Messy But Fair: The ACA’s Hospital Value-Based Purchasing Program and the Notice-and-Comment Process

Janus Pan, UCLA School of Law

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Comment Submission

“Messy But Fair: The ACA’s Hospital Value-Based Purchasing Program and the Notice-and-Comment Process”

By: Janus Pan*

Abstract: The Centers for Medicare and Medicaid Services (CMS) promulgated a new Medicare program called the Value-Based Purchasing Program (VBPP) as part of the 2010 Affordable Care Act. Like many other regulatory agencies, CMS used the Notice-and-Comment process to issue proposed rules, solicit public comments, and then publish final rules. Conventional literature suggests that CMS should disproportionately favor business interests during the Notice-and-Comment process, mainly due to the business interests’ greater resources and capacity to draft well-reasoned comments. However, this paper argues against this presumption and contends instead that CMS listened equally well to both business interest comments and private citizen comments during the formation of the VBPP. At least in the context of the VBPP and the ACA, CMS appears to be resisting disproportionate sway by business interests and is instead privileging the ACA’s goal of improving healthcare quality.

* J.D., UCLA School of Law expected 2016.
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Introduction

Mike Miller is 74 years old, lives half of the year in Maryland, and the other half in Florida. Mike has Medicare, and undergoes regular medical tests for his health. A recent visit to a Florida cardiologist (for a slow heartbeat that Mike has had all his life) had him undergoing expensive tests and being placed on a 24-hour heart rhythm monitor. As Mike tells it, doctors outside of Florida would have never recommended these unnecessary procedures. “They [the doctors in Florida] were aggressive in encouraging me to have tests even though my doctors in the North never said I needed them,” he said. “And of course the results were all normal.” As Elisabeth Rosenthal writes in her article on Mike and other seniors, “doctors who treat seniors can increase [Medicare] revenues by simply expanding the volume of such services and ordering tests of questionable utility. . . . Those high numbers cannot be explained by the presence of sicker patients, better outcomes or a desire by patients . . . for more treatment.”

Medicare accounts for one of the largest components of national healthcare spending and so any serious legislative attempt at increasing the quality of healthcare per dollar spent must address this program. Within Medicare, the largest spending segments include inpatient hospital services, Medicare Advantage plans, and prescription drugs.

The Hospital Value Based Purchasing Program (VBPP) within the 2010 Patient Protection and Affordable Care Act (PPACA) targets the largest of these segments with the goal of improving hospital healthcare quality per dollar spent. The general idea of the VBPP is to uniformly cut Medicare payments to all participating hospitals, and then reissue the collected pool of money in the form of incentive payments to those hospitals that improve their quality of services or perform at the very top percentile in terms of healthcare quality relative to all other hospitals. This program incentivizes hospitals to improve their quality of services by taking into account both patient experiences and objective measurements of quality, all while remaining relatively budget-neutral. Of course, the biggest areas of contention between supporters and critics of the VBPP concern definitions of “quality” and the fit between providing incentive payments and actually improving hospital quality.

The Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (DHHS) is the federal agency charged with administering

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2 Id. The typical forms of healthcare financing that exemplify this moral hazard of overprescribing procedures include Fee-For-Service (FFS) and Indemnity arrangements. Medicare includes many hybrid forms of financing (such as HMO and PPO plans), but the overall system still contains some healthcare purchasing incentivized by the volume of payments. See also “Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value”, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HHS.gov. Jan. 26, 2015. http://www.hhs.gov/news/press/2015pres/01/20150126a.html.
4 Id.
5 See infra Part I.
the Medicare program, including the VBPP. CMS promulgated final rules and regulations for the VBPP on May 6, 2011, after issuing previous rule proposals and garnering a total of 323 comments from the general public. CMS ostensibly used the public’s comments on the proposed rule to help inform the issuance of the final rule.

Current literature and research predicts that the typical Notice-and-Comment process for any rulemaking will disproportionately favor business interests who have more resources to pressure the rulemaking agency, at the expense of private citizen stakeholders. The general academic consensus is that because of this asymmetrical government influence, business interests are able to sway the form of the final rule to


7 Medicare Program; Hospital Inpatient Value-Based Purchasing Program [hereinafter Medicare Program, VBPP], 76 Fed. Reg. 26490 (May 6, 2011) (codified at 42 C.F.R. pt. 422, 480). There were four versions of the VBPP rule, but only the first two were open for comments. Of those two versions that were open for comments, the later version received 319 comments—the bulk of all the comments for the rule. The first version of the rule received four comments which did not substantively differ from comments and responses of the second version.

8 See Golden, Marissa Martino. “Interest Groups in the Rule-Making Process: Who Participates? Whose Voices Get Heard?” 8 J PUB. ADM’R RESEARCH & THEORY 2:245-70 (1998) (arguing that within many government agencies who promulgate regulations there is a “dearth of citizen commenters” and “the predominance of participation by business interests”); Kimberly D. Krawiec, “Don’t “Screw Joe the Plummer”: The Sausage-Making of Financial Reform”. 55 ARIZ. L. REV. 53, 53 (2013) (contrasting letters from private citizens with “meticulously drafted” letters from industry members, trade groups, law firms, and political consultants in the financial industry); Leslie Book, “A New Paradigm for IRS Guidance: Ensuring Input and Enhancing Participation”. 12 Fla. Tax Rev. 517, 527 (2012) (arguing that in the IRS’s rulemaking process, “the exiting regime for formal and informal public participation . . . has failed low-income and disadvantaged taxpayers” and calling for greater public participation); Mendelson, Nina A. “Rulemaking, Democracy, and Torrents of E-Mail”. 79 GEO. WASH. L. REV. 1343, 1356 (2011) (arguing for more consideration of public comments through the use of easy and affordable technology like e-mail); Michael Herz, “Chair’s Message”. ADMIN. & REG. L. NEWS, Winter 2012, at 1, 2 (reporting that researchers have found that “[t]he administrative state, at least on a macro level, does not seem to be substantially ossified” because “the procedural costs to rulemaking (from the agency’s perspective) are not so high as to prohibit considerable rulemaking activity by agencies”); Pierce Jr., Richard J. “Rulemaking Ossification Is Real: A Response to Testing the Ossification Thesis”. 80 GEO. WASH. L. REV. 1493 (2012) (arguing that “ossification”, or “the long length of time and extensive commitment of agency resources to use the notice and comment process to issue a rule”, is a real problem in the representation of public interests); Rachel M. Werner, R. Adams Dudley. “Medicare's new hospital value-based purchasing program is likely to have only a small impact on hospital payments”. 31 HEALTH AFFAIRS 9:1932-40 (2012) (raising questions about whether the VBPP will substantially alter the quality of hospital care and highlighting the challenges of designing effective quality improvement incentives); Shapiro, Stuart. “Does the amount of participation matter? Public comments, agency responses and the time to finalize a regulation”. 41 POLICY SCIENCES 1:33-49 (2008) (examining nine rules from the DHHS and their accompanying public comments, and determining that “agencies are most likely to change their proposals when they receive a high volume of comments on highly complex rules that are not very politically salient”); Shapiro, Stuart. “When Will They Listen? Public Comment and Highly Salient Regulations”. Working Paper No. 13-15 (2013) (finding that agencies are more likely to make rule changes in response to comments that (i) target more salient rules, (ii) request only minor clarifications, (iii) do not question the agency’s legal authority, and (iv) discuss rules with high political oversight); Yackee, Susan Webb. “Sweet-Talking the Fourth Branch: The Influence of Interest Group Comments on Federal Agency Rulemaking”. 16 J PUB. ADM’R RESEARCH & THEORY 1:103-24 (2006) (analyzing comments from interest groups in reaction to forty federal agency rules and finding “that those who voice their preferences during the notice and comment period rulemaking are often able to change government policy outputs to better match their preferences”).
better reflect their objectives (like profit) rather than goals of society at large (like fairness or justice). This theory applies to a wide variety of lawmaking entities, including the Environmental Protection Agency (EPA), Internal Revenue Service (IRS), and even CMS.

Several dominant theories explain why business interests may have greater influence over rule-issuing agencies than private interests: the business interests may have more resources; the business interests may issue more salient comments; the business interests may be disproportionately influencing the rule-making agency if the rule experiences high political oversight; the business interests may be issuing comments that are more substantive than mere comments requesting clarification; or the business interests may be “capturing” the rule-making agency.9

In the VBPP context, business interest commenters are therefore contrasted with private citizen commenters: the former represents for-profit entities like hospitals, medical device and technology companies, and other healthcare providers like doctors’ associations;10 while the latter represents families, individual healthcare professionals like nurses, or patient advocacy groups like the American Heart Association. Business interest commenters are in general primarily concerned with profitability of the healthcare system, while private interest commenters are concerned with the overall quality and delivery of healthcare services to patients.

Current literature on the Notice-and-Comment process thus suggests that the 323 received comments to the proposed VPBB rule will overly favor business interests like hospitals and profit-making businesses, at the expense of private citizen stakeholders with fewer resources. This paper shows that on the contrary, CMS privileges the goal of healthcare quality improvement while only making changes to the proposed VBPP based on critical comments from business interests that are truly warranted. CMS does not overly favor business interests at the expense of private citizens.

Part I of this paper discusses the history and provisions of the VBPP, along with the general nature of VBPP comments solicited by CMS. Part II of this paper discusses the current literature on the Notice-and-Comment process, and argues that business interests overshadow private citizens in their ability to change rules and regulations in any given setting. Part III of this paper analyzes the 323 comments received on behalf of the VBPP and discusses the corresponding responses and changes issued by CMS for the final VBPP rule. Part IV of this paper analyzes and discusses some implications for the results of Part III’s analysis, including the assertion that CMS is not disproportionately deferring to business interest comments over private citizen comments. Part V of this paper summarizes the key findings from the VBPP Notice-and-Comment process and concludes.

I. The Value-Based Purchasing Program (VBPP)

A. History and Overview of the VBPP

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9 See Part II.A.
10 Examples include the American Medical Directors Association, the Association of American Medical Colleges, and the American Medical Student Association.
In the United States, healthcare costs have been rising without corresponding increases in the quality of services provided.\textsuperscript{11} The VBPP was created as part of the PPACA\textsuperscript{12} and is one of several programs intended to “make hospitals and doctors accountable for quality and more careful stewards of public money” like Medicare funds.\textsuperscript{13} While other areas of the Affordable Care Act target the problems of increasing healthcare access or controlling healthcare costs,\textsuperscript{14} the VBPP focuses on quality as the primary goal and remains relatively agnostic with respect to the other goals of increasing healthcare access and decreasing healthcare costs.\textsuperscript{15} As the overview to the final VBPP rule states, “[t]he overarching goal of these initiatives is to transform Medicare from a passive payer of claims to an active purchaser of quality health care for its beneficiaries.”\textsuperscript{16} Specifically, the VBPP “seeks to encourage hospitals to improve the quality and safety of care for Medicare beneficiaries and all patients . . . by: eliminating or reducing occurrence of adverse events; adopting evidence-based care standards and protocols that result in the best outcomes for the most patients; [and] improving patients’ experience of care.”\textsuperscript{17} Any changes that CMS imposes on their proposed VBPP rule, in response to comments made by the general public during the Notice-and-Comment process, should theoretically therefore be made with an eye towards achieving the goal of improving healthcare quality.\textsuperscript{18}


\textsuperscript{12} Medicare Program, VBPP, supra note 7 at 26490.


