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RESEARCH SUMMARY

NO. 4 | OCTOBER 15, 2012

Summaries of critical research and cutting edge proposals by leading policy analysts, scholars, and organizations.

The Affordable Care Act's Rulemaking Process: What the Research Shows

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Abstract

The rush to issue regulations for implementing the most popular parts of the President's health insurance bill resulted in eight "economically significant" regulations of remarkably poor quality, according to Jerry Ellig of the Mercatus Center at George Mason University and Christopher Conover of Duke University. They detailed major deficiencies in the regulatory process, including poor analysis, inadequate cost–benefit analysis, a bias toward regulatory solutions, and a failure to consider alternatives. The authors suggest that the "interim final rulemaking" process used to promulgate these regulations contributes to the problem, much as it did when the Department of Homeland Security used the same process to issue final rules after the 9/11 terrorist attacks.

This paper, in its entirety, can be found at **http://report.heritage.org/rs-04**

Produced by the Center for Policy Innovation

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The Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act or ACA), heralded as President Barack Obama's signature achievement, is intended to reform and expand health insurance coverage. Despite its 906 pages of statutes covering topics from tanning booths to individual and employer mandates for insurance purchases, the scope of regulation—not merely the statutory language—will determine how the law is understood, enforced, and implemented.

The Secretary of Health and Human Services (HHS) is chiefly responsible for developing the ACA's body of regulation. While most major ACA regulations, such as the requirements on employers, do not take effect until 2014, HHS is already putting many regulations into place. The government has promulgated final rules and proposed rules and has generated hundreds of guidance documents, frequently asked questions, forms, letters, and other subregulatory documents that clarify or refine the rules.

Thus far, the most extensive academic examination of this body of regulation is "Beware the Rush to Presumption," a series of three research papers by Jerry Ellig of the Mercatus Center at George Mason University and Christopher Conover of Duke University.[1] Their analyses focus on the process used to craft the ACA regulations, and detail major deficiencies in that process, compared with other regulatory initiatives. In their review of eight "economically significant" ACA regulations[2] promulgated in 2010, Ellig and Conover reveal some key findings. First, agency analysis was often inadequate, falling short of the quality of analysis normally used by HHS and other agencies. Moreover, presidential and congressional politics and pressure heavily influenced the ACA regulatory process.

HHS issued the eight economically significant regulations as "interim final rules." Interim final rulemaking is an expedited process in which rules are created without the normal notice and comment period. Interim final rulemaking is permitted under the Administrative Procedure Act (APA) if normal notice and comment rulemaking is "impractical,

unnecessary, or contrary to the public interest" and is often invoked because of tight legislative deadlines.[3] Economically significant regulations are generally subject to a more rigorous rulemaking, including detailed cost–benefit analysis and reviewing alternative means of achieving the legislative goals.

Biased Analysis. Ellig and Conover found incomplete agency analyses that were insufficient to inform decision making. According to the authors, the result is a bias favoring regulation, based on both underestimated costs and overestimated benefits. In developing the proposed regulations, agency products exhibited a conspicuous lack of alternative approaches.

The overall effect of this bias favoring regulation was substantial. For example, for children with pre-existing medical conditions, the agency overstated the rule's benefits by a factor of three to five, based on the experience of state high risk pools. The pre-existing condition insurance plan overstated the reduction in bankruptcy risk by as much as a factor of eight, a result of overestimating the percentage of bankruptcies related to medical expense and including cases of medical expense–related bankruptcies by the insured. Likewise, Ellig and Conover estimated Early Retirement Reinsurance costs at $9.2 *billion* to $10 *billion* over four years versus HHS estimates of $39.8 *million*. Similarly, they estimated that dependent coverage for children up to age 26 would cost $0.9 *billion* to $1 *billion* annually versus the HHS estimate of $10.4 *million*.

