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The Unintended Consequences of Regulation

How Federal Initiatives (The "Top Ten Regulatory Irritants") are Driving Physicians Out of Independent Medical Practice

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Executive Summary

These are the "top ten regulatory irritants" driving independent physicians away from participation in the Medicare program.

(1) **Meaningless Work**: federal reporting requirements which add to the physician's work, without direct benefit to the patient (Chapter I);

(2) **Box checking**: federal requirements transforming the practice of medicine into the practice of box checking (Chapter II);

(3) **Data is replacing information**: central planning initiatives produce enormous amounts of data, but complicate acquisition of information the physician actually needs (Chapter III);

(4) **Quality**: The new definition of "quality" is what federal agencies say it is, regardless of evidence (Chapter IV);

(5) **Site of Service**: CMS pays hospitals to acquire physician practices, doubling the price it pays for medical services (Chapter V);

(6) **Fraud**: I can be labeled a fraud if I check a box incorrectly. Unlike hospitals, I don't have the resources to fight the RACs (Chapter VI);

(7**)** **Sustainable Growth Rate**: I am supposed to accept lower payment from CMS if the total number of Medicare patients or services goes up (Chapter VII);

(8) **PCORI and IPAB**: "comparative effectiveness research" does nothing for my patients, but will limit what I can do for my patients (Chapter VIII);

(9) **Costs:** It costs me to serve government patients (Chapter IX):

(10) **The government is coming between me and my patients**: in the name of "expanding benefits," without wanting to pay for that expansion, the government is changing my profession (Chapter X).

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Organization of the paper:

At the beginning of each section (or interspersed where necessary) the author offers a note, a commentary, an explanation, or, in the alternative, asks a question which may have occurred to you, as well as to him. The "author's note" is an attempt to share a thought process, to help the reader navigate the extraordinary complexity of this field.

Complex? Medical services (and the associated professionals, hospital and health service delivery systems, insurers, manufacturers) provide one of every six jobs in the American economy; it represents a growing part of expenditures by our trading partners and in their economies; and medical services will shortly be a major part of the economies of the developing world.

Medicare and Medicaid show a federal budgetary outlay of $737 billion for the current (FY 2013) year. The various estimates of observers of the American system peg the current total outlays to be in excess of $2.8 trillion, more than 18% of the Gross Domestic Product. Federal spending on health care—administration, services, regulation—is one quarter of the Federal budget.

This discussion of the "top ten regulatory irritants driving physicians out of independent medical practice" is organized as follows:

The "**presenting complaint:**" the type of comment heard most frequently from physicians. There is no scientific pretense to this order. The complaints are drawn from experience, physician "blogs" and newsletters, the gamut of discussion and observation by independent practitioners concerning the direction of their professional activity, as well as more formal polls (including works undertaken and published by The Physicians Foundation) underlining the disaffection of the independent physician from federal over-regulation. The "presenting complaint" is meant to characterize how independent practicing physicians might perceive the burden of regulation and central state planning.

"Other signs and symptoms:" these follow the presenting complaint, indicating information which lies behind the chief complaint.

"Diagnosis:" the diagnosis, what has gone astray with these top ten irritants. "Gone astray," in turn, means this: nobody intended that Medicare compromise or even destroy independent physician practices. But the overall burden of regulatory activity described below (and perceived in these "irritants") might

have that effect. What federal programs may be buying for the beneficiary, in other words, is not the professional, individually focused, medical care promised.

"Treatment:" the treatment is medical or surgical, depending upon the malady diagnosed. For example, it would seem impossible to stop the epidemic of "box checking" without major surgery to that part of the American Reinvestment and Recovery Act called HITECH. How would one shape such an initiative? Knock out the incentives and penalties? Defer or delay the various "stages?" Repeal the legislation altogether?

Since "regulations" stem from and follow legislation, "treatment" of necessity will involve both. However, as shown in passage of the American Taxpayer Relief Act of 2012 (see below), remedy may come from "de-funding" or "un-funding" targeted legislation (and the regulations thereto), as well.

On the other hand, there are some (as yet embryonic) initiatives that could be excised without major trauma, for example, PCORI.