\textsuperscript{15} For example, the final VBPP rule states that the Centers for Medicare & Medicaid Services (CMS) “firmly believe[s] that these [VBPP] efforts will increase the quality of care provided, resulting in improved health outcomes. However, we [CMS] will monitor and evaluate the impact of the Hospital VBPP program on access to and quality of care, including monitoring any unintended consequences.” Medicare Program, VBPP, supra note 7 at 26509.

\textsuperscript{16} Medicare Program, VBPP, supra note 7 at 26490.


\textsuperscript{18} One might also argue that the VBPP is an advanced form of the capitation model of payment, where healthcare providers are paid a fixed sum for treating each patient. Capitation incentivizes providers to minimize unnecessary healthcare procedures, and ostensibly provide care only for true quality needs. This is the same goal that the VBPP purports to achieve.
Under the VBPP, CMS measures the quality performance for over 3000 acute-care inpatient hospitals. These hospitals are defined in section 1886(d)(1)(B) of the Social Security Act of 1965, and generally include any hospital located in the United States, but exclude psychiatric, rehabilitation, long-term care, children’s hospitals, and cancer hospitals.

The VBPP then analyzes 26 factors constituting “quality” care at each of these hospitals every fiscal year. The 26 measures thus far for fiscal year 2015 include 12 clinical process-of-care measures (for example, whether surgical patients received venous thromboembolism preventive care); eight patient-experience dimensions (such as doctor and nurse communication) [measured through the Hospital Consumer Assessment of Healthcare Providers and Systems survey, or HCAHPS]; five outcome measures (including 30-day mortality rates for heart failure, pneumonia and heart attack); and one efficiency measure on spending per beneficiary.

CMS assesses each hospital’s total performance in two ways: First, CMS measures a hospital’s “improvement” by comparing each hospital’s score in the 26 factors to that hospital’s baseline period performance, which for the clinical process-of-care outcome measures in fiscal year 2014 was April 1, 2010 to December 31, 2010. Generally, the baseline period performance is a previous full year. This baseline period performance is referred to as the “performance benchmark threshold.”

The second way that CMS assesses each hospital’s performance in the 26 factors is to measure that hospital’s “achievement” against all other hospitals during the same baseline period. The achievement level that hospitals would have to surpass in order to earn achievement points is called the “achievement threshold.” The achievement threshold is the minimum level of performance for VBPP reimbursement consideration. As an example, for fiscal year 2013 the achievement thresholds are set at the 50th percentile of all hospital performance during the baseline period. Therefore, half of all participating hospitals would experience reduced Medicare payment; the “average

21 Frequently Asked Questions, supra note 32. Other hospitals that are excluded include those cited by the Secretary of the Health and Human Services for health-threatening deficiencies, those that do not participate in the VBPP Hospital Inpatient Quality Reporting Program (“IQR”), and those that do not meet the minimum number of cases required by the VBPP.
22 Rice, Sabriya. Reform Update: Some question the value of value-based purchasing. MODERN HEALTHCARE (Aug. 11, 2014), http://www.modernhealthcare.com/article/20140811/NEWS/308119964; see also generally Medicare Program, VBPP, supra note 7. These quality measures are very similar to the IRQ program that CMS first implemented in 2005. Shoemaker, supra note 27.
23 Frequently Asked Questions, supra note 32 at 14.
24 Id.
25 Id. at 15.
26 Medicare Program, VBPP, supra note 7 at 26511.
hospital will be expected to experience reduced margins as Medicare seeks to drive improvements in selected measures of quality.” The other half, of course, would expect to receive increased incentive payments above the initial Medicare payment cut.

Together, a hospital earns both “performance” and “achievement” points which informs their “Total Performance Score” and eventual ranking among all other hospitals. Each hospital bills Medicare through their patients’ Diagnosis-Related Group (“DRG”) system. Examples of DRGs include concussions (DRG 32), heart transplants (DRG 103), and viral meningitis (DRG 21). The VBPP adjusts these DRG payments up or down, depending on the hospital’s performance across the 26 quality factors (again, measured in terms of performance or achievement points). Every hospital in the VBPP program experiences an automatic DRG percent reduction each fiscal year; for fiscal year 2015, the automatic DRG percent reduction is 1.5 percent. The savings in the DRG percent reductions create the pool of available bonuses that the VBPP will then pay out as “incentive payments” for hospitals to perform well across the 26 quality factors. CMS creates a mathematical formula (currently, based on the linear ranking of the hospitals) to translate the hospitals’ scores into incentive payments in the form of DRG adjustments. Hospitals may elect to not participate in the VBPP, and therefore give up the opportunity to earn incentive payments, but they will still be subject to the mandatory across-the-board DRG reductions if they participate in Medicare.

B. Types of Comments Overview

CMS promulgated four versions of the VBPP, with the first two versions being open for comments and the latter two versions comprising technical corrections in the rule. CMS allowed the public to submit their comments on Regulations.gov, the federal website that allows the public to find, review and submit comments on federal documents. Members of the public could type their comments directly into a comment box during the open comment period, and upload an attachment with further supporting documentation if desired. These comments are accessible to all readers on Regulations.gov, and informed CMS’s final proposed VBPP rule. This rulemaking process is generally termed the Notice-and-Comment process.

There are two categories of commenters in the Notice-and-Comment process: (i) business interests, which include hospitals, medical device and technology companies, and other profit-making businesses; and (ii) private citizens. The business interests

29 Id. at 26513.
30 Kinney, supra note 20.
31 Id. at 6.
32 Frequently Asked Questions, supra note 32 at 11. This percentage will rise to 2 percent by fiscal year 2017.
33 Id.
34 Shoemaker, supra note 27; Frequently Asked Questions, supra note 32 at 10.
35 323 Comments were solicited by CMS’s initial versions of the VBPP, and garnered 151 Responses by CMS addressing any changes to the VBPP rule as a result of these Comments. The raw data of comments and responses may be accessed online. “Medicare Program: Hospital Value-Based Purchasing Program,”
usually comment on aspects of rules that would impair their ability to maximize profit. Such examples in the VBPP context include objections to certain measurements of quality, arguments that the VBPP is duplicative of other existing quality regulations, and proposals to change the achievement and benchmark thresholds that ultimately penalize hospitals.

On the other hand, private citizen comments are usually much more generalized and typically offer support for the proposed VBPP; such private citizens may include individuals who have family members that suffered due to poor healthcare quality or current healthcare professionals like nurses who see firsthand the impact of quality incentives on healthcare. Private citizen comments may also include comments issued from large organizations who have aligned interests with individual patients, their families, and the general public. Such private citizen interests in the form of large organizations will also match the private citizen interests of individuals—namely, the quality of hospital services.

The business interests generally have more resources to create a well-reasoned and polished comment in their favor than the private citizens.

II. Conventional Wisdom on the Disproportionate Influence of Business Interests in the Notice-and-Comment Process

The Administrative Procedure Act requires legislative rules to undergo the Notice-and-Comment process whereby the issuing agency solicits public comments on proposed rules, before promulgating binding final rules. It is generally well established that “those who voice their preferences during the notice and comment period rulemaking are often able to change government policy outputs to better match their preferences.”

For example, Stuart Shapiro found that the Occupational Safety and Health Administration (OSHA) made significant changes to one of their proposed rules in 2007,
in response to public comments. In its “ergonomics regulation,” OSHA requires employers to implement programs to reduce musculoskeletal disorders. In the proposed version of the regulation, some manufacturing and materials-handling firms were exempted from the program requirement. After the conclusion of the Notice-and-Comment process, however, “firms with manufacturing and materials-handling jobs were no longer placed in a special category and [were] required to implement a partial ergonomics program regardless of whether an employee had suffered an injury.” This example from OSHA shows that the Notice-and-Comment process had a significant effect on the contents of the final ergonomics rule.

Furthermore, in the Notice-and-Comment process there is often a “dearth of citizen commenters” and a “predominance of participation by business interests.” Mariano-Florentino Cuellar looked at three regulations with high comment volumes and determined that while citizen commenters raised different issues than business interest groups, agencies were more likely to listen to the commenter which was more “sophisticated”. This difference in agency treatment of business interest comments versus private citizen comments can have resounding effects on the final rule. For example, in the IRS context, the frequency differential between citizen comments and business interest comments means the rulemaking process “has failed low-income and disadvantaged taxpayers.” In the EPA context, researchers have found that changes to a set of 90 EPA air-toxicity regulations were four times as likely to favor businesses as other parties. The result of the differential between citizen comments and business interest comments is the “rough consensus . . . that organized interests tend to dominate the public-comment process and [that] businesses have the best chance of being heard at most agencies.”

A. Dominant Theories

The current literature on the Notice-and-Comment process predicts that business interests will have disproportionate sway over the rule-issuing agency and the final rule. This paper argues against this prediction in the VBPP context, however, and shows that

41 Id at 688.
42 Id at 694.
44 Cuellar, Mariano-Florentino. “Rethinking Regulatory Democracy.” ADMIN. L. REV. 57:411-99 (2005). Cuellar also separates out the identities of business interests as those who are sophisticated and concerned with profit (such as financial institutions), from governmental entities, individual private citizens, and “mass membership or public interest organizations” (internal quotations omitted). Id. at 22. In parallel, this paper simply separates out business interests from everyone else and calls the latter category “private citizen commenters.”
CMS as the rule-issuing agency pays attention to all comments fairly, regardless of commenter identity.

**Better-Resourced Business Interests:** The most intuitive explanation for the different efficacy between business interest comments and private citizen comments is that the former is more equipped with resources to issue “meticulously drafted” and better reasoned arguments that would actually influence the rulemaking agency. In the example of financial regulations (such as the Volcker Rule), citizen letters in the Notice-and-Comment process were “short and provide little evidence that citizen commenters even understand, or care, what proprietary or fund investment is, much less the ways in which the Volcker Rule might govern such activities. The contrast with the meticulously drafted, argued and researched . . . letters from financial industry members and trade groups is stark.”

