[300] This shows that study length is relevant when deciding if a project qualifies as an "[e]xperiment[], [p]ilot, or [d]emonstration."[301] The longer a study or project continues, the more difficult it becomes for that study or project to demonstrate different, new, or novel data.[302] Therefore, "experimental, pilot, or demonstration" projects will typically have more research or demonstration value when they are short-term, and that value decreases over time.[303]

In *Beno*, the Ninth Circuit quoted the Supreme Court stating that courts may "consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment."[304] Here,

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293 *Id.* at 381 (alteration in original) (quoting Plaintiff's public health expert who is not named or cited to).

294 *Id.*

295 *See id.*

296 *See id.*

297 *Id.* at 383.

298 *Id.*

299 *See* Beno v. Shalala, 30 F.3d 1057, 1069 (9th Cir. 1994).

300 *Newton-Nations*, 660 F.3d at 381.

301 *See id.*

302 *See id.*; *Beno*, 30 F.3d at 1069.

303 *See Newton-Nations*, 660 F.3d at 381.

304 *Beno*, 30 F.3d at 1073 (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971)).

CMS's 2017 guidance allowing for extensions of up to ten years for "routine, successful, [and] non-complex projects" did not consider that section 1115 waivers may only be granted for "experimental, pilot, or demonstration projects." This statutory language is a relevant factor because, as the Ninth Circuit confirmed in *Beno*, these factors are a requirement of section 1115 waivers.[305] Therefore, there was a "clear error of judgment" on the part of CMS in promulgating the 2017 guidance.[306] Due to the failure to consider the relevant factors when drafting the guidance, CMS should formally deem the 2017 guidance invalid. CMS should then rescind or amend any "routine, successful, [and] non-complex" projects extended in excess of five years under the guidance. Further, the clear error in promulgating this guidance should prevent its reimplementation at a later time by current or future administrations.

III. FOSTERING INNOVATION AND PROTECTING STAKEHOLDERS

Aside from statutory considerations, there are policy arguments to be made in favor of limiting demonstration project durations to three or five years. To be certain, this is not an argument that CMS should automatically terminate these projects at the end of three or five years. If a demonstration project is running well, benefitting Medicaid recipients, and delivering valuable data, why terminate it? Instead, this Comment argues that CMS should review demonstration projects for extension at least every five years (if not every three years) by evaluating if the projects are still serving their intended purpose. Section 1115 waivers that authorize projects that do not meet their intended purpose become nothing more than loopholes states can employ to avoid implementing federally mandated requirements into their Medicaid plans. Section 1115 waivers have great potential to benefit state Medicaid programs and serve Medicaid beneficiaries, so long as they are limited in scope and not abused.[307]

"[A]dministrative 'big waiver' authorities" are statutory provisions that give federal agencies "the power to depart from mandatory rules set by federal law."[308] Section 1115 waivers grant CMS the authority to approve state plans that deviate from the federally mandated default requirements for state Medicaid programs.[309] In allowing states to deviate from the default requirements and

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305 *See id.* at 1069.
306 *See id.* at 1073 (quoting *Overton Park*, 401 U.S. at 416).
307 *See* Albanese, *supra* note 17, at 829–30.
308 Lawrence, *supra* note 18, at 1487.
309 *Id.*

build "experimental, pilot, or demonstration [Medicaid] projects," section 1115 waivers can foster innovation by freeing states to experiment with programs that fall outside of the parameters of the law.[310] Such innovation can advance Medicaid programs leading to positive outcomes for beneficiaries, so long as section 1115 waivers are used consistent with "their original purpose: creating meaningful innovations that improve outcomes for Medicaid recipients."[311]

This Part explains how project duration impacts this purpose. First, Section A looks to meaningful innovation. Section A argues that long project duration times, such as ten years, hinder and delay innovation. Section B then looks to improving outcomes for Medicaid recipients by exploring the recipients' interests as stakeholders in state Medicaid programs. Section B argues that ten-year extension periods preclude these stakeholders from the opportunity to participate in program development for an inordinate length of time.