Regulating the Health Services Field

How can we comprehend the magnitude of federal regulatory activity and its impact on medical practice? In a nation of 315 million people, do we not have hundreds of millions of transactions every day, each one of which may be seen as having an impact on our health and on medical care? The complexity of this field defeated the efforts of then-First Lady Clinton, Ira Magaziner and many policy experts in 1993 and 1994 to develop a centrally planned state economy for health care. It was too much.

If we have difficulty comprehending the entirety of this field, what is to be said about regulating it? And, by the way, what do we mean by "regulation?" Technically, regulation is a rule promulgated under a federal or state statute through a process described in an Administrative Procedures Act. The legislation is the "DNA," the regulation the "RNA." The regulation then serves as the standard and enforcement limit for a variety of lesser tools, the "proteins" resulting from the work of the RNA. These lesser tools, such as the CMS (Centers for Medicare and Medicaid Services) Operations Manual, intermediary letters (instructions to fiscal intermediaries, now Contractors), rules for various auditors, and so on, comprise literally millions of pages over and beyond the statutes and regulations.

Periodically, surveys from professional organizations, news gatherers and blogs ask this question: "Which

are the most onerous regulations, those having the greatest impact on physicians and the least merit for society?"

Medicare regulations alone constitute an estimated 125,000 pages of official rules and policies. To implement these rules, there are the fiscal intermediaries and insurance carriers, many with their own interpretations and local medical review policies. The Office of Inspector General of the Department of Health and Human Services presides over a variety of compliance, fraud prevention and related programs. All of this might be considered to be the corpus of regulatory rule in medicine, at least that part which stems directly from federal coverage of health care for the elderly.

We will also attempt to "comprehend" the whirling blades of change in health services by reliance on the policy, economic and public health literature.

Wherever possible, we will include both peer reviewed journals and the publications of official government agencies (the Congressional Budget Office, Congressional Research Service and the General Accountability Office for Congress, CMS and other parts of the Health and Human Services Department, for the Administration).

We will note the numerous expert studies—many of them, however, supported by the very regulatory agencies being studied.

In the end, we will appeal to the common sense of the reader, to answer this question: "Is it time to slow down this effort? Do we need financial and organizational relief for the beleaguered Federal budget, and for the physicians who are, after all, supposed to provide care for patients in this scheme?"

Introduction

Two competing narratives guide current discussion of public policy in the expansion of insurance coverage for and the delivery of medical services in the United States.

One narrative is that of the "reformers," that is, the economists, policy-makers and public office holders who contend that the benefits of modern medical care can and should be made available to the widest possible participation by the public, irrespective of the inability of some to pay for those services.

This expansion of benefits can be accomplished by:

(a) Introducing efficiencies in the offices of medical practitioners and the hospitals to which they admit patients, by

(b) Automating the transmission of information, so that the transmission is contemporaneously available to all who are involved in the care of the patient,

(c) Capturing that information in electronic medical/health records so that the results might be available for future episodes of medical care needed by that patient,

(d) Transmitting that information in templates and formats organized to enable screening for compliance with quality improvement or cost containment initiatives of CMS (the Centers for Medicare and Medicaid Services) and by private commercial payors,

(e) Prosecuting deviation from the norms for patient care,

(f) Studying the patterns in the transmission of that information so that inappropriate therapies can be discouraged and appropriate ones encouraged, a field collectively known as Comparative Effectiveness Research, overseen by a board (the Patient-Centered Outcomes Research Institute, PCORI), and, ultimately,

(g) Eliminating payment for therapies found to be entirely inappropriate, work to be done by the Independent Payment Advisory Board (IPAB).

The result of this narrative would be savings of $716 billion[1], for use in (a) expansion of the federal-state Medicaid program to include an additional 16 million individuals, and (b) subsidies for another 16 million using health insurance exchanges (now, "marketplaces") to purchase mandated health insurance, for all whose family income is up to four times the annual federal poverty rate. (This is the amount the President indicated would be saved when Medicare stops "overpaying" hospitals, physicians and insurance companies.) In its March 2011 Report to the Congress, MedPAC estimated that the average Medicare margin for all hospitals is minus 7%, and that two-thirds of them lose money on Medicare already. The $716 billion was drawn from a July 24, 2012 letter from the CBO to the House Speaker, and is the sum of these changes: $517 billion "saved" from Medicare Part A (hospital), $247 billion "saved" from Medicare Part B (physicians and other outpatient), an additional $48 billion spent on Medicare Part D (drugs)).

