Agency Imprimatur & Health Reform Preemption

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At this moment, there exists nearly unanimous agreement that the American health care system requires reform, but also vehement disagreements over what form regulation should take and who should be in charge of regulating—state or federal authorities. Preemption doctrine typically referees disputes between federal and state regulatory efforts, but it also exacerbates them. There exists nearly as unanimous opinion that preemption doctrine in health law is a mess. This Article identifies an inventive structure that may help defuse some preemption problems in health reform.

The Affordable Care Act's (ACA) individual and employer mandates, health insurance exchanges, and insurance coverage standards established preemptive federal baselines for health insurance regulation. Yet the ACA also quietly permits states to apply for a waiver of all these baseline provisions, if they promise to enact state legislation with equivalent protections. Through this waiver provision—the "section 1332" or "state innovation" wavier—the federal agencies may sanction state variations if the agencies find suitable evidence that the variations will further the goals of the federal baselines.

The ACA's combination of express preemption and guided waiver raises a novel confluence of "big waiver" theory and preemption doctrine. This Article posits that this confluence offers an "agency imprimatur" model that has great potential for managing health law federalism issues by circumventing conflict. At its best, the agency imprimatur model offers advantages over preemption in expertise, transparency, and communicative federalism. These potential advantages, however, hinge on the presence of meaningful waiver standards that preserve the statutory priorities and require reliance on agencies' substantive expertise. The section 1332 wavier is not without

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 This work owes a great debt to Robert Gatter, Sidney D. Watson, Amy B. Monahan, Marcia L. McCormick, Brietta R. Clark, Elizabeth Pendo, and the 2016 Health Law Scholars Workshop, sponsored by the ASLME and Saint Louis University School of Law's Center for Health Law Studies. William W. Buzbee, David S. Rubenstein, Christopher Walker, and Micah Berman all provided generous input, as did the Ohio State University Moritz College of Law and the West Virginia University College of Law faculties. Funding from a University of Toledo Summer Research Award made this project possible, and a productive partnership with Hannah Oster, Morgan Tendam, and the *Ohio State Law Journal* editorial staff made it better in all respects.

its pitfalls, but the recently proposed mega waivers would erode all of these potential gains.

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I. INTRODUCTION

Federal and state regulatory powers overlap enormously when it comes to regulating health. States have long relied on their general police powers to regulate for the sake of their citizens' health, safety, and welfare.[1] Meanwhile, Congress has generated an expanding federal police power presence in health law by exercising its enumerated powers and delegating their execution to federal agencies.[2] State and federal regulatory authorities have exercised their respective powers concurrently, but with little coordination.[3] This concurrence and cacophony has produced frequent tensions between state and federal regulation, contributing to a fragmented health care system and, at times, an incoherent preemption doctrine.[4]

Preemption referees the frequent tensions between state and federal laws, giving duly enacted federal law preemptive power over conflicting state law.[5] Preemption doctrine has tried to answer the difficult questions of whether and to what extent federal and state laws conflict, relying on statutory text and

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[1] Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMP. L. REV. 95, 99 (2016).

[2] *See* ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE 4, 109–12 (2007); McCuskey, *supra* note 1, at 100.

[3] *See* McCuskey, *supra* note 1, at 123 fig.1.

[4] *See* FIELD, *supra* note 2, at 168–69 ("The conflict between federal and state authority permeates American political history."); Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 454–63 (2011) (tracing the evolution of federalism in health care cases and lamenting the lack of coherence). *See generally* EINER ELHAUGE, THE FRAGMENTATION OF U.S. HEALTH CARE (2010) (explaining overarching aspects of the U.S. health care system, the causes of its fragmentation, and possible approaches to health care reform); George B. Moseley III, *The U.S. Health Care Non-System, 1908–2008*, 10 AMA J. ETHICS 324, 324–28 (2008) (analyzing how U.S. systems for health care delivery and reimbursement developed from a largely unregulated, free-market-type state in the early 1900s to a highly regulated state in modern times).

[5] *See, e.g.*, *Preemption*, BLACK'S LAW DICTIONARY 1368–69 (10th ed. 2014) ("The principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation."); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 225 n.3 (2000) (using "preemption" to "refer to the displacement of state law by federal statutes (or by courts seeking to fill gaps in federal statutes)"); James G. Hodge Jr. & Alicia Corbett, *Legal Preemption and the Prevention of Chronic Conditions*, 13 PREVENTING CHRONIC DISEASE, June 30, 2016, at 1, 1–2, https://www.cdc.gov/pcd/issues/2016/pdf/16_0121.pdf [https://perma.cc/NMF3-H4S6] (offering a "Brief Primer on Legal Preemption"). *See generally* Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 782 (1994) (suggesting that the Necessary and Proper Clause offers the preemptive power); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727 (2008) (engaging with Gardbaum's theory but ultimately returning to the Supremacy Clause as the root of preemption).

divination of congressional intent as its ultimate touchstone.[6] The Supreme Court's preemption doctrine itself has become increasingly complex, prompting criticism of its fidelity to the Constitution and its refusal to acknowledge the discretionary nature of its central inquiries.[7]

While federal, state, and local regulators jostle with each other on concurrently regulated health care topics, courts have applied preemption doctrine in ways that have frustrated local, state, and federal regulators and further fragmented the health care system.[8] All this concurrent authority and contested refereeing resulted in a health law landscape overcrowded with regulation in some areas, and barren in others.[9]

Against the backdrop of piecemeal health regulation and haphazard preemption, the Affordable Care Act (ACA)[10] broke new ground by enacting federal reforms across numerous health law issues, all aimed at system-wide goals of expanding access to care and controlling its costs.[11] The seminal provisions in the ACA all addressed health insurance.[12] The individual mandate, employer mandate, health insurance exchanges, and insurance coverage regulations reformed the commercial insurance market, which has been traditionally regulated by state law.[13] The ACA eschewed preemption in some areas and embraced it in others, expressing Congress's intent that its federal insurance market reforms preempt conflicting state laws.[14]

Yet with the same pen, Congress created a waiver provision which delegated to the implementing agency, the Department of Health and Human Services (HHS), the authority to waive the major pillars of the ACA's insurance market reforms for states to pursue their own variations.[15] The section

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[6] *E.g.*, Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 96 (1992) ("The purpose of Congress is the ultimate touchstone" of preemption (citations omitted)); *accord* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992).

[7] *See, e.g.*, Gardbaum, *supra* note 5, at 808; Nelson, *supra* note 5, at 260–62; Christopher H. Schroeder, *Supreme Court Preemption Doctrine*, *in* PREEMPTION CHOICE 119, 119–43 (William W. Buzbee ed., 2009); Jamelle C. Sharpe, *Legislating Preemption*, 53 WM. & MARY L. REV. 163, 230 (2011).

[8] *See* McCuskey, *supra* note 1, at 120–29.

[9] *See* FIELD, *supra* note 2, at 142–43; *cf.* Huberfeld, *supra* note 4, at 454–60 (tracing the evolution of federalism in health care cases and lamenting the lack of coherence).

[10] *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 20, 21, 25, 26, 28, 29, 36, 42 U.S.C.); OFFICE OF THE LEGISLATIVE COUNSEL, 111TH CONG., COMPILATION OF PATIENT PROTECTION AND AFFORDABLE CARE ACT (2010).

[11] *See* Amy Goldstein, *Priority One: Expanding Coverage*, *in* LANDMARK 73, 73 (2010).

[12] *See, e.g.*, 42 U.S.C. § 300gg-12 to -17 (2012); INST. OF MED. OF THE NAT'L ACADEMIES, THE IMPACTS OF THE AFFORDABLE CARE ACT ON PREPAREDNESS RESOURCES AND PROGRAMS 135–46 (2014).

[13] *See* McCuskey, *supra* note 1, at 139.

[14] *E.g.*, 42 U.S.C. § 18041(d) (2012).

[15] *See id.* § 18052(a)–(c).

1332 waiver program, which took effect January 1, 2017, applies to the ACA's core provisions: the individual mandate, employer mandate, health insurance exchange requirements, and some coverage regulations.[16] This big waiver gives the agency the power to sanction certain state variations on the ACA's reforms and waive the otherwise preemptive requirements, as long as the state can plausibly predict its experiment will be equivalent to the ACA in affordability, comprehensive coverage, and number of people insured.[17] This represents a departure from the more familiar Medicaid waiver model, which merely permits modification of the terms on which a state receives funding from an optional Spending Clause program.[18] This is a waiver of mandatory and preemptive law. It is a giant, even among "big" waivers.

Preemption and the waiver of it strike at the heart of regulatory federalism. Scholars have recently begun to supply some much-needed theory for waiver delegations, focusing on their constitutionality, desirability, and federalism angles.[19] "Big waiver," as Professors Barron and Rakoff termed it in 2013, is now a big deal.[20] Yet statutory waiver's growing ubiquity remains "underappreciated" and its theory remains inchoate.[21] Preemption, by contrast, has already spawned a tremendous volume of theoretical scholarship, as well as some empirical analysis, on its accessibility, foundations, and impact on the core structure of federalism.[22] In the past decade, courts and scholars have engaged in vigorous debate over agencies' power to preempt and the deference courts

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[16] *Id.*; *see also* Heather Howard & Galen Benshoof, Health Affairs Blog Post, *1332 Waivers and the Future of State Health Reform*, 15 YALE J. HEALTH POL'Y L. & ETHICS 237, 237 (2015).

[17] 42 U.S.C. § 18052(b).

[18] *See* Nicole Huberfeld et al., *Plunging into Endless Difficulties: Medicaid and Coercion in* National Federation of Independent Business v. Sebelius, 93 B.U. L. REV. 1, 29 (2013); Sidney D. Watson, *Out of the Black Box and into the Light: Using Section 1115 Medicaid Waivers To Implement the Affordable Care Act's Medicaid Expansion*, 15 YALE J. HEALTH POL'Y L. & ETHICS 213, 214 (2015).

[19] *See, e.g.*, David J. Barron & Todd D. Rakoff, *In Defense of Big Waiver*, 113 COLUM. L. REV. 265, 278 (2013); Abbe R. Gluck et al., Essay, *Unorthodox Lawmaking, Unorthodox Rulemaking*, 115 COLUM. L. REV. 1789, 1818 (2015); Martin A. Kurzweil, *Disciplined Devolution and the New Education Federalism*, 103 CAL. L. REV. 565, 567–68 (2015); Zachary S. Price, *Politics of Nonenforcement*, 65 CASE W. RES. L. REV. 1119, 1137–43 (2015); *see also* David Russell, Administrative Balance 2–10 (July 6, 2016) (unpublished note), http://ssrn.com/abstract=2805464 [https://perma.cc/HDJ4-TD4F].

[20] *See* Barron & Rakoff, *supra* note 19, at 265.

[21] *Id.* at 267.

[22] *E.g.*, Robert A. Schapiro, *From Dualism to Polyphony*, *in* PREEMPTION CHOICE, *supra* note 7, at 33, 34–42; Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and Its Limits*, *in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 309, 315 (Richard A. Epstein & Michael S. Greve eds., 2007).

owe to agencies' statements about preemption.[23] Presidents have also weighed in on the issue.[24]

This Article examines the impact of the ACA's innovation waiver on preemption and develops a framework for assessing its desirability, drawing on the theoretical literatures of preemption and "big waiver." The ACA's innovation waiver, I argue here, offers an agency imprimatur model for managing preemptive conflicts that have frustrated health policy for decades. Through the ACA's big waiver process, states must submit proposed legislation and detailed evidentiary support for their claims that state law variation will serve federal objectives "at least as comprehensive[ly] as" the federal law does.[25] If the agency grants a waiver, the state commits to enacting the preapproved legislation; repeal of the state law invalidates the waiver.[26] Congress thus delegated to HHS the power to give its imprimatur to state law, much of which would be subject to federal preemption if enacted without a waiver.[27]

Agency imprimatur infuses the health law federalism choice with more substantive precision than preemption doctrine allows. It permits state variations that serve federal legislative goals and uses the agency's substantive expertise to guide these choices on a case-by-case basis as they are conceived. Preemption, by contrast, looks in hindsight to the drafting Congress's

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[23] *See, e.g.*, Wyeth v. Levine, 555 U.S. 555, 602 (2009) (giving *Skidmore*/*Mead* deference to agency statement about the impact of preemption, but finding agency statement about preemptive impact of its regulations did not merit deference) (Thomas, J., concurring); *id.* at 583–85 (proposing rejection of obstacle preemption—whether used by agency *or* by court); Geier v. Am. Honda Motor Co., 529 U.S. 861, 863 (2000) (giving "some weight" to agency views about the impact of state law on federal objectives); William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from* Chevron *to* Hamdan, 96 GEO. L.J. 1083, 1167–68 (2008); William Funk, *Judicial Deference and Regulatory Preemption by Federal Agencies*, 84 TUL. L. REV. 1233, 1233–34 (2010); Brian Galle & Mark Seidenfeld, *Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 1970 (2008); Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 697 (2008); David S. Rubenstein, *Delegating Supremacy?*, 65 VAND. L. REV. 1125, 1136–37 (2012); Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521, 528, 530 (2012) [hereinafter Sharkey, *Inside Agency Preemption*]; Robert R.M. Verchick & Nina A. Mendelson, *Preemption and Theories of Federalism*, *in* PREEMPTION CHOICE, *supra* note 7, at 13, 13–32.

[24] *See, e.g.*, Memorandum on Preemption, 74 Fed. Reg. 24,693, 24,693 (2009) (stating executive policy on agency preemption, disfavoring agency statements on preemption unless sufficiently grounded in statutory delegation and preemption doctrine, as well as directing department heads to review preemption statements of the past ten years); *cf.* Exec. Order No. 13,132, at §§ 2–3, 3 C.F.R., 1999 Comp., at 207–08 (1999) (requiring agencies to consider federalism values before promulgating preemptive regulations).

[25] *See* 42 U.S.C. § 18052(b) (2012).

[26] *Id.* § 18052(b)(2)(B).

[27] *See id.* § 18041(d).

preemptive intent, applying canons of statutory interpretation and using courts' transsubstantive interpretive expertise.

Agency imprimatur also defuses potential preemption conflicts from at least two angles. First, it avoids disputes about preemption by giving *ex ante* federal approval to state law deviations and suspending the operation of supreme federal law. Thus, granting a waiver eliminates some nascent preemption conflicts that could otherwise end up in court. Second, if the agency's decision about the sufficiency and desirability of a state variation—either a grant or a denial of a waiver—does end up in court, a court will use deferential review because it is an agency action pursuant to expertise and express delegation, *not* an agency opinion about preemptive *effect*, which is owed no deference.[28]

The imprimatur model considers how the fraught history of preemption jurisprudence might benefit from this agency-supervised, conflict-avoidance model of federalism. Health insurance regulation is particularly saturated with state law predating the ACA, and is the source of some of the most maligned preemption decisions from courts, particularly on the Employee Retirement Income Security Act of 1974 (ERISA).[29] Through the waiver, the ACA ingeniously diverts the decision whether to preserve conflicting state law from courts to the agency, giving the agency a way to avoid conflicts in the first instance and reclaim some deference if challenged. The diversion to the agency emphasizes the agency's expertise and "big-picture" perspective on substantive policy—whether state variation is *desirable*. And the shift to an imprimatur model makes the area of courts' expertise—ad hoc application of the trans-substantive interpretive canons—a secondary inquiry.

Part II of this Article describes the health law landscape and preemption doctrine before the ACA, the preemptive power of the ACA's insurance market reforms, and some of the recent legislative efforts to revise the ACA. Part III examines the details of the ACA's section 1332 innovation waiver and the contours of its delegation to HHS, as well as the waiver's contributions to "big waiver" theory. Part IV illustrates how this innovation waiver provision shifts the issue of permitted state law variation from *ex post* preemption analysis to *ex ante* agency review of state legislation—and therefore from judicial preemption doctrine to an agency imprimatur model of preemption. Part IV then proposes metrics for assessing the benefits and detriments of this shift for health law federalism and access to affordable health care, accounting for institutional competencies and the values of uniformity and experimentation.

This Article concludes with the observation that although the imprimatur model has much to commend it, its success depends on the strength of federal law and the expertise that the agency brings to bear. From an institutional

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[28] *See* Eskridge & Baer, *supra* note 23, at 1202; Rubenstein, *supra* note 23, at 1150; *see also* United States v. Mead Corp., 533 U.S. 218, 235 (2001); Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843–44 (1984); Skidmore v. Swift & Co., 323 U.S. 134, 139–40 (1944).

[29] *See* McCuskey, *supra* note 1, at 97.

competence perspective, agencies can bring substantive expertise and big-picture policy to the federalism analysis that courts confined to the post hoc application of preemption doctrine lack. And the agency imprimatur process infuses preemption choices with transparency, stakeholder participation, and direct communication between state and federal regulators that the litigation model cannot fully achieve. By encouraging state and federal agencies to directly confer on the balance of their authorities—against a backdrop of preemptive federal law—the agency imprimatur model fosters a more communicative mode of regulatory federalism.

Still, the ACA's innovation waiver may be both too demanding and too amorphous to realize its full potential. On one hand, the delegation allows HHS to grant waivers only if states can propose replacement legislation that is at least as protective as the ACA, but that is also budget neutral for the federal government. Practically, that is a difficult proposition that almost no state had approached prior to the ACA. Yet the innovation waiver also sets malleable standards by which HHS must evaluate states' evidence of potential equivalence. There is thus plenty of room in the delegation for HHS to grant waivers for potentially restrictive variations with only speculative support, as well as to deny waivers for promising state variations.

Recent proposals in Congress have included major changes to section 1332 waivers, which would create even more leeway for states to pursue waivers with very few protections and little, if any, evidentiary support. The Better Care Reconciliation Act of 2017 (BCRA),[30] proposed the most dramatic expansion to the section 1332 waiver mechanism.[31] The BCRA draft removed the equivalence criteria from section 1332 (the Secretary may only grant waivers for state variations that are "as affordable" and "comprehensive" as the ACA while extending coverage to "at least as many" people).[32] Instead, the BCRA provided that the Secretary *must* grant any state's application *unless* its plan would increase the federal deficit.[33] Plus, the BCRA waiver automatically

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[30] Better Care Reconciliation Act of 2017, H.R. 1628, 115th Cong. (as passed by House, May 4, 2017), https://www.budget.senate.gov/imo/media/doc/BetterCareJuly13.2017.pdf [https://perma.cc/J35U-ECAB].

[31] Timothy Jost & Sara Rosenbaum, *Unpacking the Senate's Take on ACA Repeal and Replace*, HEALTH AFF.: BLOG (June 22, 2017), http://healthaffairs.org/blog/2017/06/22/unpacking-the-senates-take-on-aca-repeal-and-replace/ [https://perma.cc/UY67-N5WS] ("Perhaps the most important private insurance market provision of the Senate bill comes near the end: its amendments to the 1332 state innovation waiver program."). The other legislative attempts to replace the ACA in 2017, the "American Health Care Act," the "Health Care Freedom Act," and the Graham-Cassidy bill, all similarly took aim at section 1332. *See Compare Proposals To Replace the Affordable Care Act*, HENRY J. KAISER FAM. FOUND., https://www.kff.org/interactive/proposals-to-replace-the-affordable-care-act/ [https://perma.cc/5YQ8-3XF8].

[32] *See* 42 U.S.C. § 18052(b)(1).

[33] H.R. 1628 § 207(a)(2)(A).

extended to eight years and could only be shortened by the state.[34] To get the BCRA version of a waiver, a state would need only to describe what it wants to do and how its plan might "provide for alternative means of . . . increasing access . . . , reducing average premiums, . . . and increasing enrollment."[35] This is not so much a "big waiver" as it is a suspension of federal law on demand.

The changes proposed in the BCRA would have undone the agency imprimatur model's benefits. The mega waiver would have preserved few of the protections, little of the statute's priorities, and none of the agency expertise, while diminishing the opportunities for exchange of meaningful information between state and federal regulators. The BCRA mega waiver would not even require a state to use the federal pass-through funding for health care, or any other specified purpose.[36] The proposed mega waiver thus resembled not an alternative to preemption (like the original section 1332), but a reversal of preemption, making compliance with the expressly preemptive federal law optional at the state's discretion.

It remains unclear whether Congress ultimately will revive these proposals.[37] If passed, the waiver expansions would allow states to ignore many of the ACA's regulations prioritizing meaningful coverage to stem the tide of medical bankruptcies and erode the stabilizing influence of federal law. By removing the waiver standards, these repeal efforts could return health care markets to the pre-ACA scenario of varying rules by state and health insurance policies that exclude coverage for needed care. Further, the idea that states might return to running their own health insurance markets unfettered by federal regulations will confront the reality that other unwaivable statutes—namely ERISA—remain in place to frustrate state efforts.

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[34] *See id.* § 207(a)(4).

[35] *Id.* § 207(a)(1)(A)(i)(I).

[36] *See* Nicholas Bagley, *Crazy Waivers: The Senate Bill Invites States To Gut Important Health Insurance Rules*, VOX (June 23, 2017), https://www.vox.com/the-big-idea/2017/6/23/15862268/waivers-federalism-senate-bill-essential-benefits [https://perma.cc/D9B4-8HLG] ("If state officials blow the Obamacare money on cocaine and hookers, there's apparently nothing the federal government can do about it.").

[37] *See, e.g.*, Tiana Lowe, *The Senate's 'Better Care Reconciliation Act of 2017' Finally Revealed*, NAT'L REV. (June 22, 2017), http://www.nationalreview.com/article/448881/senate-health-care-bill-revealed [https://perma.cc/AUD3-TYN5] ("More-conservative wings of the Senate may be won over by the expansion of '1332' waivers, which allow for more state flexibility, but the bill maintains Obamacare's rules regarding preexisting conditions, raising the question of the 'death spiral,' in which premiums spike as a result of removing the individual mandate and making risk pools more expensive."); Robert Pear & Thomas Kaplan, *Projected Drop in Medicaid Spending Heightens Hurdle for G.O.P. Health Bill*, N.Y. TIMES (June 29, 2017), https://www.nytimes.com/2017/06/29/us/politics/health-care-bill-senate-republicans.html [https://perma.cc/RSF3-2Q6R]. It is additionally unclear whether parts of the proposals are properly part of Congress's reconciliation powers at all. *See, e.g.*, Sarah Kliff, *Senate Rules Could Force GOP To Drop Key Policies in Health Bill*, VOX (Mar. 7, 2017), https://www.vox.com/policy-and-politics/2017/3/7/14845686/ahca-reconciliation-senate-obamacare [https://perma.cc/7JW3-A3YG].

The agency imprimatur model may preserve some of the ACA's priorities in the face of repeal efforts.[38] And it offers a useful model for revising or replacing the ACA's waiver provisions. While the political turn of course casts significant doubt on the ACA's continued existence as such, the innovation waiver's model for addressing conflicts between state and federal laws offers some innovations on preemption with enduring value. In particular, the agency imprimatur model illustrates the value of preemptive federal baselines and principled standards for their waiver.

