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HHS STAKEHOLDER RIGHTS IN AN ERA OF STATUTORY ENTRENCHMENT AND AGENCY OVERREACH

Colin Roskey & Tamara Tenney**

I. INTRODUCTION

Concerns about agency overreach are everywhere—on Capitol Hill, in courts, among regulated industries, in the presidential candidate debates. The U.S. House of Representatives is suing the Obama Administration on the theory that it acted outside its authority in establishing cost-sharing subsidies under the Affordable Care Act (ACA).¹ Members of the Catholic Church are likewise suing to protect their faith-based practices in the face of Executive Branch overreaches

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¹ *U.S. House of Reps. v. Burwell*, Case 1:14-cv-01967 (D.D.C. filed Nov. 21, 2014); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

that would diminish or squander these practices.² Elsewhere, regulated industries and affected stakeholders are expressing discomfort with new Department of Labor regulations governing the application of overtime pay requirements for companions of certain disabled individuals, despite a congressional statute expressly exempting them.³ Critics of agency excess identify a wide range of undesirable consequences of aggressive agency behavior, ranging from threats to individual rights to affront to the separation of powers undergirding our nation's constitutional structure.

In the health care arena, the consequences of agency overreach are magnified by the Obama Administration's recognized goal of "federal statutory entrenchment" for the Administration's signature accomplishment, the ACA.⁴ If the Administration's policies become deeply embedded in the health care programs administered by the Department of Health and Human Services (HHS) and its divisions, including the Centers for Medicare and Medicaid Services (CMS), a subsequent administration will face tremendous barriers when seeking to unravel those policies—a critical problem given that some of those policies conflict with governing law and fall outside agency authority. This is a concern that should not divide along party lines, since both Republicans and Democrats have an interest in ensuring that Executive Branch agencies do not transgress the duly enacted laws of Congress.

This Article explores three specific areas in which CMS has acted in excess of statutory authority, in support of statutes passed almost exclusively by congressional Democrats,⁵ as examples of the broader trend within HHS (and other Executive Branch agencies). Further, the Article seeks to place these instances of CMS overreach in the context of

² *Little Sisters of the Poor Home for the Aged v. Burwell*, No. 15-105 (and consolidated cases) (S. Ct. *cert granted* Nov. 6, 2015); *Zubik v. Burwell*, No. 14-1418 (and consolidated cases) (S. Ct. *cert granted* Nov. 6, 2015).

³ Application of the Fair Labor Standards Act to Domestic Service, 78 Fed. Reg. 60454 (Oct. 1, 2013) (effective Jan. 1, 2015) (upheld by *Homecare Ass'n of America v. Weil* (D.C. Cir. 2015)).

⁴ See Abbe R. Gluck, *Why Health Lawyers Must Be Public-Law Lawyers: Health Law in the Age of the Modern Regulatory State* (hereinafter Gluck, *Health Lawyers*), 18 J. OF HEALTH CARE L. & POL'Y 323, 338 (2015) (identifying the Administration's "federal statutory entrenchment" objective).

⁵ *More specifically*, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), discussed *infra*, was enacted over President Bush's veto (383-41 in the House, 70-26 in the Senate), while the ACA passed the Senate (60-39) and the House (219-212) without a single Republican vote.

widespread discomfort with agency self-aggrandizement—both examining important dangers of such behavior, if left unchecked, and discussing ways Congress and the courts can help reign in excessive and unlawful agency action. In particular, the Article recommends that Congress enact a novel, narrow legislative provision modeled on the *qui tam* provisions of the False Claims Act⁶ that would enable government employee whistleblowers to challenge agency overreach. Finally, an overarching theme of this Article is that health care lawyers have the opportunity, and in fact the *obligation*, to identify instances of agency overreach that may be confined to specific industry segments and thus easily overlooked but that have significant, detrimental effects in the aggregate as part of a larger pattern of agency self-aggrandizement.

II. EXECUTIVE OVERREACH IN THE OBAMA ADMINISTRATION AS EXEMPLIFIED BY *ULTRA VIRES* ACTIONS OF CMS

Executive agencies have occupied the spotlight often in recent months, with Members of Congress, Supreme Court Justices, academics, and others calling attention to executive agency overreach. Such concerns as a general matter are nothing new.⁷ Recently, however, the agency behavior underlying these concerns has grown increasingly aggressive, in particular within HHS and the division of HHS responsible for administering the Medicare and Medicaid programs, CMS, in the wake of the Obama Administration's 5-4 victory at the Supreme Court in *National Federation of Independent Business v. Sebelius* (*NFIB*).⁸ The

⁶ 31 U.S.C. §§ 3729–3733 (2012).

⁷ See Babette E.L. Boliek, *Agencies in Crisis? An Examination of State and Federal Agency Emergency Powers* (hereinafter Boliek, *Agencies in Crisis*), 81 *FORDHAM L. REV.* 3339, 3358 (2012-2013) (“The concern attributed to potential or perceived overreach of federal agencies’ delegated authority is almost cyclical over time. Distress over agency overreach has waxed and waned and has generally mirrored the countervailing concerns for agency efficiency and expediency.”).

⁸ 132 S. Ct. 2566 (2012). In this highly controversial decision, the Supreme Court upheld the ACA against challenges to the constitutionality of the individual mandate. While an adverse decision for the Administration could have dismantled the ACA, the favorable decision enabled the Administration to continue pushing forward aggressively with its implementation efforts, bolstered by the support it seemed to have garnered—for a variety of disparate reasons—from the Court’s slim majority. See, e.g., Gillian E. Metzger, *To Tax, To Spend, To Regulate*, 126 *HARV. L. REV.* 83, 84, 85 (2012) (characterizing Chief Justice Roberts’ majority opinion in

Administration's forceful attempts to weave its policy goals into the fabric of governing law make its agencies' violations of the law along the way of critical significance. Faced with federal agencies bent on entrenching their policies, often unimpeded by statutory boundaries on their authority, health care community stakeholders must be on the lookout for unlawful agency actions and prepared to challenge them in order to help protect providers and federal health care program beneficiaries against agency aggression. The following section situates these considerations in the context of existing congressional and judicial desire to reign in agency overreach and highlights the importance of this issue in the health care arena given the Administration's concentrated efforts toward entrenchment of the ACA and other Democratic health policy priorities.

A. Current Judicial and Congressional Attention to Agency Overreach

Worries about potential agency self-aggrandizement have existed perhaps as long as executive agencies themselves.⁹ Congress enacted the Administrative Procedure Act (APA) in 1946 in large part to establish some limits on agency action, implementing requirements designed to foster transparency, accountability, and legitimacy, including notice-and-comment rulemaking and judicial review.¹⁰ Still, for years, Congress has delegated authority to agencies to hammer out the details of statutes enacted by Congress, often in very broad terms. The Supreme Court has allowed this to occur, provided that the legislation offers an "intelligible

NFIB as "a consummate act of institutional diplomacy" that "avoided the unpalatable result of having the Court invalidate President Obama's signature achievement in the midst of a close reelection campaign by a 5-4 vote that would have mapped the Justices' ideological leanings," and as a "jurisprudential compromise" with many "disparate features [tied] together [by] a commitment to preserving the Court as an institution . . . allowing the Court to rise above the political fray surrounding the challenges to the ACA's constitutionality while still reinforcing the Court's supremacy in constitutional interpretation").

⁹ See *Dep't. of Transp. v. Ass'n of Am. R.Rs.*, 135 S. Ct. 1225, 1242-44 (2015) (Thomas, J., concurring in judgment) (chronicling the "ancient roots" of the "idea that the Executive may not formulate generally applicable rules of private conduct," which is in tension with the delegation of legislative authority to executive agencies).

¹⁰ 5 U.S.C. § 500 *et seq.* (2012).

principle” to guide the agency’s implementation efforts,¹¹ a test that in practice has served as a very low bar to clear.¹² Despite the resultant lack of agency adherence to statutory requirements, Congress long sat happily with this arrangement that enabled it to insulate itself from political backlash by passing broad legislation and letting agencies make the difficult and controversial implementation decisions—the hide-behind-the-agency defense (“Don’t blame us! We just voted for clean air . . . it’s the Environmental Protection Agency costing you thousands of dollars in compliance”).

However, “congressional comfort with the liberal delegation of its own legislative role has waned more in recent years,”¹³ as evidenced by the introduction of numerous regulatory reform bills in the Senate and House in the 114th Congress¹⁴ and multiple recent congressional committee hearings on agency overreach.¹⁵ Notably, in testimony for a June 2015 hearing on agency excess, Senate Judiciary Committee Chairman Chuck Grassley called upon the Judiciary Committee to “improve our oversight of [the APA]” in light of “the threat of agency overreach.”¹⁶ The introduced bills are also designed to halt agency

¹¹ *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394 (1928) (establishing the intelligible principle test).

¹² See *Ass’n of Am. R.Rs.*, 135 S. Ct. at 1246 (Thomas, J., concurring in judgment) (“Although the Court may never have intended the boundless standard the ‘intelligible principle’ test has become, it is evident that it does not adequately reinforce the Constitution’s allocation of legislative power.”).

¹³ Boleik, *Agencies in Crisis*, *supra* note 7, at 3358.

¹⁴ See George Washington University Regulatory Studies Center, *Regulatory Reform Legislation*, 114th Congress, <https://regulatorystudies.columbian.gwu.edu/regulatory-reform-legislation-114th-congress> (last visited Jan. 9, 2016) (providing a partial list of introduced regulatory reform legislation).

¹⁵ See, e.g., *Examining the Proper Role of Judicial Review in the Federal Regulatory Process: Hearing Before the Senate Committee on Homeland Security and Government Affairs’ Subcommittee on Regulatory Affairs and Federal Management* (hereinafter *Proper Role of Judicial Review*), 114th Cong. (2015); *Examining the Federal Regulatory System to Improve Accountability, Transparency and Integrity: Hearing Before the Senate Judiciary Committee* (hereinafter *Examining the Federal Regulatory System*), 114th Cong. (2015); *A Review of Regulatory Reform Proposals: Hearing Before the Senate Homeland Security and Governmental Affairs Committee*, 114th Cong. (2015).

¹⁶ *Examining the Federal Regulatory System*, *supra* note 15, (statement of Senator Chuck Grassley, Senate Judiciary Committee Chairman) (hereinafter Grassley

overreach in various ways, such as by requiring congressional approval prior to implementation of regulations that would have a significant economic effect.¹⁷

Several Justices on the Supreme Court have also taken issue with agency self-aggrandizement, including notably the Chief Justice, who cautioned recently: “When it applies, *Chevron* is a powerful weapon in an agency’s regulatory arsenal. . . It would be a bit much to describe the result [of overly generous judicial deference to agency interpretations of vague statutory language] as ‘the very definition of tyranny,’ but the danger posed by the growing power of the administrative state cannot be dismissed.”¹⁸ In several recent cases, the Court has seemed willing to use tools of statutory construction to help address this concern about agency overreach.¹⁹ The Court’s most recent and hotly contested ACA decision,

statement)) (June 10, 2015), at 1, *available at* <http://www.judiciary.senate.gov/download/06-10-15-grassley-statement>.

¹⁷ Regulations from the Executive in Need of Scrutiny Act of 2015, S. 226, 114th Cong. (2015).

¹⁸ *City of Arlington v. FCC.*, 133 S. Ct. 1863, 1879 (2013) (Roberts, C.J., dissenting) (dissenting opinion joined in full by Kennedy, J., and Alito, J.). *See also Michigan v. EPA*, 135 S. Ct. 2699, 2713 (2015) (Thomas, J., concurring) (citing multiple cases that “bring into bold relief the scope of the potentially unconstitutional delegations we have come to countenance in the name of *Chevron* deference,” and contending that “[w]hat EPA claims for itself here is not the power to make political judgments in implementing Congress’ policies, nor even the power to make tradeoffs between competing policy goals set by Congress,” but rather “the power to decide—without any particular fidelity to the text—which policy goals EPA wishes to pursue”) (internal citations omitted); *see also Perez v. Mortg. Bankers*, 135 S. Ct. 1199, 1211-112 (Scalia, J., concurring in judgment) (“By deferring to interpretive rules, we have allowed agencies to make binding rules unhampered by notice-and-comment procedures. The problem is . . . perhaps insoluble if *Chevron* is not to be uprooted”).

¹⁹ *See, e.g., Michigan v. EPA*, 135 S. Ct. at 2708 (examining the provision’s text, context, and “backdrop of [the agency’s] established administrative practice” in a one-step *Chevron* analysis and finding the Environmental Protection Agency’s (EPA’s) statutory interpretation to be “unreasonable”); *see Mellouli v. Lynch*, 135 S. Ct. 1980 (2015) (refusing to apply either *Chevron* or *Skidmore* deference when overturning a Board of Immigration Appeals statutory interpretation as “incongruous” and making “scant sense”); *see Util. Air Reg. Grp. v. EPA*, 134 S. Ct. 2427, 2439, 2441 (2014) (overturning an EPA regulation in a one-step *Chevron* analysis that relied on the “fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme”) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)).

King v. Burwell, might present courts with an enhanced toolbox, perhaps through the broader application of major questions doctrine at *Chevron* Step Zero,²⁰ whereby courts may find that an increasing number of statutes raise questions of such political or economic significance—or complexity—that courts, rather than agencies, should resolve any ambiguities,²¹ or through a more aggressive contextualist approach to statutory interpretation under which courts would use their overarching understanding of “Congress’ plan” to resolve statutory ambiguities at *Chevron* Step One and then have no reason to defer to agencies’ interpretations at *Chevron* Step Two.²² Nevertheless, the long-lasting import of *King* remains to be seen,²³ and the Supreme Court will have

²⁰ See Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187 (2006) (coining the term “*Chevron* Step Zero” to describe this preliminary consideration). Under the doctrine laid out in *Chevron v. NRDC*, in evaluating an agency’s interpretation of a statute that it administers, courts first determine whether the statute is clear and unambiguous (*Chevron* Step One); courts and agencies are bound to follow clear statutes, but courts will defer to an agency’s construction of an ambiguous statute that is “reasonable” or “permissible” (*Chevron* Step Two). *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *Chevron* applies only if Congress intended to delegate authority to resolve statutory ambiguities to the agency—a determination often called *Chevron* Step Zero. One reason a court may decide at *Chevron* Step Zero that Congress did not delegate an interpretive question to an agency is if the case presents a “major question” of “economic and political significance.” *FDA v. Brown & Williamson*, 529 U.S. 120, 160 (2000); *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015).

²¹ See *King*, 135 S. Ct. at 2489 (characterizing the statutory question in the case as “a question of deep ‘economic and political significance’ that is central to this statutory scheme” and finding that “had Congress wished to assign that question to an agency, it surely would have done so expressly”)(quoting *Brown & Williamson*, 529 U.S. at 133). See Abbe R. Gluck, *Imperfect Statutes, Imperfect Courts: Understanding Congress’s Plan in the Era of Unorthodox Rulemaking* (hereinafter Gluck, *Imperfect Statutes*), 129 HARV. L. REV. 62, 93 (2015)(“*King* . . . may have announced a more limited deference doctrine for complex statutes”).

²² *King*, 135 S. Ct. at 2496 (noting that “[a] fair reading of legislation demands a fair understanding of the legislative plan” and adopting the reading “consistent with what we see as Congress’s plan”). See Gluck, *Imperfect Statutes*, *supra* note 21, at 96 (“Perhaps *Chevron* lives on, but only for mundane or confined questions that do not implicate the functionality of the overall statutory structure”).