This expansion of benefits, in other words, including various subsidies to those so entitled, will be paid for through savings of approximately $716 billion from what would otherwise be expected to be spent by CMS in the purchase of medical care. The "otherwise expect to be spent" would be based on projections from historical rates of increase for insurance, hospitals, doctors and other Medicare expenses.

Finally, and most recently, if Medicare can't be "fixed" without changing the entirety of the American medical care system, the latter will have to be changed.

This is the narrative of the reformers, those seeking to expand benefits by changing medical practices.

The competing narrative is that of the physician in private practice.

The physician narrative is quite different. The physician narrative is that:

(a) Centralized control of medical practice is inefficient, error-prone and an enemy of quality.

(b) Centralized control begins with automated information transmission, hardly safe or secure. There is only limited evidence that automation in the gathering and transmission of medical information has led to either lower costs or improved quality. There is also evidence that cost has increased and that quality may have decreased.

[1] Perez, Ken, "Preparing for ACA Medicare Cuts," *Health Care Financial Management*, January 2013

(c) There is evidence that comparisons of alternative means of treating patients--Comparative Effectiveness Research or CER--is a flawed theory, at least at the level of individual patient care. The reason we train physicians for seven to fifteen years is so that they might use judgment in the application of known science to produce the best outcome for their patients. Economists, anticipating this line of reasoning, dismiss it as false heterogeneity, that is, they contend there is a "best practice" or a "one size" that will fit the overwhelming majority of patients.

(d) The practicing physician sees this process as one overseen by hostile forces, motivated to squeeze enough "savings" from that which would otherwise take place, in order to fund the expansion of benefits which those forces have promised. For example, the Patient-Centered Outcomes Research Institute, created in the Patient Protection and Affordable Care Act as a guide on CER matters, includes on its board not a single physician from private practice. However, it does have a chiropractor.

(e) This narrative holds that public officials and their supporters would like to extend the benefits of medical care at no cost (or at your cost, if you are less well organized than they are). This has been accompanied by pandering to existing beneficiaries who, mistakenly, believe they have "paid in" enough money to support their medical care.

(f) Finally, attempts to "fix" Medicare by "fixing" the health system are misguided. Ironically, it is the very presence of central state planning (administered prices, limited competition, growth of too-big-to-fail organizations, outsized "supercapitalist" representation by pharma, insurance and large hospital systems) which has driven up cost.

The "top ten irritants" outlined in this paper describe regulatory and bureaucratic constraints which simultaneously distort (the professional service) and inflate (the cost of health services generally) the result for all, not just for Medicare beneficiaries.

That is the practicing physician narrative.

These narratives may be visualized as a Venn diagram, of partially overlapping circles. Not all economists or policy-makers believe the "reform" narrative. Not all practicing physicians would be associated with the "physician" narrative.

I. Meaningless Work

Presenting Complaint, "Why do I need to weigh this patient?"

A former student was addressing my class in hospital management. In three years since graduation, she had ascended to her second responsible job, managing a large physician group for a prestigious academic medical center. She described typical challenges in working with doctors. One doctor, an older specialist, refused to weigh his patients, believing that the patient's weight was irrelevant to the diagnosis or treatment of the patient's condition, and that, moreover, the patient knew it and would regard the weighing process as an irrelevant intrusion.

The lesson was clear to the former student, now a manager, in an academic health center: "The doctor just doesn't get it."

What doesn't he get?

Well, someone in CMS wants to know what you weigh. In fact, they want to know that so much that they have made it one of the criteria (one of the easy ones in "stage one") of "meaningful use" to use in calculating incentive bonuses to physicians who "attest" to their use of electronic records in a "meaningful" fashion.

All over America, in fact, medical offices are weighing patients whom they formerly did not weigh. Some physicians and some specialists will find a patient's weight important. Many will not, in the routine office visit.

Patient weight is one of the readily achievable bogies for incentives to physicians. It is an easy target in the first stage of development of the meaningful use protocols under the Health Information Technology for Economics and Clinical Health (HITECH) Act, a part of the American Recovery and Reinvestment Act, the "stimulus" bill of 2009.