There are clear parallels between the Volcker Rule and the VBPP. Both are highly salient regulations that attract citizen commenters as well as business interests. Both are technical regulations whose comments from private citizens will naturally be much more generalized and less sophisticated, and therefore less persuasive, than comments from business interests with the knowledge and resources to make a well-reasoned and convincing comment. In other words, the regulating agency—whether the Financial Stability Oversight Council in the case of the Volcker Rule, or CMS in the case of the VBPP—has a much better justification (the business interest having the better argument) for bending to the will of a well-reasoned and specifically-supported comment, rather than one from a private citizen which merely expresses some conclusory notions of “justice” or “fairness.” It can thus be hypothesized that well-reasoned arguments will be more effective at changing the proposed rule, and these well-reasoned arguments tend to come from business interests rather than private citizens based on the imbalance of resources in the business interests’ favor.

Several other explanations exist to explain the disparate impact between citizen comments and business comments (besides the argument that business interests are more equipped to issue better-reasoned comments).

**Salience:** First, how visible the rule is to the public (its “salience”) directly correlates to the number of comments received. As Stuart Shapiro writes in his study of

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48 Krawiec, *supra* note 37 at 58.

49 The Volcker Rule was adopted as part of the 2010 Dodd-Frank Act and prohibits banks from proprietary trading, along with restricting commercial bank investment in hedge funds and private equity. “Volcker Rule Resource Center.” SECURITIES INDUSTRY AND FINANCIAL MARKETS ASSOCIATION. http://www.sifma.org/issues/regulatory-reform/volcker-rule/overview/. Like the VBPP, the Volcker Rule was part of a highly salient and politically visible piece of legislation (the Dodd-Frank Act) that garnered opposition from business interests and support from private citizen commenters. McGrane, Victoria. “AFR in the News: Comments Flood In on Volcker Rule.” AMERICANS FOR FINANCIAL REFORM. Feb. 16, 2012. http://ourfinancialsecurity.org/2012/02/afrointhe-news-comments-flood-in-on-volcker-rule/ (“The so-called Volcker Rule has broken the record for attracting the most comment letters submitted on any Dodd-Frank proposal. . . . The vast majority of the letters—more than 16,500 by the Fed’s count—are form letters submitted by individuals urging regulators to stand firm against financial industry attempts to water down the rule, which restricts U.S. banks from making bets with their own money.”) The regulating agency for the Volker Rule is the Financial Stability Oversight Council.

50 Krawiec, *supra* note 37 at 78.

51 Shapiro, Stuart. “Does the amount of participation matter? Public comments, agency responses and the time to finalize a regulation”. 41 POLICY SCIENCES 1:33-49 (2008). The descriptor “salience” may be
the Notice-and-Comment process for nine DHHS regulations, “[i]t is clear that salience, defined as the amount of public attention that a rule receives, may affect how responsive agencies are to public comments.”

Furthermore, the number of comments actually received, along with the complexity of the rule involved, had different effects on the eventual changes to the rule. “When coupled with low salience and high complexity, the presence of a large number of public comments led to significant changes from the proposed rule . . . . On high salience and low complexity rules, high comment volume did not lead to changes from the proposed rule. In addition, regardless of salience or complexity, low comment volume made changes unlikely.”

Yackee in studying 40 rulemakings across four regulatory agencies, further found that “when comments are submitted on both sides of an issue, the side that submits more substantive comments often is more likely to gain agency changes in its direction . . . . Not surprisingly, she found that businesses are more likely to gain changes from agencies than are other types of interest groups” such as patient-advocacy groups like the American Heart Association in the VBPP context (emphasis added).

Thus, if business interests issue more comments than private citizens, especially when the rule is highly salient, then CMS might respond more in favor of the business interests (whether consciously or subconsciously).

**High Political Oversight:** Second, if the rule has high political oversight, then the issuing agency may experience greater pressure from other political branches to bend to business interests. In particular, if a regulation is highly salient to the public, agencies may preemptively seek to change the rules to satisfy “commenters who may complain to Congress or the president.” Therefore, if business interests have disproportionate resources and influence upon other branches of government, agencies may disproportionately seek to change proposed rules to better satisfy those business interests.

High political oversight does not only come from Congress and the president—“agencies may, anticipating judicial review, go out of their way to appear responsive on regulations surrounded by [general public] controversy.” McCubbins, Noll and Weingast argue that procedures like the Notice-and-Comment process are intended to enhance political oversight and so “where political oversight is likely plentiful . . . [a]gencies with Congress, the OMB, and interest groups looking over their shoulders are more likely to defer to commenters and to make concessions where feasible. When the glare of the

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52 *Id.* at 35.
53 *Id.* at 45.
54 Yackee, *supra* note 39.
55 Shapiro, *supra* note 47 at 8. This example from Yackee further underlines the distinction between business interests and private citizen commenters, with the latter including groups that advocate on behalf of private citizens (like the American Heart Association). Again, for the purposes of this paper, business interest commenters are generally primarily concerned with profitability of the healthcare system, while private interest commenters are concerned with the overall quality and delivery of healthcare services to patients.
56 *Id.* at 14.
57 *Id.*
58 *Id.*
spotlight is not as bright, the ability to ignore commenters is greater.” In contrast, in Shapiro’s analysis of two FDA rules, both rules were of low salience—“they were ones that no one was putting pressure on the agency to finalize.” If business interests were able to leverage and increase political oversight more so than private interests, they may be able to overly sway the rule-issuing agency.

Questioning Agency’s Legal Authority: Third, comments that purport to question the agency’s legal authority are unlikely to garner a positive or affirmative change in the rule. “Agencies were far less likely to respond positively to legal arguments than to other types of arguments. And the agencies backed up their responses to legal arguments with lengthy responses defending their negative reactions.” Shapiro further speculates that “[m]any commenters who cite the legal basis for a regulation as their justification likely don’t expect changes, and instead are gearing up for a lawsuit against the regulation. Given this dynamic, the negative agency response and its length are not surprising.” While it does not seem particularly likely that in the VBPP context business interests would question CMS’s authority for the purpose of “gearing up for a lawsuit”, as opposed to having a sincere stake in changing the rule before the final version is issued, it may be true that business interests are more likely than private citizens to issue comments containing legal arguments—simply because business interests on average have more resources and legal and economical stake in the form of the final rule than private citizens. On the other hand, private citizens who have legal arguments against CMS’s authority in mind may actually come together and join up with other patient-advocacy groups like the American Health Quality Association that have resource levels on par with that of traditional business interests. These private citizens and patient-advocacy groups may actually then challenge CMS on their authority to issue a comprehensive program like the VBPP. In any case, the literature would suggest that comments that do challenge CMS’s legal authority (regardless of source) would not yield favorable responses. The issuing agency is not likely to defer to the comment, make the requested change, and jeopardize its own legitimacy.

Minor Clarifications: Fourth, comments that only request CMS to issue minor clarifications of the rule can easily obtain responses from the agency. As Shapiro found in his study of various regulations, “[c]omments merely requesting clarifications in language, without requesting policy changes, lead to agency [responses] more than half the time, whereas substantive comments lead to changes at a significantly lower rate.” However, as Yackee has found in her study where “agencies agreed with 38 percent of requests for substantive changes, it is clear that the public-comment process can produce changes, and thus may have substantive (as opposed to merely) symbolic value . . .” Therefore, if private citizen comments are more frequently mere requests for clarification, then any truly responsive changes CMS might issue to those comments would be lower in number than responses to more substantive comments (such as ones the more well-equipped business interests might submit). CMS might still issue more

60 Shapiro, supra note 47 at 19.
61 Shapiro, supra note 51 at 46.
62 Shapiro, supra note 47 at 18.
63 Id. at 18-19.
64 See infra note 95.
65 Shapiro, supra note 47 at 5.
66 Id. at 18.
overall responses to comments requesting clarification, since the cost to issue such a response and satisfy the commenter is very low. But the likelihood of change or actual degree of change that CMS might impose on the proposed rule is lower with a comment requesting clarification, than with a more substantive comment that discusses the merits of the rule itself.

Agency Capture: Fifth, business interest comments might elicit more changes from CMS than private citizen comments because businesses could be “capturing” agency officials and making an agency beholden to a particular interest group when making agency decisions. The agency capture phenomenon might in turn be explained because “[b]usinesses could (because of greater access to information) provide more useful comments. Or agencies, anticipating business opposition, could propose overly restrictive regulations in order to appear responsive to the eventual comments. . . . Agencies may be more responsive to comments because there are more comments and there is more political pressure to be responsive. Or agencies may feel pressure to produce a proposal that reflects the preferences of their political overseers and hence may be less likely to change the proposal when receiving comments.”

Indicia of the presence of agency capture may be found in CMS’s responses to VBPP comments, for example, if CMS rationalizes any change to the proposed rule based on the rule’s effects on the profit lines of business interests. This final theory of Agency Capture does overlap with other previous theories, including Political Oversight and Better-Resourced Business Interests. Nevertheless, the phenomenon of agency capture is itself distinct enough to warrant its own category of possible explanations behind business interests’ disproportionate influence in the rulemaking process.

B. Secondary Theories

Besides the dominant theories above which purport to explain why business interests have disproportionate sway over private citizens, there are a couple of other secondary theories that claim the opposite: that comments do not have any significant effect on the rulemaking agency and the final rule.

Kabuki Theater: First, there has been a minority of research literature which asserts that the Notice-and-Comment process is either largely symbolic, a method for politicians to ensure that regulatory decisions mirror their preferences, or even merely a form of “Kabuki theater” where agencies do little to respond to the public’s concerns.

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68 Shapiro, supra note 47 at 8-9.
70 McCubbins, supra note 59.
71 Elliott, E. Donald. “Re-inventing Rulemaking.” 41 DUKE L.J. 6: 1492 (1992) (“The primary function of the notice-and-comment rulemaking process in our system has shifted since the enactment of the Administrative Procedure Act (APA) in 1946. What was once (perhaps) a means for securing public input into agency decisions has become today primarily a method for compiling a record for judicial review. No administrator in Washington turns to full-scale notice-and-comment rulemaking when she is genuinely interested in obtaining input from interested parties. Notice-and-comment rulemaking is to public participation as Japanese Kabuki theater is to human passions—a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues.”).
For example, William West studied 42 rules in 2004 and found that because the comment period comes so late in the regulatory process, it is of limited usefulness to the agencies. Instead, the comments merely served to provide information to political overseers who then only made a few small changes in the proposed rule in response to public comments. This alternative “Kabuki theater” theory which asserts that the Notice-and-Comment process is not effective may be validated if CMS’s responses to all the VBPP comments are negative or result in no change at all to the rule (though it is uncertain how valid those comments would have been in garnering a warranted change in the first place).