²³ As of January 4, 2016 at least 20 federal appellate cases in nine circuits have interpreted *King*, primarily citing it for the limited, well-established principle that “the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *King*, 135 S. Ct. at 2492. See, e.g., *United States v. Chafin*, 808 F.3d 1263, 1271 (11th Cir. 2015); *ClearCorrect Operating, LLC v. Int’l Trade Comm’n*, 810 F.3d 1283, 1296 (Fed. Cir. 2015). A few circuit courts have

opportunities to clarify *King's* jurisprudential impact on the scope of *Chevron*, as early as this Term, if the Court so desires.²⁴

Importantly, as leading administrative and tax law scholar Professor Kristin Hickman cautioned:

Forecasting the future impact of any Supreme Court case is an iffy proposition. Often, a case that seemed potentially consequential when the Court decided it turns out to be a one-off, as the Court distinguishes and minimizes it into near nothingness. Such treatment seems especially likely when the case concerns a high-profile and politically-controversial issue, as in *King v. Burwell*.²⁵

Present, it is impossible to know whether *King* will end up representing a significant doctrinal statement about *Chevron's* scope, “fade into obscurity as doctrinally insignificant with respect to *Chevron's* scope,” or whether it will have an impact somewhere in between these two extremes.²⁶ Regardless, the fact remains that many of the Supreme Court's other recent decisions have showcased the Court's desire and willingness to narrow agency deference in some circumstances. Deference does seem to be on the decline.²⁷

gone further, suggesting that *King* allows courts to depart from plain statutory text. See, e.g., *G.L. v. Ligonier Valley Sch. Dist. Auth.*, 802 F.3d 601, 611 (3d Cir. 2015); *In re Schwartz-Tallard*, 803 F.3d 1095, 1100 (9th Cir. 2015).

²⁴ Briefs in the consolidated contraceptive mandate cases currently on the Supreme Court docket and in the net neutrality case pending in the D.C. Circuit, which is expected ultimately to reach the Supreme Court, are raising this question. See, e.g., Brief for the Cato Institute and Independent Women's Forum, *Amici Curiae* at 29-32, *Zubik v. Burwell*, 135 S. Ct. 2924 (2015) (and consolidated cases) (*cert granted*, Nov. 6, 2015); Brief of *Amici Curiae* Members of Congress at 11-12, *U.S. Telecom Ass'n v. FCC*, No. 15-1063 (and consolidated cases) (D.C. Cir. filed Nov. 4, 2015).

²⁵ Kristin E. Hickman, *The (Perhaps) Unintended Consequences of King v. Burwell* (hereinafter Hickman, *Unintended Consequences*), 2015 PEPP. L. REV. 56, 70, 71 (citing *Bush v. Gore*, 531 U.S. 98 (2000) “representing another example of a high-profile, politically-controversial case that the Court has largely ignored since”).

²⁶ *Id.* at 66, 71.

²⁷ See, e.g., Leandra Lederman & Joseph C. Dugan, *King v. Burwell: What Does It Portend for Chevron's Domain*, 2015 PEPP. L. REV. 72, 73, 81 (2015) (concluding that “although *King* was an ‘extraordinary case’ for the Court, *Chevron's* heyday may be on the wane” and cautioning that “our one-time expectations regarding judicial deference to agency interpretations may require reevaluation”).

*B. Agency Overreach Intensified by the Obama Administration's
Federal Statutory Entrenchment Goal*

Much has been written about the Obama Administration's aggressive pursuit of the President's political priorities. Republican presidential candidate Senator Ted Cruz, recently penned a powerful critique of the Obama Administration's executive overreach through its unconstitutional refusal to enforce laws.²⁸ Significantly, two prominent, liberal law professors, Jonathan Turley and Laurence Tribe, have levied major criticisms of the President's tactics. Professor Tribe submitting joint comments on the EPA's proposed Clean Power Plan and calling the Administration's rule a "remarkable example of executive overreach and an administrative agency's assertion of power beyond its statutory authority."²⁹ Professor Turley, serving as lead counsel in the lawsuit brought by the U.S. House of Representatives, challenging the legality of various aspects of the Administration's implementation of the ACA.³⁰ Discomfort with the Obama Administration's executive overreach is not confined to the Republican Party.

In the health care arena, agency overreach has sprung up in the context of a carefully designed Administration strategy to get the ACA (and its other policy preferences, both current and historic) "entrenched." As expressed by Yale Law School (YLS) Professor Abbe Gluck, Faculty Director of the Solomon Center for Health Law and Policy at YLS (Solomon Center), and leading national expert in, among other things, health law, legislation, statutory interpretation, and the intersection of these fields:

The whole philosophy of the ACA on the federal side is just to *get this thing in the door* and improve it down the line. It is a very pragmatic politics. The President's interest—unlike that of many state officials—is long term. He wants to get the statute entrenched. HHS, therefore, is

²⁸ Ted Cruz, *The Obama Administration's Unprecedented Lawlessness*, 38 HARV. J. OF L. & PUB. POL'Y 63, 99-100 (2015), available at, http://www.harvard-jlpp.com/wp-content/uploads/2015/02/Cruz_Final.pdf).

²⁹ Laurence H. Tribe & Peabody Energy Corp., Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (Dec. 1, 2014), at 3, available at [http://www.masseygail.com/pdf/Tribe-Peabody_111\(d\)_Comments_\(filed\).pdf](http://www.masseygail.com/pdf/Tribe-Peabody_111(d)_Comments_(filed).pdf).

³⁰ Stephen Gutowski, Jonathan Turley Named Lead Counsel for House Suit Against Obama, *The Washington Free Beacon* (Nov. 18, 2014), <http://freebeacon.com/politics/jonathan-turley-named-lead-council-for-house-suit-against-obama/>.

likely willing to do whatever it can within the limits of the law to let even resistant states adopt the ACA in some way, whether it is by restricting Medicaid, or doing something creative with the exchanges. . . . [E]ach additional state action to implement the ACA, it is critical to remember, enmeshes the statute further in a state's legal, bureaucratic, and political web. In other words, it is not that the federal government is desperate; rather, it is acting with a long term strategy of *federal statutory entrenchment*—a common story in the statutory-law literature that health lawyers need to understand. This is how to ensure that even if a Republican gets elected President, the statute is more likely to be tweaked than repealed.³¹

The Administration's goal of "entrenching" the ACA and other Democrat-"owned" statutes has animated the agencies responsible for their implementation—all the more since the Administration's 5-4 victory in *NFIB*.

Illustrating this motivation and pursuit of statutory entrenchment are the remarks delivered by former HHS Secretary Kathleen Sebelius at the November 2015 launch of the Solomon Center. In describing her work with the lawyers at HHS to implement the ACA, former Secretary Sebelius stated:

Knowing what the framework of the law was, we had a lot of issues where the statute was not totally crystal clear. I needed a creative legal team working with me to say, "Here is the goal. I don't want to break the law. That's part of your job, but the default position can't be, 'You can't do this because we can't figure it out,' because we could never make any progress that way. So I will work with you but we have to figure out how to get from here to here. And if this door closes, what other doors can open and how can we move along the way?"³²

³¹ Gluck, *supra* note 4, at 338-39 (emphasis in original) (internal citations omitted). Federal statutory entrenchment has been discussed in the context of many other statutes aside from the ACA. *See generally* William N. Eskridge, Jr. & John Ferejohn, *A REPUBLIC OF STATUTES: THE NEW AMERICAN CONSTITUTION* (2010) (articulating a theory of "superstatutes" that become "entrenched" in our nation's legal framework). *See also* William N. Eskridge, Jr. & John Ferejohn, *Super-Statutes*, 50 DUKE. L.J. 1215, 1216, 1231-32, 1237 (2000) (contending that "superstatutes" become entrenched "after lengthy normative debate" and "prove robust as a solution, a standard, or a norm over time" and characterizing numerous laws as superstatutes, including the Sherman Act of 1890, the National Labor Relations Act of 1935, and the Civil Rights Act of 1964); Kathryn E. Kovacs, *Superstatute Theory and Administrative Common Law*, 90 IND. L.J. 1207, 1209 (2015) (characterizing the APA as an entrenched superstatute).

³² Solomon Center for Health L. & Pol'y, *The New Health Care Industry: Integration, Consolidation, Competition in the Wake of the Affordable Care Act* at

This description reflects the “win at any cost” nature of the Administration’s implementation efforts in relation to the ACA and other Democrat legacy statutes—an attitude that has persisted under Secretaries since Sebelius’s tenure.³³

C. Health Care Lawyers’ Responsibility to Call Attention to Small Agency Oversteps that in the Aggregate Are Changing the Landscape

Former Secretary Sebelius is correct that problem-solving often requires having a “creative legal team,” something recognized and valued by clients of successful lawyers in many practice areas. In addition, the Administration’s goal of statutory entrenchment for the ACA, or any of its past or future priorities, could be accomplished legally as a general matter.³⁴ However, this Article contends that in the course of seeking to use all “creative legal” means to implement and entrench the ACA, the Administration has in fact overstepped its boundaries and that this aggrandizement of HHS authority with respect to the ACA has carried over to HHS’s other core objectives.

Specifically, this Article takes a close look at three statutory authorities that CMS has transgressed in recent years—testing a new payment model under the Centers for Medicare and Medicaid Innovation (CMMI) authority established by the ACA implementing a new certification requirement for Medicare reimbursement of home health services added by the ACA, and one in the course of administering payment for Medicare’s End Stage Renal Disease (ESRD) benefit under a provision added by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA),³⁵ another statutory initiative for which the Administration claims ownership rights. While the policies has CMS has pursued in each instance may appear relatively insignificant other

45:59-46:40, <https://www.law.yale.edu/solomon-center/events/inaugural-conference,> (address by Kathleen Sebelius – former Secretary, Health and Human Services, at the Nov. 12, 2015 launch of the Solomon Center, discussing the evolving landscape of health care law, policy, and governance and the connections with the practice of medicine) (last visited Dec. 26, 2015).

³³ Throughout this Article, “Secretary” refers to the Secretary of HHS.

³⁴ We bracket for now any issues regarding the constitutionality of various aspects of the ACA, noting that unconstitutional laws cannot be legally implemented through statutory entrenchment efforts or otherwise.

³⁵ Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008).

than from the perspective of the health care provider communities regulated by them, these narrow matters have import for the broader health care community because they represent a more widespread phenomenon at HHS.³⁶ To ignore CMS's unauthorized expansion of its authority in narrow situations allows a dangerous degree of agency self-aggrandizement to take root.

A critical way health care lawyers, in particular, can encourage HHS and its divisions to stay within the scope of their statutory authority is to bring detailed knowledge of a wide variety of discrete issues from daily practice, along with an intimate understanding of the functioning of HHS into ongoing national health reform conversations. A problem that is not clearly identified, or whose magnitude is not well understood, cannot be solved; health lawyers must use their expertise to bring to light statutory violations—in court, in public comments submitted to agencies, and in other forums—in order to help prevent further entrenchment of unlawful policies. Given that “[w]e . . . have a Supreme Court that . . . does not have much health law experience, does not really understand the statutory schemes, and certainly does not take a coherent approach to the issues in the field,”³⁷ active monitoring by health care lawyers and stakeholders is an essential component of curtailing the excessive HHS actions that have begun to characterize its health policy implementation efforts. Regardless of the merits of the Administration's underlying policy choices (which are debatable), the Executive Branch must comport with statutes enacted by the Legislative Branch; ends do not justify the means in a society governed by the rule of law. Health lawyers must do their part in getting HHS back on track.

³⁶ Arguably, this trend toward aggrandizement of agency authority is occurring in federal agencies across the board. *See, e.g.*, Damien M. Schiff & Luke A. Wake, *Leveling the Playing Field in David v. Goliath: Remedies to Agency Overreach* (hereinafter Schiff & Wake, *Agency Overreach*), 17 TEX. REV. L. & POL. 97 (2012-2013) (addressing aggressive overreaches by the EPA); *FERC v. Elec. Power Supply Ass'n* (Sup. Ct. Docket No. 14-840) (argued Oct. 14, 2015) (evaluating whether FERC's “demand response” rule exceeds the agency's statutory authority); *OSHA's Regulatory Agenda: Changing Long-Standing Policies Outside the Public Rulemaking Process: Hearing before the House Committee on Education and the Workforce's Subcommittee on Workforce Protections*, 113th Cong. (Feb. 4, 2014) (statement of Maury Baskin on behalf of the National Association of Manufacturers and Associated Builders and Contractors) at 1, *available at* http://edworkforce.house.gov/uploadedfiles/baskin_testimony.pdf (regarding an Occupational Safety and Health Administration (OSHA) policy that contradicts governing statutory authorities).

³⁷ Gluck, *Health Lawyers*, *supra* note 4, at 345. *See also* Abbe R. Gluck, *Symposium Issue Introduction: The Law of Medicare and Medicaid at Fifty* (hereinafter Gluck, *Symposium*), 15 YALE J. POL'Y & ETHICS 1, 19 (2015) (“health lawyers have an important role to play in educating the courts about the health statutes themselves, and the relationships among them”).

III. SIGNIFICANT EXAMPLES OF CMS OVERREACH IN THE WAKE OF NFIB

This section identifies three Medicare program policies that CMS has implemented in recent years without the statutory authority to do so. These policies are in a sense unremarkable, as they are but three of many similar examples of CMS overreach, but they are featured here because they reveal current, active legal positioning from the agency and include the same level of resistance to stakeholder concern on both merits and process. In each instance, CMS rejected, without meaningful explanation, stakeholders' challenges regarding the nature and extent of the agency's authority to proceed toward its regulatory objectives, in one instance even through a year of consequential litigation against the government in the U.S. District Court for the District of Columbia. CMS overreach of this sort has permeated the agency's ACA implementation efforts, as well as its momentous implementation work involving both prior and forthcoming Medicare law. As the Administration has sought to entrench the ACA, its agency lawyers appear to be freely applying that principle to non-ACA-related policy implementation, increasingly so after the Administration's *NFIB* win. The consequences of overreach, therefore, are broader and deeper than just the fabric of the ACA itself and its stakeholders. The evolution of Medicare law, like other federal statutory schemes, is highly dependent on career professionals at executive agencies, in this case CMS, to implement congressional imperatives. The current entrenchment logic threatens all providers and suppliers with actions that could present significant new costs or consequences with diminished access to judicial review.

A. CMS's Unprecedented and Unauthorized Mandatory Implementation of the Comprehensive Care for Joint Replacement Model

CMS recently issued a final rule adopting a new bundled payment model for hip and knee replacement surgery and recovery, called the Comprehensive Care for Joint Replacement Payment Model (CJR Model), which requires certain hospitals to participate in the model (the "CJR Final Rule").³⁸ In the CJR Final Rule, CMS cited the CMMI

³⁸ Comprehensive Care of Joint Replacement Payment Model for Acute Care, 80 Fed. Reg. 73274, 72326 (Nov. 24, 2015) (to be codified at 42 C.F.R. pt. 510).

authority created by Social Security Act (SSA) Section 1115A,³⁹ as well as the Secretary's "authority under both sections 1102 and 1871 of the [SSA] to implement regulations as necessary to administer Medicare," as affirmatively authorizing CMS to make the CJR Model mandatory for all hospitals and downstream post-acute care (PAC) providers in designated Metropolitan Statistical Areas (MSAs).⁴⁰ Contrary to CMS's claims, none of these statutes authorize the agency to mandate participation in new payment models. Moreover, CMS's cursory references to these SSA provisions in the CJR Final Rule—in response to questions raised by commenters about the agency's lack of authority—reveal a troubling lack of attention by the agency to its statutory boundaries.

