A SIGNATURE STUDY ON HOSPITAL CONSOLIDATION VIOLATES THE DATA QUALITY ACT

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I. Introduction

A. Purpose of CRE's Analysis

In this paper, the Center for Regulatory Effectiveness (CRE) will analyze a study published in *Health Affairs* which asserted that health insurance companies have insufficient leverage when negotiating with healthcare providers.[1] The study has been discussed in Forbes and other major publications.

CRE will evaluate the *Health Affairs* study to determine whether it complies with the science quality standards set forth in the Office of Management and Budget's (OMB's) government-wide "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies"[2] and related OMB guidance documents implementing the Data Quality Act (DQA).[3] The DQA is discussed in greater detail below starting on p. 8.

It should be noted that the DQA applies equally to federally-developed studies, reports and other agency information disseminations and to third-party documents which agencies use or rely on in developing their own information products. Thus, if the *Health Affairs* study is not DQA compliant, federal agencies would not be able to use the document in any of their analyses, reports, regulations or other information disseminations since it would not meet the federal data quality requirements set by Congress and OMB.

B. Background

1. CRE Staff: Extensive Experience Analyzing Health Care Policy Proposals

The Center for Regulatory Effectiveness[4] (CRE) has long been recognized for its analyses of federal health care policy proposals; CRE's analyses focus on assessing the expected regulatory and business impact of influential health policy documents. For example, in 2004, a report by the Joint Economic Committee of the US Congress discussing CRE's analysis of a major healthcare proposal stated,

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[1] Robert A. Berenson, Paul B. Ginsburg, Jon B. Christianson and Tracy Yee, "The Growing Power Of Some Providers To Win Steep Payment Increases From Insurers Suggests Policy Remedies May Be Needed," Health Affairs, May 2012, Vol. 31, No. 5, pp. 973-981, ("Berenson 2012") *available at* http://content.healthaffairs.org/content/31/5/973.abstract.

[2] *Available at*, http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf.

[3] See, http://thecre.com/post/.

[4] CRE is a regulatory watchdog and consequently acts in its own name not the name of its sponsors. CRE sponsors include a broad range of stakeholders in the healthcare industry, including durable equipment manufacturers, drug manufacturers, hospitals, pharmacies, insurers and physicians.

> *A recent study by the Center for Regulatory Effectiveness examined the Kerry health plan to assess its regulatory impact on businesses. Although the Kerry health plan is largely vague about many of the details that would accompany actual legislation and reform, the CRE study estimated the regulatory mandates that would be required in order to implement the plan. The report concluded that the Kerry health plan "would, conservatively, impose at least 225 regulatory mandates on businesses that participated in the plan. These mandates would be in addition to the uncounted number of additional regulatory mandates inherent in other aspects of the [Kerry health plan.]*.[5]

In performing the 2004 study, CRE staff leveraged their extensive experience in health care analysis. For example, a landmark 1994 study[6] of the then-proposed Health Security Act by the same authors was favorably cited by diverse organizations ranging from the DLC[7] to the Heritage Foundation.[8] Much more recently, the 1994 report was highlighted in a magazine article on health policy, thus demonstrating the enduring value of CRE's health care policy analyses.[9]

2. Health Insurers and Hospitals: An Inter-Industry Dispute with National Implications

Ensuring that federal regulatory policies are cost-effective, and ensuring that cost effectiveness can be demonstrated through the transparent use of high quality data, is a prime concern of CRE. For example, the Congressional Research Service, citing a CRE study regarding the cost-effectiveness of independent agency regulations noted that

> *Some observers have... argu[ed] that independent regulatory agencies issue regulations that have a significant impact on the economy (about $230 billion per year according to OIRA) but their rules often contain little quantitative information on regulatory costs and benefits.*[10]

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[5] "An Analysis of Senator Kerry's Health Plan: A Joint Economic Committee Study," Joint Economic Committee, United States Congress, October 2004, p. 19.

[6] Jim Tozzi, et al., "The Regulatory Requirements of the Health Security Act," Multinational Business Services, 1994.

[7] David B. Kendall, "Health Care Price Controls: A Cure Worse Than the Disease," DLC Briefing, June 9, 1994, *available at* http://www.dlc.org/ndol_ci88b7.html?kaid=111&subid=138&contentid=1420.

[8] Robert E. Moffit, Ph.D., "The Last Time Congress Reformed Health Care: A Lawmaker's Guide to the Medicare Catastrophic Debacle," The Heritage Foundation, August 4, 1994, *available at*, http://www.heritage.org/research/reports/1994/08/bg996-the-last-time-congress-reformed-health-care.

[9] Robert E. Moffit, "Repeal Obamacare: How American Health History Can Repeat Itself," Capitalism Magazine," October 28, 2010, *available at* http://capitalismmagazine.com/2010/10/repeal-obamacare-how-american-health-history-can-repeat-itself/.

[10] Curtis W. Copeland, "Federal Rulemaking: The Role of the Office of Information and Regulatory Affairs," Congressional Research Service, June 9, 2009, RL32397, p. 29.

An emerging health care cost control issue where ensuring data quality is essential concerns an inter-industry dispute between health insurance companies and hospitals. According to an article in Forbes, the Berenson 2012 study

> *highlights some of the nitty gritty details of hardball hospital/insurance company negotiations that contribute to pricing disparities across regions, and even neighborhoods, in the United States.*[11]

Even the Urban Institute,[12] a distinguished NGO that usually works on social justice issues, has become involved in the business dispute between the insurers and health care providers. The lead author of the study discussed in the Forbes article is an Institute Fellow at the Urban Institute.

The policy proposals discussed in the article and underlying *Heath Affairs* study, if valid, are important to understanding potential new health care cost control measures. As the article stated,

> *if the American public hopes to fork less of its money over to health-care providers, then it might need to hope for a stronger health insurance industry, one with enough bargaining power to slow the rise of medical bills.*[13]

What remains to be seen is whether the contentions made in the study are correct and whether health insurance companies would really be a pro-consumer force if only they were more powerful.

3. Data Quality and Interactive Public Dockets: CRE's Guiding Principles

The two principles which guide CRE's analyses of health care and other regulatory policies are:

- ***Data Quality***. CRE has an institutional commitment to ensuring that federal policy decisions are based on the transparent use of high quality data and methods. As a senior CRE official explained in the concluding statement of a *New York Times* article on the federal government establishing quality standards for scientific and other data disseminated by the Executive Branch,

> *'It's the information age,' Mr. Tozzi*[14] *said. 'Now in the world's most powerful government you're going to have to issue information that's accurate.'*[15]

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[11] Peter Urbel, "Are Insurance Companies the Key to Lower Prices?," Forbes, Octiber 1, 2012, *available at* http://www.forbes.com/sites/peterubel/2012/10/01/are-insurance-companies-the-key-to-lower-prices/.

[12] See, http://www.urban.org/about/.

[13] Ibid.

[14] Jim Tozzi was instrumental in establishing centralized regulatory review in the White House Office of Management and Budget in that he was the only career employee who was in a policy position at the initiation of the process (Johnson Administration) through the establishment of its government wide mandate (Reagan Administration). Mr. Tozzi is one of three individuals most responsible for the passage of the Paperwork Reduction Act which gave OMB's regulatory office a statutory basis. He was also the principal advocate of the

- ***Interactive Public Dockets***. The interactive nature of the internet allows for far greater substantive, informed public participation in regulatory proceedings than do static records. CRE pioneered creation and use of Interactive Public Dockets (IPDs) to facilitate effective public participation in federal policy processes.[16] As an Urban Institute study noted,

> *Moreover, we have found that the literature on the Internet and regulation (Center on* [sic] *Regulatory Effectiveness 2002; General Accounting Office 2001c) that has emerged to date has focused on (a) the use of the Internet to promote increased citizen participation in rule-making (the federal government recently launched a site for posting comments on proposed rules, www.Regulations.gov).*[17]

C. About Berenson 2012

To assist our readers in evaluating studies being analyzed, CRE considers where the study was published (if applicable) and also seeks to understand the mission and objectives of organizations performing studies which are undergoing CRE review.