Furthermore, multiple analytical inadequacies skewed the agency analysis. For instance, federal regulators failed to make the important distinction between "transfers" and "efficiency benefits." While an efficiency benefit creates cost savings, a transfer simply moves existing resources from some individuals to others. For example, "uncompensated care" is a transfer because the current system already absorbs the cost. The new regulation only changes the source of funding; it does not reduce costs.

Nor did regulators consider the "crowding out" of existing health coverage, which can have a substantial effect according to the authors. In the Early Retirement Reinsurance Program, the ACA could subsidize plans that would have existed *without* the subsidy.[4] The authors note that the failure to consider these transfers undercuts the regulators' ability to assess the equity of these transfers.

Equity Issues. The authors also contend that the regulators' assumption that early retirees may have a difficult time obtaining insurance due to age and medical condition implies an equity problem. Yet the regulators did not explore the issue beyond this assumption. An equity problem is suggested by the assumption that insured people had been paying what the regulators call a "hidden tax" to cover the uninsured, although the analysis does not clearly indicate how making this tax explicit solves the equity problem.

In other cases, the regulators merely stated or assumed that ACA regulations that remove the pre-existing condition limitations would produce "a meaningful improvement in equity." Yet, as the authors point out, the ACA regulators do not define the term or explain how it was deemed "meaningful."

Similar undefined benefits include "financial risk reduction," "cost savings," and "health benefits"—an odd oversight for a major health regulation affecting millions of Americans. Ellig and Conover discuss the

1. Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules," George Mason University, Mercatus Center, *Working Paper* No. 12-1, January 9, 2012, http://mercatus.org/publication/beware-rush-presumption-part (accessed October 3, 2012); Jerry Ellig and Christopher J. Conover, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules," George Mason University, Mercatus Center, *Working Paper* No. 12-2, January 9, 2012, http://mercatus.org/publication/beware-rush-presumption-part-b (accessed October 3, 2012); and Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part C: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules," George Mason University, Mercatus Center, *Working Paper* No. 12-3, January 9, 2012, http://mercatus.org/publication/beware-rush-presumption-part-b (accessed October 3, 2012).
2. An economically significant regulation is defined as a regulation that has an economic impact greater than $100 million annually. William J. Clinton, "Regulatory Planning and Review," Executive Order 12866, September 30, 1993, § 3 (f). The eight regulations are: (1) dependent coverage for children up to age 26; (2) pre-existing condition exclusions, limitations, etc.; (3) coverage of preventive services; (4) claims appeals and external review process; (5) medical loss ratio requirement; (6) grandfathered health plans; (7) early retirement reinsurance program; and (8) pre-existing condition insurance program.
3. 5 U.S. Code §§ 553(d)(3), 808(2). Interim final rules are promulgated 50 percent more often when there is a legislative deadline, as with the 2010 health care regulations.
4. The crowd-out phenomenon can have a substantial impact. For example, it is suggested to account for 75 percent of the Medicare Part D spending. Gary V. Engelhardt and Jonathan Gruber, "Medicare Part D and the Financial Protection of the Elderly," National Bureau of Economic Research *Working Paper* No. 16155, July 2010, http://www.nber.org/papers/w16155 (accessed October 4, 2012).

availability of established methods to quantify such benefits. The regulators simply assert other ACA benefits without quantifying or explaining them. For example, preventive services are assumed to result in cost savings, a claim disputed by an extensive body of professional literature. Curiously, the regulators did not even address why insurance companies would not cover services that so clearly yield a cost savings.

Costs over Benefits. According to Ellig and Conover, when the understated costs and overstated benefits are corrected, three of the ACA regulations—early retirement reinsurance, dependent coverage up to 26, and pre-existing condition insurance plan—clearly fail a cost–benefit analysis. The correction also raises legitimate questions about whether the benefits actually exceed the costs for two other regulations: pre-existing condition limitations and coverage for preventive services.