With respect to SSA Section 1115A, CMS posited that "[t]he statute does not require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality" and noted that "[a]lthough section 1115A(b) of the [SSA] describes a number of payment and service delivery models that the Secretary may choose to test, the Secretary is not limited to those models."⁴¹ Those brief mentions of the agency's interpretation of the statute allowed for the agency to provide a more thorough description of their policy-based reasons for preferring a mandatory participation model, which CMS described as "necessary" and "the most prudent approach."⁴² Chief among these policy reasons was CMS's contention that there is "selection bias inherent to any model in which providers may choose whether to participate" and that the agency would acquire broader and hence more useful data if it required participation from hospitals that otherwise would opt not to participate.⁴³

Despite the reasonableness of CMS's belief that a mandatory model could produce more representative data that could, in turn, better inform the agency's policy choices going forward, it is a well-established principle of statutory construction that an agency may not depart from clear statutory text in service of policy choices (without regard to the merits of those policies).⁴⁴ Departing from unambiguous statutory

³⁹ SSA Section 1115A (codified at 42 U.S.C. § 1315a (2012)).

⁴⁰ 80 Fed. Reg. at 73278; SSA § 1102 (codified at 42 U.S.C. § 1302 (2012)); SSA § 1871 (codified at 42 U.S.C. § 1395hh (2012)).

⁴¹ 80 Fed. Reg. at 73277-73278.

⁴² *Id.* at 73278.

⁴³ *Id.*

⁴⁴ *See, e.g., Friends of the Earth v. EPA*, 446 F.3d 140, 145 (D.C. Cir. 2006) (finding that an agency may not "avoid the Congressional intent clearly expressed in

language is precisely what CMS did here, given that CMS adopted a statutory interpretation that offered “broad discretion” to the Secretary—discretion that the agency relied upon to implement its preferred policy—without looking more carefully at the limitations on that “broad discretion” that are equally present in the statute. The brief discussion in the CJR Final Rule suggests that CMS read the absence of an *explicit* statement that models must be voluntary, along with the existence of a variety of models that CMS is permitted but “not limited” to pursue, as conferring very wide-ranging authority on the agency. While CMS is correct that the statute permits the Secretary broad discretion in the selection and design of models for testing, this discretion is not unlimited. The statute’s text, structure, and purpose together clearly demonstrate that one limitation upon this authority is that models may not be mandatory, regardless of the lack of an explicit statement to this end.⁴⁵

Section 1115A of the SSA is structured as a set of interlocking provisions that together establish the CMMI and govern the activities the CMMI is permitted and required to perform. The main provisions bearing on the question of whether CMS can make models mandatory are: subsection (a), which identifies the CMMI’s purpose and provides overarching guidelines (including a geographic limitation, which is key to this analysis); subsection (b), which governs the testing of models (Phase I); and subsection (c), which covers the expansion of models (Phase II).⁴⁶ Subsection (a) identifies the purpose of the CMMI as “to

the text simply by asserting that its preferred approach would be better policy”) (quoting *Engine Mfrs. Ass’n. v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996)); *S. California Edison Co. v. FERC*, 195 F.3d 17, 27 (D.C. Cir. 1999) (stating that an agency may not contravene clear and unambiguous statutory language in order “to improve, in its view, upon Congress’ design”).

⁴⁵ CMS would be well-advised to consider the D.C. Circuit’s cautioning in *Ethyl Corp. v. EPA* regarding this very type of agency attempt to divine authority based solely on the absence in the statute of an explicit denial of that power to the agency. See *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) (“To suggest, as the [agency] effectively does, that *Chevron* step two is implicated any time a statute does not expressly *negate* the existence of a claimed administrative power . . . is both flatly unfaithful to the principles of administrative law, and refuted by precedent. . . . [W]ere courts to *presume* a delegation of power absent an express withholding of such power, agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely the Constitution as well. . . . We refuse, once again, to presume a delegation of power merely because Congress has not expressly withheld such power.”) (emphasis in original).

⁴⁶ 42 U.S.C. § 1315a(a)-(c) (2012).

test innovative payment and service delivery models to reduce program expenditures under the applicable subchapters while preserving or enhancing the quality of care furnished to individuals under such subchapters.”⁴⁷ The terms “test” and “testing” are used throughout SSA Section 1115A to describe the Secretary’s activities under this provision.⁴⁸ Subsection (b) provides the Secretary with broad discretion to “select models to be tested where the Secretary determines that there is evidence . . . [of] poor clinical outcomes or potentially avoidable expenditures”—Phase I testing.⁴⁹ Subsection (c) permits the Secretary to “expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b)” if the model being tested meets certain requirements outlined in the provision (including some based on an evaluation of economic and quality data collected)—Phase II expansion.⁵⁰

It is in light of this structure of Phase I testing and Phase II expansion, that the geographic limitation in SSA Section 1115A(a)(5) provides critical insight into whether models may be mandatory. The geographic limitation reads: “For purposes of testing payment and service delivery models under this section, the Secretary *may elect* to limit testing of a model to certain geographic areas.”⁵¹ Following CMS’s reading of the statute as allowing the agency to mandate participation in the Phase I testing of a model, Section 1115A(a)(5) would allow CMS either to “elect to limit” this testing to certain MSAs and mandate participation by providers in those MSAs (as CMS has done with the CJR Model), or to elect *not* to limit the test to specific MSAs—i.e., conduct the test in all MSAs—and therefore mandate participation by providers in all MSAs. This reading is CMS’s view that it has authority to make models mandatory.

However, this reading is untenable in light of the broader context of the statute. The statute first establishes Phase I testing and, second, Phase II expansion “including implementation on a nationwide basis” after certain requirements have been met.⁵² CMS’s interpretation allows

⁴⁷ § 1315a(a)(1) (2012) (emphasis added).

⁴⁸ See, e.g., 42 U.S.C. § 1315a(a)(5) (2012) (“Testing within certain geographic areas”); § 1315a(b) (2012) (“Testing of models (Phase I)”); § 1315a(d)(1) (2012) (“Waiver authority . . . with respect to testing models described in subsection (b)”).

⁴⁹ § 1315a(b)(2) (2012).

⁵⁰ § 1315a(c) (2012).

⁵¹ § 1315a(a)(5) (2012) (emphasis added).

⁵² *Id.*; § 1315a(a)(5), (c) (2012).

the agency, through, the geographic limitation provision, to mandate a model to be tested at Phase I for all providers nationwide, which is *de facto* “implementation on a nationwide basis,” and the statute only allows for Phase II expansion.⁵³ The structure of the statute, establishing Phase I testing and Phase II expansion, prohibits this reading because it would result in the collapse of the distinction between Phase I testing and Phase II expansion. Thus, when the Secretary’s broad discretion to “test” models is read in the context of the statute as a whole, it is clearly limited by the requirement that models *not* be made mandatory.

In addition, this view of the limitation on the Secretary’s discretion coheres with the statute’s purpose as articulated in the provision itself, i.e., “to test innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care.”⁵⁴ One of the main purposes of SSA Section 1115A models is to enable CMS to collect data, on payment or delivery policies, that could lower Medicare or Medicaid program costs and improve quality of care for beneficiaries. Congress has granted the Secretary the authority to test models in recognition of the inadequacy of available data in many instances for evaluating policy reforms under consideration. Voluntary testing of these models allows CMS to gather quality and economic data that can inform future policy decisions. Mandating participation in models, prior to testing in a voluntary subset, would ignore this chief reason why the CMMI model authority exists in the first place—i.e., to allow collection of information that is absent but needed to evaluate the appropriateness of widespread implementation of a new policy. In the case of the CJR Model, the lack of comparable data across various PAC settings was so widely recognized that Congress passed the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 to enable collection of this information.⁵⁵ In contrast to CMS’s claim that “it is necessary” to mandate participation to acquire adequate data to evaluate the CJR Model’s bundled payment approach,⁵⁶ the enactment of the IMPACT Act shows that it is in fact possible for CMS to stay within

⁵³ *Id.*

⁵⁴ 42 U.S.C. § 1315a(a)(1). As reaffirmed in *King*, a statement of purpose included in the statutory text can be a useful guide to interpreting the provision. *King*, 135 S. Ct. at 2493 (“We cannot interpret federal statutes to negate their own stated purposes.”) (quoting *New York State Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 419-420 (1973)).

⁵⁵ Improving Medicare Post-Acute Care Transformation Act of 2014, Pub. L. No. 113-185, 128 Stat. 1952.

⁵⁶ 80 Fed. Reg. at 73278.

its statutory boundaries (i.e., to keep all CMMI models voluntary) and for a broader data set to be developed (in this case, through an act of Congress).

Just as the text, structure, and purpose of SSA Section 1115A do not authorize CMS to make CMMI models mandatory, neither do the other two provisions CMS cited in the CJR Final Rule for authority, SSA Sections 1102 and 1871.⁵⁷ Section 1102 of the SSA provides, in relevant part, that the Secretary “shall make and publish such rules and regulations, *not inconsistent with [the SSA], as may be necessary* to the efficient administration of the functions with which [the Secretary] is charged under [the SSA],” and SSA Section 1871 states, “[t]he Secretary shall prescribe such regulations *as may be necessary* to carry out the administration of the insurance programs under this title.”⁵⁸ In the case of both of these provisions, CMS seems to have picked out the “as may be necessary” language as authorizing CMS to mandate participation in the CJR Model—based on the agency’s view that the information to be furnished by mandatory participants in the model is “necessary”⁵⁹—without regard to the limiting language in these provisions. This limiting language is critical to an appropriate interpretation of these statutory provisions and determination of whether they do, in fact, authorize CMS to mandate participation in CMMI models.

For SSA Section 1102, this limiting language requires the Secretary to issue regulations “not inconsistent with [the SSA]”—a limitation that would preclude CMS from adopting the CJR Final Rule based on its inconsistency with SSA Section 1115A’s proper reading as authorizing only voluntary models.⁶⁰ CMS must comply with *all* SSA provisions, even if a liberal reading of one provision would seemingly permit a certain course of action. For SSA Section 1871, the limiting language stipulates that the regulations must be “necessary to carry out the administration of the [Medicare program].”⁶¹ Whereas CMS has persuasively established the *usefulness* of the data it seeks to obtain under the mandatory CJR Model, CMS’s strong policy preferences do not make mandatory implementation of the model “*necessary* to carry out the administration” of the Medicare program.⁶² Hence, these broad grants of

⁵⁷ *Id.*

⁵⁸ 42 U.S.C. §§ 1302, 1395hh (2012) (emphasis added).

⁵⁹ 80 Fed. Reg. at 73278.

⁶⁰ 42 U.S.C. § 1302 (2012).

⁶¹ 42 U.S.C. § 1395hh (2012).

⁶² *Id.* (emphasis added).

administrative authority under SSA Sections 1102 and 1871 may not properly be read as allowing CMS to violate other more detailed statutes simply by alleging that the action in question is “necessary.”⁶³ Accordingly, in the absence of any applicable statutory authorities allowing the action, CMS has acted *ultra vires* in mandating provider participation in the CJR Model.

B. CMS’s Unauthorized Addition of a Physician Narrative Requirement to the Home Health Agency Certification Provision

Since 1965, the Medicare program has paid for home health services under Part A and, after 1997, under both Parts A and B, only when a physician has certified in writing that a patient was homebound, under a plan of care established by a physician, and in need of skilled nursing services on an intermittent basis, or physical and speech therapy.⁶⁴ These requirements are part of the physician certification provision of the SSA established as an anti-fraud measure and designed to curb fraud by attaching civil and criminal penalties to false or fraudulent certifications.⁶⁵ In Section 6407 of the ACA, Congress added a new requirement to the physician certification provision, requiring the physician provider to “document” that the physician (or other specified qualified health professional) had a “face-to-face encounter” with the patient “within a reasonable timeframe as determined by the Secretary.”⁶⁶ CMS implemented this statutory provision by issuing a regulation that required the physician to:

document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date

⁶³ Long-standing rules of statutory construction stipulate that more specific statutes trump more general ones when potential interpretive conflicts arise. *See, e.g., D. Ginsberg & Sons v. Popkin*, 285 U.S. 204, 208 (1932) (“General language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment. Specific terms prevail over the general in the same or another statute which otherwise might be controlling.”) (internal citations omitted); *Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 524 (1989) (“A general statutory rule usually does not govern unless there is no more specific rule.”).

⁶⁴ 42 U.S.C. § 1395f(a)(2)(C) (2012).

⁶⁵ 42 U.S.C. §§ 1307, 1320a-7a (2012).

⁶⁶ Patient Protection and Affordable Care Act § 6407 (codified at, 42 U.S.C. § 1395f(a)(2)(C) (2012)).

or within 30 days of the start of the home health care by including the date of the encounter, *and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services* as defined in § 409.42(a) and (c) respectively.⁶⁷

This explanation was referred to as the “physician narrative” requirement.

CMS’s addition of the physician narrative requirement in this regulation represents a stark violation of the unambiguous language of the statute, based on its text, context, and congressional intent clearly expressed therein. Therefore, though CMS rescinded the physician narrative requirement effective January 1, 2015, this example of overreach is well worth discussing for two critical reasons. First, CMS’s bold imposition of tremendously burdensome, impracticable, and confusing requirements on providers for nearly four years—over and against these providers’ frequent communications with the agency regarding the unworkability of the requirement and their repeated requests for adequate guidance—reveals an agency bent on entrenching the ACA without appropriate attention to the clear language of the statute. Second, the harm caused to home health agencies (HHAs) during the time the requirement was in effect was significant and will go unaddressed, even if CMS never reinstates the unauthorized physician narrative requirement. The former issue—the significant overreach represented by CMS’s physician narrative requirement—is addressed below in this section. The latter issue—HHAs’ uncompensated costs of compliance with an unlawful regulation—is a continuing problem with agency overreach across the board, and is addressed below in Section IV.A.2. of this Article.

In a legal challenge to CMS’s authority to implement the physician narrative requirement, HHS (on behalf of CMS) contended that the statutory requirement for the physician to “document” the face-to-face encounter was sufficiently ambiguous to allow CMS to reasonably interpret it as authorizing CMS to require the physician to “document” by composing a narrative.⁶⁸ The D.C. District Court sided with HHS in this challenge, concluding that “HHS’s reading of the statute—although not the most natural one—is not foreclosed by its authorizing provision and

⁶⁷ 42 C.F.R. § 424.22(a)(1)(v) (eff. Apr. 1, 2011 – Dec. 31, 2014) (emphasis added).

⁶⁸ Memorandum accompanying Defendant’s Motion to Dismiss, at 2, *Nat’l Ass’n for Home Care & Hospice v. Burwell*, 77 F. Supp. 3d 103 (2015) (No. 1:14-cv-00950-CRC (D.D.C. Sept. 5, 2014)).

that it is otherwise reasonable.”⁶⁹ Both HHS and the D.C. District Court, however, failed to read the face-to-face encounter provision properly within the broader context of SSA Section 1814(a). Reading this provision “in [its] context and with a view to [its] place in the overall statutory scheme”⁷⁰ demonstrates that the “most natural” reading of the statute’s requirement to “document”—i.e., that “document” means sign, date, or check a box—is the only reasonable one here.

ACA Section 6407 amended the physician certification requirement, which falls within the Medicare limitation on payment provision, at SSA Section 1814(a),⁷¹ and the requirements in SSA Section 1814(a) that pre-dated the face-to-face encounter certification requirement require the physician to check a box, write a date, sign his or her name—basic tasks designed to certify critical information, but not intended to duplicate, replace, or even supplement clinical information already in the medical record.⁷² This makes sense, given that SSA Section 1814(a) was enacted as an anti-fraud measure, with significant civil and criminal penalties attaching for fraudulent certifications; the purpose of the provision is to reduce fraud by requiring physician certification, with there being both (1) adequate incentives for the

⁶⁹ *Nat’l Ass’n for Home Care & Hospice v. Burwell*, Case No. 14-cv-00950 (CRC) 2015 U.S. Dist. LEXIS 148456, *3 (D.D.C. 2015).