Ossification: Second, the lack of meaningful or critical input from citizen commenters may exacerbate a Notice-and-Comment process known as “ossification,” where the length of time and amount of committed resources towards the Notice-and-Comment process slows down an organization like CMS towards publishing a final and fair rule. After all, if the Notice-and-Comment process does not represent citizen commenters adequately, the issuing agency (i.e. CMS) might have to spend more time to solicit and consider citizen comments as part of a fair rulemaking process. In its logical extreme, the Ossification theory might cause the rule-issuing agency to not issue a final rule altogether—thereby proving that comments do not have any effect on the final rule at all, since there is no final rule to be had. Of course, other researchers argue that there is no ossification that impedes the general rule-making process from working.

Whatever mechanism predominates CMS’s motivation to make responses to the VBPP comments, the dominant literature would lead one to hypothesize that the Notice-and-Comment process for the VBPP will also disproportionately defer to business interests. However, the analysis of the VBPP comments and responses in the Notice-and-Comment process suggests otherwise.

III. VBPP Comments and Responses

A. Methodology

This paper defines business interests as those who are concerned with profitability as their chief motivator. This paper defines private citizen comments as those who are primarily concerned with the quality of hospital healthcare. (Such private citizen comments may manifest their concern for hospital quality by commenting also on the costliness of healthcare and its accompanying service, e.g., “I am a private citizen concerned that the rising cost of healthcare does not yield better quality of care.”) While business interests may also care about the quality of their healthcare services, they are

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72 West, supra note 69.
73 Id.
74 For further discussion of the normative implications of this paper’s findings, see infra Part IV.C.
76 Michael Herz, “Chair’s Message,” ADMIN. & REG. L. NEWS, Winter 2012, at 1, 2 (arguing that there is no ossification at all because agencies are actually making lots of rules and do not appear to be hindered by the administrative cost of the Notice-and-Comment process. “[T]he procedural costs to rulemaking (from the agency’s perspective) are not so high as to prohibit considerable rulemaking activity by agencies. The administrative state, at least on a macro level, does not seem to be substantially ossified.”).
first and foremost concerned with the VBPP’s effect on the operation of their business and their eventual bottom-line. The identity of the business interests can be frequently ascertained by the business interest’s entity form; hospitals, for example, are presumed to be business interests because effectively no modern-day hospital devotes 100 percent of their revenues to free care. These hospitals will care about profit to some degree.

To test the hypothesis that business interests are better-equipped to issue more well-reasoned and more persuasive arguments that sway CMS, one would expect to see a disproportionate number of CMS responses that defer to business interest comments instead of private citizen comments. Comments from business interests that advocate for a change to the rule are therefore predicted to elicit an actual rule change, while comments from private citizens that request a change to the rule or no change at all are predicted be infrequently acknowledged and considered.

This paper organizes the VBPP comments into four categories: business interest comments that supported the original VBPP proposed rule as is; business interest comments that advocated for a change to the VBPP proposed rule; private citizen comments that supported the original VBPP proposed rule; and private citizen comments that advocated for a change to the VBPP proposed rule. The comments are then further sorted into common themes and complaints, such as for example the VBPP having duplicate effects with other CMS programs, or the VBPP having a poor definition of hospital quality. (See Part III.A below for the full list of common themes.) Finally, this paper evaluates CMS’s corresponding responses to each of these comments to determine the comment’s effectiveness in eliciting the desired change to the proposed VBPP rule.

If CMS often defers substantively to business interest comments, as the dominant literature suggests, then the contents of the comments and responses may lend support to the hypothesis that business interests are better equipped to issue more persuasive comments. However, if CMS does not seem to overly defer to business interests, and instead either (i) changes the rule based on both business interest and private citizen comments equally frequently or (ii) holds firm to the originally-proposed VBPP rule, then this would be evidence for the counter-thesis that the business interests do not have a disproportionate sway over the final rule form.

B. The VBPP Business Interest Comments

Roughly 75 percent of the 323 VBPP comments come from business interests, which include hospitals, insurance companies, healthcare organizations and medical technology and device companies. The remaining 25 percent of comments come from private citizens, including Medicare recipients and nurses.

1. Business Interest Comments In Support of VBPP

77 Comments that merely asked for clarifications did receive corresponding responses from CMS, but were not relevant to the task of evaluating whether business interests comments had a disproportionate effect in swaying CMS’s comments and so were omitted from analysis.

78 This paper also excludes comments that only requested VBPP rule clarifications, since the bulk of the analysis focuses on comments that are clearly business interests (i.e. objecting to the rule for profitability reasons) or private citizen interests (i.e. commenting on the rule for motivations of health service quality).
There were a few business interest comments which did support the proposed CMS rule as is.

Examples include:

The Kentucky Hospital Association (KHA), which represents all 133 hospitals in Kentucky. KHA issued a comment that criticized the VBPP in some respects and agreed with CMS in other respects. For example, with respect to weighting the patient-experience-of-care measures at 30 percent of the Total Performance Score, the business interest wrote that “KHA supports this weighting and does not believe that assigning a 30 percent weight to HCAHPS measures is too high.

“KHA urges CMS to reject proposals to reduce the weight of the HCAHPS domain due to claims that a hospital’s HCAHPS scores are impacted by factors they cannot control, namely, patient severity of illness, race and ethnicity, or a hospital’s size and its rural versus urban location. We also do not support changing the methodology to rate hospitals against other facilities in the same state as opposed to the national average performance.”

In another example, Becton, Dickinson and Company, a global medical technology company that develops, manufactures and sells medical devices, instrument systems and reagents writes:

“[W]e understand that some have raised concerns that including the HAC [Hospital-Acquired Conditions] measures in the Hospital VBP Program effectively “double counts” the HACs against hospitals. However, it is common knowledge, as reported by CMS, that the actual HAC program payment impact, in and of itself, has had extremely minimal impact on hospital finances. Likewise, we view the inclusion of these HAC measures in Hospital VBP as an opportunity for hospitals, given that there are incentives not only for high performance, but also for improvement on the measures. Thus, hospitals who diligently address HACs could actually improve their overall payments, in addition to the collateral value they will recognize in reducing HACs. Thus, the argument that inclusion of HAC measures in the Hospital VBP Program is definitively a double negative to hospital payment is simply not the case.”

80 “HACs” are Hospital-Acquired Conditions where patients pick up an adverse illness from the hospital itself. The number of HACs in a hospital is one of the quality measures of the VBPP. Medicare Program, VBPP, supra note 7 at 26490.
Generally, business interest comments which supported the proposed VBPP articulated their support in very general terms. This general support is difficult for CMS to specifically respond to. In contrast, business interest comments which criticized at least one aspect of the VBPP were much more numerous, specific, fluent, and lengthy. These critical comments provided a much more informative sample on which to judge CMS’s degree of deference to business interests.

2. Business Interest Comments For Changes to VBPP

Most of the comments from the business interests fall into one of the following complaints.

*Comment Type 1 – Too High of Benchmarks:* CMS proposed the achievement benchmark threshold to be equal to the 95th percentile of hospital performance for all patient-experience measures (i.e., measured by HCAHPS). CMS stated that this benchmark “represents demonstrably high but achievable standards of excellence”82. Business interests responded by stating that this benchmark level was too high. Several commenters claimed that this benchmark would require hospitals to achieve near 100 percent success on several patient-experience measures, and that these measures themselves do not incorporate all “clinically relevant exclusion criteria based on every patient’s particular situation.”83

A particular example includes a nurse in Missouri who writes, “I believe that the proposed benchmarks should not be set so high. Yes, we all should strive for perfection. However, we are not perfect and our patients are not perfect. Not all cases are going to "fit" in a measure, some appropriately so. To coin a phrase I hear almost daily, "I am not going to use cookie-cutter medicine." Evidence-based medicine shows what has the best outcomes for MOST patients—not all. Smaller hospitals will get hit harder with these high benchmarks. By using your 10 case-per-year proposal [for AMIs, or Acute Myocardial Infarctions], my hospital will be measured for AMI—what if we have just one case fail? Right there we will go to 90%—below the benchmark. Hospitals are always going to have outliers—it's the nature of treating all humans. Set the benchmarks lower, let us achieve them and improve. Then set the benchmarks higher as we improve to keep us always striving to be the best we can be—not perfect. That is not achievable.”84

*Comment Type 2 – Unfair Opportunity for Lower-Ranked Hospitals:* In addition to the absolute benchmarks being too high, common complaints included the fact that already-high-performing hospitals have “less room to improve” and are therefore disadvantaged from earning performance points as compared to low-performing hospitals.

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82 Medicare Program, VBPP, supra note 7 at 26514.
83 Id.
Intermountain Valley View Medical Center in Utah writes, for example, that in their experience of “years of clinical improvement processes [it] is more difficult to move from 96% to 97% than to move from 21% to 70%. . . . [for example,] Hospital A receives fewer point [sic] than poor performing Hospital B, yet performance to its patients is higher and more consistent over time. . . . [So] CMS should consider using a non-linear formula to calculate improvement points to award more points for improvement in upper scores than for improvement in lower scores for both the HCAHPS and the clinical measures.”

Comment Type 3 – Duplicative Effects of VBPP: Other business interests commented that many of the current 26 VBPP quality measures are duplicative of other quality-measurement efforts by other programs, including the Hospital Inpatient Prospective Payment System (IPPS) and identical quality indicators which were developed in partnership with the Agency for Healthcare Research and Quality (AHRQ). If the VBPP is truly duplicative of other federal programs, then it will only add administrative burdens to business interests while not achieving any of CMS’s purported gains in hospital quality.

A particular example includes the New Jersey Hospital Association (NJHA), who wrote that the VBPP’s measurement of HAC measures are duplicative of the IPPS:

“The HAC measures are the same ones included in the current inpatient prospective payment system (PPS) HAC policy, and also are identical to the measure defined in Section 3008 of the ACA, which would financially penalize hospitals with high rates of HACs. NJHA strongly opposes the inclusion of HAC measures in both the VBP program and the HAC policy because of the opportunity for hospitals to be penalized twice on the same measures.”

Comment Type 4 – Poor Fit Between VBPP and Hospital Quality: Because the VBPP uses both clinical-process-of-care measures as well as patient-experience measures, many business interests objected to the use of patient-experience measures that are obtained from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). The commenters claim that HCAHPS is not a good proxy for quality hospital performance.

Other commenters also objected to the use of general data measures for hospital quality, claiming that this data is not truly representative of the unique hospital’s ability to control certain quality outcomes like mortality or readmission rates.