II. HEALTH LAW PREEMPTIONS AND ACA REFORMS

Health law has a particularly complicated mix of federal and state regulation, and an enormously complex preemption picture. Federal, state, and local laws crowd the health law field.[39] States' general police powers and Congress's enumerated police powers spawn enormous overlap in health care regulatory authorities.[40] Neither has been shy about exercising their concurrent authority, nor have they regulated in concert. State and federal health laws have evolved haphazardly, sometimes in reaction to each other and sometimes at cross-purposes.[41]

Preemption doctrine has managed the collisions between state health laws and federal ones.[42] The Supremacy Clause gives duly enacted federal law preemptive power over conflicting state law.[43] But the ubiquitous questions

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[38] *See, e.g.*, Timothy Jost, *ACA Round-Up: Negotiations To Revive AHCA, Alexander-Corker Bill, and Risk Adjustment*, HEALTH AFF.: BLOG (Apr. 4, 2017), http://healthaffairs.org/blog/2017/04/04/aca-round-up-negotiations-to-revive-ahca-alexander-corker-bill-and-risk-adjustment/ [https://perma.cc/AD77-S253]; Molly E. Reynolds & Elizabeth Mann, *In Wake of AHCA Failure, Will Trump Turn to States To Revise ACA?*, BROOKINGS (Mar. 28, 2017), https://www.brookings.edu/blog/fixgov/2017/03/28/will-trump-turn-to-states-to-revise-aca/ [https://perma.cc/YG3X-MJV5]. *See generally* C. STEPHEN REDHEAD & JANET KINZER, CONG. RESEARCH SERV., R43289, LEGISLATIVE ACTIONS IN THE 112TH, 113TH, AND 114TH CONGRESSES TO REPEAL, DEFUND, OR DELAY THE AFFORDABLE CARE ACT (Feb. 2017) (providing an overview of the ACA's core provisions and its impact on federal spending).

[39] *See* McCuskey, *supra* note 1, at 100. *See generally* FIELD, *supra* note 2, at 168–69 (explaining the past and present conflicts between federal, state, and local laws that have influenced the oversight of the health care industry and the complexity of the regulatory structure today).

[40] Nelson, *supra* note 5, at 225 (state and federal regulatory powers overlap "enormously"); Garrick B. Pursley, *Preemption in Congress*, 71 OHIO ST. L.J. 511, 513 (2010); Ernest A. Young, *"The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253, 254–55 (2011).

[41] FIELD, *supra* note 2, at 142–43; *see also id.* at 168 ("The conflict between federal and state authority permeates American political history."); Huberfeld, *supra* note 4, at 454–60 (tracing the evolution of federalism in health care cases and lamenting the lack of coherence).

[42] McCuskey, *supra* note 1, at 100.

[43] *See, e.g.*, *Preemption*, BLACK'S LAW DICTIONARY, *supra* note 5, at 1368–69 ("The principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation."); Merrill, *supra* note 5, at 733 (arguing that

about the scope of each law, divination of Congress's legislative intent to preempt, and the bases and contours of preemption doctrine have complicated the managerial function. The complexity of concurrent health care regulation authority has obfuscated preemption doctrine and vice versa,[44] contributing to the fragmentation of health care regulation and the health care system (or *non*system) itself.

The ACA entered this fragmented landscape with a mission to enact the first comprehensive federal health reform law, targeting cost and access through disparate parts of the health care system.[45] In approaching this giant task, the ACA performs a delicate balancing act, simultaneously exerting a strident federal regulatory reach and an unprecedented deference to state authority in many areas. This Part illustrates the preemptive intent behind this comprehensive health care legislation and the major pillars on which it stands.

A. *Health Law Preemption Before the ACA*

Heath care regulation has proceeded in piecemeal fashion since its inception. As science and regulation advanced, the concept of "health law" grew to encompass regulation of a health care *system*, or at least a complex set of interlocking parts forming a *nonsystem*.[46] State and federal authorities overlap enormously in regulating "health"—largely owing to their concurrent police powers.[47] Due to this overlap, preemption doctrine has played an outsized role in health care regulation and at times its fragmentation.[48]

Preemption doctrine has shaped health law, and health law cases have influenced the development of preemption doctrine's increasingly complex taxonomy.[49] The health care regulatory landscape before the ACA was thus littered with various preemptions that established some uniformity, but which

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preemption derives from the Supremacy Clause); Nelson, *supra* note 5, at 225 n.3 (using "preemption" to "refer to the displacement of state law by federal statutes (or by courts seeking to fill gaps in federal statutes)"); *cf.* Gardbaum, *supra* note 5, at 781 (Necessary and Proper Clause).

[44] McCuskey, *supra* note 1, at 135.

[45] Alec MacGillis, *Preface: The Best, the Worst, the Future*, *in* LANDMARK, *supra* note 11, at 65, 68.

[46] *See generally* ELHAUGE, *supra* note 4 (describing the fragmentation of the U.S. health care system and possible methods of reform); Moseley, *supra* note 4 (explaining how U.S. systems for health care delivery and reimbursement have transitioned from a largely unregulated, free-market-type state in the early 1900s to a highly regulated state today).

[47] McCuskey, *supra* note 1, at 96–97.

[48] *Id.*

[49] *Id.*; *see* McCuskey, *supra* note 1, at 104; Rubenstein, *supra* note 23, at 1137–38 (outlining taxonomy); Schroeder, *supra* note 7, at 119–43 (detailing the Supreme Court's development of this taxonomy); Louise Weinberg, *The Federal–State Conflict of Laws: Actual Conflicts*, 70 TEX. L. REV. 1743, 1745 (1992) ("The taxonomy is daunting.").

also under-enforced important initiatives, undermined experimentation, and stymied coherent health care regulation.[50]

In regulation of medical treatments, for example, Congress's awkward preemption statements (or silence) coupled with the Supreme Court's applications of preemption doctrine have produced some bizarre results. Curiously, Food and Drug Administration (FDA) approval of medical *devices* has been held to preempt state tort remedies,[51] but FDA approval of different classes of *drugs* and different tort theories are treated differently, even from each other.[52] FDA approval of *brand* name drugs does not preempt some tort remedies for faulty warnings, but approval of *generic* drugs does, via impossibility preemption.[53] And design-defect torts are preempted against both.[54] Further, the strong preemption scheme in the National Childhood Vaccine Injury Act establishes certainty and centrality with a no-fault system for injury claims against vaccine makers.[55] It supports the low-cost supply of vaccines essential for public health, but does so potentially at the expense of undercompensating some victims of injury.[56]

Health insurance regulation has been perhaps the health law topic most fraught with preemption.[57] Preemption has protected the Medicaid public insurance program from some state laws undermining access, but not others.[58]

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[50] *See generally* McCuskey, *supra* note 1, at 99–100 (identifying a tradition of presumption against preemption based on a notion of state primacy).

[51] *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343–44 (2001) (preempting injury claims based on allegations of fraud in the approval process).

[52] *See* Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013, 1019–20 (2007) [hereinafter Sharkey, *Federalism in Action*]; Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 859 (2017).

[53] *See also* Aaron S. Kesselheim et al., *Risk, Responsibility, and Generic Drugs*, 367 NEW ENG. J. MED. 1679, 1679–81 (2012). *Compare* PLIVA, Inc. v. Mensing, 564 U.S. 604, 624 (2011) (preempting failure to warn claims against generic drugs), *with* Wyeth v. Levine, 555 U.S. 555, 571–73 (2009) (holding failure to warn claims against brand name drugs not preempted).

[54] *See, e.g.*, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2470 (2013).

[55] *See* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(e) (2012); *see also* Shalala v. Whitecotton, 514 U.S. 268, 269 (1995) ("[T]he [Vaccine] Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system.").

[56] *See* Bruesewitz v. Wyeth LLC, 562 U.S. 223, 229–30 (2011) (noting that the Act gives manufacturers significant tort-liability protections in exchange for the no-fault system); John D. Kraemer & Lawrence O. Gostin, *Vaccine Liability in the Supreme Court: Forging a Social Compact*, 305 JAMA 1900, 1901 (2011); Catherine M. Sharkey, *Against Categorical Preemption: Vaccines and the Compensation Piece of the Preemption Puzzle*, 61 DEPAUL L. REV. 643, 657 (2012) [hereinafter Sharkey, *Against Categorical Preemption*].

[57] *See* McCuskey, *supra* note 1, at 96–97.

[58] *See, e.g.*, Astra USA, Inc. v. Santa Clara Cty., 563 U.S. 110, 113 (2011); Ark. Dep't of Health & Human Servs. v. Ahlborn, 547 U.S. 268, 292 (2006); *cf.* Douglas v. Indep.

On the other hand, ERISA has preempted many state efforts at expanding access to commercial health insurance provided by employers[59] and collecting health insurance data.[60] State health insurance regulation was historically the primary source of regulation.[61] But the federal government assumed a major role in insurance regulation with the passage of the ERISA in 1974, leading to a host of intractable conflicts.[62] Since then, the Supreme Court has lamented that the "unhelpful"[63] drafting of ERISA's preemption clause has "occupie[d] a substantial share of [the] Court's time"[64] and "generated an avalanche of litigation in the lower courts."[65]

While state law can, and has, traditionally regulated *insurance*, ERISA's complete preemption invalidates state regulatory efforts *related to* health insurance—if provided by an employer to its employees.[66] Employer-sponsored insurance has been the largest source of health insurance for Americans for several decades, so ERISA preemption affects nearly half of all Americans.[67] Yet ERISA also preserves state authority to regulate the commercial insurance industry, and the Supreme Court has spent substantial time on "[t]he 'unhelpful'

Living Ctr. of S. Cal., Inc., 565 U.S. 606, 610 (2012) (declining to rule on question whether private parties may maintain direct Supremacy Clause challenge to proposed state laws); *id.* at 624 (Roberts, C.J., dissenting) ("When Congress did not intend to provide a private right of action to enforce a statute enacted under the Spending Clause, the Supremacy Clause does not supply one of its own force."); Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 667–68 (2003) (holding that state efforts at achieving cost savings by subjecting drugs without negotiated prices to prior authorization were not preempted).

[59] *E.g.*, Retail Indus. Leaders Ass'n v. Fielder, 475 F.3d 180, 195–97 (4th Cir. 2007).

[60] *E.g.*, Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943 (2016).

[61] *See* McCuskey, *supra* note 1, at 135.

[62] Employee Retirement Income Security Act of 1974 (ERISA), Pub. L. No. 93-406, 88 Stat. 829 (1974) (codified as amended at 29 U.S.C. §§ 1001–1461 (2012)).

[63] N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 656 (1995) (describing the language of ERISA's preemption clauses as "unhelpful" to the interpretation of intent).

[64] Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 365 (2002).

[65] De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 808 n.1 (1997); *cf.* Brendan S. Maher & Peter K. Stris, *ERISA & Uncertainty*, 88 WASH. U. L. REV. 433, 464–65 (2010) (noting that ERISA's provisions regularly capture the Court's attention).

[66] *See, e.g.*, Maher & Stris, *supra* note 65, at 464–65.

[67] *Health Insurance Coverage of the Total Population*, HENRY J. KAISER FAM. FOUND. (2014), http://kff.org/other/state-indicator/total-population/?dataView=0&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D [https://perma.cc/NP6W-3Q3Q]; *see also* Elizabeth McCuskey, *Access, Affordability, and the American Health Reform Dilemma, Part I: Genesis of the Affordable Care Act*, OXFORD HUMAN RIGHTS HUB (Mar. 27, 2017), http://ohrh.law.ox.ac.uk/access-affordability-and-the-american-health-reform-dilemma-part-i-genesis-of-the-affordable-care-act/ [https://perma.cc/26V3-V2TM] (noting that under the "piecemeal approach to health care coverage" about half of Americans depended on their employers to provide coverage).

drafting of these antiphonal clauses"[68] with little clarity on where the preemptive line between the two should be drawn.

ERISA preempts state-law remedies for coverage denials under an employer-sponsored policy.[69] And ERISA preempts state regulatory efforts to encourage or support employer-sponsored insurance, including preemption of most state-law "employer mandate" statutes that prompt employers to share responsibility for the health care costs of employees.[70]

Despite preempting state regulatory efforts, ERISA and its revisions offered scant federal regulation of health insurance to fill the preemptive void.[71] For example, ERISA preempts *state* employer mandates,[72] but does not enact a federal mandate. ERISA preempts state laws on the content of employer-sponsored insurance, but offers very little federal law on the content of those policies.[73] Just within the past year, for example, the Supreme Court held in *Gobeille v. Liberty Mutual Insurance Co*. that ERISA preempts even a state's efforts to collect health insurance claims data from certain employer health plans—data that those plans already collect for themselves.[74] Yet ERISA does not require any similar federal collection of data.[75] While the Federal Department of Labor *could* collect that data and distribute it to states, it does not do so.[76]

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[68] *Rush Prudential*, 536 U.S. at 364–65 (citation omitted).

[69] Aetna Health Inc. v. Davila, 542 U.S. 200, 214 (2004).

[70] *E.g.*, Retail Indus. Leaders Ass'n v. Fielder, 475 F.3d 180, 195–97 (4th Cir. 2007).

[71] *See* Russell Korobkin, *The Failed Jurisprudence of Managed Care, and How To Fix It: Reinterpreting ERISA Preemption*, 51 UCLA L. REV. 457, 464–66 (2003); *see also* Brendan S. Maher, *Regulating Employer-Based Anything*, 100 MINN. L. REV. 1257, 1270–71 (2016) (noting that ERISA gets "terrible marks for its regulation of health and disability insurance").

[72] *See, e.g.*, *Fielder*, 475 F.3d at 192–93.

[73] *See, e.g.*, Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), 29 U.S.C. § 1161(a) (2012) (requiring extension after separating from employment); 29 U.S.C. § 1169(d) (2012) (requiring some coverage for pediatric vaccines); Health Insurance Portability and Accountability Act of 1996 (HIPAA), 29 U.S.C. § 1181(a) (2012) (restricting the use of preexisting condition limitations in employment-based plans); 29 U.S.C. § 1185(a)(1) (2012) (requiring some coverage for aspects of childbirth); Mental Health Parity Act of 1996, 29 U.S.C. § 1185a (2012) (prohibiting imposition of certain limitations on coverage for mental health); 29 U.S.C. § 1185b(a) (2012) (requiring some coverage for reconstructive surgery after mastectomies).

[74] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 945 (2016).

[75] *Id.* at 949–50 (Breyer, J., concurring).

[76] *See id.*; *cf.* Abigail R. Moncrieff, *The Supreme Court's Assault on Litigation: Why (and How) It Might Be Good for Health Law*, 90 B.U. L. REV. 2323, 2341–43, 2380–81 (2010) (arguing that *Aetna v. Davila*'s elimination of private Employer Sponsored Insurance (ESI) contract enforcement could empower a more effective federal regulator to pursue policy, but lamenting the lack of federal enforcement funding and agency will).

The Supreme Court decided yet another preemption case about employer-sponsored health insurance in *Coventry Health Care of Missouri v. Nevils*.[77] *Coventry Health* concerns the preemptive scope of a federal statute governing the federal government's provision of health benefits to federal employees—the Federal Employees Health Benefits Act (FEHBA)[78]—akin to the ERISA but affecting federal government employers. The Supreme Court granted certiorari in *Coventry Health* to address "an increasing disagreement" among the courts "over when to apply the presumption against preemption"—specifically on the question of whether federal law preempts health insurers' subrogation suits against tort victims.[79] The Court held that the FEHBA's preemption provision, like ERISA's, does preempt subrogation laws.[80]

ERISA and its preemption jurisprudence left large voids in health insurance regulation and significant variation among states.[81] As my prior work has explained, state law was the primary regulation for the content of commercial health insurance policies.[82] Even under ERISA, states could set coverage minimums for health insurers.[83] A handful of federal laws had added preemptive bits and pieces to states' coverage and eligibility regulations by prohibiting discrimination based on race, religion, national origin, and disability;[84] requiring extension after separating from employment;[85] requiring parity between mental health and other benefits,[86] pediatric vaccines,[87] childbirth,[88] and specific treatments; as well as restricting the use of preexisting condition

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[77] Coventry Health Care of Mo., Inc. v. Nevils, 137 S. Ct. 1190, 1194 (2017).

[78] 5 U.S.C. §§ 8901–8914 (2012); *Coventry Health*, 137 S. Ct. at 1194; *see also* Empire Healthchoice Assurance, Inc. v. McVeigh *ex rel.* Estate of McVeigh, 547 U.S. 677, 682 (2006) ("The [FEHBA] establishes a comprehensive program of health insurance for federal employees.").

[79] Brief for Respondent at 13, *Coventry Health*, 137 S. Ct. 1190 (No. 16-149); *Coventry Health*, 137 S. Ct. 446, 446 (2016) (mem.) (granting certiorari); Petition for a Writ of Certiorari at 17–19, *Coventry Health*, 137 S. Ct. 1190 (No. 16-149) (identifying circuit split); McCuskey, *supra* note 1, at 153.

[80] *Coventry Health*, 137 S. Ct. at 1194.

[81] *See* Elizabeth Weeks Leonard, Essay, *The Rhetoric Hits the Road: State Challenges to the Affordable Care Act Implementation*, 46 U. RICH. L. REV. 781, 784 (2012) (noting that ERISA preemption "has constrained states' ability to regulate" employer-sponsored insurance, but that states remained free to enact other reforms).

[82] *See* McCuskey, *supra* note 1, at 136.

[83] *See id.* at 112.

[84] *E.g.*, Americans with Disabilities Act, 42 U.S.C. § 12112(a) (2012); Civil Rights Act of 1964, 42 U.S.C. §§ 2000d–2000d-7 (2012).

[85] Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, 29 U.S.C. § 1161(a) (2012).

[86] Mental Health Parity Act of 1996, 29 U.S.C. § 1185a (2012).

[87] 29 U.S.C. § 1169(d) (2012).

[88] 29 U.S.C. § 1185(a)(1) (2012).

limitations in employment-based plans.[89] But no comprehensive, uniform set of regulations existed for commercial health insurance plans nationally.[90] ERISA preempted state efforts to regulate the employer-sponsored coverage, and thereby created a void in which states could not regulate,[91] but offered very little federal regulation to fill that space.

On this scattered landscape, the ACA added a definitive set of federal regulations, including standards for coverage and eligibility, regulations on the business of commercial health insurers, reforms to the insurance markets, as well as mandates for certain employers to provide insurance and for all individuals to have it.[92] By crafting federal regulation of all sectors in the market for health care coverage, the ACA promised to rebalance the historical relationship between state and federal regulatory authority, at least in part.[93]

B. *The ACA as Preemptive Federal Law*

The health reform momentum behind the ACA was aimed primarily at reducing the economic drain of uninsured medical care (and lack thereof) and the tragic consequences of medical bankruptcies.[94] Health care spending had accelerated over the decades preceding the ACA to consume 17% of GDP, draining the economy while producing less favorable health outcomes than in countries which spend only half as much.[95] Disturbingly, the burden of these outsized health care expenditures laid most heavily on those who could ill afford it: the uninsured and underinsured.[96]

"The ACA tackled the affordability of care largely by engaging third-party payors (insurers) and expanding access to care, rather than directly addressing

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[89] Health Insurance Portability and Accountability Act of 1996 (HIPAA), 29 U.S.C. § 1181(a) (2012).

[90] *See* McCuskey, *supra* note 1, at 135–38.

[91] *See* Weeks Leonard, *supra* note 81, at 784.

[92] *See generally Summary of the Affordable Care Act*, HENRY J. KAISER FAM. FOUND. (Apr. 25, 2013), http://kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/ [https://perma.cc/QL3H-D9UV].

[93] *But see* Sara Rosenbaum, *Can This Marriage Be Saved? Federalism and the Future of U.S. Health Policy Under the Affordable Care Act*, 15 MINN. J.L. SCI. & TECH. 167, 173 (2014) ("In many respects, the basic approach to the regulation of health insurance in the United States remains undisturbed under the Act.").

[94] *See* Elizabeth McCuskey, *Access, Affordability, and the American Health Reform Dilemma, Part II: The Affordable Care Act's First Seven Years*, OXFORD HUMAN RIGHTS HUB (Mar. 28, 2017), http://ohrh.law.ox.ac.uk/access-affordability-and-the-american-health-reform-dilemma-part-ii-the-affordable-care-acts-first-seven-years/ [https://perma.cc/KM74-VEUN].

[95] *See* MacGillis, *supra* note 45, at 64–67.

[96] *See, e.g.*, Steffie Woolhandler & David U. Himmelstein, *Life or Debt: Underinsurance in America*, 28 J. GEN. INTERNAL MED. 1122, 1123 (2013); Jenny Gold, *The 'Underinsurance' Problem Explained*, KAISER HEALTH NEWS (Sept. 28, 2009), http://khn.org/news/underinsured-explainer/ [https://perma.cc/R79A-898N].

the price of care."[97] As a comprehensive reform statute aimed at improving affordability and access, the ACA wove together moderate reforms across the layers of the health care system, including insurance, quality of care, and access.[98] But the ACA focused primarily on paying for health care, either through private health insurance or public insurance programs.[99] First and foremost, the ACA aimed to increase the number of Americans covered by health insurance to as near universal coverage as possible.[100]

1. *The Pillars of Federal Health Insurance Reform*

The statute's foundational reforms approach cost by expanding access to health insurance coverage:[101] requiring individuals to have insurance through the individual mandate;[102] giving them more access to sources of insurance with health insurance exchanges,[103] expanded Medicaid,[104] and required employer-sponsored insurance;[105] and regulating the coverage insurers can offer.[106]

The ACA regulates the content and issuance of health insurance policies, both commercial and government sponsored.[107] Before the ACA, federal coverage regulations were piecemeal and scant, comprised mainly of anti-discrimination provisions in the Americans with Disabilities Act, a few required

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[97] McCuskey, *supra* note 94, at 2; Goldstein, *supra* note 11, at 73. *See generally* STEVEN BRILL, AMERICA'S BITTER PILL: MONEY, POLITICS, BACKROOM DEALS, AND THE FIGHT TO FIX OUR BROKEN HEALTHCARE SYSTEM (2015) (critiquing the Affordable Care Act and chronicling its history).

[98] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 20, 21, 25, 26, 28, 29, 36, 42 U.S.C.); 42 U.S.C. § 300gg-11 to -19a (2012) (making reforms aimed at improving insurance coverage, including provisions on quality of care, cost, and patient protections).

[99] *See* Office of the Legislative Counsel, 111th Cong., Compilation of Patient Protection and Affordable Care Act (2010), at 13–78 (summarizing Title I of the ACA); INST. OF MED. OF THE NAT'L ACADS., *supra* note 12, at 135–46 (highlighting insurance provisions and Medicaid expansion).

[100] *See* Goldstein, *supra* note 11, at 73 (describing expanded insurance coverage as "Priority One" in drafting the legislation).

[101] *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 1001–1004, 1101–1105, 1201, 1251–1253, 1301–1304, 1311–1313, 1321–1324, 1331–1333, 1341–1343, 1401–1402, 1411–1415, 1421, 1501–1502, 1511–1515, 1551–1563, 124 Stat. 119, 130–271 (2010) (Title I).

[102] 26 U.S.C. § 5000A(a) (2012); *see* Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 561–65 (2012) (upholding individual mandate as a tax, after rejecting Commerce Clause authorization). *See generally Summary of the Affordable Care Act*, *supra* note 92.

[103] *E.g.*, 42 U.S.C.§ 18031(b)(1) (2012).

[104] *E.g.*, *id.* § 1396a(a) (Supp. I 2014).

[105] *E.g.*, 26 U.S.C. § 4980H(a) (2012).