Why should we cavil? The government is giving us money to weigh the patients. So the staff has to explain to the patients, once in a while, why we need their weight, and why we have this new scale out here in the hallway. Why do we care about any of this?

Other Signs and Symptoms: A variety of requirements associated with federal, state (and private commercial) third parties which may or may not be of use to the patient or physician, but which inevitably add to the cost of delivering services.

The "meaningful use" business comes in three stages, so far.[2] The first and least difficult stage requires the use of electronic health record functions, including electronic prescribing, drug- and drug-allergy checking and the maintenance of problem medication and allergy risk. Also in this stage there are fifteen core objectives to be met, and five additional objectives from a menu of ten. Having the patient's weight is one of the easier objectives to meet, hence the near universal weighing of patients, regardless. Even at this early stage, and with three years of boosting and two years of non-trivial incentive payments, only 12% of the estimated 509,328 eligible physicians in the United States are participating, including less than 10% of the specialists, and about 18% of the primary care providers.

Moreover, even with the enormous work invested in the development of "regional extension centers" (62 federally funded outfits aimed at helping physicians with electronic medical record adoption), only 16% of their target physicians are up to "meaningful" snuff.

Actually, there is little surprise in this assessment. Wright et. al. note "downstream effects of meaningful use of quality, safety and efficiency are not yet known…" Rather than calling for experiments, transparent trials, some evidence of linkage to outcome for the patient, the authors call for "further increases in EHR adoption…to ensure the effectiveness of the meaningful use program." In other words, three years after the fact, and literally billions of dollars of payment later, physicians - - who are quick to pick up that which is of use in the care of their patients - - have voted with their feet, some 78% of them not "attesting" to meaningful use.

At the opposite - - perhaps more realistic - - end of this question, the very same week and the very same issue came up.[3] The focus of this story was about a surgical resident in one of the nation's premier hospitals repeating the same note for several consecutive days, the result of copying and pasting the previous day's note.

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[2] Wright, Ph.D., Adam et al, "Early Results of the Meaningful Use Program of Electronic Health Records," *New England Journal of Medicine*, Feb. 21, 2013, page 779

[3] O'Reilly, Kevin, "'Sloppy and Paste' Endures Despite Safety Risk," *American Medical News*, February 4, 2011

The question is not the merit or demerit of weighing patients, or of electronic medical records generally. The question is:

(a) Why the government is focusing the attention of the practicing physician on information which may or may not be of use to the physician in treating the patient;

(b) The use to which the information will be put, and

(c) The cost to both the medical practitioner and to the federal government of that application.

The apparent long-term use of such information is in development of "best practices" and "clinical guidelines." That which is not done within those guidelines will not be reimbursed.

However, the cost of obtaining this highly structured information is that the physician's attention is focused where the government wants it to be focused, not necessarily on the patient. Moreover, the development of proposed "best practices" and "clinical guidelines" is still uncertain, often evidence-free.

A recent report by the Institute of Medicine (IOM) indicates that there are almost no clinical guidelines which have been developed that meet the requirements for such guidelines as articulated by the IOM more than a decade ago. Along the path to guidelines, there will be a new generation of consultants, entrepreneurs and legal spear carriers to fight. The push to eliminate services that do not meet the guidelines, or which collect information not found "meaningful," will "bake in" to the federal budget an enormous premium for medical services, with no direct evidence relating those guidelines or that information to the quality of those services.

Unintended consequences have resulted from other CMS "cost-saving" initiatives. For example, Medicare implemented new rules in 1983 for reimbursement of hospital care, called Diagnosis-Related Groups. The DRG meant that the hospital would be paid on a "prix fixe" basis (adjusted for the interests of the most effective hospital lobbying groups), rather than being paid on a "per diem" basis.

On the "per diem" or cost-based basis, the longer the patient stayed in the hospital, the higher the cost, and the higher the cost, the higher the payment from Medicare. DRGs, on the other hand, conveyed that, implicitly, there was a guideline for length of stay, roughly the estimated payment divided by the estimated per diem cost. Under DRGs in practice, however, the premium was on getting the patient out

of the hospital - - consuming as few days as possible - - so as to "free up" the bed for the next admission, since the cash register rings for each discharge, not for each day.