It is important to note that, although a brief review of organization's mission and objectives can improve a reader's understanding of a study, the study's authorship and/or sponsorship has no inherent bearing on its quality. Assessing a study's quality requires evaluating it against the objective criteria set forth in OMB's guidance documents implementing the DQA.

The Berenson study was published in *Health Affairs*, a well-known, highly regarded, peer reviewed health policy journal.[18]

Three of the Berenson 2012's four authors, including the lead author, are affiliated with The Center for Studying Health System Change (HSC). Another of the study's authors is the President of HSC. Thus, the study can be considered as an HSC work product.

Data Quality Act and was responsible for its enactment into law. For more information about Jim Tozzi's role in establishing the PRA and the DQA, please see the Administrative Law Review here, http://www.thecre.com/pdf/20111211_ALR_Tozzi_Final.pdf.

[15] Andrew C. Revkin, "Law Revises Standards for Scientific Study," New York Times, March 21, 2002, *available at* http://www.nytimes.com/2002/03/21/us/law-revises-standards-for-scientific-study.html?pagewanted=all&src=pm.

[16] See, Wikipedia entry on Interactive Public Dockets, http://en.wikipedia.org/wiki/Interactive_Public_Docket.

[17] Katherine Lotspeich and Michael Fix, "E-Government and Regulation: The Department of Labor's Web-Based Compliance Assistance Resources," The Urban Institute, August 2003, p. 11 *available at* http://www.urban.org/UploadedPDF/410845_e-government.pdf.

[18] See, http://www.healthaffairs.org/1500_about_journal.php.

HSC's mission "is to inform policy makers and private decision makers about how local and national changes in the financing and delivery of health care affect people."[19] HSC notes that it "does not take policy positions...."
HSC was founded by the Robert Wood Johnson Foundation (RWJF) in 1995.

HSC's funders include several federal agencies as well as RWJF and an organization called "RWJF - Changes in Health Care Financing and Organization Initiative, administered by AcademyHealth."[20]

- AcademyHealth's Vice President also serves as "Deputy Director of the Robert Wood Johnson Foundation's Changes in Health Care Financing and Organization (HCFO) program."[21]

- RJWF states prominently on their website that: "RWJF grant funds **cannot** be used to fund lobbying or political campaign activities."[22] [Emphasis In Original]

- The Lobbying Disclosure forms for AcademyHealth's registered lobbyists, Cavarocchi, Ruscio, Dennis Associates, are available from the US House of Representatives here, http://disclosures.house.gov/ld/ldsearch.aspx

- The lobbying firm describes itself as having a "strategic alliance" with HealthFutures, LLC.[23]

- HealthFutures, LLC's Lobby Registration disclosure forms show their clients to include Medco Health Solutions, Inc.

In addition to other funding it receives, HSC is a contractor to the National Institute for Health Care Reform (NIHCR). NIHCR, along with RWJF, funded the Berenson 2012 study.

NIHCR is a 501(c)3 non-profit organization established by the UAW (more formally, the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America) and the "Big 3" Detroit automakers to "conduct health policy research and analysis to improve the organization, financing and delivery of health care in the United States."[24]

NIHCR was established in 2009 during the bankruptcy proceedings of General Motors and Chrysler in the Settlement Agreements with UAW retirees that also created the UAW Retiree Medical Benefits Trust.[25]

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[19] See, http://www.hschange.com/index.cgi?file=about.

[20] See, http://www.hschange.com/index.cgi?file=funding.

[21] See, http://www.hcfo.org/about/staff.

[22] See, http://www.rwjf.org/en/grants/grantee-resources/legal-and-policy-information/legal.html#1a.

[23] See, http://www.healthfutures.com/press/CRD-HF_Announcement.pdf.

[24] See, http://www.nihcr.org/About-The-Institute.

[25] The creation of NIHCR is found in Section 31 of the General Motors Settlement Agreement http://www.sec.gov/Archives/edgar/data/1467858/000119312510078119/dex1012.htm and Section 28 of the

The UAW Retiree Medical Benefits Trust, created as a result of the GM and Chrysler bankruptcies, is now the country's largest private sector provider of health insurance. As the Trust explains,

> *When the Trust launched in January 2010, it became the largest non-governmental purchaser of retiree health care in the United States.*[26]

UAW documents state that the Retiree Medical Benefits Trust, which has assets of over $55 billion, is underfunded by $20 billion.[27]

The UAW is widely perceived as having gained an unfair advantage over other creditors in the bankruptcy proceedings for GM and Chrysler.[28] For example, an article in the American Bankruptcy Institute Law Review (edited by students at St. John's University School of Law) stated,

> *The descent of Chrysler and General Motors into bankruptcy threatens the chapter 11 reorganization process itself. In each case, a judge approved a transfer of a debtor's assets to favored creditors under circumstances where holders of other claims were denied basic safeguards.*[29]

Because of the massive $20 billion shortfall in the Benefits Trust, any relative advantages the UAW gained over other creditors during bankruptcy appear insufficient to protect the health benefits of GM and Chrysler retirees.

Thus, unless the federal government intervenes to either direct additional funds into the UAW Trust or to sharply reduce the health insurance costs, UAW retirees are at risk of having their health care benefits reduced.

II. Premise of Berenson 2012: Insurance Companies Don't Aggressively Constrain Payments

Health insurance companies are not aggressive in limiting their payments to health care providers. The preceding sentence sums up a key thrust of the Berenson study. As the study's Abstract states,

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Chrysler Settlement Agreement, http://www.sec.gov/Archives/edgar/data/1513153/000119312511078025/dex1014.htm.

[26] See, http://www.uawtrust.org/Home/about/history/history/sb.cn.

[27] Jay Greene, "UAW: Retiree benefit trust underfunded by $20B," Crain's Detroit Business, January 8, 2012, available at http://www.crainsdetroit.com/article/20120108/SUB01/301089991/uaw-retiree-benefit-trust-underfunded-by-20b.

[28] Jeff Green and Caroline Salas, "Auto Workers Pivotal to GM Said to Trump Bondholders (Update3)," Bloomberg, April 15, 2009 *available at* http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aOdH9vrC5WGc&refer=home.

[29] Barry E.Adler, "A Reassessment of Bankruptcy Organization After Chrysler and General Motors," ABI Law Review, Spring 2010, Vol. 18: 305-318, Abstract.

> *Even in markets with dominant health plans, insurers generally have not been aggressive in constraining [payment] rate increases, perhaps because the insurers can simply pass along the costs to employers and their workers.*[30]
> [Emphasis added]

The view that health insurance companies (or any other self-sustaining businesses) are not "aggressive" in containing their costs may come as a surprise to many industry observers. For example, a National Public Radio (NPR) news story stated,

> *It is a truth universally acknowledged that health insurance companies can be a pain for patients. What may be a surprise is that hospitals often complain, too. And the reasons aren't so different from those of consumers: Denied claims. Low reimbursement. Late reimbursement. Thickets of red tape.*[31]

The NPR story challenges Berenson 2012's premise by reporting that insurance companies have clout over hospitals and use that clout to limit payments. The news story also notes that the clout exercised by insurers over hospitals is analogous to the painful clout that insurers exercise over patients.

The view that health insurers don't aggressively constrain their payments to health care providers is particularly surprising since one of the reforms contained in the Affordable Care Act is setting a minimum share that insurance companies need to spend on paying claims. A 2010 article in *Health Affairs* explained this issue of medical loss ratios to their readers thusly,

> *Beginning in 2011, the Affordable Care Act will require health insurance companies to spend a minimum percentage of the premiums they collect on health care services and quality improvement activities for the people they insure. This percentage is called the medical loss ratio. Insurance companies that sell policies to groups of 100 people or more must spend at least 85 percent of their premiums on health services. Insurers selling policies to individuals or small groups with fewer than 100 people must spend at least 80 percent on health services. Companies that fail to meet these medical loss ratio requirements will have to issue rebates to their customers starting in 2012.*[32]

The *Health Affairs* article quoted above is a Health Policy Brief which "are produced under a partnership of *Health Affairs* and the Robert Wood Johnson Foundation."