The study finds that regulators failed to consider moral hazards, which result when people change behavior because they no longer bear all or any of the costs of their actions, such as the potential for health insurance to make a person more likely to participate in detrimental activities such as smoking and excessive drinking, knowing that insurance will pay for any needed medical treatment. Another form of moral hazard arises when people can use services in which the cost exceeds the benefit, such as going to an emergency room to treat a cold. Unnecessary medical expenses, the researchers note, account for 28 percent of Medicaid spending and for 10 percent of private insurance.[5]

Another component of sound regulatory analysis is an examination of regulatory alternatives, generally one more stringent and one less stringent than the preferred alternative. Ideally, Congress and the public should be informed of the alternatives. In the case of the ACA, HHS did not consider using the IRS definition of "dependent" for the extension of insurance coverage to dependent children up to 26. For preventive service coverage, HHS did not consider covering only those services likely to lead to cost savings or some specified cost per outcome, which could have greatly reduced the cost of preventive services coverage.

Comparative Performance. To ensure their review was not just an academic post hoc review detached from reality, the researchers compared the ACA rulemaking with other agency regulatory work. They found the analysis and the quality of the process fell below the standard agency work product under normal rulemaking conditions.[6] The 2010 ACA interim final rules scored substantially lower than previous HHS regulations. These lower scores are the result of incomplete analysis and limited use of that analysis in creating the regulation.

In their evaluation of the 2010 ACA regulations, the researchers ranked them on a scale of 0 to 60. Two ACA regulations received a score of 13, and the highest ranked ACA regulation received a score of 25—below the average score of previous years. HHS regulations averaged a score of 26 in 2009 and a score of 29 in 2008.[7]

The researchers found similarly low regulatory scores when they looked at the homeland security regulations developed and promulgated after September 11, 2001. These were another presidential priority enacted under a tight congressionally imposed deadline. For these rules, "the agency offered some pieces of

5. Amy Finkelstein and Robin McKnight, "What Did Medicare Do (and Was It Worth It)?" National Bureau of Economic Research *Working Paper* No. 11609, September 2005, http://www.nber.org/papers/w11609 (accessed October 4, 2012), and Emmet B. Keeler et al., "The Demand for Episodes of Medical Treatment in the Health Insurance Experiment," RAND Corporation, March 1988, http://www.rand.org/pubs/reports/2006/R3454.pdf (accessed October 4, 2012).

6. The comparison included all proposed economically significant regulation during the Bush Administration in 2008 and the Obama Administration in 2009, based on previous scoring by the Mercatus Center's Regulatory Report Card project. Additionally, the Department of Homeland Security (DHS) issued economically significant interim final rules in the wake of the terrorist attacks on September 11, 2001. Like the ACA regulations, the DHS rules were created under tight congressionally imposed deadlines and were a presidential priority.

7. The comparison used the Mercatus Center's Report Card method, which scores regulations on 12 criteria grouped into three categories: openness, analysis, and use. Each criterion is scored on a scale of 0 (no useful content) to 5 (comprehensive analysis with potential best practices), for a total possible score of 60. The comparison did not include budget regulations, which score extremely low across the board. The 2010 health care regulations classified as budget regulations received scores not substantially different from the abysmal 2008–2009 budget regulation scores. This method attempts to ensure that the rule makers reasonably covered the major elements of regulatory analysis and provided enough information for a reader to review and verify the method, data, and result. This method closely parallels the Office of Information and Regulatory Affairs checklist of November 2010 because both are based on the direction presented in Executive Order 12866 and Office of Management and Budget Circular A-4. William J. Clinton, "Regulatory Planning and Review," and Office of Management and Budget, "Regulatory Analysis," Circular A-4, September 17, 2003, http://www.whitehouse.gov/omb/circulars_a004_a-4 (accessed October 4, 2012).

theory or evidence but far from a comprehensive analysis."[8]

Ellig and Conover conclude that "incomplete analysis may be a systematic result of presidential priorities and tight deadlines, rather than a problem unique to the health care regulation."[9] To examine this hypothesis further, Ellig and Conover examined the role of presidential and congressional politics on the regulatory process.