A. Innovation Requires Experimentation and Novel Data

Congress enacted section 1115 in 1962.[312] Three years later, in 1965, Congress subjected the newly created Medicaid program to the waiver provision.[313] When Congress created section 1115 waivers, President Kennedy envisioned that these waivers would foster innovations that would help solve localized issues of public-assistance programs.[314] Senate commentary and guidance issued by the Department of Health, Education, and Welfare ("HEW"[315]) during this time "further emphasized that the waivers were to be both limited in scope and focused on innovation."[316] To illustrate this innovative function, consider a hypothetical situation in which Indiana and Illinois are seeking section 1115 waivers to implement identical demonstration projects. In this hypothetical, CMS would not need "to approve a waiver that tests the same intervention in both Indiana and Illinois unless HEW had reason to believe the affected populations were sufficiently different."[317] This is an example of the requirement that these demonstration projects produce novel data.

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310 *Id.* at 1497–98.

311 Albanese, *supra* note 17, at 847.

312 *Id.* at 829.

313 *Id.*

314 *Id.*

315 HEW became the Department of Health and Human Services in 1980. *Id.* at 830 n.15 (citing *HHS Historical Highlights*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Feb. 10, 2017), https://www.hhs.gov/about/historical-highlights/index.html).

316 *Id.*

317 *Id.*

Section 1115 waivers unlock the potential for innovation because innovation needs experimentation.[318] The Oxford Dictionary of Business and Management defines "innovation" as "[a]ny new approach to designing, producing, or marketing goods or services that creates value."[319] The Oxford Dictionary distinguishes "innovation" from "invention," explaining that the latter involves thinking up a new idea while the former "involves bringing a new idea into practical effect."[320] Therefore, "innovation" is defined by its process of bringing an idea into effect and its creation of value.[321] This is where experimentation is necessary to innovation—through tests, experimentation provides the data necessary to turn a new idea into a reality.[322]

To achieve the purpose of section 1115 waivers and develop new, innovative program designs, demonstration projects must experiment with new ideas or (at least have the potential to) produce novel data.[323] Section II.B of this Comment discussed the Ninth Circuit's analysis of the meaning of "experimental, pilot or demonstration project" in *Beno*.[324] The court concluded that the "experimental, pilot, or demonstration project" provision required that the HHS Secretary "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."[325] The court confirmed that this provision was indeed a requirement for demonstration projects approved under section 1115 waivers.[326] There is no indication that this requirement would expire or evaporate simply because CMS is reviewing a project for an extension rather than a first-time approval.

As time passes, what is new, what is novel, and what is innovative necessarily changes. The Ninth Circuit addressed this in its decision in *Newton-Nations*.[327] The Ninth Circuit reversed the district court's decision that CMS's

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[318] *See* Joshua Bixby, *Experimentation is the Key to Innovation and Developers Make It Happen*, FORBES (Jan. 8, 2021), https://www.forbes.com/sites/forbestechcouncil/2021/01/08/experimentation-is-the-key-to-innovation-and-developers-make-it-happen/?sh=1e38eb8f50af; Emilia Saarelainen, *Why There's No Innovation Without Experimentation*, UNHCR INNOVATION SERVICE, https://www.unhcr.org/innovation/why-theres-no-innovation-without-experimentation/ (last visited Jan. 3, 2022).

[319] A DICTIONARY OF BUSINESS AND MANAGEMENT 314 (Jonathan Law ed., 6th ed. 2016).

[320] *Id.*

[321] *See id.*; Saarelainen, *supra* note 318.

[322] Bixby, *supra* note 318; Saarelainen, *supra* note 318.

[323] *See* Beno v. Shalala, 30 F.3d 1057, 1069 (9th Cir. 1994).