The article goes on to explain that

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[30] Berenson 2012, Abstract.

[31] Jay Hancock, "Hospitals Gripe About Health Insurers, Too," Shots – Health News from NPR, August 21, 2012 *available at* http://www.npr.org/blogs/health/2012/08/21/159541948/hospitals-gripe-about-health-insurers-too.

[32] Jennifer Haberkorn, "Medical Loss Ratios," Health Policy Briefs, Health Affairs, November 12, 2010 (Updated November 17, 2010), available at http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=30.

> *When health insurers sell policies, they charge the buyers premiums. The share of premiums that insurers ultimately pay out on health care claims is the medical loss ratio. The rest--what they don't pay out in claims--goes toward administrative expenses, marketing costs, and profits. Proponents of health care reform argued that insurers spent too much of every premium dollar on administration and profits, and too little on medical claims.* [Emphasis added]

The Health Policy Brief also explained why there is concern that health insurance companies are not devoting enough of their resources to paying claims,

> *According to an April 2010 report prepared by the Democratic staff of the Senate Committee on Commerce, Science, and Transportation, the nation's largest health insurers in 2009 had medical loss ratios ranging from 68 percent to 88 percent in the individual market; 78 percent to 84 percent in the small-group market; and 83 percent to 88 percent in the large-group market. Because states have defined what constitutes medical care differently, their medical loss ratios differ even more than these numbers would suggest.*
>
> *Health reform proponents who wanted higher medical loss ratios imposed on commercial insurers often pointed to the contrasts with public health insurance programs. Medicare, the government program that provides health care services to people aged 65 and older and to the nonelderly disabled, maintains a medical loss ratio of 97-98 percent.*

The issue of medical loss ratios and insurer leverage will be discussed in greater detail below.

III. Data Quality Flaws in Berenson 2012

A. Overview of the DQA

In brief, the Data Quality Act (also known as the Information Quality Act) sets standards for the quality of virtually all data publicly disseminated by federal agencies. As OMB explains, their implementing guidance for the DQA provides

> *policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.*[33]

Many independent commentators and academicians have discussed the importance of the DQA as a tool for ensuring the accuracy and reliability of federal agency data. The best explanation of the importance of the law, however, is from OMB:

[33] Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication," Federal Register, Vol. 67, No. 36, Friday, February 22, 2002, p. 8452.

> *It is crucial that information Federal agencies disseminate meets these guidelines. In this respect, the fact that the Internet enables agencies to communicate information quickly and easily to a wide audience not only offers great benefits to society, but also increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines.*[34]

OMB has set even higher quality requirements for "influential scientific, financial, or statistical information" which refers to information where that "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."[35]

With respect to influential information, OMB's guidance explains that

> *If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.*[36] [Emphasis added]

Documents which implement the DQA include OMB's government-wide information quality guidelines, OMB's Final Information Quality Bulletin for Peer Review[37] and agency-specific DQA implementing guidelines that comply with OMB's government-wide requirements.

As previously noted, the DQA applies to third-party data if an agency disseminates the data directly or uses the data in its own information products. As Office of Information and Regulatory Affairs (OIRA) Administrator Graham explained,

> *If third-party submissions are to be used and disseminated by federal agencies, it is the responsibility of the federal government, under the Information-Quality Act, to make sure that such information meets relevant information-quality standards. The agency guidelines establish performance goals and procedures to assist in the agency's evaluation of all information for which agency dissemination is under consideration, whether that information was generated by the agency or by third parties.*[38]

In addition to setting quality standards for federal data, the DQA includes an administrative process allowing all affected persons to "seek and obtain correction" of information not meeting OMB standards.

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[34] Ibid.

[35] Ibid., p. 8460.

[36] Ibid.

[37] See, http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf.

[38] Speech by John D. Graham, "Information Quality: An Update on the First Year," October 8, 2003, *available at* http://www.whitehouse.gov/omb/inforeg_speeches_031008graham.

B. Analysis of the DQA Flaws in Berenson 2012: Specific Examples

This section will examine whether the Berenson study complies with the standards set by the DQA and OMB's implementing guidance documents. To evaluate the DQA compliance of the study, we will analyze findings and conclusions in Berenson 2012 and assess them against the standards set in OMB's government-wide DQA guidance.

1. **Unsupported Assertion**

- "Even in markets with dominant health plans, insurers generally have not been aggressive in constraining rate increases...."

The statement from Berenson 2012's Abstract raises several Data Quality concerns. One concern is that at first read the sentence appears to imply that health insurers have not been aggressive in limiting the rate increases they impose on their customers, health care consumers. Such an interpretation is understandable since long-standing consumer concerns regarding health insurers have resulted in increased federal oversight of the industry.

Newly created federal insurance oversight agencies include The Center for Consumer Information & Insurance Oversight (CCIIO) within the Centers for Medicare and Medicaid Services by the Affordable Care Act and the creation of the Federal Insurance Office within the Treasury Department by Dodd-Frank.

A closer reading of the complete sentence in the Abstract makes clear that the authors are asserting that it is the rates insurance companies pay to health services providers which are not being aggressively constrained. The authors' conclusion that a large industry is not pushing to significantly control its largest category of costs needs to be assessed to see if it meets OMB DQA "Objectivity" requirement that information be "presented in an accurate, clear, complete, and unbiased manner."[39]

Berenson 2012 Based on Interviews

Evaluating the study assertion cited above, requires understanding the data and methodology used in the study as the basis for its assertions and conclusions.

Berenson 2012 is based on a longitudinal study of 12 metropolitan areas, it contains no quantitative data. Longitudinal studies are described in Wikipedia as "a correlational research study that involves repeated observations of the same variables over long periods of time — often many decades."[40] Observations in the longitudinal study occurred every two years starting in 1996.

Berenson states that the round of observations that took place in 2010 included "539 interviews with local health care leaders in the twelve communities...." Berenson does not indicate whether the longitudinal Community Tracking Study interviewed health care leaders in early rounds of

[39] Ibid,. p. 8459.

[40] See, http://en.wikipedia.org/wiki/Longitudinal_study.

observation nor does it suggest that any interviews from prior years were considered. Instead the study states

> *This article is based on interviews in each site conducted with leaders of three to four major hospitals—typically the chief executive officer, chief financial officer, chief medical officer, and medical staff president of each institution. In each site we also interviewed leaders of two to three physician groups and major health plans—typically the provider network manager, marketing head, and medical director.*

Moreover, Berenson 2012 also states that

> *Additional information was provided by interviews with state policy makers and knowledgeable market observers, such as local university faculty members and health care consultants.*

Berenson's Study Data and Methods section does not indicate whether these additional interviews were conducted according to the same protocol as the interviews that took place as part of the Community Tracking Study or whether consistency in data collection technique matters.

Thus, we can see two immediate implications of the Berenson study protocol:

- Berenson does not use longitudinal data; it uses data from a single set of observations from a longitudinal study and then mixes them with other interviews conducted outside the longitudinal study; and

- There was no independence between the data collection team and the data analysis team.

The study data only from a single time point is important because it means that,

- **The Berenson 2012 study design is not capable of detecting trends**.

The study's database, as described by the article, consists of the recollections of representatives of various vested interests regarding aspects of inter-industry relations. Because the interviews were all conducted within the same several month timeframe, they cannot indicate any changes that may have taken place between industries over time. Moreover, the interview data is subject to recall bias, an issue not discussed in the study.