[106] *E.g.*, 42 U.S.C. § 18022(a) (2012).

[107] *See, e.g.*, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, §§ 1001–1004, 1101–1105, 1201, 124 Stat. 119, 130–162 (2010).

coverage items from ERISA, and process regulations for employer-sponsored plans also from ERISA.[108] Commercial insurers had to cover those items specified in each state, but remained free to exclude any other coverage items.[109] Crucially, before the ACA, most state laws permitted insurers to use medical underwriting to account for health status in a number of ways: by refusing to issue policies to individuals with preexisting conditions, by charging vastly higher premiums, and also by excluding the preexisting conditions from coverage under those expensive policies.[110]

The ACA enacted the first comprehensive set of regulations for all commercial health insurance plans on issuance, coverage, and administration.[111] On issuance, the ACA requires health plans to accept all applicants (known as "guaranteed issuance"), whether group or individual,[112] and to renew that coverage at the enrollee's request.[113] Under the ACA, insurers may not enforce eligibility rules based on health status or history.[114]

On coverage, the ACA's comprehensive coverage regulations prohibit lifetime and annual limits on benefits,[115] rescission of insurance during the plan year,[116] and medical underwriting.[117] Under the ACA, health plans must include coverage for preexisting conditions,[118] cover "preventive health services" without a co-pay or deductible,[119] provide the option to include adult children up to age twenty-six as dependents on the policy,[120] use uniform explanations and definitions of coverage in plain language,[121] and implement effective internal appeals processes for enrollees.[122] If a plan chooses to include certain

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[108] *See* McCuskey, *supra* note 1, at 123–41.

[109] *See* McCuskey, *supra* note 1, at 128–29; *Summary of Coverage Provisions in the Patient Protection and Affordable Care Act*, HENRY J. KAISER FAM. FOUND. (July 17, 2012), http://kff.org/health-costs/issue-brief/summary-of-coverage-provisions-in-the-patient [https://perma.cc/F8N6-R49T].

[110] *See Summary of Coverage Provisions in the Patient Protection and Affordable Care Act*, *supra* note 109.

[111] *See* Patient Protection and Affordable Care Act §§ 1001–1004, 1101–1105, 1201 (prescribing "immediate improvements" and "actions" to expand quality health care coverage).

[112] 42 U.S.C. § 300gg-1(a) (2012). Insurers may, however, restrict new enrollments to designated enrollment "periods." *Id.* § 300gg-1(b)(1).

[113] *Id.* § 300gg-2(a).

[114] *Id.* § 300gg-4(a)(1), (5).

[115] *Id.* § 300gg-11(a)(1).

[116] *Id.* § 300gg-12.

[117] *Id.* § 300gg(a)(1) ("prohibiting discriminatory premium rates" based on any factors other than household size, geographic rating area, age, and tobacco use).

[118] 42 U.S.C. § 300gg-3(a) (2012).

[119] *Id.* § 300gg-13(a).

[120] *Id.* § 300gg-14(a).

[121] *Id.* § 300gg-15(b).

[122] *Id.* § 300gg-19(a).

coverage items, like primary care provider designations and emergency room visits, then the ACA prohibits certain restrictions on that coverage.[123] The ACA regulates plans sold on the exchanges at a more granular level, requiring certification that those plans offer ten categories of "essential health benefits" (EHBs) and satisfy extra marketing, administration, and financial protections.[124]

The ACA built upon the existing source-dependent insurance regulation landscape, rather than radically altering it.[125] The law's incremental approach has been aptly described as "evolutionary, not revolutionary."[126] The source of one's insurance coverage "still determines the nature and extent of [its] regulation."[127] While the ACA sets some uniform federal priorities in coverage regulation, it also permits some significant state-by-state variations.[128] Overall, the ACA maintained much of the preexisting distribution of health care coverage, concentrating regulatory effort on the individual market for insurance and existing public programs.[129]

2. *Preemptive Intent*

The ACA wrote an awful lot of new federal law, particularly concentrated in areas with significant preexisting state law, like insurance.[130] The ACA preserved the existing structures of health care access and took great pains to enlist states in a cooperative federalism reform relationship.[131] Yet, the ACA

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[123] *See id.* § 300gg-19a(a)–(b), (d) (including primary care provider designation, immediate access to emergency care, and prohibition on referral requirements for obstetrical and gynecological services).

[124] *See* 42 U.S.C. §§ 18021–18024 (setting requirements for the "Available Coverage Choices for All Americans").

[125] *See* Rosenbaum, *supra* note 93, at 173 ("In many respects, the basic approach to the regulation of health insurance in the United States remains undisturbed under the [Affordable Care] Act.").

[126] Alec MacGillis, *Preface: The Best, the Worst, the Future*, *in* LANDMARK, *supra* note 11, at 68; *see also* Jamie Fletcher & Jane Marriott, *Beyond the Market: The Role of Constitutions in Health Care System Convergence in the United States of America and the United Kingdom*, 42 J.L. MED. & ETHICS 455, 470 (2014) (finding the same).

[127] McCuskey, *supra* note 94.

[128] *See, e.g.*, Abbe R. Gluck, *Federalism from Federal Statutes: Health Reform, Medicaid, and the Old-Fashioned Federalists' Gamble*, 81 FORDHAM L. REV. 1749, 1753 (2013) ("Congress gave the states a lead role in the [ACA] in those same areas in which states had previously exerted primary authority, namely, Medicaid and insurance regulation.").

[129] *See, e.g.*, Fletcher & Marriott, *supra* note 126, at 458.

[130] *See* Abbe R. Gluck, Essay, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 Yale L.J. 534, 580–82 (2011).

[131] *See, e.g.*, *id.* at 582–94.

"contains many contact points between federal and state law."[132] And Congress did, in many respects, express its wishes for preemption in the ACA, both specifically and generally.[133]

Congressional intent stands as the "ultimate touchstone" for preemption doctrine,[134] and Congress may express or merely imply its intent.[135] Congress has conveyed its intent with varying degrees of force and clarity, and it may also delegate its preemptive lawmaking authority to agencies.[136] When drafting the ACA, Congress had a buffet of preemption options from which to draw, as health law topics are peppered with preemption in nearly all of its species: complete, field, conflict, and obstacle preemption.[137]

The most forceful form of preemption is complete preemption, which applies when "a federal statute's preemptive force [is] so extraordinary and all-encompassing that it converts an ordinary state-common-law complaint into one stating a federal claim for purposes of the well-pleaded-complaint rule"[138] and precludes any state claim on the subject.[139] Health law has one of the only three recognized complete preemptions: ERISA preemption, which completely preempts remedies for coverage denials under employer-sponsored health insurance benefits.[140]

Field preemption—almost as rare as complete preemption—arises from a federal regulatory scheme "so pervasive . . . that Congress left no room for the States to supplement it" or from a federal interest "so dominant" that federal law is "assumed to preclude enforcement of state law" in that field.[141] The Supreme Court has thus far rejected field preemption for the health laws it has adjudicated, though field preemption arguably remains within the sphere of

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[132] Brendan S. Maher, *The Affordable Care Act, Remedy, and Litigation Reform*, 63 AM. U. L. REV. 649, 702 (2014).

[133] *See id.* at 703. *But see* 42 U.S.C. § 18041(d) (2012) ("Nothing in this title shall be construed to preempt any state law that does not prevent the application of the provisions in this title.").

[134] Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992) (quoting Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963)); *see also* Merrill, *supra* note 5, at 740 (describing the "touchstone" as a maxim of preemption).

[135] *See* Nelson, *supra* note 5, at 227.

[136] Geier v. Am. Honda Motor Co., 529 U.S. 861, 883–86 (2000) (holding that federal regulations may preempt state law).

[137] McCuskey, *supra* note 1, at 111.

[138] *Complete-Preemption Doctrine*, BLACK'S LAW DICTIONARY, *supra* note 5, at 345.

[139] Beneficial Nat'l Bank v. Anderson, 539 U.S. 1, 8 (2003).

[140] *See* Gil Seinfeld, *The Puzzle of Complete Preemption*, 155 U. PA. L. REV. 537, 550–52 (2007). The other two complete preemptions are found in the Labor Management Relations Act of 1947, 29 U.S.C. § 185(a) (2012), and the National Bank Act, 12 U.S.C. § 38 (2012).

[141] English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

agency power.[142] The federal statute on cigarette regulation,[143] for example, gives the FDA significant power to regulate tobacco, but the statute does not fill the field or even preempt conflicting requirements in state misrepresentation claims.[144] Field preemption at the state level, however, has wiped out local ordinances on issues like tobacco control.[145]

Conflict preemption—by far the most ubiquitous form of preemption—applies when federal and state law conflict with each other. Conflict preemption can arise in either of two ways: impossibility conflicts and obstacles.[146] Impossibility preemption wipes out state law when it would be impossible to comply with both state and federal law.[147] Obstacle preemption wipes out state laws that impede federal goals even where simultaneous compliance is technically possible.[148]

Impossibility preemption applies to all kinds of federal health laws. For example, where the FDA has approved label warnings on prescription drugs, but state tort law would create liability for failure to include *additional* warnings, impossibility preemption eclipses the state-law warnings only if the Federal Food, Drug, and Cosmetic Act (FDCA) would prohibit including additional warnings.[149] For brand-name drugs, the FDCA would permit these additional warnings, and therefore impossibility preemption would not apply.[150] But the federal law on labeling for *generic* drugs required their labels to perfectly mirror the brand name label, thus the manufacturer could not comply simultaneously with the FDA's verbatim requirement *and* a state law requirement of additional information.[151] Impossibility preemption negated the state tort law warning.[152]

Obstacle preemption is a broader, more nebulous form of conflict preemption. Obstacle preemption displaces state law even where state law merely "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" without creating an impossible conflict.[153] Even if, for example, a state law goes further than a federal law

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[142] *See* Zettler, *supra* note 52, at 871–72.

[143] Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331–1341 (2012).

[144] Altria Grp., Inc. v. Good, 555 U.S. 70, 91 (2008).

[145] *See, e.g.*, Altadis U.S.A., Inc. v. Prince George's Cty., 65 A.3d 118, 123 (Md. 2013) (holding that state law occupied the field of "packaging [and] sale . . . of tobacco products" and therefore preempted county ordinances); James G. Hodge, Jr. et al., *Public Health "Preemption Plus*,*"* 45 J. L. MED. & ETHICS 156, 156 (2017).

[146] Nelson, *supra* note 5, at 227–29.

[147] *Id.*

[148] *Id.*

[149] *Id.* at 228 n.15.

[150] *See* Wyeth v. Levine, 555 U.S. 555, 573 (2009).

[151] PLIVA, Inc. v. Mensing, 564 U.S. 604, 625–26 (2011).

[152] *Id.* at 618, 625.

[153] Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

(making it possible to comply with both), additional state requirements may frustrate Congress's statutory intent for uniformity.[154] Exactly what constitutes a sufficient "obstacle" remains a "matter of judgment" in light of "the federal statute as a whole and . . . its purpose and intended effects,"[155] which is highly discretionary.[156]

Jurists and commentators have criticized obstacle preemption doctrine as "freewheeling"[157] or worse, a discretionary doctrine that functions as a "thinly veiled means to instantiate judicial policy preferences."[158] And Caleb Nelson's seminal article, *Preemption*, argued that obstacle preemption flows from a misreading of the Supremacy Clause itself.[159] Its defenders, however, explain that obstacle preemption "plays an appropriate and indeed almost inescapable judicial role in our modern polity" by offering principles for filling in the inevitable gaps between legislative drafting and unforeseen circumstances.[160] Courts have applied obstacle preemption to health regulations, but often without consistency across fields of health care.[161]

With congressional intent as the focus of preemption doctrine, Congress may choose to express its desired preemption or nonpreemption, or to stay silent and preempt only by implication. Further, many statutes include saving clauses

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[154] *E.g.*, Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373–74 (2000) (holding that federal sanctions against Myanmar preempted Massachusetts's broader sanctions as an obstacle).

[155] *Id.* at 373.

[156] Daniel J. Meltzer, *Preemption and Textualism*, 112 MICH. L. REV. 1, 39 (2013).

[157] Wyeth v. Levine, 555 U.S. 555, 604 (2009) (Thomas, J., concurring in judgment) (criticizing obstacle preemption as "freewheeling, extratextual"). *But see PLIVA*, 564 U.S. at 640 n.13 (Sotomayor, J., dissenting) ("[Justice Thomas's] position . . . has not been accepted by this Court, and it thus should not justify [a] novel expansion of impossibility pre-emption.").

[158] Maher, *supra* note 132, at 703 (summarizing critiques); *accord.* John David Ohlendorf, *Textualism and Obstacle Preemption*, 47 GA. L. REV. 369, 372–73 (2013) (surveying commentary).

[159] Nelson, *supra* note 5, at 265.

[160] Meltzer, *supra* note 156, at 7, 37–38; *see also* Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Clarence Thomas the Lone Principled Federalist?*, 5 N.Y.U. J.L. & LIBERTY. 63, 77, 93, 112 (2010) (finding express preemption often requires reading the whole statute in context, and contextual inquiry gives courts discretion to infer purpose).

[161] *See* Diana R.H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute*, 89 TUL. L. REV. 815, 834 (2015) (citing state case that applied obstacle preemption to the NLEA after finding that the statute's express preemption provision did not apply).

identifying particular state laws Congress intends to preserve,[162] or expressing intent for conflict-only preemption.[163]

a. *Express Preemption*

The ACA sampled from all these preemption mechanisms and forms.[164] From this buffet of preemption options, Congress ultimately chose to include a muddled statement of conflict preemption in the ACA's insurance reforms.

For all of its private insurance regulations in Title I, the ACA includes a general express preemption provision. The statute states that, "[n]othing in [Title I] shall be construed to preempt any State law that *does not prevent the application of* the provisions of [Title I]."[165] Stated in negative terms, the insurance preemption provision at first appears to be a saving clause, preserving specified state law from preemption's reach.[166] In form and function, however, the provision actually saves only those state laws that would be beyond preemption doctrine's reach anyway. State laws that do not directly conflict with

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[162] *See* Rubenstein, *supra* note 23, at 1181; *e.g.*, McCarran–Ferguson Act, 15 U.S.C. § 1012(b) (2012) (preserving state regulatory authority over the "business of insurance"); 29 U.S.C. § 1144(b)(2) (2012) (ERISA's saving clause).

[163] *See, e.g.*, Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136v(a) (2012) (preserving state law that does not conflict with federal law); Clean Water Act, 33 U.S.C. § 1370 (2012) (preserving state requirements except those "less stringent" than federal law).

[164] *E.g.*, 21 U.S.C. § 343 note (2012) (Construction of Amendment by Pub. L. 111-148) ("Nothing [in the chain restaurant labeling section] shall be construed . . . to preempt [state law], unless [state law] establishes . . . nutrient content disclosures of the type required under [the ACA's additions to the Federal Food, Drug, and Cosmetic Act]."); *id.* ("Nothing [in the ACA section] shall be construed . . . to apply to any State . . . requirement . . . that provides for a warning [regarding food safety or food components]."); 29 U.S.C. § 207(r)(4) (2012) (saving "State law that provides greater protections to employees" than the ACA section about nursing time for working mothers does); 42 U.S.C. § 300gg-8(h) (2012) ("[The ACA requirement for coverage of participation in clinical trials does not] preempt State laws that require a clinical trials policy . . . that is in addition to the [ACA requirements]."); *id.* § 300gg-15(e) ("The [ACA's required streamlined and standardized explanations of coverage] shall preempt any related State standards that require a summary . . . that provides less information."); *id.* § 1320a-7h(d)(3)(A) ("[T]his section shall preempt any statute or regulation of a State . . . that requires an applicable manufacturer . . . to disclose or report, in any format, the type of information [required in the ACA]."); *id.*§ 1320a-7h(d)(3)(B) to -7(d)(3)(B)(i) ("[This section] shall not preempt [state law requiring disclosure of information] not of the type required to be disclosed [under the ACA]."); *id.*§ 18023(c)(1) ("Nothing in this Act shall be construed to preempt . . . State laws regarding . . . coverage, funding, or procedural requirements on abortions . . . .").

[165] 42 U.S.C. § 18041(d) (2012) (emphasis added).

[166] *See* Meltzer, *supra* note 156, at 12–14 (surveying saving clauses); *cf., e.g.*, 9 U.S.C. § 2 (2012) (Federal Arbitration Act (FAA) saving clause); 29 U.S.C. § 1144(b)(2) (2012) (ERISA saving clause covering the business of insurance); AT&T Mobility LLC v. Concepcion, 563 U.S. 333, 343, 352 (2011) (holding that the FAA's saving clause did not exempt state rule refusing to honor unconscionable class action waivers).

the ACA's insurance regulations would not be impossibility preempted, so it is more of an expression of *conflict* preemption than it is a saving clause.

Despite being expressed, the general preemption provision leaves significant ambiguity on which of the many kinds of conflict preemption it intends to invoke. Does the general provision contemplate solely impossibility preemption, or does it express a desire for obstacle preemption,[167] impossibility preemption's "freewheeling" sibling?[168] The application of straightforward impossibility preemption goes without saying,[169] as "neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'"[170] If the general provision intends impossibility preemption, it is inexplicably superfluous and strangely worded, unlike the statute's other obvious statements of impossibility conflict preemption.[171] Had Congress wanted the courts to stop at impossibility preemption for a general rule of construction, it could have expressed its intent more clearly.

Instead the general preemption provision wipes out state laws that "prevent the application" of the ACA.[172] "Prevent the application of" is hardly a legal term of art, though it recently has cropped up in various health law contexts.[173] The most relevant recent uses appear in ERISA and the related Mental Health Parity and Addiction Equity Act (MHPAEA),[174] as well as in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[175] ERISA and MHPAEA include cross-referenced provisions expressing intent that they not

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[167] Maher, *supra* note 132, at 702.

[168] *See* Wyeth v. Levine, 555 U.S. 555, 604 (2009) (Thomas, J., concurring) (referring to "purposes and objectives" preemption as "freewheeling, extratextual, and broad").

[169] Maher, *supra* note 132, at 702 n.255.

[170] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 343, 352 (2001) (alteration in original) (quoting Geier v. Am. Honda Motor Co., 529 U.S. 861, 869 (2000)).

[171] *See, e.g.*, 29 U.S.C. § 207(r)(4) (2012) (preempting state law that requires less and preserving "State law that provides greater protections"); 42 U.S.C. § 300gg-8(h) (2012) (preempting state law that requires less, but saving state laws imposing requirements "in addition to" the ACA's); *id.* § 300gg-15(e) (preempting state law that "provides less").

[172] 42 U.S.C. § 18041(d) (2012).

[173] *E.g.*, Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr., Inc., 413 F.3d 897, 908 (8th Cir. 2005) ("[E]ven if a state law is saved from preemption because it relates to insurance, the deemer clause *prevents the application of* that [*state*] law to self-funded ERISA plans." (emphasis added)); Impact on Md. Law of the Paul Wellstone and Peter Domenici Mental Health Parity and Addiction Equity Act of 2008 ("Parity Act"), 94 Op. Att'y Gen. Md. 3, 16 (2009) [hereinafter Maryland Letter] (opining that state-mandated insurance coverage for mental health and substance abuse benefits does not "prevent the application of" the Federal Mental Health Parity Acts and "therefore, . . . [is] not preempted"); *cf. In re* Aircrash in Bali v. PanAm World Airways, Inc., 684 F.2d 1301, 1308 (9th Cir. 1982) (holding state law that "necessarily conflicts with" the Warsaw Convention was preempted "to the extent [it] would prevent the application of" the federal law).

[174] Sources cited *infra* note 178.

[175] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, § 704(a)(1), 110 Stat. 1936, 1946–47 (1996).

be "construed to supersede any provision of State law [on group insurance] except to the extent that such standard or requirement *prevents the application* of a requirement" of the MHPAEA.[176] A House conference report suggested HIPAA's drafters intended the provision to invoke the "narrowest" preemption of state laws, and it also suggested that broader state protections would not "prevent the application of" the statute.[177]

Whether the drafters' conception of the "narrowest" preemption was *all* judicially-recognized conflict preemption (impossibility and obstacle) or solely impossibility preemption remains unclear.[178] Because the general preemption provision is the ACA's statement of intent for the insurance market reforms, it seems likely that the ERISA/MHPAEA/HIPAA language was at least contextually relevant to the choice of terms. Yet it also seems unclear how far "prevent the application" extends.[179]

The ACA general preemption provision[180] could be read to preempt state law impediments *beyond* just those that impossibly conflict with the insurance reforms. On the one hand, "prevent" seems more determinate than obstacle preemption's hallmark language of "stand[] as an obstacle to."[181] And a statute's "application" seems more concrete and pragmatic than its "purposes and objectives."[182] Of course, had Congress wished to unmistakably invoke obstacle preemption, it could have just used the well-established phrasing of "obstacle" to Congressional "purposes and objectives."[183] By choosing "prevent the application," Congress could have intended something slightly narrower than

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[176] 29 U.S.C. § 1191(a)(1) (2012) (emphasis added); 42 U.S.C. § 300gg-23(a)(1) (2012) (emphasis added); *see* 78 Fed. Reg. 68,240, 68,252 (Nov. 13, 2013) (explaining that ERISA's preemption provisions and implementing regulations extend to the MHPAEA).

[177] H.R. REP. NO. 104-736, at 205 (1996) (Conf. Rep.).

[178] *See* Abbe R. Gluck & Lisa Schultz Bressman, *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons: Part I*, 65 STAN. L. REV. 901, 942–44 (2013) (chronicling drafters' unfamiliarity with the contours and operation of preemption canons).

[179] Maryland Letter, *supra* note 173, at 16 (noting that state law mandating insurance coverage for mental health would not "prevent the application of" the MHPAEA, requiring the same thing).

[180] 42 U.S.C. § 18041(d) (2012).

[181] Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

[182] *Application*, MERRIAM-WEBSTER ONLINE DICTIONARY, https://www.merriam-webster.com/dictionary/application [https://perma.cc/3L2G-94NN] (last updated Nov. 19, 2017) (defining "application" to include putting to use or administering, as well as the "practical conclusion or lesson to be derived" from a discourse; it is synonymous with "operation" or "employment").

[183] *See Hines*, 312 U.S. at 67; *Objective*, MERRIAM-WEBSTER ONLINE DICTIONARY, http://www.merriam-webster.com/dictionary/objectives [https://perma.cc/E4J6-CLLN] (last updated Nov. 19, 2017) (showing that "objectives," by contrast, are synonymous with hopes, ambitions, and goals—the desired ends).

obstacle preemption, yet broader than impossibility preemption.[184] Despite being an express preemption provision, it is a muddle.