[324] *Id.*

[325] *Id.*

[326] *Id.*

[327] Newton-Nations v. Betlach, 660 F.3d 370, 374 (9th Cir. 2011); *see also supra* Section II.C.2 (discussing the case).

approval of Arizona's cost sharing met the requirements of section 1315, partially relying upon the fact that there was already "35-years' worth" of information on the subject of Arizona's demonstration project.[328] The court pointed out that there was "no evidence [in the administrative record] that the Secretary made 'some judgment that the project ha[d] a research or a demonstration value.'"[329] *Newton* considers a specific example of how duration and amount of data previously gathered might change whether a proposed project is deemed to have "research or . . . demonstration value."[330] The Ninth Circuit did not attempt to specify a precise length of time or amount of data that might preclude a proposed project from meeting the *Beno* requirement.[331] In fact, the court did not decide if Arizona's demonstration project had "research or demonstration value" at all (although the court did opine that it was questionable whether the Secretary could have made such a finding).[332] Instead, the court remanded the issue back to the Secretary to consider the issue and make a judgment as to whether the project had "research or demonstration value."[333] Similarly, this section does not argue that after three, or five, or ten years, a section 1115 demonstration project can no longer produce novel data and spur innovation. This section only argues that CMS should review demonstration projects at regular intervals that do not exceed five years to ensure that projects are still producing, or are capable of producing, novel data.

By reviewing demonstration projects for extension at shorter, three- or five-year intervals, CMS can avoid the pitfall of allowing a demonstration project that is not meeting its intended function to continue operating undetected. It stands to reason that the longer a project continues and the more data it gathers, the less likely it can or will demonstrate novel data.[334] Accordingly, as the opportunity for novel data through experimentation decreases, so does the opportunity for innovation.[335] Maintaining the approval of the operation of demonstration projects to five years or less provides for more timely reviews by CMS in which the agency can assess whether the projects are still capable of producing valuable, innovative ideas that can be brought into practical effect. If a demonstration project loses its "research or demonstration value" before its

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328 *Newton-Nations*, 660 F.3d at 381, 383.
329 *Id.* at 381 (quoting *Beno*, 30 F.3d at 1069).
330 *Id.* (quoting *Beno*, 30 F.3d at 1069).
331 *See id*.
332 *Id.* (quoting *Beno*, 30 F.3d at 1069).
333 *Id.* at 383 (quoting *Beno*, 30 F.3d at 1069).
334 *See id.* at 381; *Beno*, 30 F.3d at 1069.
335 *See* Saarelainen, *supra* note 318.

ten-year extension period ends, and CMS does not review the project until it expires, there is a risk for missed opportunities and wasted funds.

Experimentation for the purpose of innovation is about both gathering data and reviewing that data to make decisions about ideas and projects.[336] In other words, gathering data is not where the experiment ends.[337] Through analysis and examination, data is meant to guide projects further.[338] Data should answer questions such as: "What is the impact of the experiment?" "What needs to change?" "Do you need to repeat the same experiment, or should you create a different experiment?" "What data did the experiment produce, and do you need more data?"[339] By skipping this critical step of examining the data for periods in excess of five years, CMS is missing opportunities to ensure that demonstration projects are valuable, or to require states to make adjustments if warranted.[340]

It is not only CMS that reviews state demonstration projects—states can and do evaluate their own programs as they see fit.[341] Additionally, per Title 42, Section 431.428 of the Federal Code of Regulations, a state that is operating a demonstration project must submit an annual report to CMS.[342] However, section 431.428 does not require any action of the state or CMS once the evaluation is submitted.[343] Both examples of these state managed evaluations are internal evaluations, and even though section 431.428 requires the state to submit its completed evaluation to CMS, there is no explicit language stating that CMS must review the evaluation.[344] Considering the federal government's

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336 *Id.*

337 *See id.*

338 Bixby, *supra* note 318; Saarelainen, *supra* note 318.

339 Saarelainen, *supra* note 318; *see* Bixby, *supra* note 318.

340 States may submit applications to CMS to make amendments to existing demonstration projects, thereby affording states their own opportunity to make necessary adjustments based on gathered data. *Section 1115 Waiver Tracker Definitions*, KAISER FAM. FOUND. (Dec. 20, 2021), https://www.kff.org/report-section/section-1115-waiver-tracker-definitions/. As of December 20, 2021, there were over a dozen states with pending amendment applications. *Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State*, KAISER FAM. FOUND. (Dec. 20, 2021), https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/. However, this is not a requirement and a state can use its own discretion whether to seek an amendment or not.