The concept of "recall bias" and its significance for interview-based studies, can be understood as follows:

> *Recall bias, also called reporting bias or differential recall, can be defined as a measurement error characterized by differences in the accuracy of subject recall or report across compared groups (1). It can be caused by involuntary or voluntary underreporting of information by subjects in one group, overreporting by subjects in the other, or both. Recall bias distorts the measure of association*

> *between exposure and disease by any magnitude and direction, and this distortion may be difficult to predict.*[41]

In basic terms, recall bias may be simply defined as "a systematic error caused by differences in the accuracy or completeness of the recollections retrieved ('recalled') by study participants regarding events or experiences from the past."[42]

Another type of potential bias in the Berenson data which should be considered when evaluating the study is response shift bias.

Response shift bias concerns how a study participant's responses to past events change over time.

> *Response shift bias is an increasing problem within longitudinal studies that rely on patient reported outcomes. It refers to the potential of a subject's views, values, or expectations changing over the course of a study, thereby adding an additional factor of change on the end results. Clinicians and healthcare providers must recalibrate surveys over the course of a study to account for Response Shift Bias. The degree of recalibration varies due to factors based on the individual area of investigation and length of study.*[43]

There is no indication in Berenson 2012, however, that the researchers took into account the potential for bias in participants' responses during interviews. Not considering various types of response bias is particularly odd since many of the study participants were representatives of stakeholders with a vested interest in the issues under investigation.

The need for researchers to consider and account for the potential for types of recall and response bias during interviews is well established in the literature. For example, the Abstract of study in the *Journal of Clinical Epidemiology* explained,

> *The factors which contribute to bias due to differential recall between cases and controls in retrospective studies have been little studied. A review of the literature on recall accuracy suggests that the extent of inaccurate recall is related to characteristics of the exposure of interest and of the respondents, though a distinction must be drawn between recall which is biased and that which is simply inaccurate. Interviewing technique and the study protocol, including the design of questionnaires and the motivation of respondents, play a central role and are under the control of the investigator.*[44] [Emphasis added]

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[41] Claire Infante-Rivard and Louis Jacques, "Empirical Study of Parental Recall Bias," American Journal of Epidemiology, Volume 152, Issue 5, p. 480. [Notes omitted]

[42] See, http://en.wikipedia.org/wiki/Recall_bias.

[43] See, http://en.wikipedia.org/wiki/Quality_of_life_(healthcare)#Response_Shift_Bias.

[44] Coughlin SS, "Recall bias in epidemiologic studies," Journal of Clinical Epidemiology, 1990;43(1):87-91.

Recall bias and response shift bias produce errors in the recalled data compared with objective assessment of the same information. It is for this reason that researchers need to take into account and correct for recall bias. As the conclusion to a study in *Health and Quality of Life Outcomes* explained,

> *Agreement between conventional change and patient perceived change was not strong. A large proportion of this disagreement could be attributed to recall bias. To overcome the invalidating effect of response shift (on conventional change) and recall bias (on patient perceived change) a method of adjusting patient perceived change for recall bias has been described.*[45] [Emphasis added]

- **Recall bias and response shift bias in respondent answers have not been accounted for in Berenson 2012**.

Because the potential for bias in the dataset has not been accounted in Berenson 2012's study design, the study's data has to be considered as biased to the point of being invalid.

An additional unusual aspect of Berenson's Study Data and Methods section is that, although it recounts in detail issues regarding the transcription of interviews and even includes the name and version number of the software package used in qualitatively analyzing the data (Atlas.ti, version 5.0), the article gives no indication of what methodology/approach/analytic technique(s) were used to derive findings from the interviews. Even basic study design information, such as the hypothesis being tested and the endpoints the study was designed to measure/assess, are not stated. Thus, we can state,

- **Berenson 2012 does not include the methodology researchers used for analyzing their interview database**.

The lack of methodology raises at least two data quality concerns. First, the study lacks transparency, a Data Quality breach particularly important for "influential" data. Even if an independent researcher had access to the complete Berenson interview database, they could not attempt to replicate the study results since no methodology was provided.

The lack of transparency is also significant for the basic Data Quality standard of "Objectivity." OMB's government-wide guidelines state that

> *Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation.*

Thus, even though Berenson 2012 includes quotes from interviews, there is no indication whether other, unpublished, excerpts from the interviews would provide a different impression regarding the aggressiveness of insurers in controlling payment to health care providers.

[45] Steven McPhail, Terry Haines, "Response shift, recall bias and their effect on measuring change in health-related quality of life amongst older hospital patients," *Health and Quality of Life Outcomes*, July 2010.

The following is a summary of the study Abstract excerpt's violations of OMB's government-wide guidance for maximizing the Quality, Objectivity, Utility, and Integrity of disseminated information.

Statement:

"...insurers generally have not been aggressive in constraining [payment] rate increases, perhaps because the insurers can simply pass along the costs to employers and their workers."

DQA Violation	OMB DQA Citation	Explanation
Violation 1: Objectivity	"'Objectivity' includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner."	The study design did not consider recall bias and response shift bias, types of biases that are endemic to interview-based data collection techniques.
Violation 2: Objectivity	"...in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation."	Berenson 2012 did not provide a summary characterization of their overall dataset, *e.g.*, share of responses from various types of stakeholders which supported/contradicted the conclusions reached.
Violation 3: Utility	"when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information."	Most if not all of the respondents interviewed for Berenson 2012 were stakeholders (industry officials, consultants) with vested interests in the issue of payment negotiations between insurers and health care providers. Since no information is provided about how the researchers converted their database into specific assertions and conclusions, the basis for statement in the Abstract is non-transparent and lacks utility.
Violation 4: Reproducibility (for influential information)	"With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results..."	Because Berenson 2012 does not include any qualitative or quantitative methodology used in analyzing their interview-derived database, it would be impossible for qualified third-party researchers to "substantially reproduce" the article's results, even if the third-party had complete access to the Berenson database.

2. **Unsupported Conjectures**

- "...we present various reasons why leverage has shifted to some hospitals and physician organizations."
- "Providers' growing negotiating strength also enables them to modify contract terms...."
- "...health plans have accepted the reality of provider leverage...."

The above statements all make the same twin unsupported contentions, that hospitals have leverage over health insurance companies and that such leverage is growing. Because the above statements are based on the same premise, they will be addressed together. Two issues to keep in mind when considering the compliance of the statements with the DQA,

1. The study never makes a demonstration that health care provider "leverage" over insurance companies exists in the first place; and

2. The Berenson 2012 study could not possibly demonstrate any change in purported hospital leverage since the study is not capable detecting trends. As was discussed on p. 11, Berenson includes data from only a single point in time. Since the study can, at most, examine a situation at a static point in time, statements regarding changes in a situation, *e.g.*, "growing negotiating strength," have no basis in the dataset the researchers analyzed.

In addition to issues regarding the capabilities of the study design, the statement has an additional Data Quality flaw, it is demonstrably wrong.

Throughout the article, the authors take as a given that hospitals have leverage/clout/negotiating strength over health insurance companies and that such leverage is growing. Berenson 2012, however, never makes any demonstration, even on a qualitative basis, that such leverage/clout/etc. exists. Moreover, as we will see below, the Berenson view of the insurance industry's negotiating strength is contradicted by the industry's own data.

Although Berenson 2012 never formally defines the term "leverage" or its synonyms, it is clear from context that the authors mean that one side of the negotiating process is able to extract an "economic rent" from the other side. As the Economist's reference guide to economic terms explains that Economic Rent

> "*is a measure of MARKET POWER: the difference between what a FACTOR OF PRODUCTION is paid and how much it would need to be paid to remain in its current use. A soccer star may be paid $50,000 a week to play for his team when he would be willing to turn out for only $10,000, so his economic rent is $40,000 a week. In PERFECT COMPETITION, there are no economic rents, as new FIRMS enter a market and compete until PRICES fall and all rent is eliminated. Reducing*

> *rent does not change production decisions, so economic rent can be taxed without any adverse impact on the real economy, assuming that it really is rent."*[46]

Berenson 2012's Abstract discusses market power explicitly so we can safely say that the authors are referring to economic rent when they discuss leverage and negotiating clout.

One way of understanding the market power of the health insurance industry is through Medical Loss Ratios (MLRs) which, as noted above, are the difference between the revenues a health insurer takes in from premiums minus what they pay in claims. The difference covers the insurers' overhead and profit.