⁷⁰ *King*, 135 S. Ct. at 2489.

⁷¹ 42 U.S.C. § 1395f (2012).

⁷² *See, e.g.*, 42 U.S.C. § 1395f(a)(4) (2012) (requiring certification that inpatient psychiatric hospital services furnished cohere with the hospital’s records of such services); 42 U.S.C. § 1395f(a)(5) (2012) (requiring certification that, for inpatient hospital services provided beyond the 20th consecutive day, there were not any long-stay payment limitations in place for the hospital at the time of the patient’s admission); 42 U.S.C. § 1395f(a)(7)(A) (2012) (requiring certification that an individual receiving hospice services is terminally ill “based on the physician’s or medical director’s clinical judgment”). In addition, for home health services, while it was never clear precisely what information CMS expected to be included in the physician narratives, all relevant clinical information justifying the beneficiary’s homebound status would already be present on a variety of standardized HHA admission forms mandated by CMS. These certification requirements existed in various forms prior to the ACA before they were aggregated and, by regulation, conflated into the physician narrative requirement under ACA Section 6407. In the case of hospice, extensive Conditions of Participation (CoPs) controlled the ordering of services, the designation of a patient’s terminal illness, and the medications each received, before the ACA substituted its own judgment, and that of the Medicare Payment Advisory Commission, by inserting a face-to-face encounter requirement (similar to that required for HHAs) in ACA Section 3132(b)(2).

physician to certify accurately and (2) sufficient medical information elsewhere in the clinical record to meet other Medicare program requirements. CMS cannot create authority for itself to add new *medical record* requirements based on an anti-fraud provision addressing only basic signature and box-checking as certification. Had Congress wanted to change the medical record statutes to enable or require CMS to establish a physician narrative requirement, it could have specified so directly. Instead, Congress amended the physician certification provision, which is aimed at an entirely different goal from the medical record provision (combatting fraud versus ensuring that health care services are medically necessary). Interpreting “document” any way other than signing, dating, or checking a box does not cohere with the structure or context of SSA Section 1814(a).

Moreover, the text of SSA Section 1814(a), as amended by ACA Section 6407, limits the Secretary’s discretion to determining *when* the physician must complete the face-to-face encounter with the patient with respect to the date home health services commence. Specifically, the statute provides: “the physician must document that the physician himself or herself [or another specified qualified health professional] . . . has had a face-to-face encounter . . . with the individual *within a reasonable timeframe as determined by the Secretary.*”⁷³ Congress left the Secretary discretion to determine the length of a “reasonable timeframe” but did not authorize the Secretary either explicitly or implicitly to add a physician narrative requirement to this clear and unambiguous provision. Saying that “document” is ambiguous shows either CMS’s failure to read the rest of SSA Section 1814(a), which contains multiple examples of “check-the-box” style requirements,⁷⁴ or, worse, a willful attempt to create ambiguity where none exists in order to claim authority for implementing the agency’s favored policy.

Unfortunately, both of these possible rationales can result *in* agency overreach and entrenchment of unlawful policies, and can result *from* the high degree of deference afforded by courts to agency statutory interpretations. As noted in testimony before Congress in a hearing regarding problems with judicial deference to agency action, the *Chevron* doctrine “has fundamentally changed the way that agencies go about their business of interpreting governing statutes. The search for meaning in Congress’s commands has been replaced with a hunt for ambiguities that

⁷³ 42 U.S.C. § 1395f(a)(2)(C) (2012) (emphasis added).

⁷⁴ *See, supra*, note 72.

might allow the agency to escape its statutory confines.”⁷⁵ In the case of the physician narrative requirement, despite the D.C. District Court getting it wrong, HHAs have some relief at the moment due to CMS’s voluntary rescission of the unauthorized requirement.⁷⁶ Still, this overreach reveals CMS’s propensity to aggressively implement policy with inadequate attention to the law in efforts to entrench the ACA (and other Democratic priority statutes), and it potentially represents an emboldened agency actively searching for ambiguities to exploit as alleged justifications for its policies of choice.

C. Expansion of the ESRD PPS Bundle in Violation of the Statutory Definition of “Renal Dialysis Services”

The Medicare program began covering individuals with kidney failure regardless of age under the ESRD benefit in 1973.⁷⁷ Initially, Medicare paid for dialysis services on a fee-for-service basis. In August of 1983, pursuant to a congressional mandate,⁷⁸ Medicare began paying for dialysis services using the “composite rate” system, a blended prospective payment and fee-for-service system. Under the composite rate system, dialysis facilities received a single, prospectively determined payment amount per treatment that was intended to cover certain regularly provided drugs, laboratory tests, and supplies. Dialysis facilities billed Medicare separately for other drugs that were not included in the composite rate (“separately billable drugs”). Initially, the composite rate payment included most of the items and services routinely used in dialysis, and reimbursement for separately billable drugs was intended to help ensure that providers’ costs of furnishing other non-composite rate items were properly recognized, preserving opportunities for high-quality care for beneficiaries.⁷⁹ Over time, as new drugs were

⁷⁵ *Proper Role of Judicial Review*, *supra* note 15, (statement of Andrew Grossman, Associate, BakerHostetler and Adjunct Scholar, The Cato Institute) (hereinafter Grossman statement) (Apr. 28, 2015), at 7, available at, <http://www.hsgac.senate.gov/download/?id=00FD3227-284A-453D-9A0F-F7B9B660F7B0>.

⁷⁶ However, reimbursements withheld from HHAs due to purported noncompliance with the rescinded narrative requirement remain unreturned.

⁷⁷ Social Security Amendments of 1972, Pub. L. No. 92-603, § 2991 (1972).

⁷⁸ Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2145 (1981).

⁷⁹ Notwithstanding the design features of this two-part system, dialysis facilities in many instances faced challenges meeting their costs since the system did not include an annual updating mechanism or “market basket increase” factor, unlike every other Medicare payment system at the time.

developed and practice standards evolved, medical guidelines and physician prescribing patterns supported greater use of erythropoietin stimulating agents (ESAs) and other supportive care drugs like intravenous (IV) iron that helped improve life quality for patients on dialysis.

By the mid-2000s, regulators and Congress had begun focusing on the still-growing utilization of and cost associated with separately billable drugs, for which the system had no significant clinical or operational policy constraint (other than CMS's own sub-regulatory prescribing guidelines for ESAs, and labeling changes from the federal Food and Drug Administration, neither of which made a material impact on overall utilization).⁸⁰ Congress addressed these matters in MIPPA, enacted in 2008, which required CMS to adopt a bundled prospective payment methodology for ESRD services that would include composite rate services as well as separately billable drugs, with the expectation that the broader bundle including ESAs would lead to more efficient care delivery and lower overall resource use.⁸¹ The new system would also include, for the first time since the benefit was created, an annual automatic updating mechanism. Congress was so confident in that utilization reduction result that it built a mandatory two percent savings into the new system.

The statutory provision establishing the ESRD prospective payment system (PPS) directs the Secretary to “implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for *renal dialysis services* (as defined in subparagraph (B)) in lieu of any other payment.”⁸² Subparagraph (B) defines “renal dialysis services” as follows:

(B) For purposes of this paragraph, the term “renal dialysis services” includes—

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

⁸⁰ The composite rate system generally allowed for items and services to come into and out of the payment system, like electrocardiogram and nerve conduction testing, though the system's flaws prevented it from being financially viable in the long run. *See generally*, H.R. Rep. No. 97-208, 948-49 (July 29, 1981) (describing system).

⁸¹ Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 153(b) (codified at 42 U.S.C. § 1395rr(b)(14)(B) (2012)).

⁸² Social Security Act, § 1881(b)(14)(A) (emphasis added) (codified at 42 U.S.C. § 1395rr(b)(14)(A) (2012)).

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Such term does not include vaccines.⁸³

Congress has not modified the statutory definition of “renal dialysis services” since its adoption in 2008. Importantly, as discussed in detail below, a key deficiency in this definition is the absence of an authorized way for CMS to incorporate new technologies.

It is this four-pronged statutory provision that CMS has now violated twice in overt and dramatic ways with its own interpretations that directly contradict the clearly expressed congressional intent regarding what CMS may include in the ESRD PPS bundle—first, by adding “oral-only drugs” into the bundle in 2011,⁸⁴ and more recently, by adding new IV or injectable drugs into the bundle, effective January 1, 2016. In addition, over time CMS has gradually and quietly inserted additional items into the bundle, a phenomenon known as “bundle creep.” All of these expansions exceed the agency’s statutory authority and showcase CMS’s willingness to ignore or twist beyond the point of recognition legislative language that would otherwise get in the way of the agency’s desired policies.

CMS commenced this unauthorized expansion of the bundle when first adopting the regulations implementing the ESRD PPS—specifically, the regulation defining “renal dialysis services” paid for under the ESRD PPS.⁸⁵ The regulation text closely parallels the statutory text at each of

⁸³ Social Security Act, § 1881(b)(14)(B) (codified at 42 U.S.C. § 1395rr(b)(14)(B) (2012)).

⁸⁴ For a variety of reasons and on multiple occasions, Congress has delayed the implementation of CMS’s inclusion of oral-only drugs in the bundle until 2025. American Taxpayer Relief Act of 2012, Pub. L. No. 112–240, § 632(b), 126 Stat. 2313 (2012); Protecting Access to Medicare Act of 2014, Pub. L. No. 113–93, § 217(a)(1), 128 Stat. 1040 (2014); Achieving a Better Life Experience Act of 2014, Pub. L. No. 113–295, § 204 (2014).

⁸⁵ CMS has not altered this definition since adopting it in the calendar year 2011 ESRD PPS Final Rule. *See* End-Stage Renal Disease, 75 Fed. Reg. 49030 (Aug. 12, 2010) (adopting 42 C.F.R. § 413.171, defining “renal dialysis services” and other

the four prongs with one critical exception in the third prong regarding “other drugs and biologicals.” The third prong of the *regulatory* definition reads: “Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals *with only an oral form*).”⁸⁶ The *statutory* text, in contrast, provides for “any *oral equivalent* of such drug or biological.”⁸⁷ CMS’s change in terminology here, while subtle, results in a statutory construction that defies logic and an agency policy that flagrantly departs from the congressional limitations contained in the statute.

One point of similarity between the statutory and regulatory text is that both clearly identify this prong as including drugs *for which payment was made* prior to the January 1, 2011 implementation date of the ESRD PPS (i.e., drugs that existed and were reimbursed by Medicare as separately billable drugs before the ESRD PPS became effective). The *statute* then allows “any oral equivalent” of a previously separately billable drug to be paid under this prong, but nowhere allows *oral-only* drugs to be reimbursed because, by definition, an *oral-only* drug cannot be the “equivalent” of any non-oral drug. Drugs paid as separately billable before 2011 could have “oral equivalent” versions of them developed later and reimbursed under this prong, but because an *oral-*

terms, and adding or amending numerous other ESRD-related regulations). The regulatory definition reads:

Renal dialysis services. Effective January 1, 2011, the following items and services are considered “renal dialysis services,” and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

- (1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;
- (2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;
- (3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),
- (4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.
- (5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis. 42 C.F.R. § 413.171 (2015).

⁸⁶ 42 C.F.R. § 413.171(3) (2015) (emphasis added).

⁸⁷ 42 U.S.C. § 1395rr(b)(14)(B)(iii) (emphasis added). For purposes of this prong, “such drug or biological” refers to drugs “furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title,” i.e., separately billable drugs. *Id.*

only drug would not be “equivalent” to any separately billable drug, it cannot be reimbursed under this prong.

Despite this clear textual limitation from the statute, CMS added oral-only drugs into the regulation text, stating at the time, “. . .we believe that when the definition is viewed as a whole, it suggests a comprehensive definition that wraps in all items and services related to outpatient renal dialysis that are furnished to individuals for the treatment of ESRD.”⁸⁸ Further, CMS contended that even if oral-only drugs could not fit in the third prong of the statutory definition, they could fit in the fourth prong, which the agency described as a “catchall category.”⁸⁹ This explanation, which fails to grapple with the precise text of the statute, demonstrates CMS’s eagerness to locate an expansive “catchall,” or broad Secretarial discretion, enabling its desired policy to proceed.

A careful look at the “catchall” in prong (iv) of the statutory definition, however, shows that this prong is not the open-ended invitation for CMS to add any and all items and services into the bundle that CMS suggests it is. Specifically, the category includes “diagnostic laboratory tests and other items and services *not described in clause (i)* that are furnished to individuals for the treatment of end stage renal disease.”⁹⁰ In its efforts toward unconstrained bundle expansion, CMS has completely read this limiting language out of the text, using the “catchall” to cover any items or services *at all*, provided they were related to dialysis treatment,⁹¹ and sometimes when such items bore no connection to dialysis treatment but were inserted into the PPS for CMS’s or the patient’s convenience.⁹² When the provision is read as

⁸⁸ 75 Fed. Reg. at 49040.

⁸⁹ *Id.*

⁹⁰ 42 U.S.C. § 1395rr(b)(14)(B)(iv) (2012) (emphasis added).

⁹¹ 75 Fed. Reg. at 49040. More recently, CMS has articulated this same overly broad reading of the provision, stating, “We also read section 1881(b)(14)(B)(iv) as specifying a different category of items that must be included in the bundle—that is, items and services, which includes drugs and biologicals, not specified by sections 1881(b)(14)(B)(i), (ii), or (iii).” End-Stage Renal Disease, 80 Fed. Reg. 68968, 69016 (Nov. 6, 2015) (emphasis added). Significantly, the statutory text does not extend the catchall to items and services not described in *clauses (i), (ii), or (iii)*, but rather only to “items and services not described in *clause (i)*,” and CMS simply adds in “(ii) and (iii)” in direct contradiction of the statutory language.

⁹² For example, rather than requiring patients to make a separate trip to a clinical laboratory for phlebotomy services, the ESRD PPS for a time included a number of tests unrelated to the treatment of ESRD, since it would be more convenient for patients to have all of their testing—both ESRD- and non-ESRD related—initiated at the same site of service, namely the ESRD facility. CMS has since adjusted this

written, the limiting phrase restricts the “catchall” to items and services “*not described in clause (i)*,” meaning items and services of the sort that might have been included in the original composite rate—i.e., not drugs. The statute, with its four specific categories, clearly and precisely handles reimbursement for drugs in prongs (ii) and (iii), whereas it addresses composite rate items in prong (i) and a limited set of other dialysis-related items and services in prong (iv). While there may be room for discussion and disagreement over the scope of prong (iv) with regard to which “other items and services” are in fact provided “for the treatment of [ESRD],” that prong simply cannot accommodate drugs given the structure of the statutory definition. CMS’s departure from the statutory text here foreshadowed future statutory violations by CMS in service of the same core objective—liberal expansion of the bundle in relentless pursuit of cost-savings with blind, or willful, disregard to statutory limitations on the agency’s discretion.

Since implementing the ESRD PPS, CMS has continued to gradually add items and services into the bundle. For example, it has issued sub-regulatory guidance to contractors adding such items as venous catheter covers and other supplies, certain laboratory tests not related to the treatment of ESRD, and drugs.⁹³ CMS has acknowledged this practice, for instance noting in the calendar year (CY) 2016 ESRD PPS Final Rule:

We’ve added new drugs to the ESRD PPS bundled payment consistent with this policy [of adding new drugs into the bundle when they fit into existing functional categories] in the years since the ESRD PPS was implemented and announced those additions using change requests. These decisions have not been controversial because the drugs were substantially the same as other drugs in the functional category.⁹⁴

This continual expansion of the bundle, known as “bundle creep,” has been controversial, despite what CMS insisted here. The dialysis industry has repeatedly urged CMS to refrain from adding new items or

position and has allowed facilities to designate such non-ESRD related tests with an “AY” modifier and to bill separately for them.