341 For example, Texas created its own "evaluation design" which is separate from CMS's evaluation and reportedly determines "whether Texas continued its progress towards meeting the goals of the Demonstration and help guide future program improvements." *Waiver Renewal*, TEX. HEATH & HUM. SERVS., https://www.hhs.texas.gov/regulations/policies-rules/waivers/medicaid-1115-waiver/waiver-renewal (last visited Jan. 8, 2022).

342 42 C.F.R. § 431.428 (2021).

343 *See id.*

344 *See id.*

substantial fiscal contribution to state Medicaid programs,[345] it would be prudent for CMS to run its own, external evaluations every three or five years as well. In 2019, the federal government paid over $400 billion in funds for state Medicaid programs.[346] This accounts for more than half of the $750 billion the federal government was expected to provide state and local governments in grant money.[347] Per federal statute, the federal government must match between 50 and 83% of state Medicaid health care services, along with 50% of the state's administrative expenses.[348] Therefore, the federal government, and taxpayers, have a great deal at stake in the operation of state Medicaid programs, including demonstration projects. In Texas alone, the federal government spent $21.2 billion in 2020 for the state's Medicaid program.[349] If CMS does not externally evaluate Texas's demonstration project until 2030, the federal government risks wasting hundreds of billions of taxpayer money on a program that might not be producing novel data and fulfilling its innovative purpose.

B. Long Extensions Limit Opportunity for Stakeholder Participation

In an effort to improve transparency, over the last several years, CMS had taken steps to strengthen its education of and engagement with the public regarding both new demonstration project applications and extension requests.[350] There is a history of documented concerns regarding the transparency of the process.[351] From 2002 to 2014, the GAO expressed its concerns about the lack of transparency in CMS's review and approval of demonstration projects.[352] Additionally, Congress and stakeholders affected by the Medicaid program raised their own concerns for the need for greater transparency.[353] Transparency in the approval process is significant because, as recognized by Congress, demonstration projects can have substantial and varied impacts on Medicaid beneficiaries.[354] Accordingly, Congress decided that the application process should ensure public input.[355] Congress drafted section

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345 Lawrence, *supra* note 18, at 1522 & tbl.1.

346 Bridget A. Fahey, *Federalism by Contract*, 129 YALE L.J. 2232, 2339 (2020).

347 *Id.*

348 42 C.F.R. § 433.10(b) (2021); *Matching Rates*, *supra* note 45.

349 TEX. HEALTH & HUM. SERVS., HHS SYSTEM ANN. FED. FUNDS REP. STATE FISCAL YEAR 2020 1 (2020).

350 U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 117, at 5.

350 *Id.* at 6.

351 Review and Approval Process for Section 1115 Demonstrations, 77 Fed. Reg. 11678, 11678 (Feb. 27, 2012).

352 U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 117, at 5.

353 77 Fed. Reg. at 11678.

354 *Id.*

355 *Id.*

10201(i) of the ACA which amended section 1115 "to enhance public transparency, at both the state and federal level."[356] The amendment required CMS to develop regulations to provide for both state-level and federal-level public notice and comment periods for applications for both new and extensions of existing demonstration projects.[357] The focus of these regulations was to help facilitate sufficient opportunity for meaningful public input and accessibility of program information.[358] HHS announced its commitment to achieve transparency, input, and collaboration on April 7, 2010.[359] The agency then met with stakeholders and state officials to discuss transparency in preparation for drafting the new regulations.[360] As explained in Section I.D of this Comment, these now-codified regulations outlining state-level and federal-level public notice and comment periods contain many specific requirements, which include "processes to ensure opportunities for public input in the development of such applications by [s]tates and in the [f]ederal review of the [demonstration project] applications."[361]

Demonstration projects approved for periods of ten years effectively lock stakeholders out of the decision-making process for an inordinate amount of time. In the case of Texas's ten-year extension, CMS waived the federal-level public notice and comment period requirement for Texas.[362] This exemption effectively locked out the public, including Texas citizens and stakeholders most affected by the state's Medicaid program, from providing input to CMS for "most of the next decade."[363]

In Texas's case, there were real, not hypothetical, stakeholders who were actively invested in the notice and comment process of this extension application.[364] Before CMS granted Texas the exemption, these stakeholders wrote letters to the agency requesting that CMS provide stakeholders an opportunity for federal-level notice and comment before approving Texas's extension.[365] These stakeholders explained in detail the "significant concerns" they would have raised regarding the demonstration project—concerns that

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356 U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 117, at 3, 5.