To the extent that health insurers are able to extract economic rents from consumers and/or health care providers, they will increase their profitability absent other constraints. As the Department of Health and Human Services' Center for Consumer Information & Insurance Oversight explains the issue,

> *...many insurance companies spend a substantial portion of consumers' premium dollars on administrative costs and profits, including executive salaries, overhead, and marketing. Thanks to the Affordable Care Act, consumers will receive more value for their premium dollar because insurance companies will be required to spend 80 to 85 percent of premium dollars on medical care and health care quality improvement, rather than on administrative costs...*[47]

Since higher MLRs are consistent with improved consumer well-being, they serve as a rough proxy for market power. The more market power, aka leverage, health insurers have, the greater the difference between the revenues they take in and the claims they pay out and, therefore, the lower their MLR.

By examining changes in MLR data over time, we can get a sense of whether the study's assertions that hospitals are exercising growing market power over insurance companies are plausible.

The issue of MLRs and the market power of health insurers is one that has been of great concern to Congress. The Chairman of the Senate Committee on Commerce, Science, and Transportation, in discussing the Affordable Care Act's regulation of MLRs with the President of the National Association of Insurance Commissioners (NAIC), stated

> *...I also urge you to keep in mind the very simple principle underlying this provision – most of consumers' health insurance premium dollars should be going to pay for patient care, not for insurers' administrative costs and profits.*[48]

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[46] See second definition, http://www.economist.com/economics-a-to-z/r#node-21529784.

[47] CCIO, Medical Loss Ratio: Getting Your Money's Worth on Health Insurance, *available at* http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/medical-loss-ratio.html.

[48] Letter from Senator John D. Rockefeller, IV to Commissioner Jane L. Cline, May 7, 2010.

The Congressional Research Service (CRS) analyzed time series MLR data for the major publicly traded health insurers.[49] MLRs are characterized by CRS as a measure of health insurance profitability.

If the consolidation of health care providers (hospitals, doctors, etc.) and/or a combination of other factor were leading to them increasing their leverage over insurers, we would expect that, overall, the insurers would be taking take a hit by paying bigger and bigger shares of their premiums in claims. The table from the CRS report, reproduced on the next page, tells a very different story.

The CRS table displays MLR data from major publicly traded insurers for nine years, 2000-2008. Not every insurer on the chart was organized as an independent, publicly traded company for the entire time period, so the chart does not contain complete longitudinal data for all of the companies.

Only two of the 10 insurers for which there is data from at least eight of the nine years experienced an increase in the share of premiums they paid out in claims. For one insurer, their MLR remained flat. For seven out of 10 health insurance companies, their MLRs decreased which meant that that they were keeping a greater share of every premium dollar.

Berenson 2012's unsupported contention that care providers exercised growing leverage over health insurance companies is untenable in light of the fact that, overall, the insurers reduced the share of premiums they pay in claims. Moreover, the MLR increase for the two companies that paid a higher share of their premiums in claims was modest, from 81.0 to 81.4 in one case and from 80.8 to 84.4 in the other instance.

By contrast, the decreases in claims paid as a share of premiums for other companies was quite notable. For example, industry giant Aetna reduced their MLR from 92.1 in 2000 to 81.5 in 2008, an improvement for their shareholders of over 11%.

Cigna HealthCare's shareholders and executives were able to celebrate a 16% decline in claims payments as a share of revenue as their MLR declined from 84.2 to 70.7.

Based on the CRS data, it is clear that the Berenson 2012 statements concerning hospital and other health care provider leverage over insurance companies not meet the DQA's Objectivity requirement for accuracy because the statements are not true.

It was noted in the *Health Affairs* article quoted on page 8, that there was a Senate committee staff report that analyzed MLRs. The report, based on a Senate Commerce Committee investigation into MLRs, explained that they used data from filings with the NAIC because "the largest for-profit companies were reluctant to voluntarily share their medical loss information broken out in a way that would be helpful for consumers...."[50]

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[49] D. Andrew Austin and Thomas L. Hungerford, "The Market Structure of the Health Insurance Industry," Congressional Research Service, November 17, 2009, R40834.

[50] US Senate Committee on Commerce, Science, and Transportation, Office of Oversight and Investigations – Majority Staff, "Implementing Health Insurance Reform: New Medical Loss Ratio Information for Policymakers and Consumers," Staff Report for Chairman Rockefeller, p. 2.

Table 5. Medical Loss Ratios for Major Publicly Traded Health Insurers, 2000-2008

	2000	2001	2002	2003	2004	2005	2006	2007	2008
Aetna Inc.	92.1	89.8	89.8	76.6	78.3	77.4	79.9	80.4	81.5
Amerigroup Corp.	81.0	80.6	80.6	80.2	81.0	84.7	81.1	83.1	81.4
Anthem Inc.	84.7	84.5	84.5	82.4					
Centene Corp.	84.3	82.8	82.8	83.4	81.5	82.6	85.9	83.8	82.0
Cigna HealthCare Inc.	84.2	86.3	70.5	75.5	71.5	72.1	71.5	72.2	70.7
Cobalt Corp.	81.8	77.9	89.2	85.0					
Coventry Health Care Inc.	85.8	86.0	86.0	81.2	80.5	79.4	79.3	79.6	84.0
Health Net Inc.	82.8	84.4	84.4	82.6	89.3	86.5	85.0	86.6	88.4
Humana Inc.	84.5	83.3	83.3	83.5	84.1	83.2	84.0	83.0	84.5
Molina Healthcare Inc.				83.4	84.4	86.9	84.6	84.5	84.8
Mid Atlantic Medical Services Inc.	86.1	85.3	86.4	85.0					
Oxford Health Plans Inc.	77.5	78.9	78.9	79.4					
PacifiCare Health Systems Inc.	87.5	89.7	89.7	86.8	88.5				
RightCHOICE Managed Care, Inc.	81.7	80.3							
Sierra Health Services Inc.	95.4	91.0	84.8	79.2	79.5	79.1	79.9	84.2	
Trigon Healthcare, Inc.	83.6	84.0							
Triple-S Management, Corp.							87.6	87.0	88.9
UnitedHealth Group	85.4	85.3	85.3	81.4	80.6	80.0	81.2	80.6	82.0
Universal American Corp.								80.4	83.3
WellCare Health Plans Inc.				82.5	80.9	81.2	81.1	79.4	85.3
WellChoice Inc.			88.1	85.4	86.3				
WellPoint Health Networks Inc.	80.8	81.5	81.5	81.0	82.5	80.9	82.0	83.2	84.4

Source: A.M. Best Company, Special Reports, various years. The medical loss ratio is defined as total health benefits divided by total premium revenue.

Notes: Anthem Inc. acquired WellPoint in late 2004 and operates under the WellPoint name. Cobalt Corp. was acquired by WellPoint in late 2003. Mid Atlantic Medical Services, Inc. (also known as MAMSI) was acquired by UnitedHealth Corp. in February 2004. PacifiCare Health Systems Inc. was acquired by UnitedHealth on December 20, 2005. RightCHOICE Managed Care, Inc. was acquired by WellPoint on January 31, 2002. Sierra Health Services Inc. was acquired by UnitedHealth on February 25, 2008. Trigon Healthcare, Inc. merged with Anthem on July 31, 2002. Triple-S Management, Corp., the Blue Cross/Blue Shield affiliate for Puerto Rico, became a publicly traded company in 2006. As of December 28, 2005, WellChoice Inc. has operated as a subsidiary of WellPoint Inc. See source for additional notes.

Source: "The Market Structure of the Health Insurance Industry," Congressional Research Service, November 17, 2009.