Another example includes a hospital nurse who laments that the VBPP’s quality measures do not fit actual hospital outcomes and do not consider true hospital contexts (all spelling and grammatical errors are preserved in their original):

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“I believe the government has an obligation to explore the negative relationship that may be occurring as a result of implementing VBP. Hospitals are feeling pressure to change practices and there may be a negative consequence as a result of the government's push to implement P4P. For instance, hospitals are pressured to remove foley catheters and central lines for fear of infection, however, let's consider negative outcomes associated with that. Have fall rates increased as folelys are removed and patients are trying to rush to get to the bathroom in weakened state unassisted? Are mortality rates increasing in severe septic patients as central lines are not put in or discontinued too quickly? It is possible that the government's measures are inadvertently causing harm to patients. HCAHPS is not a reliable measure and should be removed from VBP. Staff can wash their hands 100% of the time and you can have visitors come in and cough and sneeze and not wash their hands causing infection. Hospitals can ask sick visitors not to visit and try to implement compliance with quiet hours, etc and that makes the pt. family angry, so "[patient] experience" scores go down. Hospitals cannot control everything you think they can, like visitor behavior. Outcomes are the sole indicator to focus VBP on, and you have to allow for variance as a certain% of patients are extremely ill and will develop complications and die. Documentation measures and patient experience are not reliable indicators and should not be included in payment plans.”

Comment Type 5 - Criticizing CMS’s Process of Creating the VBPP: Some comments also implicitly criticized the proposed VBPP rule as not providing enough data or information to relevant stakeholders.

An example includes Boston Scientific, the “world’s largest company focused on the development, manufacturing, and marketing of less-invasive medicine [and which] supplies medical devices and technologies . . . .” They write:

“We also suggest that CMS consider incorporating a guiding principle that the value-based purchasing incentive payments awarded in the program should be transparent and easily accessible to all stakeholders. . . .

Specifically, “[w]e also request that hospital-specific adjustments and bonuses made under the Hospital VBP program be made available in easily accessible public use data files. Alternatively, modify the current set of public use files to show what the payment amount would have been in the absence of the Hospital VBP program, the adjustment made as a result of the Hospital VBP program, and the “net” payment amount after any bonus under the Hospital VBP program. Such transparency will ensure public accountability

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for performance, and allow accurate financial modeling for diverse stakeholders of published Medicare payment rates.”

Many of the business interest comments can be seen to harbor concerns with bottom-line profitability. Indeed, some comments make this financial concern explicit; one manager at a mid-sized hospital in North Carolina wrote that “[a]lthough I look forward to the implementation of the [VBPP], I am concerned about how the patient satisfaction statistics will be collected and how often. As this statistic is highly affected by patient’s personal preferences, I am concerned about how this statistic will affect payment.”

C. The VBPP Private Citizen Comments

In contrast, the vast majority of comments from private citizens show support for the VBPP.

1. Private Citizen Comments

Many private citizens who commented on the VBPP were individuals whose family members were harmed by substandard hospital care, while other private citizens were healthcare professionals like nurses who had seen firsthand the effects of poor hospital care. For example, many similar comments from nurses asserted that the VBPP “can have significant impact on safety and quality of U.S. healthcare.” These individuals stated that their personal belief was that “tying conditions like the Hospital Acquired Conditions (HACs) and other patient safety measures to payment will have terrific impact on U.S. healthcare.” A significant number of these private citizen comments also beseeched CMS to not be swayed by “special interest” and “lobbyist” groups, ostensibly the same groups as the business interests.

Furthermore, these private citizens who believed in the efficacy of the VBPP to improve hospital quality also stated “[t]here are many special interest groups that may oppose this rule; however, I believe the data or measures do not need to be perfect to move the motivations of America’s healthcare leaders and caregivers to improving care in this country.”

One particular example is a Medicare recipient who writes, “As a Medicare beneficiary senior in my seventies and having been hospitalized this year for a low grade lymphoma, I know there are huge patient safety risks. Try as they might, my caregivers made mistakes every day I was in the hospital. Please ignore special interest groups who want to delete or water down the Hospital Acquired Conditions portion of the rule. I understand that they may complain that there may not be enough evidence to support the process. I know from what I have read that there is. It is critical that you listen to the

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89 Id.
voice of patients. Please register my support of the CMS Rule. I believe it is critical to tie payment to quality."  

An example of a negative private citizen comment comes from a Utah nurse who writes, “I understand that part of the value-based purchasing rule includes the determination that re-admissions within the same month will be lumped together and counted as the same admission and/or complications of the same admission. This is an unfair method of determination. For instance a patient may be in the hospital for an illness or medical exacerbation then return that same month because of an injury to another part of the body. These would obviously not be related, but since they occur in the same month, they would be connected in the system. Please do not include the "during the same month" determination in the new rule. Although it may be easier for recordkeeping (for some), it is not a fair way to base admissions or payments or value-based ratings.”

2. Large Organizations with Private Citizen Concerns

Positive, supportive examples include the National Business Group on Health, which represents approximately 319 large employers that voluntarily provide healthcare benefits to over 55 million American employees, retirees and their families. (The National Business Group on Health is counted as a private citizen commenter because they are a nonprofit that represents employers’ interests on “important health care problems” and are not a profit-maximizing entity like other business interests.) The National Business Group on Health wrote a comment “in strong support of [CMS’s] efforts to advance patient-centered, evidence-based medicine and improve the quality of health care for all beneficiaries and improve the efficiency of the Medicare program through the [VBPP]. With implementation of the hospital VBP program, CMS is taking the next step towards moving from being primarily a passive payer for health care to an active purchaser for health care by using its enormous power to buy the best possible care for millions of beneficiaries.”

Examples of negative comments from private citizen advocacy groups include the American Health Quality Association (AHQA), which represents the national network of Medicare Quality Improvement Organizations (QIOs). They urge in their comment further “strong protections for QIO data [when reporting measures in the VBPP]. . . . If physicians are concerned about QIO data becoming subject to disclosure and their identity becoming known, potentially for use in litigation, they may be unwilling to

92 Nurse Comment, CMS ID 2011-0003-0185. REGULATIONS.GOV (posted Mar. 10, 2011). http://www.regulations.gov/#/documentDetail;D=CMS-2011-0003-0185. Though this nurse comment could arguably be categorized as a business interest comment, it is also plausible that this nurse is commenting in her capacity as a private citizen who is interested in the fairness and accuracy of the VBPP’s quality measures.
perform reviews for QIOs or their costs for providing the review services could increase significantly.”

The American Heart Association (AHA) also writes that “there must be greater sensitivity associated with outcomes measures; risk adjustment is also needed. To this end, there must be sufficient data on which to validate the chosen risk adjustment methodology used for the measure, as well as two to three year’s [sic] worth of data to ensure that the measure does not result in any unintended consequences. Therefore, the AHA believes that one year’s worth of data on a measure may be insufficient to adequately gauge the appropriate construction of that measure. In this way, we recommend that CMS extend the time required before a measure is eligible for the program to ensure that adequate data is available to fully support the measure’s use.”

Here, both the AHQA and the AHA are providing comments critiquing various aspects of the proposed VBPP, though these organizations represent concerns of private citizens and the general public.

D. CMS’s Responses

It is important to note that almost all types of comments yielded some sort of response from CMS. Out of the 323 comments, CMS issued 151 unique responses—many of which referred to multiple similar comments made in the categories described in Part III.A above.

1. Most Favorable Comments to Business Interests (includes any affirmative changes)

There were a few comments whose corresponding responses from CMS signaled a willingness for future consideration and rule change. One comment from the Ohio State University Medical Center suggested “that CMS should develop a new value-based purchasing program specific to cancer centers.” CMS responded by stating that they would “certainly take [this] suggestion under advisement for future quality improvement efforts.”

Another comment from Trinity Health, which represents 46 hospitals and 400 outpatient clinics in Michigan, opposed CMS’s proposal to implement a subregulatory process for adding or retiring quality measures, and called on CMS to use full notice and

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98 Medicare Program, VBPP, supra note 7 at 26529.

99 Id. While this response is not an affirmative change in the present, it indicates an optimistic opportunity for affirmative change to the VBPP in the future.
comment rulemaking instead. CMS responded with: “We believe that we must act with all speed and deliberateness to expand the pool of measures used in the VBP system . . . however, we are aware of stakeholders’ concerns about the proposed subregulatory process . . . In response to those comments, we will not finalize the proposed subregulatory process for adding or retiring measures. Instead, we have proposed . . . that we might choose to propose to simultaneously adopt one or more measures for the VBP program.” Here, CMS is keeping open the option of proposing future VBPP quality measures, and is not committing at this time to the originally proposed subregulatory process for adding or retiring measures.

And when CMS does decide to change part of the VBPP plan, they do so only after conducting their own internal analyses to validate and verify the commenters’ arguments. For example, when commenters like the Kentucky Hospital Association (which represents 133 hospitals in Kentucky) requested that CMS adopt a 12-month performance period for mortality measures instead of the originally proposed 18-month period, CMS “conducted additional reliability analyses on the hospital-level risk standardized mortality rates . . . using 12 months, 18 months, and 24 months, and have concluded that 12 months of data provides moderate to high reliability. . . . Therefore, [CMS] is finalizing a 12-month performance period of July 1, 2011 to June 30, 2012 for the . . . proposed mortality measures for the FY 2014 Hospital VBP payment determination” (emphasis added). This is a good example of CMS changing one part of the VBPP after listening to a business interest comment.

2. Unfavorable Responses to Business Interests

Too High of Benchmarks: Comments that asserted that VBPP’s standards were so high as to be not achievable were met with the following response:

“We consider a benchmark to be an empirically-observed level of excellent performance to which we believe hospitals generally should aspire. Using the proposed definition of a benchmark (mean value for the top 10 percent of hospitals during the baseline period), typically only about 5 percent of all hospitals will be observed to have achieved the benchmark level for an individual measure during the baseline period.

“However, any number of hospitals could score at or above the benchmark during the performance period, and under the proposed performance scoring methodology, such hospitals would receive the full 10 points on the measure. A benchmark level of 100 percent is a special case in which at least 10 percent of hospitals achieved a 100 percent success rate on the measure during the baseline period. When a benchmark for a measure is 100 percent, at least half of all reporting hospitals will receive at least some achievement points on the measure.