357 *Id.* at 3; 42 C.F.R. §§ 431.408(a)(1), 431.416 (2021).

358 U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 117, at 5, 10.

359 77 Fed. Reg. at 11679.

360 *Id.*

361 *Id.* at 11700; *see supra* Section I.D.

362 Texas v. Brooks-Lasure, No. 6:21-cv-00191, 2021 WL 5154219, at *2 (E.D. Tex. Aug. 20, 2021).

363 Brief of Amicus Curiae for Every Texan in Opposition to Plaintiffs' Motion for Preliminary Injunction at 2, Texas v. Brooks-Lasure, No. 6:21-cv-00191 (E.D. Tex. Aug. 20, 2021).

364 *See id.*

365 *Id.* at 1–2.

"CMS would have been required to reasonably address."[366] This example shows that public notice and comment periods are not just procedural formalities that the public overlooks, but that stakeholders have a genuine interest in participating in the decision-making process.[367] If CMS chooses to leave these excessive extension periods in place, beneficiaries and stakeholders will not have an opportunity to provide input into the development and implementation of demonstration projects for seven years in some states, and for a decade in others. This outcome impedes Congress's and CMS's goals for greater transparency, public input, and collaboration.[368]

Additionally, much can change in ten years—affected stakeholders will change as people age, have children, develop illnesses, heal, and lose and gain employment. By affording the public the opportunity to participate in notice and comment every three or five years, CMS and the states provide new stakeholders an opportunity to add their individual and unique input into the process. However, if CMS leaves the ten-year extensions in place, citizens of the affected states may never have a voice in a program that suddenly greatly affects them.

Furthermore, the ten-year extension periods effectively solidify the negotiations and agreements between two administrations, one state-level and one federal-level,[369] for an unreasonable amount of time. Medicaid is a spending clause program, meaning that it is enacted pursuant to Congress's Spending Clause power.[370] The Supreme Court has recognized that these programs operate in the nature of a contract—states agree to implement administrative programs that follow federal requirements in exchange for federal funds.[371] Medicaid operates a bit differently in that it "offers states a menu of options and requires them to submit 'state plans' . . . and make assurances that they will comply with various conditions."[372] Just as with contracts, when the state and federal government enter into agreements with one another, they negotiate.[373] The section 1115 "waiver decision-making process . . . involves repeated 'informal negotiations' between state and federal officials in which federal officials may instruct the state on the telephone, over email, or in letters, what steps the state

366 *Id.* at 4–6.
367 *See id.*
368 *See* Review and Approval Process for Section 1115 Demonstrations, 77 Fed. Reg. 11678, 11678 (Feb. 27, 2012).
369 *See* Fahey, *supra* note 346, at 2399.
370 *Id.* at 2339.
371 *Id.*
372 *Id.* at 2340.
373 *Id.* at 2372.

must take in order to obtain approval."[374] These informal and private negotiations[375] appear to operate contrary to Congress's and CMS's goals for greater transparency in the approval process of demonstration project applications.[376] In the case of Texas, the state applied for a five-year extension, but, without explanation, CMS approved Texas's extension for a period of ten years.[377] This indicates that there were likely *informal* communications and negotiations between Texas and CMS that led to the ten-year extension period. If so, the question is, should future voters be bound by the negotiations between current state and federal administrations if and when those administrations change? The public votes state and federal administrations and representatives in and out of office several times during the span of ten years. To protect the interests of future voters and the agendas they vote for, CMS should not be permitted to grant ten-year operating periods for demonstration projects, and any such extensions should not stand. Ten-year extensions solidify politically motivated negotiations and agreements relating to demonstration projects—projects that have significant impacts on the lives and health of Medicaid beneficiaries—for a duration of time that could see several administration changes.[378]