Congressional Politics. The authors conclude that Congress often affects the quality and thoroughness of regulations by imposing deadlines. Congress may impose tight deadlines to ensure that a law and its enacting regulations are in place before an election or before new Members take office. Potential changes in composition of Congress and the congressional committees directly overseeing the federal regulators encourage tight deadlines to allow Congress to ensure that the resulting regulations reflect the legislative priorities.

Congress enacted the ACA in the face of public opposition: only 10 of nearly 140 polls between July 2009 and passage of the bill showed majority popular support. Between passage of the bill and August 10, 2011, only one of 87 polls opposed repeal. With the 2010 congressional elections only seven months away, Members of Congress had a clear incentive to put the more popular provisions of the law in place, in hopes that people would support the new law to keep these popular benefits.

Presidential Politics. The White House impact on federal regulatory action is routine. Based on the extensive and detailed formal directives issued by the Clinton and Bush Administrations, agencies often review regulations in light of presidential priorities. This "administrative presidency" model discourages independent agency analysis and limits review by the Office of Information and Regulatory Affairs (OIRA). Agency economists confirm that when presidential priorities create decisions that precede analysis, the subsequent analysis is nothing more than a document written to convince OIRA to approve the regulation.[10]

The ACA was a presidential priority. The President filled key Administration positions with ideological supporters of his ambitious health care agenda, and these key players were deeply involved in the process and championed aggressive executive authority. For example, months prior to the release of a rule, when a question arose about the meaning of the pre-existing condition exclusion for children under 19, HHS Secretary Kathleen Sebelius wrote a letter to a major health insurance industry group declaring a guaranteed issue requirement, even though the law did not require it until 2014.[11]

In short, ACA rules were produced under abbreviated procedures to comply with tight legislative deadlines and to satisfy presidential priorities. Historically, the rulemaking process is not a mere formality, but an opportunity for the agency to gather information. Shorter notice and comment periods, abbreviated OIRA review, and failure to fully analyze costs and benefits short-circuited the usual checks inherent in the process. It also eliminated opportunities for innovative solutions. The formal rulemaking process is designed to allow time for thorough and thoughtful analysis to produce appropriate regulations.

According to the authors, the poor quality of the ACA regulations resulted from tight congressionally imposed deadlines. Because the rules had high stakes for the White House, the federal regulators crafted analysis to support a decision rather than to assist policymakers in making an informed decision. These factors are not unique to the ACA. A similar convergence of presidential priority and congressional pressure resulted in similar procedural shortcuts for a series of interim final rules from the Department of Homeland Security after the 9/11 attacks.

Ellig and Conover conclude that this pattern demonstrates a need for additional procedural safeguards. In addition to reining in the use of interim final rulemaking, they suggest other procedural safeguards, such as requiring formal rulemaking within a specified period for regulations implemented as "interim final rules" or some system of external review of agency analyses.

8. Ellig and Conover, "Beware the Rush to Presumption, Part B," p. 21.
9. Ibid., p. 22.
10. Richard Williams, "The Influence of Regulatory Economists in Federal Health and Safety Agencies," George Mason University, Mercatus Center, *Working Paper* No. 08-15, July 2008, http://mercatus.org/publication/influence-regulatory-economists-federal-health-and-safety-agencies (accessed October 4, 2012).
11. Kathleen Sebelius, letter to Karen Ignagni, March 29, 2010, http://abcnews.go.com/images/Politics/Letter_Sebelius_to_Ignagni_100330.pdf (accessed October 4, 2012).

Summary of Key Findings.

- The early and relatively minor provisions of the Affordable Care Act that Members of Congress believed would be popular took effect more quickly, but the shorter deadlines undermined the quality of the process. Major and more complex provisions of the law—such as the mandates on individuals, employers, and states—must meet deadlines for implementation in 2014.
- The agency analyses of the regulations that implement the early ACA provisions suffered from inadequate cost–benefit analysis and insufficient consideration of regulatory alternatives. Thus, these analyses failed to properly inform the regulatory decision-making process.
- The ACA regulatory process fell below the normal standards of HHS and other agencies in writing regulations.

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