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101 Medicare Program, VBPP, supra note 7 at 26508.
102 Supra note 79.
103 Medicare Program, VBPP, supra note 7 at 26495.
(assuming no general degradation of performance among hospitals), which is the same as every other measure. Arbitrarily setting benchmark levels (for example, at 80th percentile) would undermine its empirically-based definition, as would, for example, arbitrarily setting the benchmark at 100 percent for every measure.104

Unfair Opportunity for Lower-Ranked Hospitals: In addition to comments that higher-ranked hospitals will have “less room to improve” and be disadvantaged compared to lower-ranked hospitals, one hospital commenter wrote: “Those who already beat national benchmarks get no recognition for the work they've already done. They are actually incentivized to do poorly in the short run so they can show improvement to get better payment.”105

CMS writes in response:

“We assume that the commenter is suggesting a scenario in which a high-performing hospital might attempt to intentionally score lower on one or more measures during the baseline period in order to score improvement points during the performance period.

“First, we expect all Medicare hospitals to provide high quality care to their patients regardless of whether they are included in the Hospital VBP program or not.

“Furthermore, we disagree that high-achieving hospitals would have an incentive to lower their performance in order to win improvement points in the Hospital VBP program. We note that under the proposed . . . Methodology, the maximum number of achievement points possible on a given measure is higher (10 points) for achieving the benchmark, than the maximum number of improvement points possible (9 points). It is difficult to envision a scenario in which a high-performing hospital would earn more overall points on a measure (that is, the higher of achievement and improvement points) by intentionally lowering its performance during the baseline period and increasing performance during the performance period versus simply maintaining high performance during the baseline period and seeking to maintain or improve on that performance during the performance period. However, we plan to closely monitor and evaluate the impact of the Hospital VBP program on the quality of care provided to Medicare beneficiaries. . .” 106

Again, CMS is sticking to their original goal of improving hospital quality and only making changes that they believe would further that goal. Simultaneously, CMS assures the commenter that they will continue monitoring these issues for the future in anticipation of needed subsequent changes to the VBPP.

104 Id. at 26515.
106 Medicare Program, VBPP, supra note 7 at 26515, 26534.
**Duplicative Effects of VBPP:** Comments that asserted overlap between the VBPP and other statutes or regulations yielded responses from CMS that they would continue “monitoring the interactions” between various regulations. For example, the American Health Information Management Association (AHIMA), which represents more than 61,000 health information management professionals in the healthcare industry, contended that the VBPP overlaps with other quality measurement programs like the “EHR incentive program and other HHS quality measurement programs.” 107 The AHIMA asked CMS “to address the various incentives created by the Affordable Care Act, how it intends to differentiate among separate policies, and how it will ensure that incentives will not overlap or be duplicative.” 108 CMS responded by stating that “[w]hile there may be specific areas of overlap addressed by the various statutory provisions and policies, [these provisions and policies] represent interrelated but distinct areas of efforts to improve quality in the Medicare program. We will continue to monitor the interactions between the policies cited by the commenter and will continue discussions with stakeholders on this topic.” 109

**Poor Fit Between VBPP and Quality:** Comments that criticized the VBPP’s methodology of measuring quality performance mostly yielded responses that re-asserted the validity of CMS’s measurement methodology. For example, commenters like the Society of Hospital Medicine, which represents 31,000 hospitalists across the nation, 110 “argued that the low incidence rates of HACs, particularly in academic medical centers, would lead to unstable statistics on which to base comparisons between hospitals.” 111 CMS responded by stating that “low incidence of events does not equate to unstable rates for those events . . . [R]eporting their prevalence, though rare, is still meaningful. We believe that [the VBPP] must emphasize patient safety and improved quality of health care, and that all of the proposed HAC measures are important to measure and report.” 112 Therefore, where CMS truly disagreed with the premise or point of a comment, CMS stuck to their original rule proposal in the pursuit of healthcare quality.

**Criticizing CMS’s Process of Creating the VBPP:** Finally, comments that criticized CMS’s methodology in creating the VBPP (for example, asserting a lack of transparency in CMS’s selection of studies and analyses) yielded responses that flatly disagreed. In one instance, a health policy and regulatory consultancy named T. Giovanis & Company 113 commented that “the specific process for how the agency proposes to achieve ‘transparency’ is not described or attained,” 114 and that the VBPP rule did not contain

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108 Medicare Program, VBPP, supra note 7 at 26494.

109 Id.


111 Medicare Program, VBPP, supra note 7 at 26506.

112 Id.


114 Medicare, VBPP Program, supra note 7 at 26491.
sufficient information and disclosure of the “methods and data the agency proposes to use” in developing the VBPP. CMS responded by stating, “We disagree. We believe that we have been transparent in making public our goals for the Hospital VBP program and numerous documents that informed our rulemaking on this program, including the 2007 Report to Congress, Congressional testimony and public listening session transcripts. We also believe that the proposed rule contains detailed information regarding the data and analyses we considered in developing our proposals.”

3. Favorable Comments to Private Citizens

In keeping with the major finding of no undue influence from business interests, there were a few private citizen comments that directly counteracted business interest comments and which CMS deferred to (despite the number of total business interest comments outweighing the number of private citizen comments). For example, many business interests complained that the quality of VBPP data was either incomplete (in the instance of clinical-process-of-care measures), or an imperfect proxy for actual quality (in the instance of patient-experience measures). In direct contradiction, several individual comments stated that they “believe that the data or measures do not need to be perfect to move the motivations of America’s health care leaders and caregivers to improving care in our country.” One example of such a commenter is Joan Liechty, from Newport Beach, CA, who writes:

“I am a working professional and have two family members with mental health issues.

Please record my full support of the proposed rule #CMS-3239-P (Medicare Program; Hospital Inpatient Value-Based Purchasing Program) because it can have a significant impact on safety and quality of U.S. healthcare.

There are many special interest groups that may oppose this rule; however, I believe that the data or measures do not need to be perfect to move the motivations of America's health care leaders and caregivers to improving care in this country.

I give my full support to this rule.

Sincerely,
Joan Liechty”

CMS responded in support of these individual commenters, stating that they believe their chosen quality measures selection process had been endorsed by “consensus-developing entities and through notice and public comment rulemaking . . . .

115 Id.
This has resulted in [CMS’s] adoption of meaningful measures that assess the quality of care furnished by hospitals.”

In other instances, CMS sided with some private citizen comments when they disagreed with business interest comments. The National Rural Health Association (NRHA), for example, agreed with CMS’s use of a linear function to “translate each hospital’s total performance score into an incentive payment . . .” In contrast, there were several hospital associations that opposed the linear model; arguing that CMS needed “to provide greater incentives to lower performing hospitals in the initial implementation of the Hospital VBP program, such as through the use of a cube root exchange function.” CMS replied:

“We agree with the commenters who supported our proposed linear exchange function. It provides all hospitals with the same marginal incentive to continually improve. It more aggressively rewards higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions. It is also the simplest and most straightforward of the mathematical exchange functions discussed in the Hospital Inpatient VBP Program proposed rule.

We disagree with the commenters who stated that we need to provide greater incentives to lower performing hospitals in the initial implementation of the Hospital VBP program, such as through the use of a cube root exchange function. At this time we believe it would be prudent to examine the experience and data from the initial implementation of the program before considering increasing the incentives to lower performing hospitals.”

Again, CMS is offering to keep future options of change open, but will not bend unduly to one type of interest (e.g. business interests) over another (e.g. private citizen advocacy groups).

4. Unfavorable Responses to Private Citizens

Even when a private citizen commenter tried to persuade CMS towards a change in their favor, like over-weighing the patient-experience measures, CMS resisted. This private citizen, who did not sign the comment nor identify himself, wrote:

“I had heard that the patient experience of care was going to be equally weighted to the clinical outcome measures. I was somewhat disappointed when I read it was going to stay as originally proposed at 70% / 30% [in other words, 70% weight to the clinical-process-of-care measures and 30% weight to the patient-experience-of-care measures when calculating a hospital’s final Total Performance Score]. It has been many years in coming that the healthcare industry paid attention to the patient as a true consumer whose perceptions of care should be given the highest

117 Medicare Program, VBPP, supra note 7 at 26501.
118 Id. at 26529.
119 Id. at 26534.
120 Id.
regard. If there is consideration of them [the two types of measures] being equally weighted on the table, I would be fully supportive of that change to the rule.”

CMS issued a direct response in the negative:

“One commenter suggested that we weight the patient experience of care domain higher than 30 percent of the Total Performance Score. . . . However, we disagree with weighting the patient experience of care domain either higher or lower than proposed. As we detailed in the Hospital Inpatient VBP Program proposed rule (76 FR 2457), we considered many factors when determining the appropriate domain weights . . . including the number of measures in each domain, the reliability of individual measure data, systematic effects of alternative weighting schemes on hospitals according to their location and characteristics, and Departmental quality improvement priorities. We also believe that delivery of high-quality, patient-centered care requires us to carefully consider the patient's experience in the hospital inpatient setting.”

Thus, even when CMS had an opportunity to be overly-lenient towards private citizen comments, they did not do so and instead stuck to their original conceptions of quality.

Of course, at the end of the day the majority of private citizen comments still remain in favor of the VBPP as proposed, and consistently beseech CMS to not give in to “special interest groups” like business interests. In response to these shows of citizen support for the VBPP, CMS consistently reiterated their thanks.

IV. Analysis

A. Overall Impression of Comments

Comments and responses like these show that CMS is considering private citizen comments as equal to business interest comments. CMS is paying attention to all comments and taking them into account in pursuing true healthcare quality, beyond merely resisting any proposed change to the rule from either a business interest or private citizen (as the literature would suggest). CMS is seriously considering comments from both business interests and private citizens, and employing them when useful towards CMS’s true motivation. The true motivation for CMS is to improve hospital quality—

121 Private Citizen Comment, CMS ID 2011-0003-0004. REGULATIONS.GOV (posted Jan. 14, 2011). http://www.regulations.gov/#/documentDetail;D=CMS-2011-0003-0004. For the final issued rule on July 5, 2011, CMS only scored two domains—the clinical process-of-care and patient-experience-of-care measures. The other types of measures were to be phased in with their own weights in subsequent years. Medicare Program, VBPP, supra note 7 at 26525.

122 Medicare Program, VBPP, supra note 7 at 26526.

123 As another example, a previous Acting Deputy Director of Strategic Development and Technical Assistance at CMS stated that CMS does affirmatively listen to all comments solicited in the making of regulations, and does find stakeholder input to be very valuable in shaping the final rule or program. Sarah Summer, Guest Speaker at UCLA, Mar. 31, 2015.
not to consciously defer to private citizens, nor to consciously correct any intrinsic bias of overly-deferring to business interests.

Overall, because the vast majority of private citizen comments aligned with CMS’s original VBPP proposal, there were few instances where CMS issued a response disagreeing with a citizen comment. This contrasts with CMS’s responses to the business interest comments, where CMS was much more vehement and vocal about their disagreement with many of the business interests’ suggestions.