CRS-42

With respect to the detailed MLR data that the Committee sought, the report went on to state that the

> *companies' failure to voluntarily provide this information was troubling because segmented medical loss ratios are extremely useful information for individuals or small businesses trying to purchase health insurance in a particular market.*[51]

The majority staff report's statement can be interpreted as indicating that the insurers were withholding information so as to protect their exercise market power. The collective decision of the insurance industry was thus a team effort to block pro-competition policies. The staff report clearly found that health insurance companies exercised their market power over smaller purchasers of insurance by increasing the share of each premium dollar from smaller businesses and individuals they keep. The collective business decision of the insurance

Based on an analysis of health insurer filings with the NAIC, the Committee staff developed a chart in which MLRs for 2008 and 2009 were broken down by three market segments, individual consumers, small group purchasers, and large group purchasers. Below is the staff report chart.

	Individual		Small Group		Large Group	
	2009	2008	2009	2008	2009	2008
Aetna	75.7%	73.9%	84.2%	82.0%	87.2%	82.0%
CIGNA	88.1%	86.9%	92.1%	---	85.2%	37.2%
Coventry	71.9%	65.8%	78.2%	79.1%	86.0%	82.7%
Humana	68.1%	71.9%	80.0%	77.2%	88.2%	82.4%
UnitedHealth	70.5%	70.3%	81.1%	78.7%	83.3%	83.5%
WellPoint	74.9%	73.1%	81.2%	79.0%	84.9%	85.2%
TOTAL	73.6%	72.5%	81.2%	79.7%	85.1%	83.9%

TABLE I – 2009 Medical Loss Ratios by Market Segment – Largest For-Profit Insurers

The Senate staff report characterized the above data from health insurance companies by explaining,

> *Demonstrating a spread of more than 11 percentage points, insurers extracted a larger portion of premium dollars paid by their individual and small business customers for administration and profits than they did for their large group customers.*[52]

The above statement is at odds with Berenson 2012's contention that insurance companies are not aggressive about containing their claims payments and that they "have accepted the reality of provider leverage." Rather, it seems that health insurers not only have leverage, they use it to the detriment of health care consumers.

[51] Ibid., p. 2.

[52] Ibid., p. 3.

Berenson 2012's Central Theme: "...health plans have accepted the reality of provider leverage...."

The statement that "...health plans have accepted the reality of provider leverage...." is at the heart of Berenson 2012 since it discusses the researchers' central contention, that insurance companies are not aggressively containing the rates they pay health care providers. Understanding Berenson's statement about health plans and providers is, thus, central to understanding the overall study and may help in understanding the larger federal policy issues regarding the two industries.

Another, more neutrally worded phrasing of Berenson's point, would be to state that health plans are passively accepting their having a disadvantageous negotiating balance of power with hospitals. The immediate question then is why? Why would health insurers accept a situation that they believe to be financially harmful?

Berenson provides one possible answer. In the Berenson 2012 Abstract, when trying to explain why insurance companies are not aggressive in controlling their payments to providers, the authors' state, "perhaps because the insurers can simply pass along the costs to employers and their workers."

A common term for an industry able to quickly and simply pass cost increases to their customers is "oligopoly." As the University of North Carolina's Illustrated Encyclopedia of Economics notes in discussing oligopolies, "Concentrated industries appear to quickly pass along cost increases as they occur."[53]

Thus, if Berenson is right about insurance companies not aggressively containing payments to providers, we can see two possible explanations, either:

1. A large component of the financial services industry is not aggressively confronting a drain on their profitability; or

2. Health insurers are working in a non-competitive manner that improves their financial well-being at the expense of consumers.

In considering which of the above two explanations better accounts for the phenomena observed by Berenson, there are two facts that need to be kept in mind. First, as discussed above, the largest health insurance companies were sharply criticized by Senate staff for their common refusal to provide information which could benefit consumers and small businesses. Second, as is discussed further below, health insurance companies receive a special antitrust exemption under the McCarran-Ferguson Act.

[Continued next page]

[53] University of North Carolina, Department of Economics, "Economicae, an illustrated encyclopedia of economics," *available at* http://www.unc.edu/depts/econ/byrns_web/Economicae/oligopoly.html.

Statements:

"...we present various reasons why leverage has shifted to some hospitals and physician organizations."

"Providers' growing negotiating strength also enables them to modify contract terms...."

"...health plans have accepted the reality of provider leverage...."

DQA Violation	OMB DQA Citation	Explanation
Objectivity	"'Objectivity' includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner."	The Berenson 2012 statements about growing leverage by care providers and their negotiating strength over health insurers are inaccurate and contradicted by Congressional Research Service and Senate documents demonstrating growing health insurer market power.

3. **Statement that Defies Explanation**

- "Because employers require a broad choice of providers for their employees, most academic health centers now have the leverage to require that their contracts cover all services...."

The first question to be asked about the accuracy of the above statement is, who are these employers who require (!) a broad choice of providers for their employees? The question is important because the statement serves as Berenson 2012's conclusion regarding the "leverage" of an entire class of large, highly regarded health centers.

The great majority of employees are fortunate if they have even one health plan available, irrespective of whether it allows any choice of providers. A report by the Center for American Progress Action Fund, citing data from the Kaiser Family Foundation and Health Research Education Trust, found that

> ***Among companies that offer insurance, most offer no health plan choice****. Just 1 percent of companies that offer employee health insurance benefits give their employees a choice of three or more plan types (such as a PPO, HMO, or conventional plan), and only 14 percent offer two plan types. That leaves 85 percent of companies offering their employees just one health plan type.*[54] [Emphasis In Original]

[54] Peter Harbage and Karen Davenport, "Competitive Health Care: A Public Health Insurance Plan that Delivers Market Discipline," Center for American Progress Action Fund, March 2009, p. 4.

More recently, Kaiser Health News published an article titled, "Large Companies Are Increasingly Offering Workers Only High Deductible Health Plans."[55] The business owners and benefits experts interviewed for the article cited cost savings as the reason why companies are reducing health care coverage for employees. There is no suggestion in the article that employers were willing to accept higher insurance costs in order to ensure their employees enjoyed a broad range of provider choices.

It is particularly difficult to understand how such purported employer demands for provider choice would translate into leverage for hospitals over insurance companies since insurance companies increasingly provide large employers with only administrative services, leaving the employer with financial responsibility for provider payments. Berenson 2012 makes no mention of the phenomena of insurance companies increasingly basing their revenue streams on their skills in negotiating with providers and related administrative functions. The new business model of major insurers is discussed in a story by the Center for Public Integrity, a non-profit, nonpartisan investigative news organization.

> *In fact, it is a stretch to even call the big companies insurers these days. The number of people whom those companies actually "insure" has been dwindling for a decade. Their preference is to encourage employers and other large groups to "self insure" and then hire the insurance companies as administrators. If you look closely at the big insurers' books of business, you will see their revenue from "administrative services only" (ASO) customers has been growing while cash from the selling of actual insurance has been falling.*
>
> *Most Americans who have coverage get it through the workplace, but chances are very few of them realize that it is actually their employer assuming the risk of insuring them, not the company whose name is on their insurance card.*
>
> *In an ASO arrangement, the employer pays a substantial fee to a company like Aetna or Cigna to negotiate contracts with doctors and hospitals and make decisions about whether or not an employee will actually get coverage for potentially life-saving procedures like transplants.*[56] [Emphasis added]

The issue health insurers increasingly providing Administrative Services Only for large employers raises another question relevant to understanding Berenson 2012; if insurance companies are weak and getting weaker in their ability to negotiate with health care providers, why do large sophisticated employers increasingly pay them to do that job?

Berenson 2012's assertion that employers require a broad choice of providers for their employees is particularly perplexing since one of the main health insurance reforms in the Affordable Care Act is the Small Business Health Options Program (SHOP), intended to make is possible for small business

[55] Michelle Andrews, "Large Companies Are Increasingly Offering Workers Only High Deductible Health Plans," Kaiser Health News, Mar 26, 2013, *available at* http://www.kaiserhealthnews.org/features/insuring-your-health/2013/032613-michelle-andrews-on-high-deductible-plans-and-large-employers.aspx.