⁹³ See, e.g., CMS, Transmittal 2588 (Nov. 5, 2012), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2588CP.pdf> (adding peginesatide to the bundle); CMS, Transmittal 2949 (May 7, 2014), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2949CP.pdf> (adding ferric carboxymaltose to the bundle).

⁹⁴ 80 Fed. Reg. at 69017.

services to the bundle outside of rulemaking, without adequate funding, and most importantly, when those items and services do not constitute “renal dialysis services.” CMS took a partial step toward acknowledging the latter concern in its December 2014 update to the Medicare Benefit Policy Manual, in which it noted throughout that only “renal dialysis services” that are “related to the treatment of ESRD” properly belong in the ESRD PPS.⁹⁵ Still, the revisions in the Medicare Benefit Policy Manual may be a symbolic victory; to the extent that bundle creep has not been forestalled, it demonstrates the broader, dangerous trend of agencies slowly usurping more and more authority in small ways that eventually add up to a significant acquisition of unwarranted authority.

CMS’s most recent major departure from the statutory definition of “renal dialysis services” came with the agency’s decision to add new IV or injectable drugs into the bundle. In the CY 2016 ESRD PPS Final Rule, CMS adopted a process for adding new injectable and IV products into the ESRD PPS bundle, contending that both Section 217(c) of the Protecting Access to Medicare Act of 2014 (PAMA)⁹⁶ and the statutory definition of “renal dialysis services”⁹⁷ give the agency authority to do so.⁹⁸ However, neither of these statutes, in fact, confers upon the agency the authority it has claimed. While PAMA Section 217(c) directed the Secretary to “establish a process” for “including new injectable and intravenous products into the bundled payment under such system,”⁹⁹ it did not revise or supplant the existing “renal dialysis services” definition in the SSA, nor did it separately authorize CMS to *implement* that process without regard to the statutory definition. Section 217(c) of PAMA and the “renal dialysis services” definition must be read in conjunction with one another under the well-established statutory construction principle disfavoring repeals by implication, which dictates that subsequent statutes do not replace preexisting laws unless Congress has clearly indicated so.¹⁰⁰ Accordingly, while PAMA Section 217(c)

⁹⁵ See, e.g., CMS, *Medicare Benefit Policy Manual* (CMS Pub. 100-02), Ch. 11, at §§ 20, 20.2A, 20.3 (rev. Dec. 2014), available at, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html>.

⁹⁶ Pub. L. No. 113-93.

⁹⁷ 42 U.S.C. § 1395rr(b)(14)(B) (2012).

⁹⁸ 80 Fed. Reg. at 69016.

⁹⁹ Protecting Access to Medicare Act of 2014, § 217(c).

¹⁰⁰ See, e.g., *Rodriguez v. United States*, 480 U.S. 522, 524 (1987) (“[R]epeals by implication are not favored . . . and will not be found unless an intent to repeal is

requires CMS to *design a process* for adding new IV or injectable drugs to the bundle, the narrowly tailored categories of the “renal dialysis services” definition prohibit CMS from *employing* that process to add such drugs into the bundle without further congressional action.¹⁰¹

More specifically, none of the four prongs of the “renal dialysis services” statutory definition can accommodate new IV or injectable drugs. The first prong explicitly includes only composite rate items and services paid for as of December 31, 2010, thus precluding the addition of any new items under this prong. The second prong is limited to Epogen (EPO) and oral forms of ESAs and, as such, will not allow new non-ESA IV or injectable drugs. Prong (iii) is date-stamped and tied to previously reimbursed items (i.e., separately billable drugs paid for prior to January 1, 2011) and also includes “any oral equivalent of *such* drug or biological” (i.e., separately billable drug)—so presumably it can accommodate new *oral equivalent* drugs here, but not new *IV or injectable* drugs. This leaves prong (iv), which, far from being the expansive “catchall” that CMS has treated it as, is limited to certain “other items and services *not described in clause (i)*,” indicating its unavailability for drugs, which are handled specifically and completely by prongs (ii) and (iii).¹⁰² Hence, in the absence of explicit congressional authorization to implement the drug designation process, CMS is brazenly pursuing policy without regard to the governing statute.

clear and manifest.”) (internal citations omitted); *Branch v. Smith*, 538 U.S. 254, 293 (2003) (O’Connor, J., concurring in part and dissenting in part) (noting that “[w]e have not found *any* implied repeal of a statute since 1975. And outside the antitrust context, we appear not to have found an implied repeal of a statute since 1917”) (internal citations omitted).

¹⁰¹ Even on the view that PAMA Section 217(c)’s directive for CMS to “establish a process” is ambiguous with respect to whether “establish” means “design” (without implementing) versus “put into practice,” such ambiguity would not justify CMS beginning to implement that process, because the “renal dialysis services” definition so clearly lacks space to accommodate new IV or injectable drugs, any ambiguity regarding the meaning of “establish” must be resolved in favor of “design” (without implementing), lest the “renal dialysis services” definition be violated. PAMA Section 217(c) did not authorize repeal by implication of the existing “renal dialysis services” statutory definition. See *Rodriguez*, 480 U.S. at 524 (requiring “clear and manifest” congressional “intent to repeal” in order to interpret a later statute as impliedly repealing a preexisting one).

¹⁰² 42 U.S.C. § 1395rr(b)(14)(B)(iv) (emphasis added).

IV. BROADER IMPLICATIONS OF THIS DISCUSSION

In each example discussed above, CMS adopted an interpretation of the relevant statutory provision that enlarged the agency's authority and allowed it to pursue its chosen program goals. Each agency overreach, in isolation, has caused significant difficulty for the health care providers directly subject to the *ultra vires* agency action. Moreover, health care providers who have escaped the direct effects of these specific overreaches should still take note because these relatively narrow instances are part of a more widespread trend within CMS (and HHS more generally) to expand its authority. Every time the agency cites the Secretary's "broad discretion" and proceeds to act in excess of actual statutory authority—and wins or is unchallenged—it becomes easier for the agency to do this again the next time. This pattern of adopting unsupportable statutory interpretations that facilitate the agency's chosen policies and increase its authority is, thus, potentially problematic to all parties under the regulatory authority of CMS.

A. Major Challenges Presented to Providers and Beneficiaries by Each Instance of CMS Overreach

Hospitals mandated to participate in the CJR Model, HHAs subjected to the impracticable physician narrative requirement, and dialysis facilities obligated under an ever-expanding bundle have all suffered from CMS's unauthorized actions. In each instance, Congress had written an unambiguous statutory provision that CMS is obligated to follow. This section discusses the practical consequences to regulated parties and others affected by these abuses of authority.

1. Challenges for Acute Care Hospitals, Downstream Providers, and Beneficiaries Under the CJR Model

It is important to understand that whereas CMS has mandated participation in the CJR Model by acute care hospitals in designated MSAs, the structure of the CJR Model effectively mandates participation in the model by PAC providers that serve beneficiaries treated in these hospitals. That is, under the model, CMS pays the hospital a single bundled payment amount to cover the hip or knee joint replacement procedure performed in the hospital on a Medicare beneficiary as well as all PAC services received by the beneficiary relating to that procedure. Accordingly, since all the hospitals in a selected MSA (with very narrow

exceptions) would be mandatory participants, PAC providers who treat Medicare beneficiary patients from these hospitals would have the “choice” either to accept reimbursement under the CJR Model’s bundled payment or elect not to treat Medicare beneficiaries—not a meaningful choice in light of economic realities for PAC providers that tend to have Medicare-heavy patient mixes. Therefore, any harmful effects of the CJR Model would be experienced not only by acute care hospitals in the selected MSAs, but also by downstream PAC providers and Medicare beneficiaries receiving hip or knee joint replacement treatment in those MSAs.

One of the key risks posed by mandatory implementation of the CJR Model stems from the inversion of the appropriate order for exploring new payment or delivery models—i.e., first, testing the model with a subset of providers (and beneficiaries) to allow data collection, and, second, evaluating whether to expand the model more broadly later, based on data collected, for all providers (and beneficiaries) in the payment system. In the case of the CJR Model, Congress has already explicitly recognized the lack of comparable PAC data and enacted the IMPACT Act to address this. CMS is, therefore, acting not only *ultra vires* but also unnecessarily, putting beneficiaries and providers at risk of a widely implemented, mandated model that could fail with substantial adverse consequences. It is not a secret that some new models (or demonstration projects) fail—whether because the new policy does not save money, lowers quality of care, places unmanageable administrative burdens on providers, or for some other reason.¹⁰³

In ordinary situations (of voluntary models), this does not pose a major problem, since providers can drop out of the model if needed and return to the applicable conventional Medicare program payment system. Also, the “self-selection” risk CMS is troubled by (because it may skew data in voluntary models) actually provides a measure of protection in voluntary models because presumably providers know their own financial, clinical, and administrative capacities better than government regulators and choose to participate in models only when they believe they have a reasonable likelihood of viability under the model. On the contrary, mandating all providers to participate—precisely to avoid self-selection bias—removes this built-in protection for providers and the patients they serve. By characterizing self-selection as a hurdle to be

¹⁰³ See, e.g., Deborah Peikes, *et al.*, *Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries*, 301 J. OF THE AM. MED. ASS’N 603 (2009).

overcome in pursuit of more “robust” data¹⁰⁴ rather than the valuable provider and beneficiary protection mechanism that it is, CMS has put providers and beneficiaries at risk, unnecessarily and without justification.

2. *Challenges for HHAs and Beneficiaries Under the Physician Narrative Requirement*

For over three-and-a-half years, HHAs were subjected to significant administrative difficulties, confusion, and extensive costs of compliance by the unauthorized physician narrative requirement. Numerous Members of Congress were concerned about the “significant burden on home health providers and physicians in [their] districts,” including the increased “paperwork burden and cost to home health agencies which are struggling to comply with this regulation” and the potential “disincentive for physicians to recommend home health services.”¹⁰⁵ Although CMS rescinded this requirement, effective January 1, 2015,¹⁰⁶ HHAs cannot recoup the time and money they spent seeking to comply with that requirement for the nearly four years it was in effect.¹⁰⁷

In the final rule rescinding this requirement, CMS mentioned that “[t]he home health industry continues to voice concerns regarding the implementation of the Affordable Care Act face-to-face encounter documentation requirement” and explained its decision to remove the narrative requirement as “an effort to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with

¹⁰⁴ 80 Fed. Reg. at 73276.

¹⁰⁵ See Letter from Members of Congress to Marilyn Tavenner, CMS Administrator (Sept. 17, 2013), available at <http://www.hca-nys.org/documents/FinalF2FLetter091713.pdf>. The 75 signatures on this letter represent both Democrats and Republicans from across the country whose constituencies include urban, suburban, and rural populations.

¹⁰⁶ Calendar Year 2015 Home Health Prospective Payment System Update, 79 Fed. Reg. 66032 (Nov. 6, 2014).

¹⁰⁷ Realistically, HHAs would have begun to incur compliance costs prior to the April 2011 effective date of the physician narrative requirement, nearer to when CMS first proposed this requirement in July 2010, as providers must begin preparing for final rules before their effective dates.

certification requirements.”¹⁰⁸ It is certainly encouraging when CMS seems to take seriously issues raised by providers and to develop or modify regulations and policies appropriately based on providers’ on-the-ground knowledge and experience. The notice-and-comment process established by the APA was designed to foster exactly that type of meaningful opportunity for regulated parties to communicate with agencies and affect agencies’ policy decisions as a result; regulators acting in the public interest will care about regulated parties’ concerns, and it is always welcomed when CMS and other agencies meaningfully consider regulated parties’ views when respectfully expressed and clearly articulated.

Unfortunately, all too often agencies fail to address critical issues raised in this fashion, leaving regulated parties with little recourse aside from litigation. In the case of the physician narrative requirement, that was precisely what happened. For the better part of four years, beginning almost immediately after CMS proposed the requirement in July 2010,¹⁰⁹ HHAs petitioned CMS to remove the overly burdensome, unauthorized, and incomprehensible physician narrative requirement—and, if nothing else, to provide clear guidance to physicians so that HHAs would not continue facing unpredictable and improper claims denials from Medicare contractors. As CMS continued to remain largely unresponsive to providers’ significant difficulties, the national trade association representing HHAs ultimately brought suit, seeking relief for its members.¹¹⁰ During the course of the litigation, CMS rescinded the physician narrative requirement.¹¹¹ It is impossible to tell whether CMS ultimately changed its mind based on provider input, fear of losing in court, political pressure, or some other reason. Still, this situation may demonstrate the importance of persistence among providers, given that legal challenges can potentially spur agencies to retreat from harmful policies even if the challenges do not ultimately prevail in court.

¹⁰⁸ 79 Fed. Reg. at 66043. CMS further stated: “While we do not agree that the narrative requirement goes beyond Congressional intent, we agree that there should be sufficient evidence in the patient’s medical record to demonstrate that the patient meets the Medicare home health eligibility criteria.” *Id.*

¹⁰⁹ Home Health Perspective Payment System Rate Update for Calendar Year 2011, 75 Fed. Reg. 43236 (proposed July 23, 2010).

¹¹⁰ *Nat’l Ass’n for Home Care & Hospice v. Burwell*, No. 14-cv-00950, 2015 WL 6736165, (D.C. Cir. June 5, 2014).

¹¹¹ While the D.C. District Court later found for the government in a motion for summary judgment, CMS has not sought to reinstate the unlawful requirement. *Id.* at 10.

In addition to the un-recoupable costs of compliance, another problem caused by the unlawful physician narrative requirement was its lack of logic and basic fairness as applied. Specifically, the regulation made receipt of an adequate physician narrative a condition of HHAs' Medicare reimbursement but prohibited HHAs from drafting the narratives or assisting physicians with the drafting. This policy therefore unfairly punished HHAs if Medicare contractors determined that physicians had failed to comply with CMS's ambiguous and confusing (also unnecessary and unauthorized) physician narrative requirement, while simultaneously tying HHAs' hands to prevent them from helping ensure that the narratives would be considered complete by contractors. Over the course of over three-and-a-half years, HHAs placed in this unfair position faced tens of thousands of retrospective claim denials based on Medicare contractor findings of incomplete physician narratives—despite the fact that (1) CMS had not provided adequate guidance to physicians, (2) CMS's own contractors were applying the narrative requirement inconsistently, (3) claims would be denied if contractors deemed the narratives “insufficient” even if the patients' overall medical records demonstrated the need for home health services, and (4) CMS had no authority in the first place to impose this requirement.

Had CMS not rescinded the physician narrative requirement, this volume of unwarranted claims denials ultimately could have severely threatened many HHAs' ability to survive, which, in turn, would have posed major access problems for vulnerable Medicare beneficiaries requiring home health services. Health care providers are, unfortunately, accustomed to receiving inadequate Medicare reimbursement and managing cumbersome administrative burdens imposed by payers (including Medicare). However, providers are not invincible, and there are policies—such as the physician narrative requirement—that are so detrimental that they could force providers to close up shop. As such, CMS should be mindful of how its own overreach can have adverse effects on the very beneficiaries it is charged with protecting under the Medicare program.