These general findings oppose the dominant literature theories which suggest that business interests have disproportionate influence over private citizens in the Notice-and-Comment making process. Moreover, these findings also run counter to the secondary literature theories which suggest that rule-making agencies ignore commenters outright. Instead, the findings from Part III show that CMS is neither privileging business interest comments nor ignoring all their commenters outright; they are pursuing a third path which takes true hospital quality as its goal in dictating the level of appropriate changes and responses to all commenters—regardless of the commenters’ identities.

B. Comments Do Not Support Current Theories of Notice-and-Comment Process

1. Comments Do Not Support Dominant Theories of Disproportionate Business Interest Influence

The literature on the Notice-and-Comment process suggests that CMS would disproportionately defer to business interests. Yet, the comments above show the opposite: CMS maintains the goal of measuring and incentivizing quality healthcare, and does not let business interests sway their measurement methodology or VBPP rule implementation. Instead of bending to business interests, or even overly-deferring to private citizens in any comment they make, CMS appears to be genuinely using quality as the true barometer of whether a proposed comment should change the VBPP program.

Better-Resourced Business Interests: Out of all the possible explanations for why business interests might have undue influence in the Notice-and-Comment process at the expense of private citizen comments, the most compelling is that business interests are better equipped with resources to issue “meticulously drafted” and better reasoned arguments. These comments generally cite evidence for their assertions, whether in the form of own hospital data or aggregate industry data. The requests are also much more specific; e.g. “We request a 90th percentile benchmark instead of a 95th percentile benchmark.” In contrast, private citizen comments are usually much more generalized, e.g. “We support the VBPP because it will improve hospital quality.” Agencies like CMS thus have a broader base and justification upon which to issue a response when they are dealing with more sophisticated comments.

[124] The lack of CMS disagreement with private citizen comments may be in part attributed to the small sample size of available private citizen comments which criticized the VBPP. Therefore, it is difficult to absolutely determine whether CMS is truly agreeing with private citizens because their comments are valid and good policy for the VBPP and hospital quality, or because the private citizen comments are simply easy and convenient for CMS to agree with. This paper argues for the former, but the lack of negative private citizen comments towards providing a true counterweight comparison to the positive private citizen comments is a defect that should be remedied in future studies of the Notice-and-Comment process.
However, despite the literature’s prediction that CMS would respond to and be swayed by business interest comments, the actual VBPP responses show otherwise: CMS does take the time to respond to all comments, most of which are business interest comments, but does not overly-rely on those comments to change the VBPP rule. Instead, CMS uses its goal of improving healthcare quality to guide what changes are appropriate to the VBPP plan. For example, when many businesses objected to what they perceived to be excessively high achievement and performance benchmarks, CMS conceded that:

“[T]ypically only about 5 percent of all hospitals will be observed to have achieved the benchmark level for an individual measure during the baseline period. However, any number of hospitals could score at or above the benchmark during the performance period, and under the proposed performance scoring methodology, such hospitals would receive the full 10 points on the measure. . . . When a benchmark for a measure is 100 percent, at least half of all reporting hospitals will receive at least some achievement points on the measure. . . .[T]his suggests that achieving 100 percent success on a measure is not prohibitively difficult as a portion of hospitals will have actually achieved that standard.”

At the same time, CMS signaled to the commenters that they took the comment seriously by stating that “[a]s new information becomes available concerning possibly unintended consequences of measures, their specifications can be reviewed and revised as necessary. . . .This process is ongoing and, we believe, is a better way to deal with rare cases instead of setting a benchmark at an indiscriminate, low value such as the 80th percentile.” Thus, commenters understood with this response that CMS was guiding their actions based on their genuine perception of how to best achieve hospital quality.

It does not appear that CMS is disproportionately favoring business interests, regardless of whether those business interests have more resources than private citizens in the first place. CMS is considering all comments fairly, even less sophisticated comments from private citizens.

Salience: It is both true that the VBPP had relatively high salience with the public as part of the PPACA and that CMS took the entire Notice-and-Comment process seriously. The ACA is one of the biggest and most sweeping pieces of legislation in recent political history, and within the ACA the goal of improving healthcare quality has been touted in the general media and press. Therefore, it is unsurprising that the VBPP has generated many comments and is highly salient to the public. The dominant literature (for example, by Yackee) would suggest that business interests which submit more comments are “more likely to gain agency changes in its direction” simply because they are more frequent and representative in CMS’s mind. However, the results from Part III show that CMS does respond to nearly all comments and only issues changes when appropriate for the goal of improving hospital quality. CMS is not being subconsciously influenced by business interest comments simply because of their volume. Instead, CMS is taking the Notice-and-Comment process seriously because of the VBPP’s high salience.

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125 Medicare Program, VBPP, supra note 7 at 26515.
126 Id.
127 Supra note 39.
128 Id.
and is using hospital quality (not voluminous business interests) as their true guide towards issuing responses.

*High Political Oversight:* Similarly, the analysis of comments and responses in Parts III and IV do not show disproportionate influence from other governmental agencies to sway CMS towards or against business interests. Because the VBPP directly controls the purse strings of Medicare, which is one of the biggest sources of federal entitlement spending, this program is likely to experience high political oversight. The High Political Oversight theory would suggest that CMS should defer to commenters more when “political oversight is likely plentiful,” but the results of this paper show that CMS actually defers to commenters and makes a change to the VBPP relatively infrequently. Usually, CMS simply acknowledges the importance of the issue flagged by the comments, makes changes if truly warranted by the goal of improving hospital quality, and does not disproportionately sway to business interests—regardless of whether those business interests have the ear of Congress or the President.

*Questioning Agency’s Legal Authority:* A few comments did yield responses which asserted that the commenter’s proposal fell outside the purview of CMS’s authority. For example, when Next Wave, a health policy consulting firm, suggested that CMS establish a “Pay to Share” pool under which “funding would be provided to enable high-rated hospitals to instruct lower-rated hospitals on best practices,” CMS dismissed this proposal by stating that they did not have the statutory authority to implement such a program. As the literature would predict, comments that challenge an improper expansion or limitation of CMS’s statutory authority were not well-received. However, because such comments were very infrequent, it is not clear whether CMS is improperly dismissing private citizen comments in favor of business interest comments, as the literature would suggest. Most likely, CMS is simply dismissing comments outside their statutory authority, regardless of the commenters’ identities.

*Minor Clarifications:* As mentioned elsewhere in this paper, comments requesting minor clarifications of the VBPP are relatively costless for CMS to respond to and are therefore not very informative to the question of whether CMS favors business interests over private citizens. (For what it’s worth, business interests did tend to issue more request for rule clarifications than private citizens, and CMS simply answered them without any fanfare or accompanying rule changes.)

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129 “Medicare: A Primer”, *supra* note 3.
131 It is theoretically possible that the High Political Oversight theory should not even apply in the VBPP case, if all of the business interest commenters do not have any political influence at all with other branches of the government like Congress or the President. However, it is unlikely that any of the large business interests in this paper—hospitals, medical associations, technology companies—have no influence whatsoever with Congress, and especially when the VBPP is such a highly-salient rule. Therefore, the fact that CMS does not overly bend to any business interest does not arise out of the lack of high political oversight, but rather directly contradicts the results that the High Political Oversight theory would suggest.
133 Medicare Program, VBPP, *supra* note 7 at 26494.
134 Comments that merely asked for clarifications did receive corresponding responses from CMS, but were not relevant to the task of evaluating whether business interests comments had a disproportionate effect in swaying CMS’s comments and so were omitted from analysis.
Agency Capture: The final set of explanations for why regulatory agencies are more responsive to business and organized interests include: the fact that business could be “capturing” agency officials; the possibility that there are more business comments and so agencies have more political pressure to be responsive to them; or the fact that agencies could be strategically proposing overly restrictive regulations in order to appear more responsive to the eventual comments.135 None of these explanations seems particularly applicable to the VBPP context: it is hard to imagine that businesses could successfully capture an entire organization as large and complex as CMS; there does not seem to be any evidence that CMS is bowing to more political pressure to be responsive to business interests; and it seems counterintuitive and inefficient for CMS to propose “overly-strict” regulations now just to appear to give concessions later in the future. Rather, instead of seeming to play any political games or tactical maneuvers, it simply appears that CMS is sincerely trying to fulfill the true purpose of the Notice-and-Comment process: Issue a rule proposal that aims for quality healthcare, and then adjust the rule as minimally as necessary in furtherance of that same goal (and also to avoid any unforeseen adverse side-effects). Nothing about the business interests’ identities, nor that of private citizens, would change the decision calculus in issuing proposals, considering responses, and rendering the final VBPP regulation rule.

2. CMS Is Privileging Healthcare Quality As Top Goal

In fact, considering all of the dominant theories collectively, it could very well be the case that CMS is carefully considering all comments because the VBPP is highly salient and politically important. These two factors encourage CMS to not fall victim to the sway of influential business interests. Instead of being disproportionately influenced by business interests, CMS considers the VBPP’s legislative goal of improving hospital quality and uses that goal as their guide towards adopting any changes to the final rule.

When CMS does decide to change part of the VBPP plan, they do so only after conducting their own internal analyses to validate and verify the commenters’ arguments. In the Kentucky Hospital Association example,136 when commenters requested that CMS adopt a 12-month performance period for mortality measures instead of the originally proposed 18-month period, CMS “conducted additional reliability analyses on the hospital-level risk standardized mortality rates . . . using 12 months, 18 months, and 24 months, and [has] concluded that 12 months of data provides moderate to high reliability. . . . Therefore, [CMS] is finalizing a 12-month performance period of July 1, 2011 to June 30, 2012 for the . . . proposed mortality measures for the FY 2014 Hospital VBP payment determination.”137 CMS made this change “in response to the commenters’ concern about how the use of a period that is not equal to a year (or multiple years) could introduce seasonal fluctuations into the measure,” despite the original rule proposal to use an 18-month performance period “in order to be able to increase the reliability of the measure rates by including more cases.”138 In this example, CMS is balancing the increased reliability of the measure when using 18 months of data against the decreased reliability.

135 Shapiro, supra note 47 at 8-9.
137 Medicare Program, VBPP, supra note 7 at 26495.
138 Id.
reliability of the measure from introduced seasonality. As a measured and reasonable compromise, CMS agreed with the commenters that 12 months of data were sufficient for the mortality measures. Again, CMS is using its own analysis and intuition as to what constitutes “quality healthcare” (i.e. “increased reliability”) and what changes proposed by the commenters are appropriate for the VBPP. CMS is not overly-relying on any group of comments, either sophisticated ones from business interests, or simplistic ones from private citizens. Nor is CMS stubbornly refusing to make any changes at all to the VBPP as a result of the Notice-and-Comment process, as this comment example illustrates.