CONCLUSION

The original purpose of section 1115 waivers was to create meaningful innovations and improve outcomes for Medicaid beneficiaries.[379] Ten-year extension periods obstruct these purposes. First, ten-year extensions provide for large interim periods between demonstration project review and data analysis. Accordingly, these long project durations hinder and delay innovation by allowing stagnate projects to continue to operate for extended periods of time under CMS's radar. More regular reviews conducted at intervals of five years or less provide more opportunities for external data examination so CMS and states can make any necessary adjustments and employ new, innovative approaches. Second, ten-year extensions block stakeholders, including Medicaid

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374 Lawrence, *supra* note 18, at 1533.

375 *Id.*

376 *See* Review and Approval Process for Section 1115 Demonstrations, 77 Fed. Reg. 11678, 11678 (Feb. 27, 2012).

377 TEX. HEALTH & HUM. SERVS., SECTION 1115 DEMONSTRATION FAST TRACK EXTENSION TEMPLATE FOR PROGRAM CHANGES 2 (2020), https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tx-healthcare-transformation-cmplt-ltr-state-phe-app-20201215.pdf; Waiver Approval Letter to Texas, *supra* note 172, at 12.

378 *See* 77 Fed. Reg. at 11678.

379 Albanese, *supra* note 17, at 847.

beneficiaries, from participating in the decision-making process for an inordinate amount of time. Stakeholders have shown that they value the opportunity to participate in public notice and comment periods regarding section 1115 waivers and that they do not want to wait ten years to do so. Additionally, ten-year extensions effectively solidify the negotiations and agreements made between two administrations—one state and one federal—for an unreasonable amount of time. The effect of this is that future administrations and future voters will be bound by a contract negotiated by individuals who may no longer be in office. Solidifying political agendas and bargaining for ten-year periods creates barriers for newly elected administrations that try to implement new policies and improve existing programs.

CMS's 2017 guidance clearly flouted section 1315, the governing statute of section 1115 waivers. The statute explicitly limits waiver extensions to three- or five-year periods in two separate provisions. Congress did not leave a gap for CMS to fill in regard to waiver durations, and CMS's 2017 guidance is an impermissible construction of the statute. Additionally, section 1115 waivers may only be granted for "experimental, pilot, and demonstration" projects. These are projects that have experimental value in that the projects test or trial experimental procedures. But CMS's 2017 guidance allowed for the approval of ten-year waiver extensions for "routine, successful, non-complex" demonstration projects. Routine, successful, and non-complex projects would not have experimental value—such projects would have already been evaluated and labelled successful with well-established procedures. Accordingly, routine, successful, and non-complex projects cannot also be experimental, pilot, or demonstration projects.

Accordingly, going forward, CMS should refrain from granting extensions in excess of the statutory three- or five-year limits. Further, CMS must rescind or amend those extensions approved for periods in excess of five years granted under the 2017 guidance. By revising the extensions to the statutorily prescribed operating periods, CMS would not only improve the functionality of the demonstration projects, but it would also address the invalidity of the 2017 guidance, thereby deterring administrations from reimplementing the 2017 guidance and ten-year extensions in the future.

Fortunately, CMS has replaced the 2017 guidance with 2015 guidance that reimplements the statutory three- or five-year extension limits. However, to best protect the interests of Medicaid beneficiaries, and to pave the way for health care innovation, CMS must take the next step of challenging the validity of the 2017 guidance and excessive extensions granted under it. This is but one step

needed to achieve Congress's and HHS's goal of making the waiver approval process more transparent and engaging for the public. However, this step is urgent and important. If CMS fails to challenge the ten-year extensions, as it has done thus far, current and future administrations will have no reason not to begin granting these excessive waiver extensions again. And the citizens of the states with existing excessive extensions will suffer the consequences of CMS's failure to act.

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