[56] Wendell Potter, "OPINION: putting big health insurers in their place," July 1, 2013, available at http://www.publicintegrity.org/2013/07/01/12908/opinion-putting-big-health-insurers-their-place.

to offer employees a choice of plans. A *Health Affairs* Health Public Brief discussing the SHOP explains that

> *Small companies often have difficulty "shopping" for health insurance because health plans can vary greatly in the benefits they cover; the cost sharing that they require of people enrolled in the plan; and the providers that are included in a plan's network, if it has one. Because small companies usually lack expertise in managing health insurance benefits, they often rely on agents and brokers to help them select a plan. What's more, small businesses must often pick only one plan for all of their workers because insurance companies typically impose rules that require a minimum number of workers to participate.*[57]

Thus, rather than employer demands resulting in care provider leverage over health insurers, it is the health insurance companies that are exerting leverage over small businesses trying to provide insurance for their employees.

Statement:

"Because employers require a broad choice of providers for their employees, most academic health centers now have the leverage to require that their contracts cover all services...."

DQA Violation	OMB DQA Citation	Explanation
Objectivity	"'Objectivity' includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner."	The Berenson 2012 statement regarding the leverage of academic health centers is wrong; most employers that provide health insurance focus on limiting their costs, not ensuring employee choice of care provider.

4. **Statements Dismissing the Potential Effectiveness of Antitrust Enforcement**

- "...the consolidation taking place in many markets often falls outside transactions that are subject to traditional antitrust enforcement."
- "Markets display various forms of provider consolidation not reflected in standard measures of concentration."
- "Our findings did not suggest that more aggressive antitrust enforcement, although clearly warranted in particular situations, would successfully restrain provider pricing power more generally."

[57] Julia James, "Small Business Insurance Exchanges," Health Policy Briefs, *Health Affairs*, February 9, 2012.

On one hand, Berenson 2012 expresses concern that hospital consolidation is one of the factors driving a purported increase in provider leverage over insurers. One the other hand, the study dismisses the potential for antitrust officials to even meaningfully measure such consolidation, let alone take effective action to protect consumers from the exercise of market power.

As was previously discussed, the DQA sometimes requires that when "disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation." This is one of those times. It is not possible to understand the potential for antitrust enforcement to protect consumers in the care provider marketplace without considering the exemption from antitrust enforcement enjoyed by health insurance companies.

The article, "Consolidation in Health Care Markets, A Review of the Literature," supported by the Robert Wood Johnson Foundation and co-authored by a former senior official at the Federal Trade Commission's Competition Bureau and the Department of Justice Antitrust Division, explained the health insurance companies' antitrust exemption this way,

> *Congress should repeal the McCarran-Ferguson Act which provides an antitrust exemption for health insurance. The Act restricts the full range of antitrust enforcement actions and effectively bars the FTC from bringing consumer protection actions against health insurers. Repealing the Act would allow the FTC and DOJ an opportunity to fully challenge possible anticompetitive and deceptive behavior within the health insurance industry.*[58]

The author's support for reforming the health insurance industry's antitrust exemption was also noted in the previously cited CRS report on the health insurance industry.[59]

Thus, Berenson's rejection of enhanced antitrust action to promote competition in the provision of health care needs to be understood in light of the health insurers' exemption from antitrust action.

Statements:

"...the consolidation taking place in many markets often falls outside transactions that are subject to traditional antitrust enforcement."

"Markets display various forms of provider consolidation not reflected in standard measures of concentration."

"Our findings did not suggest that more aggressive antitrust enforcement, although clearly warranted in particular situations, would successfully restrain provider pricing power more generally."

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[58] David A. Balto and James Kovacs, "Consolidation in Health Care Markets: A Review of the Literature," January 2013, *available at* http://www.dcantitrustlaw.com/assets/content/documents/2013/balto-kovacs_healthcareconsolidation_jan13.pdf.

[59] Market Structure of the Health Insurance Industry, p. 47.

DQA Violation	OMB DQA Citation	Explanation
Objectivity	"...in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation."	Berenson 2012's observations and findings regarding the limited potential for antitrust enforcement to enhance competition needs to be viewed in light of the health insurance industry's antitrust exemption.

5. Berenson 2012's Lack of Data and Analytic Methodology

Berenson 2012 does not specify what methodology was used in analyzing the interview database. This issue of Berenson 2012's opaque methodology was briefly discussed early with respect to specific statements in the study not meeting OMB's DQA requirements. The Berenson 2012 methodology, however, deserves greater attention as the study's lack of transparency undermines the entire document, not merely selected excerpts.

The study contains a section titled "Study Data and Methods" which fails to provide both items in the section title. With respect to study data, there are no tables, chart or specific citations to the referenced study. Berenson 2012 contains no output or results from the analysis software that the authors state they used.

The study also fails to disclose what methodology was used to derive its findings from the interviews referenced in the article, an issue that is every bit as crucial for qualitative analyses as it is to quantitative research.

Berenson 2012's lack of observable data is notable given that HSC prominently notes on their website notes that the organization is affiliated with Mathematica Policy Research and has been affiliated with Mathematica since HSC was founded.

Although the study is qualitative, not quantitative, that does not explain the lack of data. As an interactive clinical research textbook made available by NIH explains, "Qualitative analysis is real work."[60] The textbook further emphasizes that

> *A challenge, a joy, or possibly a nightmare is the proper analysis of qualitative data.*[61]

The textbook discusses four qualitative analysis techniques:

[60] Marguerite Steves, Ph.D., "Chapter 7: Selected Qualitative Methods," Interactive Textbook on Clinical Symptom Research, available at http://painconsortium.nih.gov/symptomresearch/chapter_7/sec4_5/cmss45pg1.htm.

[61] Ibid.,

1. Content Analysis;
2. Grounded Theory;
3. Narrative Summary Analysis; and
4. Triangulation.

The summary of Grounded Theory provided by the textbook gives a brief explanation of one of the qualitative ways in which health care-related data can be subject to rigorous analysis,

> ***2) Grounded Theory***
>
> *This is the classic and still standard technique for analyzing health data and for lots of other data too. Grounded theory uses a systematic hierarchical set of procedures to develop inductively derived theory grounded in data. Glaser and Strauss invented Grounded Theory in the 1960s to analyze data on caring for dying patients. Their books are classics and in wide use today because of the insights they provide, particularly in the field of palliative care. To visit a website devoted to Grounded Theory which includes an audio interview with Glaser click here. Gifford, 1999, and Lewis, 1997, are examples of analyses conducted with Grounded Theory.*

An overview of the basic process steps associated with Grounded Theory qualitative analysis are summarized below. For the complete summary discussion, see Dr. Simmons' complete article here. Of note is the first step in Grounded Theory analysis which requires minimizing pre-conceptions – a step that is fully consistent with OMB's DQA requirements.

> ***1. Preparation:*** *Minimizing preconceptions. No preliminary literature review. General research topic, but no predetermined research "problem."*
>
> ***2. Data Collection:*** *Most common form: intensive interviews...*
>
> *Initial analysis determines where to go and what to look for next in data collection. ...*
>
> ***3. Analysis: Constant Comparative Analysis*** *Relating data to ideas, then ideas to other ideas.*
>
> *Substantive Coding*
>
> ***
>
> *Sensitizing concepts....*
>
> *In vivo concepts....*
>
> *Open Coding*

Coding for anything and everything....

Selective Coding

***

Closed coding involves limiting the coding to things related to the core variable.

Theoretical Coding

Theoretical codes conceptualize how the substantive codes may relate to each other as hypotheses to be integrated into the theory....

***4. Memoing**: Memos are the theorizing write-up of ideas about codes and their relationships.*

***

Integrating the Literature

Once you are confident in your theory, you can begin to analyze and integrate relevant existing literature into it.....

***5. Sorting & Theoretical Outline:** Sorting refers not to data sorting, but to conceptual sorting of memos into an outline of the emergent theory....*

***6. Writing**:...*[62]

Even though a wide range of qualitative analysis techniques are discussed in the literature,[63] Berenson 2012's methodology section lacked any discussion of the process, analogous to the Grounded Theory analytic overview cited above, that the authors used in developing their findings based on their database.