3. Challenges for Dialysis Facilities and Beneficiaries Under the ESRD PPS

In implementing the ESRD PPS, CMS has transgressed statutory boundaries twice in bold, significant ways—first, in the unauthorized

addition of oral-only drugs into the bundle¹¹² and, second, in the unauthorized use of a process to add new IV or injectable drugs into the bundle—and on a more discrete and incremental basis with the pervasive addition of items and services into the bundle (“bundle creep”). These unsanctioned bundle expansions pose challenges to dialysis facilities that are paid a fixed amount per treatment under the ESRD PPS. These same facilities have received zero percent updates from Medicare since 2012 that will continue through 2016, but still are expected to provide beneficiaries with an increasing number of items and services in exchange for the same fixed payment amount, all while attaining and maintaining quality imperatives under at least three different Medicare measurement regimes, all of which add operational cost to the treating facility.¹¹³ While CMS often seems to let providers “fend for themselves” despite inadequate Medicare reimbursement across care settings, the situation is acutely worse at the moment for dialysis facilities with new dialysis drugs on the horizon that could be game-changing for patient treatment but extremely expensive in a system that has historically had difficulty attributing accurate cost data to prescription drugs, leaving facilities to absorb shortfalls.

More specifically, an IV version of the single source drug Sensipar is expected to become available in 2016. The drug is expensive, and its clinical profile is not well understood, yet nephrologist and patient demand for it may be high. Should CMS turn a blind eye to dialysis facilities’ plight by adding this new drug into the bundle without properly accounting for its cost to ESRD facilities (as has occurred time and time again over the course of the ESRD PPS), this would severely strain dialysis facilities. Because these facilities are charged with caring for some of the most vulnerable patients, it is critical that they are adequately reimbursed so they can continue furnishing high-quality care and maintaining access for Medicare beneficiaries. The CY 2016 ESRD PPS Final Rule suggests that, with respect to new therapies like Sensipar (i.e., new phosphate binders or calcimimetics), CMS will proceed cautiously and develop a “computation” for the cost and utilization of the new drug and pay facilities an average sales price-based alternative temporarily

¹¹² As noted above, implementation of this policy has been delayed by statute until 2025. *See, supra* note 84.

¹¹³ While CMS does adjust the bundle payment amount annually through the regulatory process, increases to the bundle payment rate have not kept pace with expansions of the bundle and have been blocked by acts of Congress. In addition, dialysis facilities must meet quality performance targets under the Quality Incentive Program, the Facility Compare and Star Rating Systems, and CROWNWeb.

before the agency simply drops the new drug into the bundle—an outcome about which facilities are cautiously optimistic.¹¹⁴ But, given the agency’s long history of manipulating statutes and statistics to its advantage and to achieve its Medicare and Medicaid program goals, it is an outcome over which trained eyes should be watchful. The near-term result may quell facility worries about unfunded bundle expansion. The longer-term reality is that CMS may in no way be willing or able to adequately compensate dialysis facilities for the price of Sensipar.

Regardless of the outcome on Sensipar, the consequences of CMS’s overreach and self-aggrandizing regulatory decision-making extend beyond dialysis facilities to the vulnerable patient population they serve. In a fragile economic system, providers, expected to do more and more with fewer and fewer resources, may ultimately close facilities, forcing complex, chronically ill beneficiaries to travel farther to receive dialysis care (three times per week for at least four hours per session), interrupting their care, disrupting their “medical home,” and resulting in tremendous logistical and even clinical difficulties for these patients. Medicare beneficiaries on dialysis are disproportionately poor (48 percent are dually eligible for Medicare and Medicaid), elderly (51 percent are over age 65), and chronically ill (chiefly diabetes and hypertension).¹¹⁵ This is a population that, without aggressive resistance and pushback from Congress and the judiciary, may be the least capable of supporting itself in the wake of CMS’s self-centered decision-making that harms dialysis facilities and, as a result, puts dialysis patients at risk.

Congress recognized this uniquely critical role of dialysis facilities when creating the ESRD PPS. During the debates leading to the establishment of the ESRD PPS, Senator Kent Conrad, then-Chair of the Senate Budget Committee, highlighted these issues, noting that “[w]hen Congress enacted the Medicare ESRD program, we recognized that this disease was unique and deserved special consideration,” urging Congress to act to ensure that these facilities be properly funded to continue providing high-quality care to a vulnerable patient population.¹¹⁶ Senator

¹¹⁴ 80 Fed. Reg. at 69025.

¹¹⁵ Medicare Payment Advisory Commission, *Health Care Spending and the Medicare Program, A Data Book*, Ch. 11, 186, 187 (June 2015), available at <http://www.medpac.gov/documents/data-book/june-2015-databook-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0>.

¹¹⁶ 153 Cong. Rec. S2277 (daily ed. Feb. 27, 2007) (statement of Sen. Conrad). Senator Conrad mentioned in particular that inadequate reimbursement had caused dialysis facilities to “experience[] difficulties in hiring qualified health care professionals and purchasing new technology.” *Id.*

Max Baucus, then-Chair of the Senate Finance Committee, later echoed these sentiments during the debates on MIPPA, observing that the new ESRD PPS “would ensure that Medicare payments keep up with costs,” “giving [dialysis facilities] a little bit of predictability.”¹¹⁷ To balance these dual concerns for the Medicare program’s fiscal integrity and dialysis facilities’ need for adequate reimbursement to care for vulnerable Medicare beneficiaries, Congress carefully drafted the “renal dialysis services” definition in the ESRD PPS statutory provision. By contravening the “renal dialysis services” statutory definition in pursuit of its own policy objectives, CMS has been disrupting the very balance Congress established to address these complex considerations, posing a threat not only to dialysis facilities but also to the vulnerable patients they serve.

B. CMS’s Expansive Interpretations of Its Statutory Authority as a Case Study of the Risk of Unchecked Agency Self-Aggrandizement

While acute care hospitals in designated MSAs required to participate in the CJR Model (and downstream PAC providers), HHAs subjected to the physician narrative requirement, and dialysis facilities paid inadequately under the ESRD PPS may already be attuned to CMS overreach and its harmful consequences, others in the health care provider community should be alert as well. Agency self-aggrandizement in one area can reveal an agency’s propensity to overreach and further embolden the agency to overreach in the future if it proceeds unchallenged. This means that all parties subject (or potentially subject) to regulation by an agency should take notice if that agency develops a pattern of overreach.

1. Overreach Begets Overreach

A primary example of agency overreach expanding from one setting to another is CMS’s move from conducting only voluntary payment and delivery models to finalizing two mandatory models in rapid succession, both in the absence of statutory authority. In the CJR Final Rule, CMS noted:

[A]lthough CJR will be the first Innovation Center model in which acute care hospitals are required to participate, we refer readers to the 2016 Home Health Prospective Payment System (HHP[P]S) Final Rule, which finalizes the Home Health Value-Based Purchasing (HHVBP)

¹¹⁷ 154 Cong. Rec. S6477 (daily ed. July 9, 2008) (statement of Sen. Max Baucus).

model. Home health agencies in selected states will be required to participate in the HHVBP model beginning in January 2016.¹¹⁸

CMS have intended this remark to allay commenters' worries about the novelty of the CJR Model's mandatory participation requirement by pointing out another instance of a similar CMS mandate. However, rather than alleviating concerns, CMS's response here actually causes further unease, regarding both the HHVBP Model's mandatory implementation and the trend of CMS's failure to follow statutory authorities.

With respect to the HHVBP Model, CMS identified its authority for the model under SSA Sections 1102, 1115A, and 1871,¹¹⁹ which are the same authorities it cited as permitting the CJR Model's mandatory implementation.¹²⁰ As addressed above in Section III (A), none of these provisions allows CMS to make models mandatory, and CMS did not attempt to explain why the agency believed these provisions authorized it to mandate participation in the HHVBP Model. Instead, CMS focused on the policy reasons why it wanted to mandate participation in the model (i.e., to gather broader, unbiased data) and insisted that mandatory provider participation was "necessary" to achieve this goal.¹²¹ Still, because basic statutory construction principles prohibit agencies from deviating from clear statutory text to pursue their policy agendas,¹²² none of CMS's cited authorities permit mandatory implementation of the HHVBP Model.

This is problematic not only because it signals a trend of CMS mandating provider participation in CMMI models absent statutory authority, but also because of the underlying attitude revealed by CMS.

¹¹⁸ 80 Fed. Reg. at 73277.

¹¹⁹ Home Health Value-Based Purchasing Model, 80 Fed. Reg. 68624, 68657 (Nov. 5, 2015).

¹²⁰ 80 Fed. Reg. at 73278. In the context of the HHVBP Model, CMS described these statutory provisions as together "authoriz[ing] the Secretary to issue regulations to operate the Medicare program and test innovative payment models to improve coordination, quality, and efficacy of health care services furnished under Title XVIII." 80 Fed. Reg. 68624, 68657.

¹²¹ See *id.* at 68659 ("We believe it is necessary to require all HHAs delivering care within boundaries of selected states to be included in the model" because this "ensures that: (1) There is no self-selection bias, (2) competing HHAs are representative of HHAs nationally, and (3) there is sufficient participation to generate meaningful results.").

¹²² See *e.g.*, *Friends of the Earth*, 446 F.3d at 145; *Engine Mfrs. Ass'n.*, 88 F.3d at 1089; *S. California Edison Co.*, 195 F.3d at 27.

In both the CJR Final Rule and the CY 2016 HHPPS Final Rule, CMS's primary focus was described in terms of benefits of a broad, unbiased data set and of the "need" to mandate provider participation in order to obtain this information.¹²³ CMS's discussions lacked meaningful attention to the baseline question of whether mandating provider participation was permitted under governing authorities. CMS's attempted justification of its authority to mandate participation in the CJR Model was sparse and not reflective of a careful consideration of the statutes, and no explanation of the agency's statutory interpretation (only citation to the provisions) was given regarding the HHVBP Model.

Moreover, CMS appears either not to recognize or not to care about the shaky statutory ground upon which it is mandating participation in CMMI models. By pointing to the HHVBP Model in the CJR Final Rule in response to comments challenging the CJR Model's mandatory implementation as unprecedented and unlawful, CMS is evincing either a woeful lack of attention to the governing authorities, an intentional diversion of attention, or an arrogant belief that its own actions have precedential value regardless of the law. Such a "Look! We're doing the same thing over here too!" response will *not* create statutory authority but *can* result in further overreach as the agency comes to believe its own press. Further, such overreach, and the attendant harm to providers and risk to beneficiaries, will continue unless action is taken to restore accountability to the administrative state.

2. *Challenges in Dislodging Entrenched Policies from the Federal System*

While agency overreach is problematic generally, CMS's overreaching is highly problematic due to the Administration's goal of entrenching the ACA and other Democratic statutory priorities, which effectively incentivizes CMS to act aggressively to get its policies cemented before President Obama leaves office. Moreover, the adverse consequences are greater for regulated parties when entrenched policies lack statutory authority or otherwise violate the law. Entrenchment of the Obama Administration's *lawful* policies may be a political irritation to an incoming Republican administration, but entrenchment of *unlawful* policies should be troubling to any law-abiding citizen, Democrat or Republican.

Once health care policies (lawful or unlawful) are entrenched in the federal system (the United States Code, the Code of Federal

¹²³ 80 Fed. Reg. at 73278; 80 Fed. Reg. at 68659.

Regulations, etc.), unlocking or dislodging them is an extremely burdensome task fraught with risk, political and procedural, for any future administration and Congress, including those naturally in support of and those strongly opposed to the overarching statutes. For Republican opponents of the ACA (and other Democratic statutory priorities), dislodging entrenched federal health policy decisions often comes with political friction from constituents who have grown accustomed to the laws' benefits. Furthermore, in the case of the ACA, Republican Members of Congress who oppose the ACA also face hostility from their home state senators and downright political resistance from state governors in their respective capitals, who, notwithstanding early rhetoric against the law and its Medicaid expansion in particular, are lining up to obtain the generous federal resources associated with Medicaid expansion.¹²⁴

For Democrats in Congress or the White House who may object to the Obama Administration's unlawful implementation of the ACA and other Democrat-backed statutes, dislodging entrenched policy would potentially be even harder, since many of them would have been, passively or actively, involved in the entrenchment. Backing out of positions long-fought-for would conceivably be difficult but not impossible. Thus far, with support from Republicans, Democrats have repealed the controversial tax on medical device sales, delayed for two years the start of the so-called "Cadillac tax" on high-cost health plans, and delayed the fee imposed on all health insurance products for one year.¹²⁵ All of these repeals and delays were extremely popular with consumers, industry, and labor unions, however, so extracting them from their prior entrenched position was not difficult politically.¹²⁶

¹²⁴ See Robert Pear, *State-Level Brawls Over Medicaid Reflect Divide in G.O.P.*, NEW YORK TIMES, Dec. 27, 2015, http://www.nytimes.com/2015/12/28/us/politics/state-level-brawls-over-medicaid-reflect-wider-war-in-gop.html?_r=0. See also Jayne O'Donnell, *President to propose incentive to lure more states to expand Medicaid*, USA TODAY, Jan. 14, 2016, <http://www.usatoday.com/story/news/nation/2016/01/14/president-propose-incentive-lure-more-states-expand-medicaid/78769622/> (identifying further Administration efforts to entrench its Medicaid expansion policy before the next election).

¹²⁵ See generally Consolidated Appropriations Act, 2016, H.R. 2029, 114th Cong. (2015).

¹²⁶ The "institutional pathologies" of Congress slow and complicate efforts to enact health care legislation in the first place, let alone efforts to muster the political will to repeal or enact revisions to existing law. See Gluck, *Symposium*, *supra* note 37, at 14. See also *infra* Part V(B). 140.

Still, the core features of the ACA—the tax credits and subsidies, the Medicaid expansion, the free preventive screening benefits, and, as this Article shows, the less glamorous but still hugely consequential payment and regulatory reforms—continue unabated, despite outcries from stakeholders and from Congress about overreach and aggressiveness by regulators. The truth is, unless health care lawyers remain vigilant from the start, *before these policies become entrenched*, it may be too late to ever uproot them and to make a material difference on behalf of their clients' rights as HHS stakeholders in an era of statutory entrenchment and agency overreach.

V. WHERE DO WE GO FROM HERE?

It is one thing to identify and understand a problem and quite another to propose and evaluate solutions to it; both parts of the equation are essential. Without careful definition of a problem, including its sources and its scope, solutions cannot be formulated or evaluated properly; without an accurate understanding of a problem's magnitude, stakeholders may fail to give the attention necessary to address it. The primary focus of this Article is the former task—definition of the problem of Executive Branch agency overreach, by examining specific examples of CMS *ultra vires* action, situating these examples in the broader context of executive agency self-aggrandizement, and urging health care providers and lawyers to be on the lookout for further instances of this pattern as CMS continues on its mission to entrench the ACA and the Democratic health reform agenda. The remaining section of the Article turns to some potential means of addressing the problem. This discussion is not intended to be exhaustive but rather to call attention to some of the options currently being considered and to offer a preliminary recommendation for congressional consideration. Future work will provide more specific policy recommendations.

A. *Where is the Judiciary?*

Judicial deference to agency statutory interpretations has garnered much attention in recent years, especially leading up to the *King* decision, as well as in its wake. This attention is well-placed, given the high degree of deference courts afford to agencies in statutory cases. A major empirical study of over 1000 Supreme Court cases from 1984 to 2006 involving an agency statutory or regulatory interpretation found an

average agency win rate of 68.3 percent.¹²⁷ Empirical studies of circuit courts have found similar affirmance rates.¹²⁸ Of note, the D.C. Circuit, which decides more than 25 percent of all circuit court cases reviewing agency actions,¹²⁹ defers measurably less than other circuit courts—11 percent or 12 percent less, according to two empirical studies.¹³⁰

Many observers have been critical of these high rates of judicial deference to agencies, contending, among other things, that excessive judicial deference to agencies has “blurred the lines that once separated the Legislative Branch, the Executive Branch, and the Judicial Branch”¹³¹ and that such deference also results in agency self-aggrandizement, as “[a]gencies are emboldened to take more aggressive and daring positions on the assumption that courts are unlikely to rebuff their actions.”¹³² Of note, over the course of the October 2014 Term, Justice Thomas

¹²⁷ 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, 1100 (2007-2008).