The few courts that have had the opportunity to interpret the ACA's general preemption provision have given it mixed effect as well. Whereas a district court found that the provision "does little more than invoke conflict preemption," broadly defined to include both impossibility and obstacle,[185] on appeal the Eighth Circuit determined that "[t]his preemption clause is a narrow one, and only those state laws that 'hinder or impede' the implementation of the ACA run afoul of the Supremacy Clause."[186] The district court had invalidated any state attempt to regulate ACA insurance navigators as an obstacle, but the Eighth Circuit remanded for the district court to consider § 18041(d)'s more "limited" preemptive effects, namely the limitation to conflict preemption.[187]

The ACA's insurance preemption definitively expresses intent *to* preempt (as opposed to save) and legislates *conflict* preemption, as opposed to the heavier complete or field preemptions.[188] Whether Congress intended its expression to constrain excessive discretion by limiting obstacle preemption or to preserve obstacle preemption in the face of mounting judicial resistance to the doctrine remains unclear.[189]

The ACA's muddled clarity on preemptive intent creates some uncertainty on how far states may go toward enacting additional health reforms or enforcing existing laws. Certainly, under either reading the ACA's insurance market reforms preempt state laws that are *less* stringent and therefore create an

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[184] *See* Maher, *supra* note 132, at 703 (posing that the provision might be "narrower" than obstacle preemption, included as a "curb" to courts' use of broad obstacle preemption, but observing that "neither the height nor slope of the curb contained in § 18041(d) is self-evident"). On the other hand, "prevent" is defined as "hinder or impede," *Prevent*, BLACK'S LAW DICTIONARY 1380 (10th ed. 2014), and "impediment" is synonymous with "obstacle," *Impediment*, MERRIAM-WEBSTER ONLINE THESAURUS, https://www.merriam-webster.com/thesaurus/impediment [https://perma.cc/P52T-4WQZ] ("impediment" synonyms).

[185] St. Louis Effort for AIDS v. Huff, 996 F. Supp. 2d 798, 802 (W.D. Mo. 2014).

[186] St. Louis Effort for AIDS v. Huff, 782 F.3d 1016, 1022 (8th Cir. 2015).

[187] *Id.* at 1022, 1028.

[188] *See* Maher, *supra* note 132, at 702 & n.254; *see also* Am. Council of Life Insurers v. D.C. Health Benefit Exch. Auth., 73 F. Supp. 3d 65, 82 (D.D.C. 2014) ("The ACA expressly grants the States the choice of operating their own Exchanges, pursuant to state law, rather than adopt [sic] a Federal Exchange, plainly undercutting any perceived congressional intent to control the entire field of local Exchanges." (citation omitted)), *vacated*, 815 F.3d 17, 21 (D.C. Cir. 2016) (vacated for lack of jurisdiction).

[189] Within conflict preemption, the ACA's chosen language invokes synonyms of "obstacle," and contemporaneous courts recognized obstacle preemption, *see* Ohlendorf, *supra* note 158, at 372, though with diminishing regularity, *e.g.*, Wyeth v. Levine, 555 U.S. 555, 604 (2009) (Thomas, J., concurring). The general provision thus can be fairly read to encompass both impossibility (the narrower form) and obstacle (the broader form) conflict preemption.

impossibility conflict.[190] State health insurance laws requiring only nine of the ten essential health benefits—or not mandating categories of benefits at all—could not be enforced in light of the ACA's EHB regulations.

The extension to obstacle preemption, however, would become crucial in determining the fate of state laws that impose different requirements (like establishing a coverage minimum at some actuarial payment level), additional requirements (like requiring coverage for fertility treatment not on the EHB list), or establishing parallel systems (like creating a separate exchange for Medicare Part C plans). These state activities would not necessarily produce an impossible choice because compliance with both is technically achievable. But the disuniformity (coverage minimums), added cost (for additional mandatory benefits), and potential for confusion and diversion (with multiple exchanges) could each pose "obstacles" or "impediments" to the implementation of the ACA's universal coverage and affordability scheme.

Obstacle preemption might best serve the purposes of the ACA because obstacle preemption is especially useful in adapting statutory language to unforeseen or evolving circumstances, which abound in health care regulation.[191] Further, obstacle preemption is particularly well-suited to a statute that heavily delegates rulemaking to agencies, as the ACA does, because obstacle preemption's flexibility recognizes that these rules will not be set at the time the statute is enacted.[192] Adaptability is a benefit that obstacle preemption shares with big waiver, discussed below.[193]

Despite this flexibility, one statutory obstacle remains. None of the ACA's preemption statements, under any reading, put a dent in ERISA preemption.[194] Although the ACA directly regulated employer-sponsored insurance in ways that ERISA had prevented states from doing, the ACA did nothing to alter the preemptive force of ERISA.[195] The Supreme Court in *Gobeille* further noted that the ACA should *not* be construed to alter ERISA's application, but passed

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[190] *See* Nelson, *supra* note 5, at 228 & n.15; Louise Weinberg, *The Federal-State Conflict of Laws: "Actual" Conflicts*, 70 TEX. L. REV. 1743, 1753–54 (1992) (actual conflicts).

[191] *See* Meltzer, *supra* note 156, at 14–15 (arguing that implied preemption is needed because Congress cannot identify all preexisting state laws that might conflict, let alone those enacted after the legislation is drafted).

[192] *See id.* at 15, 18.

[193] *See Infra* Part III.

[194] *Cf.* Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 18023(d) (2012) (express provision stating that "[n]othing in [the ACA] shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including . . . this title").

[195] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016).

on the question whether ERISA might prevent application of some ACA provisions.[196]

b. *Implied Preemption*

Even those provisions not covered by the muddled general preemption provision could have preemptive effect when they make contact with state law.[197]

The individual mandate, for example, is not covered by the Title I general preemption provision and does not have its own preemption provision.[198] Yet reviewing courts have held that the ACA preempts state efforts to exempt state citizens from the mandate and other obstructionist state laws passed in resistance to the ACA. In 2014, the Ninth Circuit reviewed the effect of an Arizona constitutional amendment allowing its citizens to forego minimum health insurance coverage and abstain from paying any penalties.[199] The Ninth Circuit held that the Arizona law "presents a classic case of preemption by implication because [it] 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,'"[200] and is, therefore, preempted under the Supremacy Clause. While impossibility conflict would preempt the Arizona nonmandate, the Ninth Circuit applied the broader obstacle preemption,[201] and the Supreme Court denied certiorari.[202] Other litigation challenging the wave of ACA-protesting state laws has ended with a similar implied preemption analysis invalidating the state law.[203]

The scope of Congress's general preemptive intent—the "touchstone" of preemption analysis[204]—remains muddled with respect to the ACA's seminal insurance reforms. For present purposes, the important point emerging from this muddle is that Congress intended its ACA insurance market reforms to have preemptive effect.

Overall, the ACA somewhat bucks the trend of piecemeal health legislation by making law incrementally in nearly every sphere of health care regulation

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[196] *Id.*; *see* 29 U.S.C. § 1191(a)(2) (2012) (providing that the new ACA provisions shall not be construed to affect or modify the ERISA preemption clause as applied to group health plans); 42 U.S.C. § 300gg-23(a)(2) (2012) (same).

[197] *See* Nelson, *supra* note 5, at 227–29; Sharkey, *Inside Agency Preemption*, *supra* note 23, at 525.

[198] *See* 26 U.S.C. § 5000A (2012) (lacking a preemption provision).

[199] Coons v. Lew, 762 F.3d 891, 902 (9th Cir. 2014) (reviewing ARIZ. CONST. art. XXVII, § 2(A)(1)–(2)), *cert. denied*, 135 S. Ct. 1699 (2015) (mem.).

[200] *Id.* ("A state law . . . is preempted if it interferes with the methods by which the federal statute was designed to reach [its] goal." (alteration in original) (quoting Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 103 (1992))).

[201] *Id.*

[202] Coons v. Lew, 135 S. Ct. 1699, 1699 (2015) (mem.).

[203] *See, e.g.*, St. Louis Effort for AIDS v. Huff, 782 F.3d 1016, 1023 (8th Cir. 2015).

[204] Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963).

and expressly preempting contrary state laws. The statute's muddled preemption statement does little to bring clarity to the muddy waters of health law preemption.

Yet the ACA creates a waiver program that allows a federal agency to suspend application of otherwise preemptive law and sanction a state's deviation from the ACA.[205] Through this waiver mechanism, discussed in Part III below, the ACA contains its own escape hatch. As long as a state credibly promises to pursue federal goals by enacting laws of comparable affordability, access, and comprehensiveness, Centers for Medicare and Medicaid Services (CMS) can waive the biggest parts of the statute and enable the state to strike out on its own.[206] This may be the ACA's repeal from within, or its salvation.

III. PREEMPTION MEETS "BIG WAIVER" IN THE ACA

Nestled among other provisions for "State Flexibility to Establish Alternative Programs,"[207] the ACA's section 1332 establishes a waiver mechanism that can suspend the individual and employer mandates, operation of the insurance exchanges, essential health benefits, subsidies, and other coverage regulation in the individual market for states to pursue their own alternative programs.[208]

Specifically, the ACA's "Waiver for State innovation" provides:

> (1) In general
> A State may apply to the Secretary for the waiver of all or any requirements described in paragraph (2) with respect to health insurance coverage within that State for plan years beginning on or after January 1, 2017. Such application shall—
> (A) be filed at such time and in such manner as the Secretary may require;
> (B) contain such information as the Secretary may require, including—
> (i) a comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under this section; and
> (ii) a 10-year budget plan for such plan that is budget neutral for the Federal Government; and
> (C) provide an assurance that the State has enacted the law described in subsection (b)(2).
>
> (2) Requirements

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[205] 42 U.S.C. § 18052 (2012).

[206] *See* John E. McDonough, *The Demise of Vermont's Single-Payer Plan*, 372 NEW ENG. J. MED. 1584, 1585 (2015).

[207] 42 U.S.C. §§ 18051–18054. The other "flexibility" alternatives include establishing state "basic health programs for low-income individuals not eligible for Medicaid," *id.* § 18051, and offering multi-state plans, *id.* §§ 18053–18054.

[208] 42 U.S.C. § 18052 (2012).

> The requirements described in this paragraph with respect to health insurance coverage within the State for plan years beginning on or after January 1, 2014, are as follows:
> (A) Part A of this subchapter [qualified health plan and essential benefits provisions].
> (B) Part B of this subchapter [health insurance exchange, individual market risk pooling, and financial integrity provisions].
> (C) Section 18071 of this title [cost-sharing provisions].
> (D) Sections 36B, 4980H, and 5000A of title 26 [premium assistance tax credits, employer and individual mandates].[209]

While the ACA gives section 1332 the title, "Waiver for State Innovation,"[210] this waiver provision goes by many names. Many commentators refer to it as the "section 1332 waiver."[211] CMS and others call it the "State Innovation Waiver."[212] Other scholars have proposed that "[a] better name for this program might be Waivers for State Responsibility, because they do not exempt states from accomplishing the *aims* of the ACA, but give them the ability (and responsibility) to fulfill them in a different manner, while staying between certain guardrails."[213] This moniker, or even "insurance market waiver," would help distinguish 1332 from other "innovation" waivers and the preexisting "Medicaid waivers."[214]

The 1332 waiver could be called the ACA's "big waiver," as well. By any name, section 1332's waiver has been aptly classified by Barron and Rakoff as an exemplar of their "big waiver" theory because the provision delegates power to an agency to "substantially revise and not modestly tweak" the statute's core requirements.[215]

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[209] *Id.* § 18052(a)(1)–(2).

[210] *Id.*

[211] The Act section number differentiates it from another longstanding HHS waiver power—the Medicaid section 1115 waiver. *See* Ctrs. for Medicare & Medicaid Svcs., *About Section 1115 Demonstrations*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html [https://perma.cc/N8XT-YN7W]; Kevin Lucia et al., *Innovation Waivers and the ACA: As Federal Officials Flesh Out Key Requirements for Modifying the Health Law, States Tread Slowly*, COMMONWEALTH FUND: TO THE POINT (Feb. 17, 2016), http://www.commonwealthfund.org/publications/blog/2016/feb/ innovation-waivers-and-the-aca [https://perma.cc/F8T8-YXM5] (comparing the "so-called section 1115 waiver" with the section 1332 waiver).

[212] *See, e.g.*, Ctr. for Consumer Info. & Ins. Oversight, *Section 1332: State Innovation Waivers*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/cciio/programs-and-initiatives/state-innovation-waivers/section_1332_state_innovation_waivers-.html [https://perma.cc/D8DX-GAF7].

[213] Howard & Benshoof, *supra* note 16, at 237.

[214] *Cf.* Lucia et al., *supra* note 211, at exhibit 1 (summarizing 1332 waivers under the title "State Waivers of the ACA's Private Health Insurance Rules").

[215] Barron & Rakoff, *supra* note 19, at 278.

This Part first describes how the 1332 innovation waiver works, then situates it within the theoretical context of "big waiver," and finally examines some recent proposals to revise the statute.

A. *The ACA's State Innovation Waiver*

The ACA's innovation waiver provision sets parameters for the who, what, when, and how of the innovation waiver, delegating additional technical detail, as well as application of the statutory standards, to the implementing agencies.

1. *Waiver Authority*

The statute authorizes the Secretary of HHS to review and determine waiver applications.[216] The Secretary has delegated this authority to CMS, in coordination with the Department of the Treasury (Treasury).[217] CMS and Treasury together have promulgated regulations and guidance on the waiver process,[218] though CMS has assumed the lead role in reviewing and processing the applications.[219]

Section 1332 authorizes waiver of the ACA's core private insurance market reforms:[220]

(A) the qualified health plan and essential benefits provisions;[221]
(B) the health insurance exchange, individual market risk pooling, and financial integrity provisions;[222]
(C) the cost-sharing provisions;[223] and
(D) the premium assistance tax credits,[224] employer[225] and individual mandates.[226]

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[216] *See* 42 U.S.C. § 18052(a)(1) (2012) (noting that states "may apply to the Secretary"); *id.* § 18052(b) (noting that "[t]he Secretary may grant" a waiver).

[217] Delegation of Authorities, 76 Fed. Reg. 53,903, 53,903–04 (Aug. 30, 2011).

[218] *See, e.g.*, 31 C.F.R. § 33.100, .102, .108, .112, .116, .120, .124, .128 (2017); 45 C.F.R. § 155.1302 (2016) (detailing the application process regulations).

[219] *See* 45 C.F.R. § 155.1302 (2016) (noting that waiver applications are to be filed with CMS and the agency will refer any relevant requests to Treasury).

[220] 42 U.S.C. § 18052(a)(2) (2012); *see* Barron & Rakoff, *supra* note 19, at 281 ("[The Act] allows a state to propose a health care scheme alternative to that provided by the Act and to ask for a waiver of key provisions of the Act . . . .").

[221] *See generally* 42 U.S.C. §§ 18021–18024 (detailing qualified health plans and essential health benefits of the ACA).

[222] *See generally id.* §§ 18031–18033 (detailing the health insurance exchange, individual market risk pooling, and financial integrity provisions of the ACA).

[223] *See generally id.* § 18071 (detailing the cost-sharing provisions of the ACA).

[224] *See generally* 26 U.S.C. § 36B (2012) (detailing the tax credit scheme).

[225] *See generally id.* § 4980H (detailing the employer mandate).

[226] *See generally id.* § 5000A (detailing the individual mandate).

These four groups of provisions constitute pillars of the ACA's reform of the commercial insurance markets serving individuals and employers[227]—which accounts for more than half of Americans.[228] Each of these pillars plays an integral role in the ACA's reforms, and all four interact with each other on some level.

The first waivable pillar, group (A), sets a uniform federal minimum for the coverage, marketing, and reporting standards in all policies sold on the exchanges by certifying health plans as "qualified" (QHPs) and dictating categories of "essential health benefits" (EHBs) that must be covered, some without co-pay.[229] In addition to the bare-bones "preventive health services" all insurance must cover, the "essential health benefits" establish a higher federal minimum for coverage in plans sold on the exchanges.[230] Any health plan may be offered on an exchange only if it meets this federal minimum, "*notwithstanding* any provision of law that may require benefits *other than* the" federal EHBs.[231] But, under the ACA, a state *may* require benefits "in addition to" the EHBs for its QHPs, as long as the state will "defray the cost of any additional benefits" required.[232]

While the (A) provisions regulate plan coverage, communication, and enrollment, the (B) group of waivable provisions extends to operation of the health exchanges, health insurers' financial practices, and the affordability of coverage.[233] The (B) group regulations include those requiring that exchanges implement certification procedures, maintain consumer assistance hotlines, rate plans, provide Medicaid eligibility information, establish a Navigator program, and use standardized formats for presenting plan options.[234] Among other transparency provisions in group (B),[235] the exchanges must require QHPs to

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[227] The other pillars of the ACA concentrated on expanding the role of public programs through the Medicaid expansion and quality initiatives. *Cf.* Gillian E. Metzger, *Agencies, Polarization and the States*, 115 COLUM. L. REV. 1739, 1782 (2015) ("Medicaid and health exchanges stand as alternative pillars of the ACA . . . .").

[228] *See* JESSICA C. BARNETT & MARINA S. VORNOVITSKY, U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2015, at 6 (Sept. 2016), https://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-257.pdf [https://perma.cc/E8R5-9MT2].

[229] *See generally* 42 U.S.C. § 18021 (2012) (discussing the requirements of QHPs); *id.* § 18022 (discussing the requirements of EHBs).

[230] *See id.* §§ 18022(a)(1), 18031(c)(1) (stating additional requirements referenced in § 18052 and setting these qualification criteria "at a minimum" of what the Secretary of HHS must establish).

[231] *Id.* § 18031(d)(3)(A) (2012) (emphasis added) (describing the "[r]ules relating to additional required benefits").

[232] *Id.* § 18031(d)(3)(B)(i). Cost-sharing reductions for lower-income enrollees are also not available for costs incurred by state additional benefits. *Id.* § 18071(c)(4).

[233] *See, e.g.*, *id.* § 18031 ("Affordable Choices of Health Benefit Plans").

[234] *Id.* § 18031(d)(4).

[235] *See* 42 U.S.C. § 18031(e)(3) (2012) ("Transparency in coverage").

disclose information on claims, enrollment, and finances,[236] as well as to "submit a justification for any premium increase prior to" implementing it, and account for any increase in the certification decision.[237]

The risk-pooling provisions in group (B) require exchange plans to treat all individual enrollees as a single risk-pool and all small-group plan enrollees in a single risk pool, which generally evens out premiums across individuals.[238]

Finally, in the (C) and (D) groups, the statute permits waiver of the income-based subsidies available in the individual market through the exchanges, and the insurance mandates—which apply in *all* insurance markets.[239] The (C) group of waivable provisions are the cost-sharing subsidies, requiring reduced co-pays and deductibles for exchange-based silver plan enrollees with household income falling in the subsidized range (100%–400% of the federal poverty level).[240]

The (D) group of provisions are the insurance mandates and the premium subsidies.[241] While the individual mandate most famously compels individuals to find coverage or pay a tax, the individual mandate also sets the de facto true federal minimum of insurance coverage, for it applies to any and all sources of health insurance coverage, obtained on or off the exchanges.[242] Individuals may satisfy the mandate in one of three ways: public program insurance (like Medicaid or Medicare), individual market policies bought on the exchanges, or employer-sponsored policies.[243] In effect, this means that the minimum insurance required varies with the source of that insurance. Public programs have their own definitions of the minimum benefits required, which tend to be fairly comprehensive (though Medicaid has significant state-by-state waivers of those requirements)[244] and automatically satisfy the mandate.[245] Exchange-

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[236] *Id.* § 18031(e)(3)(A).

[237] *Id.* § 18031(e)(2).

[238] *Id.* § 18032(c). Because the (B) group provisions also limit "qualified individuals" shopping on the exchanges to non-incarcerated U.S. citizens and lawful residents, *id.* § 18032(f), a waiver potentially could extend exchange qualification to individuals with other immigration statuses.

[239] *See generally id.* §§ 18071, 18052 (discussing the ACA's cost-sharing provisions as well as the insurance mandates and premium subsidies).

[240] 42 U.S.C. § 18071(b) (2012).

[241] *Id.* § 18052(a)(2)(D).

[242] *See* 26 U.S.C. § 5000A(f) (2012).

[243] *See* U.S. Ctrs. for Medicare & Medicaid Servs., *Types of Health Insurance that Count as Coverage*, HEALTHCARE.GOV, https://www.healthcare.gov/fees/plans-that-count-as-coverage/ [https://perma.cc/N7F6-2W7S].

[244] *See* Watson, *supra* note 18, at 221–31 (surveying the various state-by-state waivers of the Medicaid requirements attempted).

[245] *See* 26 U.S.C. § 5000A(f)(1)(A) (defining "minimum essential coverage" to mean coverage under government-sponsored programs including Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, the Department of Veterans Affairs, or Peace Corps).

based policies for the individual and small-employer markets by definition must meet all of the commercial regulations, plus cover EHBs[246] and also automatically satisfy the mandate.[247]

But large group plans (employer-sponsored, including self-funded plans), which cover almost half of Americans, are subject only to the issuance and preventive health services minimums, not the QHP or EHB requirements.[248] "Coverage under an eligible employer-sponsored plan" satisfies the individual mandate, despite the reality that those plans may provide much skimpier coverage than the plans sold on exchanges.[249]

Under the innovation waiver, CMS could waive application of the insurance mandates themselves in a particular state, which could alter the incentives for participation in the individual market for health insurance and the scope of employer-sponsored health benefits.[250] Thus, 1332 permits waiver of the individual and small-group market exchange reforms, as well as the universal individual and employer mandates. This is a substantial portion of the ACA's total reforms and would apply to a substantial portion of the population.[251]

Three major pieces of the ACA remain beyond 1332's immediate reach: (1) some reforms to the issuance and coverage of commercial health plans (for example, guaranteed issue, no medical underwriting, dependent coverage to age twenty-six, preventive health services covered without co-pay, and mandatory medical loss ratio reporting);[252] (2) reforms to public programs, notably the Medicaid expansion, which is subject to its own waiver processes (found in

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[246] *See* 42 U.S.C. § 18022.

[247] *See* 26 U.S.C. § 5000A(f)(1)(C) (defining "minimum essential coverage" to include "coverage under a health plan offered in the individual market").

[248] *See* Timothy Jost, *Implementing Health Reform: 'Minimum Value' Plans Must Have Hospital and Physician Coverage*, HEALTH AFF.: BLOG (Nov. 4, 2014), http://healthaffairs.org/blog/2014/11/04/implementing-health-reform-minimum-value-plans-must-have-hospital-and-physician-coverage/ [https://perma.cc/B9X2-84BF].

[249] 26 U.S.C. 5000A(f)(1)(B).

[250] Accounting for the section 1115 and section 1915(b) waivers in the Medicaid program brings the total population subject to CMS-waivable insurance regulations up to 75%. *See Health Insurance Coverage of the Total Population*, HENRY J. KAISER FAM. FOUND. (2016), http://www.kff.org/other/state-indicator/total-population/?dataView=0&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D [https://perma.cc/EHT5-TTAZ] (detailing that, in 2016, 7% of Americans had Non-Group coverage in the individual market, 19% had Medicaid, and 49% had employer-sponsored insurance; totaling 75% of people covered by a source of insurance with provisions waivable by CMS). Medicare, as a fully federal program, does not have as significant waiver provisions. Arguably, § 1332's waiver of the individual mandate could impact 100% of tax-filing citizens.