Because the study describes no *a priori* analytic technique that was applied to the interview data, there is no basis for any of the study's findings. Berenson 2012, thus, is less a study than it is a set of assertions backed by anecdotes.

[Continued next page]

[62] Odis E. Simmons, Ph.D. "Outline of the GT Process", *available at* http://www.groundedtheory.com/what-is-gt.aspx.

[63] See, for example, Leech, Nancy L.; Onwuegbuzie, Anthony J., "Qualitative data analysis: A compendium of techniques and a framework for selection for school psychology research and beyond," School Psychology Quarterly, Vol. 23(4), Dec 2008, 587-604 which describes "18 qualitative analysis techniques...."

IV. Statistically Sound Longitudinal Surveys are Not the Basis of Berenson 2012

A. Issue Background

Berenson 2012 states that "In this article, we present findings from the Community Tracking Study...." The Community Tracking Study (CTS) is conducted by the Center for Studying Health System Change and is funded by the Robert Wood Johnson Foundation and National Institute for Health Care Reform. CTS is an ongoing longitudinal survey that was started in 1996 and probes metropolitan households and physicians, in an every-two-year alternating cycle, *e.g*. Household survey followed by Physician survey.

The Berenson study concluded that hospital consolidation was one of the major contributors to perceived care provider negotiating leverage over the private health care insurers regarding payments for services. More specifically, the researchers opined that, because of hospitals and physician groups consolidating and because some institutions, due to their reputations and "must-have status" of well regarded, top-tier hospitals, health care providers are increasingly able to demand higher payment rates from insurers. The study asserts that the insurers have no leverage due largely to the medical specialty coverage of certain hospitals and as a result of their positive reputations and industry consolidation.

CRE has conducted a review of the statistical methodologies used in the Berenson 2012 study. CRE's assessment reviews the availability and relevance of the Community Tracking System survey data as well as other factors that may have been overlooked with regards to causes for high medical payment rates.

B. Summary

The overall finding of CRE's assessment of the CTS is that there is no statistical evidence to support the claim that hospitals have significant enough clout to secure steep payment increases from private insurers. Details are provided directly below, to support this primary finding.

1. *Regarding the referenced Community Tracking System (CTS) longitudinal survey study: does it provide an accurate basis for the conclusions reached in the Berenson study?*

   Assessment: The CTS survey scope does not cover the issues addressed in Berenson 2012 nor does it support the conclusions reached in the study.

The Berenson Study claims the CTS as the centerpiece study data for its conclusions. Berenson cites the seventh round of metropolitan site visits conducted in 2010, involving "539 interviews with local health care leaders in…twelve (metropolitan areas)." The Study goes on to state that site interviews were conducted with leaders of three to four major hospitals – typically the CEO, CFO, Chief Medical Officer, and Medical Staff President of each institution. The researchers also interviewed leaders of two to three physician groups and major health plans – typically the provider network manager, marketing head, and medical director; state policy makers and market observers.

The CTS longitudinal survey only collects data on households and physicians. Thus there is no CTS trend data collected from the health insurer side.

According to the CTS description found at www.hschange.org, as of 2008, the CTS Physician Survey questions have changed.

> *In 2008, the CTS Physician Survey was replaced by the HSC Health Tracking Physician Survey, which included information from more than 4,700 physicians and was conducted by mail by Westat. The new survey name reflects the substitution of the clustered 60-site sample design with a more efficient national sample. Additional changes to the survey include using a mailed survey instrument instead of telephone interviews, and significant modifications to the survey instrument to better represent current issues in care delivery and to adapt to the new data collection mode.* [64]

Moreover, HSC explicitly states that the data from 2008 and subsequent years cannot be compared with earlier years. This raises the question of why Berenson 2012 stated that the CTS data goes back to 1996 without mentioning the change in data collection protocol renders impossible any meaningful comparison of 2008 and 2010 data with earlier years. As HSC explains

> *Because of changes in survey administration, **results from the 2008 physician survey cannot be compared to findings from earlier CTS Physician Surveys**. However, the HSC 2008 Health Tracking Physician Survey establishes a new baseline that will allow future tracking of how physicians organize and practice medicine.*[65] [Emphasis added]

Berenson 2012 only considers interviews in 2010; there no evidence of a time-series analysis and changes in CTS methodology would render any time series analysis meaningless. Thus, for example, when the authors state on page 974 that, "…respondents thought that hospital negotiating strength was growing" they could not possibly be basing their claim on CTS data because no such trend data exists in the study.

2. *Is the researcher's data transparent?*

Assessment: Berenson 2012's use of CTS and other data is non-transparent, the Study is not Data Quality Compliant and cannot be used to formulate national policy.

A review of the CTS data posted at www.hschange.org reveals that the 2010 "seventh-round" interviews are not available. It appears that only the non-CTS interviews, conducted by Berenson's research were the actual basis for this study. The non-CTS interviews are not available to the public and therefore there is no way to independently verify trend-increase statements such as the one found

[64] Center for Studying Health System Change, "CTS Physician Surveys and the HSC 2008 Health Tracking Physician Survey," available at http://www.hschange.com/index.cgi?data=04.

[65] Ibid.

on page 976: "According to study respondents, multihospital systems with varying degrees of leverage now dominate health delivery in most of the twelve (metropolitan) markets."

3. Is quantitative data used to support the opinions gathered in the interviews?

Assessment: Quantitative data, even from a single point in time, is not provided in the report.

The primary thesis of the Berenson Study is that hospitals are securing steep payment increases from insurers. However, much to his credit Berenson states that the study "…did not gather data on actual payment rates…" [p. 975]

V. CRE Conclusions: Berenson 2010

1. The Community Tracking System longitudinal study cited as the study's major data source does not contain any trend data about health insurers. All CTS and supplemental interview data used in Berenson are from a single point in time and are therefore incapable of detecting or assessing any changes or trends.

2. The study's data is biased; the authors did not, as is customary, correct for the types of bias common in interview-based data collections.

3. The study is not compliant with the Data Quality Act and therefore could not be used by any federal agency. Thus, agencies could not make use of Berenson 2012 in reports, rulemakings and reimbursement decisions.

4. The study's methodology is opaque, there is no indication of the process by the study's conclusions were derived from the dataset.

5. The study's contention that hospitals are gaining leverage over health insurers is contradicted by extensive data:

    - ✓ Health insurers have been keeping a larger and larger share of premium dollars received, reducing the share they pay out in claims. Congress finally enacted requirements capping the share of premiums insurers are able to keep.

    - ✓ Health insurers increasingly specialize in negotiating with providers and of plan management, leaving financial responsibility for paying claims with the employer.

6. The study's contention that enhanced antitrust enforcement would not benefit healthcare consumers ignores the antitrust enforcement exemption healthcare insurers enjoy under the McCarran-Ferguson Act.

[Continued next page]

VI. The Public Is Invited to Comment on the CRE Analysis

CRE was the initial proponent of the Data Quality Act. For this reason, CRE goes to extraordinary measures to ensure its reports are DQA complaint. The statute prohibits any federal agency from using data in studies that are not DQA compliant.

In order to facilitate public comment on its studies CRE has developed Interactive Public Dockets (IPDs) to allow interested parties to offer their comments in any easy and anonymous manner (if they wish) without registration.

The IPD for this CRE report is here; the public is encouraged to submit comments.

There are number of "Good Government laws" which "regulate the regulators" meaning that federal agencies must be in compliant with all such laws prior to issuing a final agency action be it a reimbursement decision or a final regulation. CRE has not reviewed the Berenson report for compliance with the totality of these laws but the public is encouraged to offer comments on the same.

CRE staff performs the aforementioned analysis in their role as a regulatory watchdog.

The consideration and ultimate acceptance of the material on an IPD by federal regulators and their regulatory overseers depends, in large part, on the recognized regulatory expertise and federal credentials of the managers of the organization which hosts the IPD.