¹²⁸ See Richard J. Pierce Jr., *What Do the Studies of Judicial Review of Agency Actions Mean?* (hereinafter Pierce, *Judicial Review*), 63 ADMIN. L. REV. 77, 84 (2011) (citing Thomas J. Miles & Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of Chevron*, 73 U. CHI. L. REV. 823, 849 (2006); Thomas J. Miles & Cass R. Sunstein, *The Real World of Arbitrariness Review* (hereinafter Miles & Sunstein, *Arbitrariness Review*), 75 U. CHI. L. REV. 761, 766-68, 776, 779 (2008); Kristin E. Hickman & Matthew D. Krueger, *In Search of the Modern Skidmore Standard*, 107 COLUM. L. REV. 1235, 1275 (2007); Frank B. Cross & Emerson H. Tiller, *Judicial Partisanship and Obedience to Legal Doctrine: Whistleblowing on Federal Courts of Appeal*, 107 YALE L. J. 2155, 2168, 2172 (1998); Orin S. Kerr, *Shedding Light on Chevron: An Empirical Study of the Chevron Doctrine in the U.S. Courts of Appeals*, 15 YALE J. REG. 1, 30 (1997); Peter H. Shuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law* (hereinafter Shuck & Elliott, *Empirical Study*), 1990 DUKE L. J. 984, 1007, 1008, 1030 tbl. 3, 1038.

¹²⁹ Miles & Sunstein, *Arbitrariness Review*, *supra* note 128, at 794-95.

¹³⁰ *Id.* at 795 (finding 11% less deference than other circuits from 1996 to 2006); Shuck & Elliott, *Empirical Study*, *supra* note 128, at 1041-42 (finding 12% fewer affirmances in 1984).

¹³¹ *Proper Role of Judicial Review*, *supra* note 15 (statement of Senator James Lankford, Chairman of the Senate Committee on Homeland Security and Government Affairs’ Subcommittee on Regulatory Affairs and Federal Management) (Apr. 28, 2015), *available at* <http://www.hsgac.senate.gov/hearings/examining-the-proper-role-of-judicial-review-in-the-federal-regulatory-process>.

¹³² Schiff & Wake, *Agency Overreach*, *supra* note 36, at 106.

repeatedly raised significant challenges to the constitutionality of the administrative state and the judicial deference doctrines.¹³³ Some observers have noted a recent trend at the Supreme Court to scale back its application of existing deference doctrines and have predicted an increase in this practice, and as discussed above, *King* could signal the continuance of this trend.¹³⁴

Should the Court continue scaling back its deference to agency statutory and regulatory interpretations, this could help combat the “aggressive executive action [that] has pushed [the deference doctrines’] latent defects to the surface” in recent years.¹³⁵ As such, movement at the Supreme Court, and as a result at the circuit courts, regarding the

¹³³ See, e.g., *Perez v. Mortg. Bankers*, 135 S. Ct. at 1220, 1221 (2015) (Thomas, J., concurring in judgment) (“Because the agency is thus not properly constituted to exercise the judicial . . . under the Constitution, the transfer of interpretive judgment raises serious separation-of-powers concern”) (“[t]he judiciary has a responsibility to decide cases properly before it,” including “not only constitutional challenges to particular statutes, including those based on the separation of powers, but also . . . more routine questions about the best interpretation of statutes, or the compatibility of agency actions with enabling statutes.”) (internal citations omitted); *B&B Hardware v. Hargis Indus.*, 135 S.Ct. 1293, 1316 (2015) (Thomas, J., dissenting) (raising constitutional separation-of-powers concerns about agency adjudication of “claims involving core private rights”); *Dep’t. of Transp. v. Ass’n of Am. R.Rs.*, 135 S. Ct. at 1254—55 (2015) (Thomas, J., concurring in judgment) (“We have too long abrogated our duty to enforce the separation of powers required by our Constitution. We have overseen and sanctioned the growth of an administrative system that concentrates the power to make laws and the power to enforce them in the hands of a vast and unaccountable administrative apparatus that finds no comfortable home in our constitutional structure.”).

¹³⁴ See, e.g., Richard J. Pierce, Jr., *The Future of Deference* (Oct. 12, 2015) (unpublished article) (on file with the George Washington Univ. L. Sch.), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2672979; Gluck, *Imperfect Statutes*, *supra* note 21, at 94. As mentioned *supra*, two possible outgrowths of *King* are that the Court could expand major questions doctrine at *Chevron* Step Zero to remove more statutory interpretation cases from agencies, or that the Court could apply its own view of the “legislative plan” more proactively to find more statutes clear and unambiguous at *Chevron* Step One. *But see* Hickman, *Unintended Consequences*, *supra* note 25, at 66, 71 (cautioning that “although Chief Justice Roberts arguably tried to make a significant doctrinal statement about *Chevron*’s scope, it seems unlikely that his colleagues intended to embrace the most sweeping interpretation of his views” and that “if a majority of the justices are not really on board with the doctrinal adjustment, then much like *Brown & Williamson Tobacco, King v. Burwell* will fade into obscurity as doctrinally insignificant with respect to *Chevron*’s scope”).

¹³⁵ Grossman statement, *supra* note 75, at 9.

deference doctrines will be important to all regulated parties—both in terms of the level of deference afforded by courts to the agency interpretations that regulated parties may wish to challenge, as well as in terms of the reduction in agency overreach that could potentially follow from agency awareness that courts are not deferring as extensively as in the past. Either more careful scrutiny of agency interpretations and actions by the judiciary or increased agency self-regulation (in the form of closer attention and fidelity to authorizing statutes in the absence of such a heavy hand on the scales in their favor as at present) would be a welcome step in containing agency overreach. Much remains unsettled at present, however.

In particular, the D.C. Circuit recently issued a disconcerting opinion regarding an HHS interpretation of a statutory provision regarding inpatient psychiatric hospital reimbursement.¹³⁶ The court analyzed HHS's interpretation under *Chevron*, upholding the agency interpretation as “not only reasonable but also the best interpretation of the statute”—in and of itself a debatable, but not unusual conclusion.¹³⁷ What is troubling in the opinion is the court going out of its way to note that “[t]he Supreme Court has made clear that courts must give *heightened deference* to [an agency's] interpretation of a ‘complex and highly technical regulatory program’ such as Medicare.”¹³⁸ As mentioned above, agencies already have incentives to push the bounds of statutory language, knowing that courts are highly likely to grant their interpretations deference under *Chevron*. In this light, the D.C. Circuit's recent reaffirmation that it will give “heightened deference” to interpretations of the Medicare statute by HHS and its divisions is highly concerning, due to (1) the added incentives that this stated position of the court gives to HHS and CMS to continue pushing the envelope, counting on receiving increased levels of judicial deference, (2) the fact that HHS has already demonstrated a dangerous pattern of overreach, which may only be exacerbated by more highly deferential review in the D.C. Circuit, and (3) the fact that the D.C. Circuit hears such a high percentage of challenges to agency action and thereby directly controls the outcome in many agency cases and also holds substantial influence over other circuit courts in administrative law matters. Rather than granting “heightened *deference*” to HHS, courts should be applying heightened *scrutiny* to HHS in the face of its established tendency to overstep

¹³⁶ *Wash. Reg'l Medicorp v. Burwell*, 2015 U.S. App. LEXIS 22742 (D.C. Cir. 2015).

¹³⁷ *Id.* at *11.

¹³⁸ *Id.* at *10 (emphasis added) (internal citations omitted).

statutory authority. Because of this troubling reversal of appropriate levels of deference to HHS recently announced by the D.C. Circuit, and the uncertainty in general surrounding doctrinal development at the Supreme Court, the discussion in the following section of congressional solutions is all the more critical.

B. Where is Congress?

In light of the increasing problem of agency overreach, as well as the heightened threat posed by the current Administration's efforts to entrench its health care policies, Congress must act to address these issues. Because of Members' responsibilities to constituents, many of whom benefit from specific acts of agency overreach (when they are the "winners" in the given instance) and from certain elements of the ACA more broadly, and because of the fractious and shortened work weeks in Washington, "politics as usual" effectively prohibits (or discourages) many in Congress from pushing back and addressing agency self-aggrandizement. This characterization does not extend to all Members, however, as those who serve on committees of jurisdiction over health care have probed deeply into the conduct of ACA programs in 2015.¹³⁹ While judicial efforts to decrease deference to agency statutory and regulatory interpretations could help ensure that agencies act in closer accord with their congressional delegations of authority, Congress must do its part as well, despite "institutional patholog[y]" against such action stemming from party politics (i.e., allies of the Executive Branch tend to stay "in line" while opponents are dismissed as "agitators").¹⁴⁰ It is much

¹³⁹ The House Ways and Means Committee and Energy and Commerce Committee, and the Senate Finance Committee, in particular, have convened multiple hearings addressing problematic aspects of the Administration's ACA implementation efforts. See *infra* note 147. Senator Marco Rubio, member of the Committee on Small Business and Entrepreneurship, has led a relentless effort to prevent taxpayer-funded bailouts of health insurance companies under the ACA. See, e.g., *Obamacare Taxpayer Bailout Prevention Act*, S. 123, 114th Cong. (2015). Senators Ron Wyden and Chuck Grassley of the Senate Finance Committee spearheaded an investigation into excessive drug prices that were further enabled by the ACA's Medicaid expansion. S. Prt. No. 114-20 (2015), *The Price of Sovaldi and Its Impact on the U.S. Health Care System*, available at <http://www.finance.senate.gov/newsroom/ranking/download/?id=8c1720be-ed5d-4abb-830b-e4dba70faa83>.

¹⁴⁰ See Gluck, *Symposium, supra* note 37, at 14 (identifying the need for a "study of how Congress's institutional pathologies affect health policy"). Congressional passivity as "patholog[y]" in health policy is in many ways "institutional," largely stemming from: (1) the assignment of particular health care issues to distinct expert panels, enabling Members to easily sidestep calls to address specific issues with the

overdue for Congress to step up its oversight of the regulatory process and agency action, and time is of the essence for the enactment of even incremental regulatory reform initiatives that give Congress and the public more transparency and a greater voice in decision-making and direction of taxpayer resources.

Some tools for congressional oversight have long been in place but have generally been underutilized as a historic matter. Importantly, the APA, enacted in 1946 and described as “the bill of rights for the new regulatory state,”¹⁴¹ includes some built-in safeguards to help ensure transparency and accountability of the rulemaking process and the proper judicial oversight of agency action.¹⁴² The Senate and the House Judiciary Committees have jurisdiction over the APA, which allows these committees to oversee the APA’s operation, study its effectiveness, and, where appropriate, legislate revisions. However, over the years, these committees have largely failed to hold executive agencies to the law under their APA oversight authority, as noted recently by Senate Judiciary Committee Chairman Chuck Grassley in testimony for a Judiciary Committee hearing focused on the need for enhanced agency oversight. Chairman Grassley lamented that, “we see repeated efforts today by agencies to undermine the public’s role in the rulemaking

“sorry, not an expert, not on that committee” dodge; (2) the outsized role played by the annual federal budget process and Congress’s chief actuary, the Congressional Budget Office (CBO), allowing Members to play the “sorry, CBO said it had no time to ‘score’ my bill” card; and (3) the inherent difficulty in passing legislation at all (especially health care or Medicare legislation) in a leadership-driven Congress (cue the “sorry, maybe we’ll look at it next year” deflection). *See id.* at 14-16 (discussing these and other “institutional features of Congress” bearing on health law and policy matters). All of these institutional features essentially create a Congress frozen in its ability to effectively oversee and manage implementation of health care initiatives in federal agencies, which is especially troubling in an era of overreach and entrenchment inside virtually all agencies responsible for implementing the ACA.

¹⁴¹ George B. Shepherd, *Fierce Compromise: The Administrative Procedure Act Emerges from New Deal Politics*, 90 NW. U. L. REV. 1557, 1558 (1996).

¹⁴² For instance, Section 553 of the APA establishes the notice-and-comment rulemaking process, including publication in the *Federal Register*, opportunities for stakeholder comments, and finalization only after the agency has reviewed comments submitted. 5 U.S.C. § 553 (2012). Section 706 of the APA provides that “the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action,” though of course in practice, the judicial deference doctrines have greatly reduced the extent to which courts meaningfully perform these functions of judicial review. 5 U.S.C. § 706 (2012).

process—and tactics that render the notice-and-comment process a mere formality” and called upon the Judiciary Committee “to improve our oversight of [the APA]” to help curb these regulatory excesses.¹⁴³ Enhanced oversight under the existing authority of the Senate and House Judiciary Committees would be a critical first step in addressing agency overreach by helping ensure that safeguards already included in the APA function as intended.

Beyond the Senate and House Judiciary Committees and their jurisdiction over the APA, other committees also have jurisdiction over specific statutes and executive agencies. For HHS and CMS and the federal health care program statutes, the committees of jurisdiction are: House Energy and Commerce; House Ways and Means; Senate Health, Education, Labor, and Pensions; Senate Finance; and to a limited extent, the Senate Special Committee on Aging. Both the House and the Senate also have permanent oversight committees or subcommittees that each have health and entitlement program oversight.¹⁴⁴ The House and Senate Small Business Committees are also frequently approached about federal agency overreach. These committees have authority to call Administration witnesses, issue subpoenas for documents, interview interested parties, hold hearings, and issue reports and findings.¹⁴⁵ In 2015 alone, these committees have used their authority to call multiple

¹⁴³ *Examining the Federal Regulatory System* (Grassley statement), *supra* note 16, at 1, 2. Testimony at the hearing covered a wide variety of existing problems with the regulatory process, including agency failure to comply with existing congressional and executive transparency and accountability requirements, agency “closed mindedness” and “circumvention” of the APA’s notice-and-comment process, and inadequate oversight of “citizen suits.” See *Examining the Federal Regulatory System*, *supra* note 15 (statement of William Kovacs, Senior Vice President, Environment, Technology & Regulatory Affairs, U.S. Chamber of Commerce) (June 10, 2015), at 11, 12, 14, available at <https://www.judiciary.senate.gov/imo/media/doc/06-10-15%20Kovacs%20Testimony.pdf>; *Examining the Federal Regulatory System*, *supra* note 15 (statement of Ellen Steen, General Counsel and Secretary, American Farm Bureau Federation) (June 10, 2015), at 10, available at <https://www.judiciary.senate.gov/imo/media/doc/06-10-15%20Steen%20Testimony%20Update.pdf>.

¹⁴⁴ These committees are, in the House, the Oversight and Government Reform Committee, and in the Senate, the Permanent Subcommittee on Investigations of the Senate Homeland Security and Governmental Affairs Committee.

¹⁴⁵ In general, subpoena power is controlled by the majority and while conventional court rules, including the Federal Rules of Civil Procedure and the Federal Rules of Evidence, do not apply, respondents are entitled to some protections especially under Senate Rules.

witnesses and hold several hearings regarding problems in the implementation of the ACA and other Democrat-supported health policies.¹⁴⁶ Despite this laudable effort, these exercises alone are simply not enough. Congress needs more than a microphone to reign in the excesses of these and other future Executive Branch bureaucrats dedicated to essentially flouting and tying the hands of Congress.