[251] *See id.*

[252] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 1001–1253, 124 Stat. 119, 130–62 (2010) (codified as amended in scattered sections of 42 U.S.C.) (detailing the immediate improvements to and expansion of quality health care).

sections 1115 and 1915(b) of the Social Security Act);[253] and (3) quality coordination, public health, and workforce improvements.[254] But recent proposed legislation would extend the 1332 waiver power to cover (1) and radically alter the entire Medicaid program (2), as detailed below.[255]

The innovation waiver provision expressly denies CMS authority to waive other laws under this delegation.[256] Most notably, the ACA expressly stated its intent *not* to alter ERISA,[257] which neither CMS nor Treasury administer. Thus, while CMS may waive the employer mandate for a particular state, the waiver does not alter ERISA's prohibition on state laws targeting employer-sponsored health benefits.[258]

2. *Waiver Standards and Process*

The innovation waiver provisions constrain the agency's discretion by prescribing standards for granting a waiver, and procedures the agency must employ in processing applications and making its decisions.

While the insurance coverage regulations, exchanges, and mandates became effective between 2011 and 2015, the ACA innovation waiver did not become available until the plan year beginning January 1, 2017—after the 2016 presidential election.[259] Before the election, several states already had expressed their intent to seek innovation waivers: Massachusetts, Rhode Island, Oregon, Indiana, and Ohio. Massachusetts and Rhode Island enacted legislation authorizing state agencies to pursue waiver applications.[260] In 2016, Oregon authorized its agency to apply for a waiver, but requires legislative preapproval of any waiver application and that the agency submit to the legislature "its

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[253] *Id.* §§ 2001–2955, 124 Stat. at 271–352 (detailing the role of and expansion of Medicaid under the ACA). The background of preemption largely distinguishes the ACA innovation waiver from the Medicaid waiver system, *see* 42 U.S.C. §§ 1315, 1396n (2012), because states may choose initially whether the federal Medicaid law will apply.

[254] Patient Protection and Affordable Care Act §§ 2001–5701, 9001–9023 (detailing quality coordination, public health, workforce improvements, and revenue restrictions under the ACA).

[255] *See infra* Part II.C.

[256] 42 U.S.C. § 18052(c)(2) ("The Secretary may not waive under this section any Federal law or requirement that is not within the authority of the Secretary.").

[257] *See* 29 U.S.C. § 1191(a)(2) (2012) (providing that the new ACA provisions shall not be construed to affect or modify the ERISA preemption clause as applied to group health plans); 42 U.S.C. § 300gg-23(a)(2) (detailing the same); *see also* Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016) (finding ACA had no bearing on ERISA preemption analysis).

[258] *See* Marea B. Tumber, Note, *The ACA's 2017 State Innovation Waiver: Is ERISA a Roadblock to Meaningful Healthcare Reform?*, 10 U. MASS. L. REV. 388, 409 (2015).

[259] *See* 42 U.S.C. § 18052(a)(1) (stating that states may apply for the waiver starting with "plan years beginning on or after January 1, 2017").

[260] MASS. ANN. LAWS ch. 176Q, § 3(x) (LexisNexis Supp. 2016); 42 R.I. GEN. LAWS § 42-157-5 (2015).

recommendations for submitting an application" by March 1, 2017.[261] In 2011, Indiana enacted legislation instructing that its Secretary of Family and Social Services and its Department of Insurance "shall investigate; and . . . may apply" for the waiver.[262] Ohio's legislature has gone the furthest, precommitting its state agency to apply for a waiver and prescribing the goal and some of the contents of the waiver application—notably requiring that the application request waiver of the individual and employer mandates.[263]

In the final year of President Obama's Administration, Alaska, California, Hawai'i, and Vermont filed waiver applications.[264] CMS granted Hawai'i's waiver request to supplant its state fund for the small-business exchange required by the statute.[265] California withdrew its waiver application days before the inauguration.[266] Vermont's application for an alternative to the small-business exchange was denied based on incomplete actuarial support.[267]

After the 2016 presidential election, the fate of the ACA and its innovation wavier program appeared uncertain. Yet a new Executive Order instructed the Secretary of HHS to rely on his waiver authority to the "maximum extent permitted" by the ACA.[268] Former Secretary Price actively encouraged state governors to apply for waivers.[269] Shortly after Secretary Price's letter,

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[261] H.R. 4017, 78th Leg., Reg. Sess. § 2(3) (Or. 2016).

[262] IND. CODE § 4-1-12-4 (2011).

[263] OHIO REV. CODE ANN. § 3901.052 (West Supp. 2017).

[264] Ctr. for Consumer Info. & Ins. Oversight, *supra* note 212.

[265] Ctr. for Consumer Info. & Ins. Oversight, *Fact Sheet: Hawai'i Innovation Waiver*, CENTER MEDICARE & MEDICAID SERVICES (Dec. 30, 2016), https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Hawaii-1332-Waiver-Fact-Sheet-12-30-16-FINAL.pdf [https://perma.cc/9GXA-RMTU].

[266] Letter from Peter V. Lee, Exec. Dir., Covered Cal., to Kevin J. Counihan, Dir. & Marketplace Exec. Officer, U.S. Dep't of Health & Human Servs. (Jan. 18, 2017) [hereinafter Letter from Peter V. Lee], https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Application-Withdrawal-Request-01-18.pdf [https://perma.cc/34W8-FUC2].

[267] Letter from Sylvia M. Burwell, Sec'y, U.S. Dep't of Health & Human Servs., to Peter Shumlin, Governor, Vt. (June 9, 2016), https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Vermont-Notice-of-Preliminary-Determination-of-Incompleteness-.pdf [https://perma.cc/AXF6-8DRA] (providing Notice of Preliminary Determination of Incompleteness to the Governor of Vermont).

[268] Exec. Order No. 13,765, 82 Fed. Reg. 8351, 8351 (Jan. 20, 2017) (emphasizing the "imperative" that agencies "prepare to afford the States more flexibility" and instructing HHS to "exercise all authority and discretion available . . . to *waive*, defer, grant exemptions from . . . any provision . . . that would impose a fiscal [or regulatory] burden on any State" (emphasis added)).

[269] *See* Letter from Thomas E. Price, Sec'y, U.S. Dep't of Health & Human Servs., to State Governors (Mar. 13, 2017), https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/March-13-2017-letter_508.pdf [https://perma.cc/TPT9-TL8A].

Minnesota submitted a waiver application.[270] Alaska's application was accepted in January and granted in July, 2017.[271] By statute, CMS must rule on a state's waiver application within six months of receiving the application.[272]

From March through September 2017, Congress drafted several proposals to modify the ACA's core structure, nearly all of which focused on using the 1332 waiver provision to gut the ACA without officially repealing it,[273] as discussed in part C, below. These legislative efforts failed, but the 2017 open enrollment period drew near amid chaos and uncertainty about whether the ACA's exchange provisions would be funded and enforced.[274] Several more states submitted waiver applications aimed at stabilizing their individual markets, most with relatively modest requests.[275]

The ACA imposes five criteria on CMS's waiver authority that circumscribe the "maximum extent" of its waiver power. CMS may grant a waiver only after determining that a state's proposed new law will provide coverage:

1. "as least as comprehensive as" the EHBs offered on the exchanges;[276]
2. "at least as affordable as" the ACA private insurance coverage and cost sharing protections;[277] and

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[270] *See* Letter from Mark Dayton, Governor, Minn., and Minn. Legislators, to Steven Mnuchin, Sec'y, U.S. Dep't of the Treasury, and Thomas E. Price, Sec'y, U.S. Dep't of Health & Human Servs. (May 5, 2017), https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Minnesota-Section-1332-Waiver.pdf [https://perma.cc/A7ZR-ENNJ] (application and cover letter thanking the Secretary for his letter to state governors and requesting "swift review" of Minnesota's application for a waiver on its state reinsurance program).

[271] Letter from Sylvia M. Burwell, Sec'y, U.S. Dep't of Health & Human Servs., to Bill Walker, Governor, Alaska (Jan. 17, 2017) [hereinafter Letter to Walker], https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/SMB-Letter-Gov-Walker-1332.pdf [https://perma.cc/8YXB-KMCB]; Letter from Bill Walker, Governor, Alaska, to Lina Rashid, Senior Policy Advisor, Ctrs. for Medicare & Medicaid Svcs. (July 31, 2017), https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Alaska-STCs-signed-by-Treasury.pdf [https://perma.cc/3WUY-QG74] (accepting final terms and conditions of waiver approval).

[272] 42 U.S.C. § 18052(d)(1) (2012).

[273] *See* Timothy Stoltzfus Jost, *Much Activity, Uncertainty Remains*, 36 HEALTH AFF. 1864, 1864 (2017).

[274] *See* Rabah Kamal et al., *How the Loss of Cost-Sharing Subsidy Payments Is Affecting 2018 Premiums*, HENRY J. KAISER FAM. FOUND. (Oct. 27, 2017), https://www.kff.org/health-reform/issue-brief/how-the-loss-of-cost-sharing-subsidy-payments-is-affecting-2018-premiums/ [https://perma.cc/V5J2-EF9A].

[275] Oregon, Oklahoma, and Iowa submitted applications. *See* Jost, *supra* note 273, at 1865.

[276] 42 U.S.C. § 18052(b)(1)(A) (2012) (incorporating 42 U.S.C. § 18022(b)) (describing and requiring "Essential Health Benefits").

[277] *Id.* § 18052(b)(1)(B) (referring to ACA Title I provisions generally).

3. "to at least a comparable number of [state] residents" as the ACA private insurance regulations would,[278]
4. without increasing the federal deficit.[279]

Additionally, the state must:

5. promise that it has, or will enact the state law described in its plan.[280]

The statute sketches out content for the waiver applications, but delegates the detail to HHS. The statute requires at least "an assurance that the State has enacted the law described" in its application,[281] and former Secretary Burwell emphasized the role of this precommitment in the consideration of Alaska's application.[282]

The statute only partially defines the standards of proof to which CMS will subject state applications.[283] For example, the ACA's evidentiary standard for determining whether a waiver plan is "as comprehensive as" the exchange regulations' EHBs must be "certified by [the] Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by this Act and the provisions of this Act that would be waived."[284] CMS regulations further require state applications to provide actuarial analyses and actuarial certifications, economic analyses, data and assumptions, targets, an implementation timeline, and other necessary information to support the state's estimates that the proposed waiver will comply with these requirements.[285]

If CMS *grants* a waiver, the statute requires the agency to notify the state of its decision, as well as the "terms and effectiveness" of the waiver granted.[286] But if CMS *denies* waiver, CMS must notify both the state *and* "the appropriate committees of Congress" of the decision to deny the wavier *and* "the reasons" for the denial.[287] Barron and Rakoff postulate that "[t]his difference in statutory structure indicates Congress's approval of waivers with broad effects; if Congress were concerned about the breadth of waivers under this provision, presumably the notification procedure would be reversed such that Congress

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[278] *Id.* § 18052(b)(1)(C) (referring to ACA Title I provisions generally).

[279] *Id.* § 18052(b)(1)(D).

[280] *Id.* § 18052(b)(2)(A) ("Requirement to enact a law"); *id.* § 18052(a)(1)(C) (noting that the application must certify that the state has already or will enact the waiver plan law). A state's repeal of the law terminates the waiver, if granted. *Id.* § 18052(b)(2)(B).

[281] *Id.* § 18052(a)(1)(C).

[282] Letter to Walker, *supra* note 271.

[283] *See* 45 C.F.R. § 155.1308 (2016).

[284] 42 U.S.C. § 18052(b)(1)(A).

[285] *See* 31 C.F.R. § 33.108(f)(4)–(g) (2015); 45 CFR § 155.1308(f)(3)(iv) (detailing the application, review, and reporting process for waivers for state innovation final rule).

[286] 42 U.S.C. § 18052(d)(2)(A).

[287] *Id.* § 18052(d)(2)(B).

would be notified of waiver approvals but would not require notification of denials."[288]

The statute further directs CMS to develop a "process for coordinating" the 1332 waiver applications with the Medicaid waiver applications that will permit "a single application" for waiving both (and for all other federal laws relating to the provision of health care "items or services").[289]

B. *The Giant Among Big Waivers*

Because it addresses core features of the ACA, the innovation waiver has enormous potential to undo the statute's seminal provisions based on speculative evidence. It is, undeniably, a *big* delegation of waiver authority. The revisions proposed thus far would only expand the breadth of the 1332 waiver delegation, as discussed in section C below.

The concept of statutory waiver is neither new nor unique to health law, but statutory waivers that apply to the very core of the statute itself recently have risen to prominence and attracted unique theoretical treatment. Professors Barron and Rakoff launched "big waiver" theory in 2013 with their *In Defense of Big Waiver*.[290] Big waivers, according to their classification, "confer broad policymaking discretion so that the agency may choose to displace a regulatory baseline that Congress itself has established."[291]

While many statutes grant agencies the power to waive statutory requirements, Barron and Rakoff distinguish the common "little waiver" provisions from the more consequential "big waiver" provisions.[292] Little waivers "delegate a limited power to handle the exceptional case," that is a "power to merely 'modify' or 'tinker' with a statute through the lifting of limited aspects of a requirement . . . to handle an unusual application."[293] "Big waiver," by contrast, subjects the "heart of the statutory framework—the express provisions of it that seem most central to its effective operation as a regulatory mechanism"—to administrative waiver.[294] As a tool of legislative delegation, big waiver "certainly differs from other techniques that Congress has tried" and big waiver's "operation is also clearly more legally consequential than the mere exercise of enforcement discretion."[295]

Barron and Rakoff suggest that the inclusion of big waivers in legislation over the past few decades comes from the convergence of several historical

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[288] Barron & Rakoff, *supra* note 19, at 282 n.54.

[289] 42 U.S.C. 18052(a)(5).

[290] *See generally* Barron & Rakoff, *supra* note 19 (discussing agency use of the wide discretion provided by "big waivers" to displace statutory requirements set by Congress).

[291] *Id.* at 291.

[292] *Id.* at 276–78.

[293] *Id.* at 277.

[294] *Id.*

[295] *Id.* at 291.

forces.[296] First, the growth of Spending Clause legislation, which conditions regulation on the receipt of funding and therefore inherently invites negotiation.[297] It is worth noting, however, that the ACA's big waiver suspends preemptive federal law made pursuant to the Commerce and Taxation powers, not a Spending Clause program.[298] Second, the expansion of federal statutes and the "waning appeal of command and control regulation" brought cooperative federalism to the fore.[299] Third, the "growth of professional lobbying," the rise of legislative gridlock, and a divided government sent legislators seeking creative solutions.[300]

In their defense of big waiver, Barron and Rakoff argue that big waivers may encourage legislators to overcome gridlock, imbue legislation with a pragmatic flexibility to adapt to changing or unforeseen circumstances, as well as provide a statutory updating mechanism more responsive than the lugubrious process of passing new legislation.[301] All of these supposed values likely will be tested on the ACA, while Congress considers a full statutory repeal and the implementing agencies consider how to appropriately fulfill Executive Order 13765 in the meantime.

Barron and Rakoff used the ACA's innovation wavier as one of the six examples of statutory waivers that exemplify "big waiver" principles.[302] The innovation waiver, in targeting multiple essential pillars of the health reform law (individual and employer mandates, the exchanges, and some coverage regulations), waives the heart of the statutory framework and therefore exemplifies big waiver.[303] While the ACA innovation waiver fully embraces all the principles of big waiver and applies to preemptive law, it is not the "biggest" possible waiver in the Barron-and-Rakoff formulation because it still requires state application to trigger it and confines agency discretion both in the prescribed process and its standards.[304]

Yet the multiple-pillar approach and waiver of expressly preemptive law situates the ACA innovation waiver among the biggest of the existing big waivers.[305] The ability to suspend important swaths of preemptive law make the

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[296] Barron & Rakoff, *supra* note 19, at 293, 299–309.

[297] *Id.* at 293.

[298] *See, e.g.*, Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 565–66, 568–74 (2012) (holding that the individual mandate was properly enacted through the taxation power); *cf.* Barron & Rakoff, *supra* note 19, at 279, 284 (using education and welfare Spending Clause programs as exemplars of big waiver).

[299] Barron & Rakoff, *supra* note 19, at 299–304.

[300] *Id.* at 304–09.

[301] *Id.* at 309–11.

[302] *Id.* at 281; *cf. id.* at 283 (describing the ACA's Independent Payment Advisory Board as also reflecting some big waiver principles).

[303] *See id.* at 281.

[304] *Id.* at 278.

[305] Barron & Rakoff, *supra* note 19, at 281.

innovation waiver a particularly big waiver.[306] Within the waivers covered by "big waiver" theory, the ACA innovation waiver is a giant.[307] Recently proposed revisions to 1332 would convert it into a mega waiver, approaching the "biggest" waiver designation by removing significant constraints on granting the waiver.[308]

The ACA made law incrementally in nearly every sphere of health care regulation. Primarily, the ACA created a tremendous amount of new federal health law, expressly preempting conflicting state law. Yet the ACA counters preemption's rigidity with a waiver program that can suspend the application of preemptive law by preapproving state legislation.

C. *The Proposed Mega Waiver*

The innovation waiver's flexibility may give the ACA durability in a time of political upheaval. Or, the proposed mega waiver may swallow the statute's regulatory protections entirely.

The 1332 waiver is the ACA's escape hatch: as long as a state credibly promises to pursue federal goals by enacting laws of comparable affordability, access, and comprehensiveness, CMS can waive the biggest parts of the statute and enable the state to strike out on its own.[309] The escape hatch was set to open shortly before a new Congress convened to address the full statutory repeal promised by a new executive.[310] While this turn of course casts significant doubt on the ACA's continued existence as such,[311] the innovation waiver appears poised to play a major role in determining health care regulation in the near-term while Congress debates statutory reforms.[312]

Before the 2016 presidential election, health policy advocates expressed concern that the ACA innovation waiver could circumvent—or even undo—the

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[306] *Id.* at 281–84; McDonough, *supra* note 206, at 1585.

[307] Barron & Rakoff, *supra* note 19, at 281.

[308] *See id.* at 278 (defining the "biggest" waiver); Jost & Rosenbaum, *supra* note 31 (explaining proposed waiver expansions in the BCRA).

[309] *See* McDonough, *supra* note 206, at 1585.

[310] *See, e.g.*, REDHEAD & KINZER, *supra* note 38, at 1–2; Robert Pear et al., *G.O.P. Plans Immediate Repeal of Health Law, Then a Delay*, N.Y. TIMES (Dec. 2, 2016), https://www.nytimes.com/2016/12/02/us/politics/obamacare-repeal.html?_r=0 [https://perma.cc/WU8Q-P9NK].

[311] *See, e.g.*, Alison Kodjak, *Trump, GOP Lawmakers Back Off from Immediate Obamacare Repeal*, NPR (Feb. 6, 2017), http://www.npr.org/sections/health-shots/2017/02/06/513718166/trump-congressional-gop-back-off-from-immediate-obamacare-repeal [https://perma.cc/2TQ9-PUBM].

[312] *See* Exec. Order No. 13,765, 82 Fed. Reg. 8351, 8351 (Jan. 20, 2017) (announcing the new administration's intention to repeal the ACA and prioritize state flexibility moving forward).

law's seminal reforms by granting waivers based on speculative evidence.[313] After the election, the concerns shifted.

The new President signed Executive Order 13765 on January 20, 2017, signaling an executive "policy" of asking Congress to repeal the ACA at some time in the future, while directing the ACA's implementing agencies to use their existing "authority and discretion" to promote efficiency and state flexibility.[314] Without expressly mentioning the innovation waiver—or any other ACA provision—the Executive Order seems to emphasize resort to waivers to the "maximum extent permitted" by the statute.[315]

Meanwhile, Republican members of Congress have worked on introducing legislation to "repeal and replace" the ACA in fits and starts. The initial attempt to repeal the ACA's core provisions and pass replacement legislation failed in dramatic fashion on March 24, 2017, leaving the ACA intact.[316] It remains to be seen whether Congress will repeal the ACA wholesale, as has been threatened, and whether Congress will replace it with legislation containing similarly large waivers.[317]

The most recent proposal would significantly relax the section 1332 waiver standards and procedure, which would create even more leeway for states to pursue waivers with very few protections and little, if any, evidentiary support.[318] The discussion draft of H. R. 1628, the Better Care Reconciliation Act of 2017 (BCRA),[319] dramatically expands the section 1332 waiver mechanism. Under the BCRA proposal, the Secretary *must* grant any state's

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[313] *See* McDonough, *supra* note 206, at 1585.

[314] *See* Exec. Order 13,765, 82 Fed. Reg. at 8351 (setting a goal to "Minimiz[e] the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal").

[315] *Id.* (emphasizing the "imperative" that agencies "prepare to afford the States more flexibility" in sections 1 and 4, and instructing HHS to "exercise all authority and discretion available . . . to *waive*, defer, [or] grant exemptions from . . . any provision . . . that would impose a fiscal [or regulatory] burden on any State" in section 2) (emphasis added).

[316] Robert Pear et al., *In Major Defeat for Trump, Push To Repeal Health Law Fails*, N.Y. TIMES (Mar. 24, 2017), https://nyti.ms/2mYwVod [https://perma.cc/YC9V-J8W9]; Jennifer Steinhauer, *Republicans Land a Punch on Health Care, to Their Own Face*, N.Y. TIMES (Mar. 24, 2017), https://nyti.ms/2n0TKHP [https://perma.cc/GZS7-NP7P].

[317] *Compare* Timothy Jost, *Taking Stock of Health Reform: Where We've Been, Where We're Going*, HEALTH AFF.: BLOG (Dec. 6, 2016), http://healthaffairs.org/blog/2016/12/06/taking-stock-of-health-reform-where-weve-been-where-were-going/ [https://perma.cc/6GTR-6WPK] (discussing plans for replacing and repealing the ACA), *with* Billy Wynne, *Five Reasons the ACA Won't Be Repealed*, HEALTH AFF.: BLOG (Dec. 7, 2016), http://healthaffairs.org/blog/2016/12/07/five-reasons-the-aca-wont-be-repealed/ [https://perma.cc/NK9F-ULXL] (explaining why the ACA will not be repealed).

[318] Jost & Rosenbaum, *supra* note 31 ("Perhaps the most important private insurance market provision of the Senate bill comes near the end: its amendments to the 1332 state innovation waiver program.").

[319] Better Care Reconciliation Act of 2017, H.R. 1628, 115th Cong. (as passed by House, May 4, 2017), https://www.budget.senate.gov/imo/media/doc/BetterCareJuly13.2017.pdf [https://perma.cc/J35U-ECAB].

application *unless* its plan would increase the federal deficit.[320] To get this new waiver a state would need only to describe what it wants to do and how its plan might "provide for alternative means of . . . increasing access . . . , reducing average premiums, . . . and increasing enrollment."[321] The new waiver would last eight years instead of five, and only the state could shorten it.[322] All told, the proposed changes simply suspend the core of the ACA at a state's demand. The BCRA mega waiver does not even require a state to use the federal pass-through funding for health care, or any other specified purpose.[323]

More importantly for this present project and health care regulation in the longer term, the innovation waiver's model for addressing conflicts between state and federal laws offers some alternatives to conventional regulatory preemption modes that may have enduring value.

IV. AGENCY IMPRIMATUR AND ITS POTENTIAL FOR HEALTH CARE PREEMPTION

Preemption operates as a lever, shifting the center of authority over an issue. That shift can occur along three axes: the regulatory axis (from state to federal regulators), the enforcement axis (from judicial enforcement of private remedies to executive agency enforcement of public law),[324] and the interpretive axis (from judicial to legislative pronouncements of preemptive intent).[325] This Part explores a new doctrinal axis based on the innovation waiver's shift from preemption doctrine to agency imprimatur in managing health law federalism.