3. Comments Do Not Support Kabuki Theater Theory

While the Kabuki Theater theory might suggest that all of CMS’s responses to comments would be negative or neutral, this theory does not bear out. Instead, CMS is affirmatively considering all comments seriously and in good faith towards achieving a VBPP rule that would result in improved hospital quality. This includes making changes to the VBPP inspired by comments, when warranted (for example, finalizing the 12-month period for the performance period instead of an 18-month period). This is the directive of the VBPP legislation and the Notice-and-Comment process, and is actually what CMS is doing.

Furthermore, it is true that CMS does use both private citizen and business interest comments to influence their decision-making of the VBPP (as shown in Part III.D.3, supra). In the National Rural Health Association example, CMS agreed with private citizens’ support of the linear exchange function over many business interest arguments to use a different mathematical ranking function.

When CMS does respond to comments with promises and assurances that they will “continually monitor” further developments in the rollout of the VBPP, and use continued stakeholder input to inform further VBPP amendments, they are seriously engaging with the commenter and explaining valid reasons for the temporary postponement of any immediate change. For example, on the issue of hospitals transitioning to the ICD-10 coding system and its uncertain effects on the VBPP, CMS wrote in response: “We will closely monitor the impact of ICD–10 implementation on the Hospital VBP program[,] measure achievement and improvement trends[,] and consider this information in future rulemaking. We agree that this fundamental change in categorizing diagnoses and procedures could potentially impact Hospital VBP performance scores through changes in measure rates due to measure population definition changes and coding definition changes.” Here, CMS agrees that the ICD-10 issue is a significant and important one, and also simultaneously recognizes that any advance accommodation to the VBPP for this issue could very well be premature and result in adverse consequences. CMS is therefore balancing the risk of moving too early in changing the VBPP, against the proposed benefit of bending to this commenter’s suggestion. They decided ultimately, as the rule-issuing agency, that instituting the

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139 Supra Part IV.B.1. See also Summer, note 123.
141 Medicare Program, VBPP, supra note 7 at 26537.
requested change in this case would run counter to the goal of improving hospital quality. Therefore, CMS did not accede to the commenter’s request.

What this exchange shows is that CMS devotes considerable time and resources towards thinking about every comment seriously. (Other examples of CMS acting in good faith include CMS’s constant acknowledgement of thanks for all the submitted comments, regardless of their content or commenter’s identities.) CMS is not deferring to proposed changes to the VBPP in order to “play the role of attentive regulator convincingly,” as the Kabuki Theater theory might suggest. In contrast to West’s study of 42 rules, a non-trivial number of VBPP comments actually elicited an affirmative change to the initial-proposed VBPP: removing individual AHRQ measures which were duplicative of composite AHRQ measures, or electing to not finalize CMS’s initial proposed subregulatory process for adopting and retiring certain VBPP measures in the future. Therefore, unlike West’s study which showed that the comment process is of “limited usefulness” to the agencies, in the VBPP case the comments actually did result in a few changes to the VBPP. At the very least, it is clear that CMS is using the comments to flag important issues that may arise with the VBPP in the future (such as continued interaction between the VBPP and other federal programs; adverse consequences of the proposed linear exchange function upon both high-performing and low-performing hospitals, etc.).

Even when CMS’s response is merely to promise continued monitoring of an issue, they very rarely ignore a comment outright or fail to take it seriously. Thus, there is little fear that for the VBPP, the Notice-and-Comment process is largely symbolic or ineffective.

4. Comments Do Not Support Ossification Theory

The Ossification Theory would propose that the high volume of comments would require so much time and so many resources from a rule-issuing agency that the final rule may not be issued at all, leaving all the commenters in the dust without any influence whatsoever. Here, it appears that there were seven months between the very first rule proposal and the final issued rule, so it does not seem as if this length of time indicates severe ossification in the Notice-and-Comment process. (In contrast, the average

142 West, supra note 69.
143 Medicare Program, VBPP, supra note 7 at 26507.
144 Medicare Program, VBPP, supra note 7 at 26508.
145 West, supra note 69.
146 The small number of changes that CMS does impose as a result of comments does not necessarily mean that these are token responses by the agency as part of their “Kabuki theater”. It could very well be, as this paper argues, that these few comments were the only ones that CMS felt could warrant affirmative changes to the VBPP program and actively advance the goal of hospital quality. Further empirical work would have to be conducted to determine the statistical significance of these few VBPP changes that CMS adopts.
147 See West, supra note 69.
148 There were four versions of the VBPP, though only two versions were open for substantive comments. 319 of the total 323 comments were received in the earlier version that was open for comments. The first version was issued on January 7, 2011, and the last final rule was issued on July 5, 2011.
149 The average timespan for a complete Notice-and-Comment process obviously varies drastically with the scope of the proposed rule, the statutory deadline requirements for the rule to be finalized, and even the specific point in a President’s tenure. For example, there are more completed rules in the last three months
timespan between OSHA’s proposed rules and final rules from 1988 to 2000 was four years.\textsuperscript{150} There does seem to be a large amount of resources dedicated to the Notice-and-Comment process. But, as mentioned before, CMS appears to be considering all comments seriously, and so perhaps the amount of resources spent in this process is worth the increase in hospital quality and degree of stakeholder engagement. Therefore, the amount of resources spent does not seem disproportionate to the carefully calibrated result of the final rule. There does not seem to be ossification occurring in the VBPP Notice-and-Comment process; on the contrary, this paper confirms that there is serious engagement on the part of CMS to respond to concerns articulated by all commenters, regardless of their identities or institutional bargaining power.

Therefore, none of the dominant theories posited by the literature review in Part II which purport to explain the differential efficacy of private citizen comments versus business comments bear out. Furthermore, neither of the secondary theories predicting the inefficacy of comments bear out either. Instead, CMS is considering all comments seriously, and not giving more deference to any set of commenters simply because of their form or frequency.

C. Avenues of Further Research

One might characterize CMS’s unwillingness to deviate from their proposed VBPP rule as the agency being intractable. It is true that the majority of CMS’s responses to business interest comments are neutral or unfavorable, rather than being an affirmative change as the comments often requested. However, it is less clear whether this lack of bending to business commenters is a result of (1) being defensive in the face of an excess of critical business comments, (2) a conscious effort on CMS’s part to specifically counter the dominant theories and \textit{not} bend to business interests, or (3) actual justification on CMS’s part to respond neutrally or unfavorably to business interests because that is what upholding true hospital quality demands. This paper suggests the last reason as the true explanation, based on the findings in Part III of CMS’s equal consideration of both business interest and private citizen comments.

Similarly, one might characterize CMS’s acknowledgment of positive, praising private citizen comments as empty and without teeth, since these private citizen comments merely reaffirm CMS’s original work and serve to validate CMS as sort of a litmus test for the agency’s prior work. Critics might see these positive citizen comments—and therefore CMS’s corresponding responses—as subsequently uninformative to the question of potential bias in CMS’s rulemaking. However, it is again less clear whether CMS’s positive responses to these positive private citizen comments are (1) a result of bias towards the private citizen comments, or (2) the correct response if one were truly concerned with upholding hospital quality as the ultimate goal of the Notice-and-Comment process. Again, this paper argues the latter.

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\footnotesize{\textsuperscript{150} Shapiro, \textit{supra} note 60 at 694.}
Looking at some preliminary results, a recent California Healthline article shows that few California hospitals will actually profit under the VBPP; “52% will receive a penalty” under the VBPP program.\(^{151}\) The fact that the majority of hospitals, as part of the businesses group, do not profit under the VBPP’s incentive payments is one result of CMS sticking to their goal of upholding quality healthcare. However, the normative evaluation of such a result remains yet elusive. On the one hand, the positive fact that hospitals are being penalized in the VBPP speaks to the program’s efficacy in providing motivations to increase hospital quality. For example, though some hospital advocates questioned the VBPP’s program at the outset to accurately measure and effectuate improvement in hospital quality,\(^{152}\) many hospital executives are now truly responding to the dual carrot-and-stick incentive of withholding Medicare funds and only returning them when the hospital achieves a certain level of quality. For instance, Thomas Filiak, the chief operating officer at Auburn Community Hospital in New York which received the largest VBPP penalty in 2012, said that his hospital has begun initiatives to lower noise near patient hallways, improve the quality of food, and focus teams of workers on patient health problems to improve overall performance.\(^{153}\)

On the other hand, further empirical research would have to be conducted to evaluate the actual causal relationship between the VBPP and improvements in hospital quality. It is possible that the VBPP is penalizing hospitals without any attendant aggregate improvement in hospital quality; the program could be merely shifting funds around from hospital to hospital without a net positive effect on the health of Americans. Therefore, the “success” of the VBPP program itself, separate from its success in formation through the Notice-and-Comment process, will have to be determined in the future.

V. Conclusion

Despite the disparity between the number of citizen comments and business interest comments, the majority of CMS’s responses to comments do not deviate from the proposed VBPP rule. Instead, CMS promises to continue monitoring many objected issues, and consistently defends their VBPP rule rationale in upholding and improving the quality of healthcare when they do make changes to the proposed VBPP rule. CMS responds to both private citizen as well as business interests comments seriously, and does not let the identity of the commenter nor the frequency of their comments unduly influence the Notice-and-Comment process for the final rule’s goal of healthcare quality improvement. CMS privileges the goal of healthcare quality improvement while only making changes to the proposed VBPP based on critical comments from business interests that are truly warranted.

Dominant theories that explain why business interests may have disproportionate influence over a rule-issuing agency (e.g., business interests are better equipped to issue better-reasoned comments; business interests may be capturing agencies; etc.) are directly


\(^{153}\) Rau, supra note 13. As Filiak said, “We know we started off at the bottom, but we are going to work our way to much more acceptable scores.”
contradicted by CMS’s fair consideration and response to all comments. Secondary
theories that predict the symbolic posturing of the Notice-and-Comment process also do
not bear out in light of CMS’s affirmative changes and acknowledgement of the
comments’ proposed rule modifications.

The findings of this paper paint the Notice-and-Comment process for the VBPP in
a positive light. It appears the Notice-and-Comment process is working as intended, with
CMS affirmatively considering all comments in good faith. In contrast to what the
dominant literature would suggest, this is a good sign for further Notice-and-Comment
processes for other regulations. However, further research would have to be conducted to
connect the success of the Notice-and-Comment process to the success of the VBPP
specifically. Additionally, any single commenter may argue that the Notice-and-
Comment process for the VBPP was a failure if their personal proposals were not adopted
by CMS. In the aggregate, however, it appears that CMS is taking healthcare quality for
all as their true guide towards considering and adopting comment proposals, not the
identity and disproportionate influence of business interests.