Another existing but historically underutilized tool of congressional oversight was established by the Congressional Review Act (CRA), enacted in 1996.¹⁴⁷ The CRA enables Congress to reject final agency rules by passing a joint resolution of disapproval, a safeguard designed to help restore Congress's ability to supervise executive agencies' implementation of the legislative powers delegated to them by Congress.¹⁴⁸ Since the CRA's enactment, agencies have submitted more than 60,000 final rules to Congress, but Congress has used the CRA process to disapprove only one rule.¹⁴⁹ Congress's underuse of The CRA largely stems from the fact that a joint resolution of disapproval, once passed by both the House and Senate, must be

¹⁴⁶ See, e.g., *Hearing on the State of Obamacare's CO-OP Program Before the House Ways and Means Committee's Subcommittee on Health*, 114th Cong. (2015) (calling Mandy Cohen, CMS Chief Operating Officer and Chief of Staff, to testify); *Hearing on Reviewing HealthCare.gov Controls Before the Senate Finance Committee*, 114th Cong. (2015) (discussing results from the Government Accountability Office's undercover testing of the enrollment and application controls of the federal Health Insurance Marketplace); *Hearing on An Overdue Checkup Part II: Examining the ACA's State Insurance Marketplaces Before the House Energy and Commerce Committee's Subcommittee on Oversight and Investigation*, 114th Cong. (2015) (calling Andy Slavitt, CMS Acting Administrator, to testify).

¹⁴⁷ 5 U.S.C. §§ 801—808 (2012).

¹⁴⁸ For instance, CRA Section 801 requires agencies to submit rules to Congress before they become effective, and CRA Section 802 establishes procedures Congress may use to cause such rules to “have no force or effect.” 5 U.S.C. §§ 801(a)(1)(A), 802(a) (2012).

¹⁴⁹ Specifically, Congress disapproved OSHA's November 2000 final rule on ergonomics in March 2001, and the President signed the joint resolution of disapproval into law on March 20, 2001. U.S. Department of Labor, OSHA, *Ergonomics Program*, 65 Fed. Reg. 68261 (Nov. 14, 2000); S.J. Res. 6, 107th Cong. (2001) (became Pub. L. No. 107-5). See Curtis W. Copeland, *Congressional Review Act: Many Recent Final Rules Were Not Submitted to GAO and Congress* (July 15, 2014), at 12, available at <https://www.acus.gov/sites/default/files/documents/CRA%2520Report%25200725%2520%25282%2529.pdf>.

presented to the President who most likely would veto the joint resolution (supporting the Administration's own agency's rule).¹⁵⁰

Still, Congress could seek to maximize the "less discernable effects" of the CRA.¹⁵¹ As noted by one expert:

CRA resolutions of disapproval can be a valuable tool of Congress of congressional oversight even if the resolution is not ultimately enacted. Simply by introducing a resolution, a Member of Congress can draw attention to a rule of concern, and may put pressure on the issuing agency to delay or withdraw the rule. Recorded votes on the resolutions can put Members on the record regarding controversial rules.¹⁵²

In fact, the 114th Congress has already been making increased use of the CRA (for a variety of complex reasons), with both houses passing resolutions of disapproval three times in 2015.¹⁵³ Congress should continue using the CRA to highlight and address agency overreach, especially during the election cycle when Members may have increased opportunities to leverage the CRA process. This puts political pressure on those who are up for reelection, and seeks to increase the accountability of agencies to Congress and that of Members of Congress to their constituents.

In contrast to the CRA and some congressional committee oversight tools (such as hearings), which are used to evaluate agency action after the fact, Congress also has the ability to address problems of overreach on the frontend by drafting clearer, more detailed statutes, rather than leaving such extensive ambiguities to be resolved by agencies. As Senate Judiciary Committee Chairman Grassley recently observed:

¹⁵⁰ Copeland, *supra* note 149, at 12. While Congress can override presidential vetoes of joint resolutions, as with other legislation, it is not easy to garner the two-thirds majorities needed in both houses to do so.

¹⁵¹ *Id.*

¹⁵² *Id.* at 47. See also Morton Rosenberg, *The Critical Need for Effective Congressional Review of Agency Rules: Background and Considerations for Incremental Reform*, Report Prepared for the Administrative Conference of the United States (July 18, 2012), at 14-17, available at https://www.acus.gov/sites/default/files/documents/CRA%20_%20Final%20Report.pdf (discussing several examples of congressional efforts to use the CRA's joint disapproval process to affect agency action).

¹⁵³ President Obama vetoed one of these joint resolutions, S.J.RES. R.8, addressing a National Labor Relations Board rule, in March 2015 and the other two, S.J.RES. R.23 and S.J.RES. R.24, both regarding EPA rules, in December 2015. Authority regarding vetoing of joint resolutions.

It's equally important that Congress recognize its own responsibility in the expansion of the administrative state. For too long, Congress has delegated in broad strokes, asking the agencies to sort out the details. If Congress is going to ask courts to tackle the tough questions, it needs to be willing to do so itself by reasserting its lawmaking power—and by speaking clearly and precisely when it chooses to use that power.¹⁵⁴

Under the existing deference doctrines under which courts review agency interpretations of statutes and regulations, Congress is incentivized to draft broad statutes (either to ease enactment, or deflect public criticism, or both) and allow agencies to make the detailed decisions required for implementation—a task that often involves picking winners and losers among regulated parties and/or imposing significant regulatory burdens on individuals and organizations—knowing that agency interpretations are likely to be sustained in court.¹⁵⁵ Thus, while Congress certainly profits from the existing arrangement, it must sacrifice some of these political benefits in the service of combating the agency self-aggrandizement that follows from broad and unmonitored delegations of legislative authority to agencies.¹⁵⁶

The APA, CRA, and congressional committee process have all shown their limits. While well intentioned, they have not changed the subject or the environment one bit. Good congressional oversight can embarrass federal agencies and, in the best circumstances, lead to resignations. However, those cases are few and far between, and are insufficient given the size and scale of the threat faced by rogue agencies that are more committed to getting their policies “in the door” than to implementing policies consistent with the rule of law and congressional intent. Congress needs a *new mechanism* to monitor and put an end to this behavior. The mechanism should be neutral enough to survive and thrive under any administration and any concoction of political leadership in the House and Senate; that is, it should be bipartisan.

¹⁵⁴ *Examining the Federal Regulatory System* (Grassley statement), *supra* note 16, at 3303.

¹⁵⁵ *See, e.g.,* Pierce, *supra* note 128, at 84 (citing empirical studies finding that circuit courts and the Supreme Court defer to agency statutory interpretations in approximately two-thirds of cases under the courts' deference doctrines).

¹⁵⁶ Leading thinkers, including Justice Thomas, have argued that such delegation of legislative authority to executive agencies is unconstitutional in the first place, though such arguments are outside the scope of this Article. *See, e.g., Dep't. of Transp. v. Ass'n of Am. R.R.'s*, 135 S. Ct. 1225, 1240-55 (2015) (Thomas, J., concurring).

Moreover, it should give Congress the confidence that the laws it passes are fairly and effectively implemented within the letter and the spirit with which they were written—not ignored or contorted beyond the point of recognition by an agency with any objective in mind other than that of the Members who drafted, argued, revised, debated, voted, and ultimately sent to the President a public law as direct representatives of their constituent taxpayers.

The success of the *qui tam* provisions of the federal False Claims Act (FCA)¹⁵⁷ in curbing waste, fraud, and abuse provides an apt model here, albeit more analogical than actual. The *qui tam* provisions allow individual whistleblowers (“relators”) to pursue cases in federal district court alleging fraud, abuse, and government wrongdoing. Depending on the nature of the case and whether the Department of Justice “intervenes” or “declines” participation, if successful, relators may recover treble damages.¹⁵⁸ The House, particularly the Senate Judiciary Committees, have always been Congress’s strongest supporters of the FCA and of private rights of action pursued by “private attorneys general.” Recognizing that neither the Judiciary Committees nor Congress can monitor every action of every federal agency at once (not even the handful of agencies responsible for implementing the ACA), the Judiciary Committees should consider a narrow, limited private attorney general-like provision that would allow government employee whistleblowers of any level to bring forth evidence of agency overreach (either in development or after the fact) to either the Judiciary Committees or to Congress’s auditors, the Government Accountability Office (GAO), and authorize an investigation based on the whistleblower’s claims. Whistleblowers would need to be protected, including preservation of their anonymity and other reasonable accommodations to secure their status as federal employees. If the investigation concluded that the agency had, in fact, overreached and intentionally violated or recklessly disregarded congressional language and intent in implementing an act of Congress, then the whistleblower should be awarded a remedy, such as a share in the savings associated with termination of employees responsible for the misconduct, a step promotion, and/or a time-off award.

Finally, Congress should carefully consider the regulatory reform bills currently pending, as well as any that may be introduced. Some of these bills are aimed at ensuring adequate congressional review of new

¹⁵⁷ 31 U.S.C. §§ 3729–3733 (2012).

¹⁵⁸ 31 U.S.C. § 3729(a) (2012).

costly regulations before they take effect,¹⁵⁹ while others are focused on eliminating existing regulations that are unnecessary or excessively costly.¹⁶⁰ Still others would require federal agencies to conduct “sunset” reviews of significant regulations—and empower individuals adversely affected by such regulations to petition for “sunset” review—to help prevent the retention of regulations that have become outdated or duplicative.¹⁶¹ Well-designed regulatory reform legislation enacted now could help curb agency overreach if the next administration’s agencies behave like the Obama Administration’s agencies. Such legislation is important in addressing overreach by all agencies and is of critical significance vis-à-vis agencies, like CMS at present, seeking to entrench unlawful policies.

VI. CONCLUSION

Agency overreach and self-aggrandizement permeate the current legal and regulatory landscape, affecting countless sectors of our economy and society. Such unauthorized action is growing for a variety of reasons, including inadequate congressional oversight, excessive judicial deference to agency statutory interpretations, and increase in the number of agencies.¹⁶² Especially in the domain of CMS/HHS where the Obama Administration is working with an intentional strategy of entrenching its policy positions, the longer federal agencies are allowed to aggressively implement policies, the more difficult these unauthorized regulations and practices will be to replace with lawful regulations and

¹⁵⁹ See, e.g., Regulations from the Executive in Need of Scrutiny Act, S. 226, 114th Cong. (2015).

¹⁶⁰ See, e.g., Searching for and Cutting Regulations that are Unnecessarily Burdensome, SCRUB Act, H.R. 1155, 114th Cong. (2015).

¹⁶¹ See, e.g., Regulatory Review and Sunset Act, H.R. 2010, 114th Cong. (2015).

¹⁶² As lamented by the Chief Justice in his striking dissent in *City of Arlington* a few terms back, Congress has established over 50 new agencies in the past two decades, and the ACA “creates, requires others to create, or authorizes dozens of new entities to implement the legislation.” *City of Arlington v. FCC*, 133 S. Ct. 1863, 1878 (2013) (Roberts, C.J., dissenting) (quoting Curtis W. Copeland, *New Entities Created Pursuant to the Patient Protection and Affordable Care Act* (2010), at 1, available [at https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwi6jbjZmJPKAhVJVh4KHSRyDN0QFggdMAA&url=https%3A%2F%2Fwww.aamc.org%2Fdownload%2F133856%2Fdata%2Fcrsentities.pdf.pdf&usg=AFQjCNEGfdik7L6aLqBarhOY4KVyR0b0dg&sig2=9PxmyzNAwhmKPZFmmSStEQ](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwi6jbjZmJPKAhVJVh4KHSRyDN0QFggdMAA&url=https%3A%2F%2Fwww.aamc.org%2Fdownload%2F133856%2Fdata%2Fcrsentities.pdf.pdf&usg=AFQjCNEGfdik7L6aLqBarhOY4KVyR0b0dg&sig2=9PxmyzNAwhmKPZFmmSStEQ)).

policies. Moreover, much of the harm done by agency overreach cannot be undone even once an unauthorized policy has been stopped. By the time an illegal policy is reversed, regulated parties may have already spent thousands of dollars in compliance efforts, not to mention the time and money it may have cost the party that challenged the agency in court and the cost to taxpayers of the government's efforts defending its unlawful policy. Reigning in executive agencies is critical in curtailing such government waste, injustice to regulated parties, and violation of rule of law principles.

Without delay, Congress should step up its oversight of agency action under its existing oversight authority, and should also enact regulatory reform legislation designed to address existing, and prevent future, agency excess. Regulated industry stakeholders and their advocates must remain vigilant with regard to agency overreach, calling attention to unauthorized government action and bringing challenges in court when necessary. In the realm of health care law, in particular, lawyers have the unique opportunity and imperative to contribute to nationwide policymaking efforts, including identifying and combating entrenchment of unauthorized CMS policies and promoting better implementation efforts going forward. As Former Secretary Sebelius underscored at YLS's recent launch of the Solomon Center, "[t]here is no time in our country where there has been more need for people who emerge from a discipline with an integrated knowledge of the impact of law on health and health on law, and what business means to all of that, and can bring that expertise both into the courtroom but into the policy offices across the country . . ."¹⁶³ The Solomon Center's groundbreaking, multidisciplinary approach has immense potential to accomplish its goal of "influenc[ing] regulatory, business, judicial, and legislative policy" going forward, and health care industry stakeholders will be well-served by keeping a pulse on the promising work of the Solomon Center.¹⁶⁴

After years of health reform battles, the attention of Congress and of the electorate in this critical election year is rightly focused on health care. In this era marked by cutting-edge medical advances, including the transformative possibilities of personalized medicine—but also pervaded by threats of increasing costs of care, rising national debt, uncertainty about the future of the Social Security system, and international economic crises—the need for wise, well-informed, measured policy-

¹⁶³ Solomon Center for Health L. & Pol'y, *supra* note 32, at 23:53-24:21.

¹⁶⁴ Solomon Center for Health L. & Pol'y, *About the Center*, available at <https://www.law.yale.edu/solomon-center/about-us/about-center> (last visited Jan. 8, 2016).

making is at a premium. There is vast potential to enhance the well-being of citizens throughout the nation—and the world—with the resources, knowledge, skills, and technology now in existence and in development, and at such a momentous time in history, short-sighted, hasty, and politically-motivated decision-making could result in catastrophic consequences for years to come. Now is not a time to seek to entrench political priorities before the clock runs out or to promote policies that will garner good soundbytes in the popular media and trade press but that will not accomplish the benefits they promise over time. Now is a time for robust discussion of health policy, including voices from academia, government, business, law, and the non-profit sector, in order to capitalize on all the potential gains there are to be made. The Solomon Center stands perfectly poised to accomplish just this—bringing together a wide variety of multidisciplinary experts to debate, research, and explore policy solutions—and to make a vital impact on future health reform efforts. Health lawyers should seek ways of becoming and remaining involved in such efforts, bringing their in-depth knowledge of the federal health law and regulatory landscape and the agencies charged with implementing these authorities as well as their awareness of places where these agencies need to be held more carefully to the governing statutes.

In order to ensure that the benefits of any advances made in health reform are not lost due to illegalities in the substance or procedure of agency implementation efforts, the next administration must make legal implementation a priority. Agency aggrandizement and disregard for the law is in many ways a top-down problem. The next president has the tremendous opportunity and responsibility to strike a fundamentally different tone than the Obama Administration has, and to set our nation back on its proper course, wherein separation of powers is respected by all three branches of government, the rule of law governs, and a short-term political gain mentality is replaced with a longer-term concern for the actual effects of policies on all players, not just on the president's favored groups at the expense of those he wants to make pay for his promises.