By imposing preemptive federal health insurance law, coupled with the big-waiver power to officially sanction state-law variations, I argue here that the ACA creates a preemption-diffusion mechanism favoring agency expertise on whether state variations serve federal purposes and objectives. This mechanism puts an agency imprimatur[326] on state dalliance and represents a shift toward conflict avoidance in a field saturated with state and federal laws. Giving federal license to state variation also represents a shift from preemption to waiver as a preferred tool of federalism and from judicial arbiters of acceptable conflicts to agency ones.

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[320] *Id.* § 207(a)(2)(A)(i).

[321] *Id.* § 207(a)(1)(A)(i)(I).

[322] *See id.* § 207(a)(4).

[323] *See* Bagley, *supra* note 36 ("If state officials blow the Obamacare money on cocaine and hookers, there's apparently nothing the federal government can do about it.").

[324] *See* Moncrieff, *supra* note 76, at 2363; *see also* Maher, *supra* note 132, at 701–02.

[325] *See* Sharpe, *supra* note 7, at 167.

[326] *See Imprimatur*, MERRIAM-WEBSTER ONLINE DICTIONARY, https://www.merriam-webster.com/dictionary/imprimatur [https://perma.cc/2U5C-QY5P] (last updated Nov. 22, 2017) ("[Imprimatur is defined as] approval of a publication under circumstances of official censorship.").

This Part introduces the imprimatur model of health care regulation and its constraints, as well as some normative implications of the imprimatur model for statutory reforms to health insurance. It concludes by posing some metrics by which to judge the applications of imprimatur and the current mega-waiver proposals.

A. *Preempting Preemption: The Agency Imprimatur Model*

Because preemption displaces state law with supreme federal law, applications of preemption doctrine usually "present . . . shifts of authority from state to federal forums"[327] that are both "obvious"[328] and decisive. Cooperative federalism[329] and concurrent regulation, by contrast, can have subtler and "more muddled shifts in the general direction of federal forums,"[330] while preemption of state *remedies* shifts enforcement authority from the judiciary to an executive agency.[331]

As a transsubstantive interpretive canon employed case-by-case in dispute resolution, preemption doctrine is not particularly well suited to promoting stability or coherence in any one body of substantive law.[332] The complex and uncertain development of health insurance preemption precedent painfully illustrates the shortcomings in addressing preemption through litigation.[333]

The ACA creates a substantial body of preemptive law,[334] which already has spawned numerous preemption arguments in litigation.[335] And yet its

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[327] Moncrieff, *supra* note 76, at 2363.

[328] *Id.* at 2364.

[329] *See Cooperative Federalism,* BLACK'S LAW DICTIONARY 729 (10th ed. 2014) ("Distribution of power between the federal government and the states whereby each recognizes the powers of the other while jointly engaging in certain governmental functions."); Kurzweil, *supra* note 19, at 578.

[330] Moncrieff, *supra* note 76, at 2363.

[331] *Id.* at 2325, 2330–31, 2362.

[332] *See* Merrill, *supra* note 5, at 772–73 (arguing that although the judiciary is preferable to agencies in resolving preemption judgments, there remain significant complications in how courts should decide preemption issues).

[333] *See supra* Part II.A (discussing the "scattered landscape" of health law preemption outside of the ACA); *see also* Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 365 (2002) (lamenting that ERISA preemption "occupies a substantial share of [the Supreme] Court's time"); De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 808 n.1 (1997) (complaining that ERISA preemption "ha[s] been the focus of considerable attention from this Court"); N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 656 (1995) (describing ERISA's preemption clauses as "unhelpful" to the interpretation of intent).

[334] *See supra* Part II.B.2 (highlighting the fact that the ACA "wrote an awful lot of law" in areas with significant amounts of state law already established).

[335] *See, e.g.*, St. Louis Effort for AIDS v. Huff, 782 F.3d 1016, 1024 (8th Cir. 2015); Coons v. Lew, 762 F.3d 891, 902 (9th Cir. 2014), *cert. denied*, 135 S. Ct. 1699 (2015) (mem.); Stormans, Inc. v. Wiesman, 794 F.3d 1064, 1074 (9th Cir. 2015), *cert. denied*, 136

waiver provision permits HHS to preapprove state-law variations on those most important new pieces of federal law.[336] This represents a shift from reliance on post hoc judicial application of preemption doctrine to an *ex ante* federal agency approval of potentially conflicting state law. The waiver gives federal agency imprimatur to state-law variants which might otherwise trigger preemption doctrine in litigation.

1. *The Agency Imprimatur Model*

The imprimatur model asserts federal power over a regulatory topic, sets federal objectives and parameters for that topic, and then guides and sanctions state-law variants the agency identifies as properly serving the federal objectives. As deployed in the ACA innovation waiver, imprimatur pushes state law out of the regulatory space with preemption, then invites state law into that space if the *agency* determines state law will serve federal objectives.

a. *Preemptive Federal Boundaries*

The ACA builds incrementally on topics with preexisting federal and state regulation, some more rigorous than others.[337] The ACA filled some of the blank federal space left by ERISA preemption and annexed some of the occupied state space on insurance content regulation.

Before the ACA, state law primarily regulated the content of commercial health insurance, but those regulations varied widely among the states.[338] The ACA planted a federal flag in the commercial insurance market, creating a unitary federal regulatory infrastructure and making preemptive federal law on coverage, issuance, and underwriting.[339] The ACA mandates that all individuals have health insurance coverage,[340] that every state has a health insurance

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S. Ct. 2433, 2433 (2016); Am. Council of Life Insurers v. D.C. Health Benefit Exch. Auth., 73 F. Supp. 3d 65, 80 (D.D.C. 2014), *vacated*, 815 F.3d 17, 21 (D.C. Cir. 2016) (vacated for lack of jurisdiction).

[336] *See supra* Part III (analyzing the ACA's "big waiver" provision).

[337] *See supra* Part II.B.1 (discussing the areas in which the ACA can be reformed and expanded upon).

[338] *See, e.g.*, Amy B. Monahan, *Value-Based Mandated Health Benefits*, 80 U. COLO. L. REV. 127, 164 (2009) (detailing variations among states in regulating infertility coverage). *See generally* Amy B. Monahan, *Fairness Versus Welfare in Health Insurance Content Regulation*, 2012 U. ILL. L. REV. 139, 153–212 (2012) [hereinafter Monahan, *Content Regulation*] (presenting case studies of state health insurance content regulation, revealing that state laws are enacted without an evidentiary basis and respond to intense interest-group pressure).

[339] *See supra* Part II.B.1 (examining the ACA's regulations regarding the issuance, coverage, and administration of the commercial insurance market).

[340] 26 U.S.C. § 5000A(a) (2012).

exchange (even if the federal government has to run it),[341] and that the insurance policies sold on the exchanges conform to a set of detailed federal requirements.[342] All of this mandatory law expressly preempts conflicting state standards and, in some provisions, expressly preempts even parallel state regulation.[343]

The Supreme Court in *National Federation of Independent Business v. Sebelius*[344] and *King v. Burwell*[345] validated the ACA's federal claim on commercial health insurance regulation as constitutionally permissible (the individual mandate in *Sebelius*)[346] and intended for national uniformity (the exchange subsidies in *King*).[347] The ACA thus brought federal uniformity to content regulation, largely through the health insurance exchanges.[348] For individual and small-group insurance, the ACA asserts a strong, preemptive interest in the regulatory space and fills it with uniform federal regulations that states may tailor at the margins to fit their populations.[349]

By contrast, the ACA did relatively little to alter the sparse content regulation of policies sold to large employers,[350] a regulatory space already federalized through ERISA.[351] The ACA's employer mandate, however, at last filled the vast regulatory void created by ERISA preemption. ERISA preempts state efforts to enact an employer mandate because the mandate directly "relate[s] to" an employer-sponsored benefit.[352] Until the ACA, that space remained mostly empty[353] because ERISA and its amendments offered very

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[341] 42 U.S.C. § 18031(b)(1) (2012) ("Each State shall . . . establish an American Health Benefit Exchange . . . for the State . . . .").

[342] *Id.* §§ 18021–18022.

[343] *Id.* § 1320a-7h(d)(3)(A) (2012).

[344] Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 589 (2012).

[345] King v. Burwell, 135 S. Ct. 2480, 2496 (2015).

[346] *Sebelius*, 567 U.S. at 567–69.

[347] *King*, 135 S. Ct. at 2496.

[348] *E.g.*, 26 U.S.C. § 4980H(a)–(b) (2012) (requiring qualifying employers to provide minimum coverage to its employees or pay a penalty); 42 U.S.C. § 18022(b)(4)(F) (2012).

[349] *See* Monahan, *Content Regulation*, *supra* note 338, at 153 tbl.1.

[350] *See id.* at 152–53, 153 tbl.1.

[351] *See id.* at 152 ("Such plans remain subject only to ERISA's limited substantive requirements.").

[352] Jay Conison, *ERISA and the Language of Preemption*, 72 WASH U. L.Q. 619, 623–24, 655 (1994).

[353] Except in Hawai'i, which has a special statutory exemption from ERISA, 29 U.S.C. § 1144(b)(5)(A)–(B)(ii) (2012), and Massachusetts, where the state employer mandate went unchallenged by ERISA preemption, *see* Mary Ann Chirba-Martin & Andrés Torres, *Universal Health Care in Massachusetts: Setting the Standard for National Reform*, 35 FORDHAM URB. L.J. 409, 409–10 (2008).

little federal regulation to fill the preempted area.[354] The employer mandate, which applies with preemptive force, exercises federal regulatory power long dormant under ERISA.[355]

The ACA thus reinforced the preemptive boundary around employer-sponsored health insurance and established a new preemptive border around individual and group market regulations, though the precise extent of those preemptive boundaries is somewhat unclear.[356] The statute asserts federal power over that regulatory space and gives notice that it intends to clear away state-law obstacles to achieving federal goals and objectives.

b. *Supervising State Law Within Federal Regulatory Space*

The ACA's innovation waiver provision then invites states back into the reclaimed federal regulatory space, but only under direct supervision of CMS.

First, the waiver operates as an invitation, not an immunization. The ACA's provisions, by statutory design, had been in effect with preemptive power for over six years before states became able to ask for the waiver.[357] So, for example, state efforts to suspend the individual mandate were preempted in the period during which the state could not (and therefore did not) request a waiver and offer a replacement.[358]

Similarly, the ACA provisions on the insurance exchanges contain considerable flexibility for states to implement the statute in cooperation with HHS.[359] But the existence of the exchange and the baseline substantive rules for the insurance offered on it are mandatory, federal, and preemptive of state conflicts for at least the first six years.[360] States may choose whether to operate their own exchanges without a waiver, but they may not choose whether to have an exchange at all and must abide by federal law inside it.[361]

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354 Katherine T. Vukadin, *Unfinished Business: The Affordable Care Act and the Problem of Delayed and Denied ERISA Healthcare Claims*, 47 J. MARSHALL L. REV. 887, 888–89 (2014).

355 *See* Chirba-Martin & Torres, *supra* note 353, at 433; Vukadin, *supra* note 354, at 892.

356 *See* 42 U.S.C. § 18042(a) (2012); *supra* Part II.B.2 (emphasizing the preemption doctrine's reliance on congressional intent, which can be difficult for courts to determine).

357 *See* 42 U.S.C. § 18052(a)(1) (requiring states to wait until 2017 to apply for a waiver).

358 Coons v. Lew, 762 F.3d 891, 902 (9th Cir. 2014), *cert. denied*, 135 S. Ct. 1699 (2015) (mem.).

359 *See* 42 U.S.C. § 18042.

360 *See id.* §§ 18031–18033 (exchanges established); *id.* § 18052(a)(1) (setting waiver at January 1, 2017 plan years).

361 *See id.* §§ 18021–18022 (defining a "qualified health plan" and related terms, and outlining the minimum health benefits, cost-sharing limitations, and coverage levels required of such plans); King v. Burwell, 135 S. Ct. 2480, 2496 (2015).

Second, the waiver provision contemplates an advisory role for HHS in the state legislative process. Section 1332 requires a state to point out the existing or proposed legislation that would secure its replacement program, which makes enacting the state legislation a precondition on granting a waiver.[362] Plus, the provision makes the waiver, if granted, conditional on the continued validity of the state law.[363] CMS is, in essence, preapproving new state law or sanctioning existing state law as consistent with federal law. The state legislature is accountable to CMS if a waiver is granted, promising to enact and keep state law on the books.[364]

Third, the ACA sets substantive parameters and standards that states' current or future legislation will satisfy. If the state plan falls short in theory or evidence, CMS has no authority to approve it.[365] If the state plan passes in theory but fails to deliver in practice, CMS may revoke the waiver.[366] Even if the state plan delivers results, the waiver automatically expires after five years and requires a state reapply for renewal.[367]

CMS thus supervises state law, pursuant to a heavy delegation of waiver authority and under the auspices of federal regulatory infrastructure and priorities.[368] The agency's imprimatur on state variations suspends the application of preemptive federal law in this innovation waiver.

c. *Defusing Preemptive Conflicts*

CMS's supervision of the innovation waiver can defuse potential conflicts with state law by bestowing the agency's imprimatur on those state-law variations the agency believes will serve federal priorities. This imprimatur model can directly defuse preemptive conflicts which would otherwise invalidate the state variation.

Consider, for example, a state law that (1) exempted all employers in the state from the employer mandate, and (2) entitled all state citizens to coverage under a single-payer plan to be offered and administrated by the state to the exclusion of all other plans. This is a modified hypothetical from the real effort

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362 42 U.S.C. § 18052(a)(1)(A)–(C).

363 *Id.* § 18052(e).

364 *See, e.g.*, Letter to Walker, *supra* note 271 (emphasizing prerequisite that the state legislature enact the proposed law).

365 42 U.S.C. § 18052(b); Letter to Walker, *supra* note 271.

366 42 U.S.C. § 18052(b)(2)(B); Letter to Walker, *supra* note 271.

367 42 U.S.C. § 18052(e); Ctr. for Consumer Info. & Ins. Oversight, *Alaska: State Innovation Waiver Under Section 1332 of the PPACA*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 11, 2017), https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Fact-Sheet.pdf [https://perma.cc/TT4J-L9TN] ("State Innovation Waivers are approved for five-year periods and can be renewed.").

368 *See* Daniel T. Deacon, *Administrative Forbearance*, 125 YALE L.J. 1548, 1558–60 (2016).

that recently failed in Vermont.[369] Part (1) would be impossibility preempted as conflicting with the individual mandate,[370] while part (2) might not impossibly conflict with the ACA's coverage and exchange regulations *if* that single-payer plan covered all the ACA bases *and* was offered to individuals on an exchange.[371] The deviations necessary to make the state single-payer option feasible likely would contradict the ACA's detailed requirements and therefore be impossibility preempted,[372] even though the state law as a whole goes further toward the ACA's stated purposes of coverage and affordability than the statute itself does.

Imprimatur also can indirectly defuse obstacle conflicts, which may or may not preempt some state variations. Most state law that simply adds to the ACA commercial insurance reforms should survive impossibility preemption.[373] But some of those additional laws might still run afoul of obstacle preemption, particularly with respect to uniform summary of coverage requirements.[374]

Obstacle preemption can invalidate parallel but unique state regulations if they would frustrate the ACA's purposes and objectives.[375] While CMS might not want to go after state regulations that add to ACA insurance market protections,[376] individuals subjected to these concurrent regulations might challenge them in litigation as impermissible obstacles. Lower courts continue to apply obstacle preemption doctrine, but its continued application at the appellate and Supreme Court levels is no longer so assured.[377] In addition to avoiding this murky area of preemption doctrine, CMS approval of state

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[369] *See* McDonough, *supra* note 206, at 1584 (describing the financial and political factors that sank Vermont's single player plan); Jessica Marcy, *Vermont Edges Toward Single Payer Health Care*, KAISER HEALTH NEWS (Oct. 2, 2011), https://khn.org/news/Vermont-single-payer-health-care/ [https://perma.cc/F4D5-5C4L] (describing Vermont's efforts to build a single-payer health care system).

[370] *See* Coons v. Lew, 762 F.3d 891, 902 (9th Cir. 2014), *cert. denied*, 135 S. Ct. 1699 (2015).

[371] *See* Avik Roy, *Six Reasons Why Vermont's Single-Payer Health Plan Was Doomed from the Start*, FORBES (Dec. 21, 2014), https://www.forbes.com/forbes/welcome/?toURL=https://www.forbes.com/sites/theapothecary/2014/12/21/6-reasons-why-vermonts-single-payer-health-plan-was-doomed-from-the-start [https://perma.cc/9LHU-DNYF] ("The Vermont plan aimed to replace employer-sponsored and individually-purchased private insurance with a single, state-run insurer. But the state couldn't preempt Medicare, or military health care, or large companies . . . .").

[372] *See, e.g.*, *id.*

[373] *See* Weinberg, *supra* note 190, at 1753 (stating additional requirements survive actual conflicts).

[374] *See* 42 U.S.C. § 300gg-3(a) (2012) (preempting all state regulation of the same "type" as the federal disclosure and coverage explanation requirements).

[375] *See* Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

[376] *See* Moncrieff, *supra* note 76, at 2340–41, 2341 n.83.

[377] *See* Sharkey, *supra* note 160, at 86–93.

variations through the waiver signals the agency's view that the state law helps, not hinders, federal objectives.[378]

The waiver provision operates as an *ex ante* decision on preemptive effect by CMS.[379] It can be *pre*-preemption, defusing some potential conflicts of state and federal law.

2. *Imprimatur in Its Doctrinal Context*

The idea that agencies play an important role in preemption is far from novel.[380] Nor is the federalism debate in preemption doctrine.[381] In the past decade, courts and scholars have vigorously engaged over agencies' power *to* preempt state law ("agency preemption")[382] and the deference courts owe to agencies' statements about preemption.[383] The agency imprimatur model brings a fresh perspective, using a different posture than agency preemption. Agency imprimatur offers a theoretical perspective on agency decisions to *un*-preempt, or to preempt the preemption inquiry itself by formally sanctioning state-law variations.

Similarly, Barron and Rakoff's conceptualization of big waiver has attracted significant critical attention and theoretical development on delegation and cooperative federalism, while neglecting preemption.[384] Daniel Deacon recently

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[378] *See* St. Louis Effort for AIDS v. Huff, 782 F.3d 1016, 1021 (8th Cir. 2015); *see also* St. Louis Effort for AIDS v. Huff, 170 F. Supp. 3d 1219, 1224, 1226 (W.D. Mo. 2016) (granting summary judgment on remand after holding state-law provision on navigators "impedes Federal Navigators' and CACs' ability to fulfill their [ACA] duty to inform consumers about health plans").

[379] *See* 42 U.S.C. § 18052.

[380] *See, e.g.*, Nina A. Mendelson, Chevron *and Preemption*, 102 MICH. L. REV. 737, 753 (2004) [hereinafter Mendelson, Chevron *and Preemption*]; Mendelson, *supra* note 23, at 695; Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 DUKE L.J. 2023, 2069–72 (2008); Sharkey, *Inside Agency Preemption*, *supra* note 23, at 524; Young, *supra* note 40, at 278–79.

[381] *E.g.*, Schapiro, *supra* note 22, at 42; Epstein & Greve, *supra* note 22, at 315.

[382] *See* Kent Barnett, *Improving Agencies' Preemption Expertise with* Chevmore *Codification*, 83 FORDHAM L. REV. 587, 595 (2014).

[383] *See, e.g.*, Wyeth v. Levine, 555 U.S. 555, 577 (2009) (reviewing agency statement about the impact of preemption with *Skidmore* deference, but affording no deference to agency policy statement about preemptive effects); *id.* at 582–85 (Thomas, J., concurring) (proposing rejection of obstacle preemption by agencies and courts); Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000) (giving "some weight" to agency views about the impact of state law on federal objectives); Eskridge & Baer, *supra* note 23, at 1088; Funk, *supra* note 23, at 1239–40; Brian Galle & Mark Seidenfeld, *Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 1937 (2008); Mendelson, *supra* note 23, at 698; Rubenstein, *supra* note 23, at 1136–37; Sharkey, *Inside Agency Preemption*, *supra* note 23, at 525–26; Verchick & Mendelson, *supra* note 23, at 13–32.

[384] *See, e.g.*, Barron & Rakoff, *supra* note 19, at 266–67; Deacon, *supra* note 368, at 1552 & n.5; Gluck et al., *supra* note 19, at 1818 & n.158; Kurzweil, *supra* note 19, at 567 &

extrapolated big waiver to a broader context of "administrative forbearance"—"[d]elegations to agencies of the power to deprive statutory provisions of legal force and effect."[385] Deacon's examination highlights the policy implications and intra-agency applications of delegated forbearance authority within administrative law.[386] He deeply engages with a normative comparison of administrative versus legislative decision making, highlighting the Voting Rights and Clean Air Acts,[387] but intentionally leaves the "vertical-federalism implications of forbearance" for other work.[388] Preemption doctrine squarely addresses these state-versus-federal law questions of vertical federalism.[389]

Combining big waiver and cooperative federalism, Martin Kurzweil has proposed an alternate governance framework of "disciplined devolution."[390] In the disciplined devolution governance framework, a big waiver permits states to deviate from a federal legislative scheme, requires federal approval and monitoring of state plans, encourages collaboration with local stakeholders, and compares the resulting experiences under state variations.[391] The disciplined devolution framework, developed to describe Spending Clause education law,[392] bears similarities to the ACA's innovation waiver, but it is not concerned with the preemption dimensions.

The agency imprimatur model explored here views cooperative federalism through the lens of preemption. Agency imprimatur thus bridges the literatures of preemption and big waiver by illuminating big waiver's role in answering preemption's ultimate federalism question.[393] Agency imprimatur emphasizes the foundation of preemptive federal statutory law, and it illustrates how waiver

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n.1; Price, *supra* note 19, at 1137 & n.95*; see also* Mila Sohoni, *On Dollars and Deference: Agencies, Spending, and Economic Rights*, 66 DUKE L.J. 1677, 1701 (2017).

[385] *See* Deacon, *supra* note 368, at 1551.

[386] *See id.* at 1551–52.

[387] *See id.* at 1568–1602, 1608–14.

[388] *See id.* at 1552 n.5.

[389] *See* Erin O'Hara O'Connor & Larry E. Ribstein, *Preemption and Choice-of-Law Coordination*, 111 MICH. L. REV. 647, 650 (2013) ("[V]irtually all preemption scholars seem focused on the proper allocation between state and federal power, a concern that we label 'vertical coordination[,]' . . . [which is] clearly the central issue embedded in the Supremacy Clause . . . ."); *see also* Brannon P. Denning, *Vertical Federalism, Horizontal Federalism, and Legal Obstacles to State Marijuana Legalization Efforts*, 65 CASE W. RES. L. REV. 567, 571 (2015) (assessing vertical federalism in the "preemption puzzle").

[390] *See* Kurzweil, *supra* note 19, at 568–69.

[391] *See id.*

[392] *See id.* at 569.

[393] *See* Verchick & Mendelson, *supra* note 23, at 14 (describing preemption's two biggest waivers as (1) when Congress should preempt a law, and (2) when a court should find preemption).

of preemptive law realigns the preemption analysis and reassigns the management of some preemption questions from courts to agencies.[394]

Agencies with express delegations of rulemaking authority manage preemption by promulgating preemptive rules, or deciding not to.[395] An agency's choice whether to make a rule that will conflict with state law represents a choice of whether to permit state variations to persist.[396] A big waiver of preemptive law, however, inverts that management function and expands it, as the ACA innovation waiver demonstrates.[397] First, the statute and its duly promulgated regulations are preemptive to the extent of the delegation and the nature of the conflict with state law.[398] Second, the state requests preapproval for its variations rather than the agency being the one to make new law.[399] Third, the agency may suspend, rather than invoke, the preemptive force of law.[400]

With conflict preemption as the default position, this process for lending agency imprimatur to variant state law defuses conflicts that otherwise might trigger preemption disputes.[401]

B. *Assessing Agency Imprimatur*

The waiver of preemptive law represents a shift in the mechanism for calibrating health law's federalism balance—a shift from judicial preemption doctrine to agency imprimatur.[402] This shift in preemption policy toward agency discretion may portend both benefits and detriments for health reform, largely mirroring the institutional competencies of each branch and the tension between

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[394] *See id.* at 20 (discussing the "delegated program" structure wherein a state's implementation of federal law must meet the federal program's goals); *see also* sources cited *supra* note 23.

[395] *See* Susan Bartlett Foote, *Administrative Preemption: An Experiment in Regulatory Federalism*, 70 VA. L. REV. 1429, 1429 (1984); Rubenstein, *supra* note 23, at 1148; Sharkey, *Inside Agency Preemption*, *supra* note 23, at 531.

[396] *See* Sharkey, *Inside Agency Preemption*, *supra* note 23, at 525–26 (outlining the FDA's attempt to preempt state law by including a statement of preemptive intent in a drug labeling rule's preamble).

[397] *See supra* Part III.

[398] *See* Rubenstein, *supra* note 23, at 1137–38; *supra* Part II.B.2.

[399] *See* Sharkey, *Inside Agency Preemption*, *supra* note 23, at 529–30.

[400] *See* Foote, *supra* note 395, at 1445; Gluck et al., *supra* note 19, at 1818.

[401] *See* Gardbaum, *supra* note 5, at 775–77 (describing such conflicts). The statute's general delegation of power to promulgate standards and the agency's considerable discretion in doing so empower HHS to import state standards to define federal terms. *See* Rubenstein, *supra* note 23, at 1149.

[402] *Compare* McCuskey, *supra* note 1, at 96–97 (highlighting the relevance of judicial preemption doctrine), *with* Samuel R. Bagenstos, *Federalism by Waiver after the Health Care Case*, *in* THE HEALTH CARE CASE 227, 231–35 (Nathaniel Persily et al. eds., 2013) (arguing that "federalism by waiver" trend should be accelerated).

uniformity and experimentation.[403] The imprimatur model's normative value for health reform has only begun to be tested under the ACA's innovation waiver. Some metrics for assessing its utility—either under the ACA or a potential replacement—are needed.

1. *Delegation and Discretion*

Even under a very big waiver, the sweep of agency imprimatur is not boundless. It may be constrained by express statutory delegation and limitations on inter-statutory waiver authority. The ACA has both limitations, each of which can promote or hinder the agency imprimatur model's potential to untangle preemption issues.

Arguably the most important limitation on any executive agency's power is the concept of delegation, which scrutinizes Congress's statutory authorization of agency action.[404] Congress may delegate lawmaking powers to executive agencies as long as Congress provides the agency with "intelligible principle[s]" to follow in that task.[405] Agencies may not exercise power that exceeds Congress's delegation.[406] The waiver delegation in the ACA constrains CMS's imprimatur power by limiting waivers to four enumerated pieces of the statute,[407] and by prescribing five substantive prerequisites for any grant of waiver.[408] CMS guidance on the waiver process hews to those flexible constraints.[409]

The procedural requirements in the ACA also cabin the agency's use of imprimatur. The statute prescribes general rules for the application process on which CMS may elaborate, but from which it may not deviate.[410] The imprimatur model does not empower the agency to waive preemptive law sua sponte.[411] Imprimatur is an inherently reactionary power that depends initially on states' willingness to apply for waivers.[412]

The waiver provision expressly denies CMS authority to waive other laws under this delegation.[413] The agency's ability to effectuate coherent policy

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[403] *See* Bagenstos, *supra* note 402, at 227.

[404] *See, e.g.*, Lisa Schultz Bressman, Essay, *Reclaiming the Legal Fiction of Congressional Delegation*, 97 VA. L. REV. 2009, 2015 (2011).

[405] J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928).

[406] *See* Rubenstein, *supra* note 23, at 1126–27.

[407] *See supra* Part III.A.1; *see also* Clifton Williams, Expressio Unius Est Exclusio Alterius, 15 MARQ. L. REV. 191, 193 (1931) ("[T]he enumeration of the requirements in the statute excluded all others not enumerated . . . .").

[408] *See supra* Part III.A.2.

[409] *See* 31 C.F.R. § 33.108 (2015) (application procedures).

[410] *See supra* Part III.A.2.

[411] *See* 42 U.S.C. § 18052(a)(1) (2012).

[412] *See id.*

[413] *Id.* § 18052(c)(2) ("The Secretary may not waive under this section any Federal law or requirement that is not within the authority of the Secretary.").

within health insurance law—and other varied health law topics—is limited when the imprimatur authority is confined to just the innovation waiver.[414] For a comprehensive set of waivable health laws, the agency must look for other delegations that are sparse and which include only the ACA's Medicare IPAB provision,[415] the Medicaid waivers,[416] and a very limited "national security" wavier for some investigational new drugs.[417] The waiver imprimatur thus takes one step in the direction of agency-supervised health law federalism,[418] but stops far short of any broader power to unite policy and avoid conflict.

This confinement further diminishes CMS's power to defuse ERISA preemption conflicts. The ACA innovation waiver provision explicitly allows waiver of the employer mandate for an equivalent state plan.[419] Thus, if a state waiver application requests suspension of the employer mandate, then the state must satisfy CMS that its suspension will not create a gap in coverage.[420] ERISA would preempt almost every state effort to replace the employer mandate with a law that "relates to" employer-sponsored insurance.[421] CMS does not administer ERISA and the ACA expressly stated its intent *not* to alter ERISA,[422] leaving states with few effective replacement options for the employer mandate.

On the other hand, CMS's *separate* waiver authority in Medicaid sections 1115 and 1915(b) provisions has serious potential to expand—rather than constrain—the agency's reliance on the innovation waiver. CMS's experience with the Medicaid waiver application onslaught after *National Federation of Independent Business v. Sebelius*[423] could color its approach to the distinctive innovation waiver process.[424] Although found in different

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414 *See* McCuskey, *supra* note 1, at 143–44 (arguing that nearly every topic in health law has federal dimensions).

415 42 U.S.C. § 1395kkk.

416 *See* Office of Family Assistance, U.S. Dep't of Health & Human Servs., Guidance Concerning Waiver and Expenditure Authority Under Section 1115, TANF-ACF-IM-2012-03 (July 12, 2012), http://arts-attic.com/blog/wp-content/uploads/2014/05/TANF-ACF-IM-2012-03-Guidance-concerning-waiver-and-expenditure-authority-under-Section-1115-Office-of-Family-Assistance-Administration-for-Children-and-Families.pdf [https://perma.cc/6MCA-KPWM].

417 *See* 10 U.S.C. § 1107(f)(1) (2012) (giving the President power to waive the prior consent requirement for an "investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation").

418 *Cf.* James G. Hodge, Jr. et al., *Nationalizing Health Care Reform in a Federalist System*, 42 ARIZ. ST. L.J. 1245, 1247 (2010/2011) (stating that the success of health care reform could depend on federal-state cooperation).

419 42 U.S.C. § 18052(b)(1).

420 *Id.*

421 Tumber, *supra* note 258, at 413.

422 Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947 (2016).

423 Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012).

424 *See* Bagenstos, *supra* note 402, at 233; Watson, *supra* note 18, at 220–21; Nicole Huberfeld, *Medicaid at 50: From Exclusion to Expansion to Universality*, HEALTH AFF.:

statutes passed at different times, the ACA innovation provision allows combined applications and review.[425] While the efficiency is laudable, the much more liberal standard in the Medicaid waiver should not be allowed to bleed over into consideration of the innovation waiver.[426]

The agency's discretion in granting waivers, and the constraints in its delegated authority to do so, could be both detrimental and beneficial. If the delegated discretion is too broad, then an agency may grant waivers for state proposals that would significantly erode federal goals of uniform protections and access. But, if the delegation is too constrained and the criteria are too stringent, then many promising state efforts will be denied and remain preempted, stifling experimentation. By setting fairly rigorous equivalent protections as the criteria for granting the waiver, the ACA sets a bulwark against the most significant erosions of uniformity. But the ACA's evidentiary standards for proving equivalence invite state experimentation based on speculative proof, which could erode uniform protection during the experiment period.

And, as with most matters of agency discretion, the expertise and outlook of agency leadership can vary widely between administrations. Regulatory capture of an agency poses a serious threat to realizing any of the benefits from delegation to agency expertise and discretion.[427] This delicate balance of uniform protections and experimentation depends largely on the administrators' values and appetites for evidence.

2. *Institutional Competence*

The values of agency expertise and discretion in the agency imprimatur model must be measured against courts' expertise and discretion in determining the same issue: which state variations on federal law may persist.[428] Courts long have claimed primary responsibility for implementing the contours of legal doctrine—particularly preemption.[429] The innovation waiver reallocates some preemption policy responsibilities from the judiciary to the executive branch.[430]

BLOG (Nov. 14, 2014), http://healthaffairs.org/blog/2014/11/14/medicaid-at-50-from-exclusion-to-expansion-to-universality/ [https://perma.cc/W6YW-YY4M] (tracing the waves of waiver applications before and after *Sebelius* and arguing that "federal policy should not accommodate the rent-seeking behavior of the states").

[425] *See* 42 U.S.C. § 18052(a)(5).

[426] *Cf.* Huberfeld, *supra* note 424 (discussing negative effect of federalism on Medicaid).

[427] *See generally* Jean-Jacques Laffont & Jean Tirole, *The Politics of Government Decision-Making: A Theory of Regulatory Capture*, 106 Q.J. ECON. 1089 (1991) (noting that regulatory capture poses a serious threat).

[428] *Cf.* Deacon, *supra* note 368, at 1552 (comparing the decision making of agencies and Congress in the forbearance model without addressing the "vertical-federalism" question).

[429] *See* Meltzer, *supra* note 156, at 39.

[430] *See* 42 U.S.C. § 18052(b)(1) (delegating to the agency the task of determining if state innovations comply with federal law).

And the ACA's express preemption statement reclaims some interpretive power for Congress, too.[431]

Institutional choice theory offers a useful tool for evaluating the wisdom of this "deciding who decides"[432] aspect of the preemption wavier. Institutional choice theory poses that "[w]hat law is, can be, or ought to be is determined by the character of those processes that make, interpret, and enforce law."[433] Comparisons among courts, legislatures, and agencies focus on the institutions' strengths and weaknesses relative to the legal question studied.[434] Which, then, is best suited to address the preemptive effects of federal health law? And does the imprimatur model choose wisely?

In the ACA's innovation waiver, Congress delegated the power to the agency to "substantially revise" the ACA's requirements[435] by "displac[ing] regulatory baseline[s] that Congress itself has established."[436] Congress is not particularly agile at creating new law or motivated to revise old law,[437] and thus it is not the ideal institution to which updating should be entrusted.[438] Big waiver provides a means of ensuring that new law has "a ready means of staying fresh,"[439] and "a salutary means of managing the practical governance concerns that make traditional delegation unavoidable."[440] It allocates to the representative body (Congress) the task of the "first draft" with less paralyzing consideration of the law's innumerable consequences.[441] It also allocates to the more nimble executive body (the agency) the task of managing and accounting for those consequences.[442]

Drilling down on the substantive issue of which institution is best suited for the task of determining whether state or federal health law should apply requires

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[431] *See* Sharpe, *supra* note 7, at 163; *cf.* Deacon, *supra* note 368, at 1553 (describing Congress's ability to use negative delegations to set requirements via "broad strokes").

[432] *See* Merrill, *supra* note 5, at 727 (quoting NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 3 (1994)).

[433] NEIL K. KOMESAR, LAW'S LIMITS: THE RULE OF LAW AND THE SUPPLY AND DEMAND OF RIGHTS 3 (2001).

[434] *See generally* HENRY M. HART, JR. & ALBERT M. SACKS, THE LEGAL PROCESS (William N. Eskridge, Jr. & Philip P. Frickey eds., 1994) (comparative institutional analysis); KOMESAR, *supra* note 433, at 3 (law and economics of comparative institutional analysis); ADRIAN VERMEULE, JUDGING UNDER UNCERTAINTY: AN INSTITUTIONAL THEORY OF LEGAL INTERPRETATION (2006) (institutional theory).

[435] Barron & Rakoff, *supra* note 19, at 278.

[436] *Id.* at 291.

[437] *See* Merrill, *supra* note 5, at 753–54.

[438] *See* Barron & Rakoff, *supra* note 19, at 269.

[439] *Id.* at 271.

[440] *Id.* at 270.

[441] *Id.*

[442] *Id.*

a comparison of institutional competence on three issues: preemption analysis, substantive health law issues, and federalism.[443]

a. *Preemption*

Courts have expertise in the interpretive method and in preemption doctrine. And yet "[p]reemption cases are not known for their methodological consistency."[444] Obstacle preemption in particular "vests considerable decisional discretion in the judiciary,"[445] which can be good or bad depending on one's view of the judgment.[446] The fraught history of health law preemptions[447] suggests that dexterity with interpretive doctrine has not helped courts fashion substantively desirable preemption boundaries. The Supreme Court has expressed exasperation with its own doctrinal development, particularly on health insurance preemptions.[448]

b. *Substantive Health Law*

Courts may be somewhat better than agencies at determining preemption, but agencies have an informed perspective on "the practical impact of state rules on the effectuation of federal statutory purposes,"[449] which can elude courts' anecdotal experiences. CMS, for example, has only some experience with preemption,[450] but considerably more expertise in the health care system and health care markets. Health and safety legislation frequently delegates to agencies the decision of whether to preempt or exempt state laws.[451] From an institutional competence perspective,[452] this sort of delegation efficiently defers

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[443] *See infra* Parts IV.B.2.a–c.

[444] Meltzer, *supra* note 156, at 56.

[445] *Id.* at 39.

[446] *See* Scott L. Greer & Peter D. Jacobson, *Health Care Reform and Federalism*, 35 J. HEALTH POL. POL'Y & L. 203, 203–04 (2010); Verchick & Mendelson, *supra* note 23, at 32 ("[Preemption] will inevitably pit your principles against a desired outcome.").

[447] *See* McCuskey, *supra* note 1, at 96–97; *supra* Part II.A.

[448] *E.g.*, Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 947–48 (2016) (Thomas, J., concurring) (doubting whether "ERISA pre-emption" jurisprudence "is consistent with [the Court's] broader pre-emption jurisprudence"); *id.* at 953, 958 (Ginsburg, J., dissenting) (disagreeing with the Court's application of the "opaque" preemption clause, which uses doctrine still lacking determinacy, and "dissent[ing] from the Court's retrieval of preemption doctrine that belongs in the discard bin").

[449] Meltzer, *supra* note 156, at 44; *see also* Merrill, *supra* note 5, at 777 (asserting that agencies are best equipped to assess the impact of diverse state rules).

[450] *See* Christopher J. Walker, *Inside Agency Statutory Interpretation*, 67 STAN. L. REV. 999, 1066 (2015) (discussing the fact that agency rule drafters are generally familiar with the canons of interpretation and administrative law doctrines).

[451] *See* Foote, *supra* note 395, at 1437.

[452] *See infra* Part IV.B.2.

to the big-picture experts on the efficacy and desirability of a mix of state and federal laws.[453]

Agencies' substantive expertise features prominently in administrative law and in the canons of judicial deference to agency actions.[454] Exercise of expertise can support judicial deference.[455] Scientific and technical expertise, such as what HHS possesses in health law, may even attract more judicial deference than is warranted or normatively desirable.[456] For a granular analysis of whether state law will effectuate federal purposes, agencies seem to have the advantage.[457] Agencies can draw not only on their own substantive and big-picture expertise, but can also draw on other types of experts.[458] Access to this interdisciplinary expertise and the ability to engage in factual investigation also gives the agency a better ability to grasp the "impact of uniformity and diversity on a national commercial [health care] market than does either Congress or the courts."[459]

As Thomas Merrill has argued, preemption analysis includes "an evaluation of the real-world impact of state regulation on maintaining a national commercial market," which statutory text rarely illuminates.[460] The "multifaceted, high-stakes discretionary policy judgment" inherent in preemption policy "requires considerable sophistication if it is to be exercised properly. It is a fair question whether any legal institution is up to the task."[461] Addressing the question of regulations' practical impact on markets and industry further raises the specter of regulatory capture,[462] an infirmity in agencies, but not as much in the federal judiciary.[463]

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[453] *See* Foote, *supra* note 395, at 1461.

[454] *See generally* Barnett, *supra* note 382 (considering how agency expertise does and should inform judicial review); Eskridge & Baer, *supra* note 23 (discussing the importance of agency expertise in areas where the Justices lack technical or specialized knowledge).

[455] *See* Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

[456] *See* Emily Hammond Meazell, *Presidential Control, Expertise, and the Deference Dilemma*, 61 DUKE L.J. 1763, 1809 (2012); Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 756 (2011).

[457] *See* Merrill, *supra* note 5, at 755.

[458] *Id.*

[459] *Id.*

[460] *Id.* at 744.

[461] *Id.*

[462] *See* Edna Earle Vass Johnson, *Agency "Capture": The "Revolving Door" Between Regulated Industries and Their Regulating Agencies*, 18 U. RICH. L. REV. 95, 95 (1983).

[463] *Cf.* Patrick Luff, *Captured Legislatures and Public-Interested Courts*, 2013 UTAH L. REV. 519, 521 (2013) (discussing why private interests are unable to capture the judiciary in the same way they are generally understood to be able to capture the legislature).

c. *Federalism*

On the ultimate federalism issues involved in preemption, courts and agencies bring different skills to bear. Courts have expertise in the underlying structures and theories of federalism.[464] As Nina Mendelson has argued, agencies are not natural experts in federalism per se.[465] But their capacity for gathering and analyzing information can bring valuable empirical perspective to any decision whether to displace state law, as Catherine Sharkey has illustrated.[466]

The innovation waiver subtly divides the labor on the ultimate federalism questions.[467] The agency's imprimatur on state variations that *further* federal objectives is insulated from judicial review, relying on the agency's analysis of data and legislation provided by the state and other agencies. But the agency's decision that a state variation does *not* sufficiently further federal objectives ultimately gets de novo judicial review, drawing on the courts' expertise in this more sensitive federalism posture.[468] This imbalance is also reflected in the statutory requirement that the agency explain only those decisions that *deny* a waiver, not the decisions that grant one.[469]

Despite the potential gains from a policy perspective in delegating some of this labor to the agency, concerns about regulatory capture of that agency remain. While the innovation waiver itself constrains agency discretion to some extent, the imprimatur model relies on agency expertise and independence that are far from given. The imprimatur model's success should, to some extent, be judged by the precision with which it delegates responsibility for managing preemption to the more competent institution on each metric.

3. *Reviewability and Review*

The ACA shift to agency imprimatur engenders a potential shift in the review of state deviation. By administratively sanctioning state-law variants *ex*

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[464] *See generally* Mendelson, *supra* note 23 (discussing courts' analysis of the federalism issue in a variety of cases).

[465] *Id.* at 721–22.

[466] *See* Catherine M. Sharkey, *Federalism Accountability: "Agency-Forcing" Measures*, 58 DUKE L.J. 2125, 2153 (2009) [hereinafter Sharkey, *Federalism Accountability*]; Sharkey, *Inside Agency Preemption*, *supra* note 23, at 578–90 (arguing that agencies should rely on empirics when determining whether state laws contravene federal purposes).

[467] *See generally* 42 U.S.C. § 18052 (2012) (outlining waiver for state innovation with respect to health insurance coverage).

[468] *Cf.* Merrell Dow Pharms. Inc. v. Thompson, 478 U.S. 804, 810 (1986) (characterizing questions about federal jurisdiction over state cases as involving particularly "sensitive judgments").

[469] 42 U.S.C. § 18052(d)(2)(B).

ante, the imprimatur model may avoid some of the post hoc preemption analysis that arises through litigation and judicial review.

In the ordinary working of things, preemption questions come up in litigation about the rights and duties of particular parties.[470] In the course of adjudicating those rights and duties, the court must consider the reach of a federal law on the books and a state law on the books, determining whether they conflict and, if so, whether Congress intended the federal law to supersede the state.[471] That is, usually courts are tasked with answering the ultimate question whether existing federal law and state laws on a particular issue may coexist.[472] And courts approach the question in a litigation posture de novo, looking to Congressional intent as the touchstone of the analysis.[473]

The innovation waiver carves two alternative routes to pursuing preemption's ultimate question.[474] Rather than waiting for litigation to trigger a conflict ripe for judicial review, a state may apply to the agency for a similar determination.[475] If the agency *grants* the request for a waiver, it sanctions the particular state variant and suspends federal law's preemptive force, defusing the potential conflict.[476] If the agency *denies* a request for a waiver, then that decision itself becomes reviewable.[477] If the state enacts the law without a waiver, federal law retains its preemptive force and a court may review the preemption question in an appropriate litigation posture.[478]

Figure 1, below, roughly illustrates the paths the state–federal conflict may take.

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[470] *See* Mendelson, *supra* note 23, at 721–22; Sharkey, *Inside Agency Preemption*, *supra* note 23, at 578–90; Catherine M. Sharkey, *Preemption as a Judicial End-Run Around the Administrative Process?*, 122 YALE L.J. ONLINE 1, 1 (2012) [hereinafter Sharkey, *Preemption as a Judicial End-Run*] ("Private parties wield preemption—typically as a defense. . . . Courts are then called upon to decide the extent to which state law is inconsistent with federal law.").

[471] *See* Nelson, *supra* note 5, at 260.

[472] *Id.*

[473] *Id.* at 276; *see also* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 236 (1947).

[474] 42 U.S.C. § 18052(d)(2).

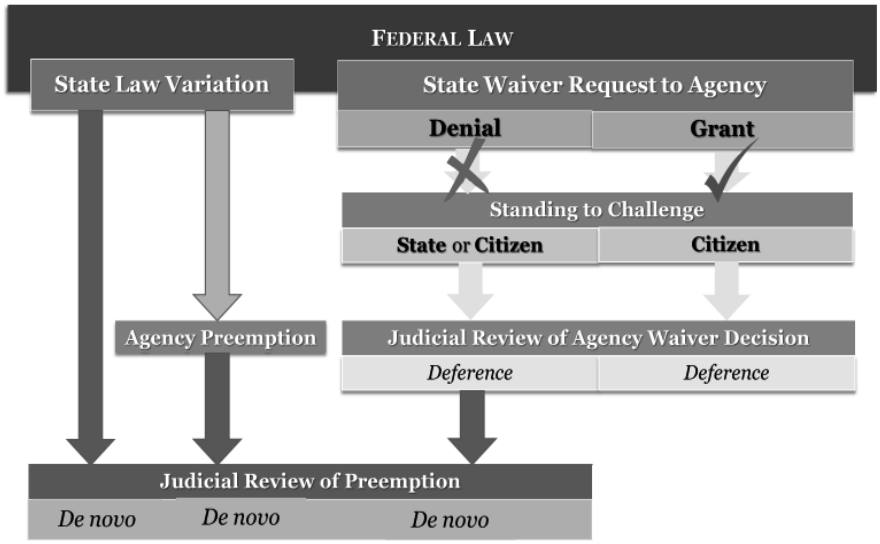
[475] *Id.* § 18052(a)(1).

[476] *See id.* § 18052(b)(1).

[477] *See* 5 U.S.C. § 706 (2012) (judicial review of agency action).

[478] *See id.*

Figure 1: *Review and Preemption in the ACA Innovation Waiver*



The left column represents the ordinary workings of preemption. Where federal law and state law overlap, the parties to litigation may raise preemption to press claims,[479] defend against the enforcement of state law,[480] or even to invoke federal jurisdiction.[481] In this litigation posture, the preemption question proceeds directly to judicial review, under a de novo standard.[482] Or, preemption issues may arise during agency rulemaking or adjudication.[483] When challenged in litigation, courts review agency decisions about preemptive effect with diminished deference, a standard akin to de novo, but one which remains "murky" at best.[484]

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[479] *Cf.* Douglas v. Indep. Living Ctr. of S. Cal., Inc., 565 U.S. 606, 610 (2012) (declining to rule on whether private parties may maintain direct Supremacy Clause challenge to proposed state laws).

[480] *See* Sharkey, *Preemption as a Judicial End-Run*, *supra* note 470, at 1.

[481] *See* Metro. Life Ins. Co. v. Taylor, 481 U.S. 58, 66 (1987) (holding that ERISA's civil enforcement provisions and accompanying preemption provides a basis for removal jurisdiction); *see also* 29 U.S.C. § 1132(a) (2012) (showing that ERISA complete preemption provision is jurisdictional). *See generally* Seinfeld, *supra* note 140 (discussing the fact that conferral of jurisdiction on the federal courts is designed to secure a hospitable forum for federal law claims and to yield uniformity in federal law interpretation).

[482] *See, e.g.*, Bldg. & Constr. Trades Dep't, AFL-CIO v. Allbaugh, 295 F.3d 28, 32 (D.C. Cir. 2002); Santino v. Provident Life & Accident Ins. Co., 276 F.3d 772, 774 (6th Cir. 2001) ("The district court's ruling that ERISA preempts Santino's state law claims is a legal conclusion, which this Court reviews *de novo*.").

[483] Sharkey, *Preemption as a Judicial End-Run*, *supra* note 470, at 1.

[484] *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 n.3 (2011) (deferring to "agency's interpretation of its regulations," but not "agency's ultimate conclusion about" preemption); *see also* Miriam Seifter, *Federalism at Step Zero*, 83 FORDHAM L. REV. 633, 642–43 (2014)

The two paths on the right half of Figure 1 represent the development of preemption questions in a waiver regime. States may request a waiver from the federal agency. If the agency *denies* the waiver, it must explain why. If the state wishes to pursue the variation from its denied application, the state or a citizen could challenge the agency's decision as an aggrieved party. A court would review the agency's waiver-denial decision deferentially. If the state proceeds with its law without a waiver, that conflict may proceed to preemption analysis through litigation. In litigation, a court examines preemption de novo—or something like it.

If instead the agency *grants* the waiver, it suspends the preemptive force of the federal law and eliminates the conflict. Though CMS is not compelled to explain a waiver grant, it is likely to include an explanation with the decision. Granting the waiver suspends the federal law. But a state could still challenge the agency's grant if the decision does not accept *all* of the provisions the state proposed. Or a citizen could challenge the agency's grant if the citizen alleged she would have been entitled to greater protections under the ACA than under the waiver. A court reviewing the agency decision to grant the waiver would apply *Skidmore* deference. But no preemption question remains for further litigation because the agency has suspended the force of the federal law.

The proliferation of paths can alter the reviewability and review of potential conflicts between federal and state laws. First, by defusing some state–federal conflicts before they start, the imprimatur model may avoid altogether the kind of dispute likely to trigger litigation or other judicial review.[485] Second, imprimatur essentially diverts preemption decisions from the post hoc litigation context to the *ex ante* regulatory context.[486] While courts treat preemption disputes in litigation essentially de novo, courts treat agency action with varying degrees of deference.[487]

Were states simply to make their own insurance market laws and wait for litigation to challenge any conflict with the ACA, a court would begin and end

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("After *Wyeth*, scholars have understood preemption, as a category, to be relevant to whether *Chevron* will apply . . . even if the doctrinal rule is still murky."); Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 252 n.126 (2007); *cf.* Mendelson, Chevron *and Preemption*, *supra* note 380, at 739–40 (discussing *Smiley v. Citibank*, 517 U.S. 735, 744 (1996), where the Court assumed without deciding that courts should resolve de novo the threshold question); Merrill, *supra* note 5, at 775 (arguing for a review of agency preemption that is "sui generis").

[485] Preiser v. Newkirk, 422 U.S. 395, 401 (1975) ("[A] federal court [lacks] the power to render advisory opinions . . . ."); *see also* Flast v. Cohen, 392 U.S. 83, 97 (1968).

[486] *Cf.* Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 419 (1971) ("[Finding that agency] affidavits were merely 'post hoc' rationalizations, . . . which have traditionally been found to be an inadequate basis for review." (citations omitted) (citing Secs. & Exch. Comm'n v. Chenery Corp., 318 U.S. 80, 87 (1943))).

[487] *See* Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843–44 (1984) (stating deference requires either express or implied delegation of power to an agency); Skidmore v. Swift & Co., 323 U.S. 134, 139–40 (1944).

its analysis of that conflict with judicially crafted preemption doctrine.[488] The determination of whether state law impossibly collides with the ACA or stands as an obstacle to its purposes and objectives would fall within the court's discretion, guided by transsubstantive interpretive canons on congressional intent,[489] as well as the ACA's expressed preference for preemption of state laws that "[do] not prevent the application of" its insurance market provisions.[490] A court would afford very little respect—if any at all—to the agency's bald opinion on the preemptive force of its own regulations or decisions.[491]

If, however, a state first pursues a waiver for its variant law, then the path to litigation becomes more circuitous and the ultimate judicial review more deferential. Under the ACA innovation waiver, a state's application for a waiver will prompt a ruling from CMS within six months.[492] Meanwhile, CMS must provide a notice and comment period of at least thirty days for each waiver application.[493] Once CMS finalizes its decision on the waiver and any administrative appeals are exhausted, the decision becomes subject to judicial review in a federal district court.[494]

A CMS *denial* of a waiver application seems to present the more direct route to judicial review because the state whose application was denied would constitute an "aggrieved" party with standing to challenge the decision in court.[495] But a *grant* of the waiver application may still aggrieve parties enough to confer standing, even if less obviously.[496] If, for example, a state's waiver proposal would offer less generous or more expensive coverage than the ACA, then a citizen of that state whose insurance would shrink or whose costs would grow could challenge the waiver grant as an agency action that "adversely affected" her.[497] Or, potentially, a state whose waiver application CMS grants only in part might be aggrieved about the denial of a waiver for the remainder.[498]

If an aggrieved party does seek judicial review, a federal court most likely will let the agency decision stand unless it was arbitrary and capricious, rather

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[488] *See* Nelson, *supra* note 5, at 231 (finding preemption derives from the Supremacy Clause, but is an interpretive tool).

[489] *See* Eskridge & Baer, *supra* note 23, at 1202 (describing preemption as a discretionary, interpretive canon).

[490] 42 U.S.C. § 18041(d) (2012).

[491] *See* Wyeth v. Levine, 555 U.S. 555, 567 (2009) (disregarding FDA's blanket opinion on the preemptive force of its labeling requirements).

[492] *See* 42 U.S.C. § 18052(a)–(b).

[493] *Id.* § 18052(a)(4)(B)(iii); 31 C.F.R. § 33.120(c)(1) (2015).

[494] *See* 5 U.S.C. § 704 (2012).

[495] *See id.* § 702 ("A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.").

[496] *Id.*

[497] *Id.*

[498] *Id.*

than reviewing it de novo.[499] The informal adjudication powers and procedures prescribed by the ACA's innovation waiver provisions invoke CMS's substantive expertise on evaluating data and policy objectives, as well as authorize it to promulgate further regulations on the waiver process.[500] Accordingly, a reviewing court likely will defer to CMS's reasonable interpretations of the ACA's innovation waiver and the accompanying regulations.[501]

The judicial deference owed to agency action insulates the agency's imprimatur on state law from searching judicial review and amplifies the capacity to preempt preemption questions.[502]

4. *Transparency, Participation, and Communicative Federalism*

The imprimatur model further may facilitate dialog among stakeholders, federal, and state regulatory authorities, fostering a more direct and intentional division of regulatory power over health insurance coverage and access. The agency imprimatur model has the potential to imbue health law federalism decisions with more transparency and public participation opportunities than judicial preemption decisions afford.[503] But these opportunities are not certain to materialize even under the waiver regime as currently formulated.

The innovation waiver requires that CMS provide notice and a period for public comments upon receipt of a waiver application.[504] CMS has stated that it will vary the comment period based on the complexity of the waiver application, but all will be at least thirty days.[505] The administrative process for the waiver invites broader participation and perspectives on the preemption question than litigation does.[506]

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[499] *See* Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 413–14 (1971); Hyatt v. Kappos, 625 F.3d 1320, 1344–45 (Fed. Cir. 2010) ("[T]he circumstances under which de novo review of factual issues is appropriate are 'narrow indeed.'" (citation omitted)).

[500] *See* 42 U.S.C. § 18052(a) (2012); 31 C.F.R. § 33 (2012); 45 C.F.R. § 155.1300–.1328 (2016).

[501] *See* Eskridge & Baer, *supra* note 23, at 1144. Additional deference may even be warranted because the ACA health insurance provisions are fairly technical and complex. *See, e.g.*, Me. Med. Ctr. v. Burwell, 841 F.3d 10, 17 (1st Cir. 2016) ("[D]eference is most pronounced when the issue involves 'a complex and highly technical regulatory program,' such as Medicare . . . ." (quoting S. Shore Hosp., Inc. v. Thompson, 308 F.3d 91, 97 (1st Cir. 2002))).

[502] Defusing these conflicts also prevents courts from developing preemption precedent about them.

[503] *Cf.* Watson, *supra* note 18, at 214 (discussing concerns about the lack of transparency in the waiver approval process).

[504] *See* 42 U.S.C. § 18052(a)(4).

[505] *See* 31 C.F.R. § 33.112; *see also* 45 C.F.R. § 155.1312.

[506] *See* 31 C.F.R. § 33.112; 45 C.F.R. § 155.1312.

Standing requirements and joinder rules limit direct participation in litigation to those parties with a personal stake or vested interest in the outcome.[507] Representative litigation broadens litigation participation by authorizing joinder of all those similarly situated to the litigants.[508] Courts may permit amicus briefs from interested folks without formal standing, but there are procedural hurdles and qualifications, typically with little impact on the court's analysis.[509] Public comment in the administrative process, by contrast, is not limited to stakeholders or really anyone else.[510] Plus, in the waiver process, the applicant is the state itself, a party that by its very existence should represent all its citizens.[511]

For sensitive questions about the federalism boundaries of health law—and especially for regulations affecting health care's cost and accessibility—this broadened public participation could be useful to inform the agency's ultimate decision, and to inform citizens about the proposals.

Shifting these health law federalism decisions from courts to an agency imprimatur model may also infuse the determinations with greater transparency. The enormous discretion in courts' application of preemption doctrine, as many commenters have lamented, makes preemption precedents opaque and unpredictable.[512] Preemption doctrine has numerous different tests for how to identify preemptive conflicts and construe the respective state and federal laws.[513] The waiver provision at least specifies the same substantive criteria for each agency decision on the existence of state law in the federal scheme.[514] Still, the agency has plenty of discretion in assessing the congruence of the proposed state law and speculating on its likely effects.

Under the ACA, CMS need not offer reasoning for *granting* a waiver, but if CMS *denies* waiver, the agency must offer to both the state *and* "the appropriate committees of Congress" its "reasons" for the denial.[515] Publicly

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[507] *See* Sharkey, *Preemption as a Judicial End-Run*, *supra* note 470, at 5 ("[D]irect APA challenges to preemptive rules promulgated by the Food and Drug Administration . . . are few and far between [because] standing and ripeness barriers . . . loom large . . . ."). *See generally* Daniel O. Bernstine, *A "Standing" Amendment to the Federal Rules of Civil Procedure*, 1979 WASH. U. L.Q. 501 (1979) (proposing that the Federal Rules of Civil Procedure be amended to preclude a defendant from asserting any defense based on plaintiff's lack of standing once the court has determined the merits of the claim).

[508] *See* FED. R. CIV. P. 23 (class action); Miss. *ex rel.* Hood v. AU Optronics Corp., 134 S. Ct. 736, 736 (2014) (*parens patriae*).

[509] *See, e.g.*, Paul M. Collins, Jr. et al., *The Influence of Amicus Curiae Briefs on U.S. Supreme Court Opinion Content*, 49 LAW & SOC'Y REV. 917, 917 (2015).

[510] 5 U.S.C. § 553 (2012) (APA rule making process).

[511] *See* Margaret S. Thomas, Parens Patriae *and the States' Historic Police Power*, 69 SMU L. REV. 759, 795 (2016).

[512] *See, e.g.*, Nelson, *supra* note 5, at 289; *see also* Sharpe, *supra* note 7, at 233.

[513] *See supra* Part IV.A.1.

[514] 42 U.S.C. § 18052 (2012).

[515] *Id.* § 18052(d)(2)(B).

offering reasoned explanations can promote transparency and legitimacy, if properly executed.[516] Yet the lopsided incentives in the innovation waiver draw out only half of this transparency.[517] Based on the statutory criteria for granting a waiver, one must presume that a granted application satisfied all four substantive criteria, but CMS need not explain *why* it does.[518] Pragmatically, however, CMS likely would offer reasons for a grant, even if not compelled by statute to do so because the deference accorded will depend on the strength of the reasons stated.[519]

CMS's discretion and lopsided incentives to offer reasoned explanations may prevent the agency imprimatur model from realizing transparency gains over court adjudication. But inverting the usual lines of communication may foster a more engaged federalism debate between federal and state agencies. As Catherine Sharkey has suggested, when federal agencies intend to *displace* state law, the federalism debate would be well served if the federal agency gathered empirical evidence to support the desirability of preemption, as well as consulted with state representatives, interest groups, and attorneys general.[520] Although executive orders require agencies to think about and articulate the federalism implications of preemptive action,[521] agencies typically do not have to go this far when doing so. The innovation waiver, by contrast, gives states a means for initiating the dialog and tasks states with gathering the evidence that their proposed laws will not impede federal objectives.

C. *Waivers Without Standards*

The agency imprimatur model, if properly calibrated, has the potential to improve on preemption in institutional competence and expertise, transparency, stakeholder participation, and the exchange of information between federal and state regulators. These gains depend on the strength of the statute's preemptive baseline, the extent of the agency's delegation and its reliance on substantive expertise, and the standards and processes required for the waiver of preemptive law. While it is too soon to observe whether the ACA's 1332 waiver is well calibrated to achieve these gains,[522] it seems instantly predictable that the proposed mega waiver expansions to 1332 are not.

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[516] *See* Mathilde Coen, *Reasons for Reasons*, *in* APPROACHES TO LEGAL RATIONALITY 119, 119–21 (Dov M. Gabbay et al. eds., 2010); Elizabeth Y. McCuskey, *Submerged Precedent*, 16 NEV. L.J. 515, 547–51 (2016).

[517] *See* 42 U.S.C. § 18052.

[518] *See id.*

[519] *See, e.g.*, Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

[520] *See* Sharkey, *Inside Agency Preemption*, *supra* note 23, at 582–90.

[521] *See* Exec. Order No. 13,132, at §§ 2–3, 3 C.F.R. § 206 (1999); Memorandum on Preemption, 74 Fed. Reg. 24, 693, 24,693 (2009).

[522] The waiver program has only been available less than a year and five states have submitted applications. *See* Ctr. for Consumer Info. & Ins. Oversight, *supra* note 212 (noting that Alaska, Hawai'i, California, Vermont, and Minnesota have submitted applications).

Waivers with minimal standards, or with minimal role for agency discretion and expertise do not fit well within the agency imprimatur model, as defined here, and are not likely to perform well on any of its proposed metrics. The recently proposed mega waiver revisions to 1332 offer an example.[523] The BCRA's proposed revisions affect the standards, procedure, scope, and duration of the original 1332 waiver.

Perhaps most crucially, the BCRA would remove the agency's discretion in reviewing waiver applications. Where the ACA said the Secretary "may" grant a waiver that met all three equivalence standards and did not add to the federal deficit, the BCRA would have changed the law so that the Secretary "shall" grant any waiver request "unless" it will increase the deficit.[524] This converts the considered decision of the agency into a nearly automatic suspension of federal law on demand.[525] The BCRA's only criteria for the agency's substantive expertise is the question of financial impact,[526] which hardly falls within HHS's health law purview. The reviewing agency would have no discretion to make a health policy or health law federalism determination about the desirability of the state variation.[527] It could only check the state's math.[528]

Further, the BCRA provision would have diluted the ACA's equivalence standards for granting a waiver. The ACA allows the agency to waive preemptive law only if the agency is satisfied that the state variation will result in comprehensive coverage, affordability, and a number of insured equivalent to or surpassing the ACA.[529] The BCRA would have removed those equivalence criteria from the standards for "granting of waivers."[530] Instead of criteria for granting a waiver, the BCRA required only that the application itself "contain information" on "*how* the State plan . . . would . . . take the place of" the federal law it asks to be waived, and "provide for alternative means of . . . increasing access to comprehensive coverage, reducing average premiums, providing consumers the freedom to purchase the health insurance of their choice, and

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Two of the five have been withdrawn. *See* Peter Hirschfeld, *Shumlin: It's 'Not the Right Time' for Single Payer*, VPR NEWS (Dec. 17, 2014), http://digital.vpr.net/post/shumlin-its-not-right-time-single-payer#stream/0 [https://perma.cc/5TRC-USRH] (reporting that Vermont would abandon its effort to pursue a single payer system using waivers); Letter from Peter V. Lee, *supra* note 266 (withdrawing California's waiver application).

[523] Better Care Reconciliation Act of 2017, H.R. 1628, 115th Cong., § 207 (as reported by House, May 4, 2017), https://www.budget.senate.gov/imo/media/doc/BetterCareJuly13.2017.pdf [https://perma.cc/J35U-ECAB].

[524] *Id.* § 207(a)(2)(A)(i)(I)–(II).

[525] *See id.*

[526] *Id.*

[527] *See id.*

[528] *Id.*

[529] 42 U.S.C. § 18052(b)(1)(A)–(C) (2012).

[530] H.R. 1628, § 207. Indeed, the BCRA removes all standards from the "Granting of waivers" criteria, other than neutral impact on the federal deficit. *See id.* § 207(a)(1)(A)(i)(II).

increasing enrollment."[531] Ostensibly the agency could reject as incomplete or insufficient an application that failed to provide this information. But as long as the state includes the information, the revision appears to suggest the agency must grant it as long as the deficit numbers seem right.[532]

The drafters of these provisions probably did not have agency imprimatur in mind. The BCRA's intent was to "repeal" the ACA, or at least alter large segments of it, but to target only those provisions that have a budget effect subject to reconciliation. These mega-waiver provisions constrain the agency's ability to *deny* a waiver, while employing very little substantive expertise in the decision to *grant* a waiver. The goal is to waive the ACA's regulations, writ large, without having to fully address a repeal.[533] Certainly, the mega waiver would avoid large swaths of preemption because it allows states to suspend federal law with relatively little effort and very little consideration of how the state variation would fit within the preemptive federal scheme.

While the BCRA revisions maintained the transparency provisions of 1332, they retained few of the opportunities for communication between HHS and state regulators. First, the new application standards would require much less information from states. Second, the decision process on the applications is focused on deficit impact, denying the incentive for a back-and-forth on whether and how each aspect of the plan might work on the health insurance markets. Finally, the BCRA waivers, once granted, would have lasted for eight years, imposed no reporting requirements to keep the pass-through funding, and been revocable only by the state's own initiative. There would be no apparent mechanism for HHS to supervise the implementation of the state waiver plan or to monitor how its variation fares.

Rather than the agency giving its considered seal of approval to useful-but-possibly-preempted state variations, the BCRA waiver would have given the agency a rubber "grant" stamp, while taking away its "deny" stamp. The dilution of standards and discretion eviscerates the preemptive force of the statute's baseline regulations, and also dilutes any advantages in institutional competence and communicative federalism.

The precision and execution of the imprimatur model depend on the existence and strength of a federal statutory baseline and the expertise and independence of the agency assessing proposed variations. Both of these prerequisites to success currently are precarious as Congress considers a vast

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[531] *Id.* § 207(a)(1)(A)(i)(I).

[532] The BCRA adds to the Secretary's reporting requirements that he must report to Congress on the reasons for denying a waiver "and provide the data on which such determination was made." *Id.* § 207(a)(3). This further suggests that the decision to *deny* a waiver—rather than merely reject an application—must be based on financial data.

[533] The BCRA further allows a state to get a waiver even if it does not have a law in force to guarantee the protections, and allows a state to apply for a waiver based not on a promise to enact a law, but merely a "certification" from the state's governor and insurance commissioner that they have the authority to implement the plan. *Id.* § 207(a)(1)(A)(ii).

recalibration of federal health law and opponents of the ACA lead its implementation.

V. CONCLUSION

The Affordable Care Act's fate remains uncertain, though the federal impulse to reform the health insurance system remains strong and popular.[534] The ACA's innovation waiver may render the landmark statute flexible enough to survive upheaval, or the innovation waiver in a new form may enable the ACA to rise from its own ashes. Among the ACA's numerous experiments in health law federalism, the innovation waiver offers some enduring value as an agency imprimatur model for wrangling thorny preemption issues in health law.

Agency imprimatur as an alternative to preemption adjudication in health law has a lot to recommend it. The agency can draw on its considerable substantive expertise and experience to make more accurate judgments about the impact of state experimentation on a national system. The agency likewise can manage state variations in furtherance of a coherent set of federal goals. And the agency imprimatur process can account for more viewpoints and public participation than the old litigation model of preemption can.

Yet the agency's discretion in determining state applications, coupled with the deferential review it will receive by any court, raise serious concerns about the wisdom of suspending supremacy in this manner. Agency imprimatur—just like its sibling preemption doctrine—still belies a level of subjectivity that may undermine its potential to bring coherence and harmony to health law's federalism. Agency imprimatur, as well as the ACA or its successor, should be judged on their ability to maximize institutional competencies and promote a communicative health law federalism.

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[534] *See Poll: Public Divided on Repealing Obamacare, but Few Want It Repealed Without Replacement Details*, HENRY J. KAISER FAM. FOUND. (Jan. 6, 2017), http://kff.org/health-costs/press-release/poll-public-divided-on-repealing-obamacare-but-few-want-it-repealed-without-replacement-details/ [https://perma.cc/3ACY-JH6J].