Now, CMS has discovered (fifteen years later) that they have a problem, namely the readmission of patients who have just been discharged. In fact, one of every five Medicare patients in 2008 – 2010 was readmitted within thirty days of discharge.

Would this have something to do with the patient being hustled out the door? I suppose you could argue, in defense of the DRG theory, that most patients, most of the time, were ready to be cared for at home, by a visiting nurse, or in skilled nursing or other resources. But whether or not you thought that was a good theory, the fact remained the same, which is that a significant number of the patients bounced back.

Now we have new penalties, up to 1% of the hospital's reimbursement rate, for patients discharged and readmitted within 30 days who had diagnoses of congestive heart failure, pneumonia and myocardial infarction, to be expanded in 2013 to additional diagnoses and higher penalties.

After all of that (the readmission penalty, a whirl of effort newly focused on saving Medicare up to 1%), it turns out that the entire effort may be focused on the wrong problems.

Harlan Krumholz[4], always worth reading, has published evidence that a great deal of the "bounce back" of patients has nothing to do with factors that might have been controlled by a hospital (systematically) or by individual physicians.

Krumholz shows that, for four conditions at initial discharge (heart failure, pneumonia, and COPD and GI problems), the subsequent readmissions are, from 60 – 80% of the time, for other causes, entirely. These patients are generally sick, with multiple organ system challenges, on top of which they have now have been in a hospital - - which takes its own toll, in what Krumholz calls "post-hospital syndrome" - - an "acquired, transient condition of generalized risk."

Krumholz' new paper may lead not unreasonably to this conclusion: an important predictor of future hospitalization is recent past hospitalization.

[4] Krumholz, Harlan, "Post-Hospital Syndrome – An Acquired, Transient Condition of Generalized Risk," *NEJM*, 368;2, January 10, 2013

Having looked at this, how foolish does the "readmission" penalty appears? The theory is that the hospital and its professionals were doing an inadequate job on selected diagnoses (this year, as noted, CHF, pneumonia and MI), and that patients "bounce back" within thirty days as a result of the inadequacies of that job, and that a penalty should follow.

But what sense does it make to penalize hospitals for the subsequent medical needs of patients, needs having nothing to do with the condition of the patient at initial discharge? In any event, CMS will save (up to) its 1%, the field will spend a fortune attempting to "manage" the post-hospital status of patients, a set of social tasks generally felt to be best performed by almost any organization other than a hospital.

Now what? Hospitals on the brink will inevitably find themselves facing this question: what do we do with the sicker patient (multiple co-morbidities) who has extensive social problems (homelessness)? Some will strive mightily (through additional expenses post-discharge) to ensure that the patient doesn't come back. Others will not. Entirely unintended, but predictable.

The "Medical Loss" Ratio

The new use of language in support of policy goals means that phrases with historic context now mean different things to different parties in the health field. This is especially true if the new use of language - - policy "newspeak" - - has economic consequence.

For almost all of the history of modern managed care plans, success was measured by controlling the "medical loss ratio" (where the numerator of the ratio is the aggregate of medical expenses utilized in the care of the patients, the denominator is the premium income). Health insurers struggled to minimize the numerator through "cost containment" (denial of admissions, denial of specialty diagnostic studies, selection of healthier groups to insure, etc.).

The most admired players in the commercial managed care industry (such as United Healthcare) specialized in low medical loss ratios, indicating to investors that they would have more money left over from premium and investment income to return to those investors. Indeed, one year United celebrated these returns by awarding its chief executive total compensation in excess of $1 billion. The "lowest of the low" year in and year out was generally Sierra Health Plan in Nevada, now part of United. Sierra frequently paid 70% (sometimes less) as a medical loss ratio (leaving 30% for administration and profit).

A typical non-profit Blue Cross plan would pay 85%. A commercial insurer seeking to gain market share by lowballing premiums might pay more.

Now, with the requirement (under PPACA) that medical loss ratios be 85% in urban markets, 80% in smaller markets and states with limited competition, you would think that the incentive was changed. By way of background, HMOs appear to make very little money from their commercial business, which is largely self-insured. Also, HMOs run into trouble in the smaller group and individual markets, with rescissions, "claims-based underwriting" and other controversial market conduct practices. Since the origin of the Medicare Advantage Program, Medicare Advantage (Part D) has been the only consistent source of profit for the HMO industry; plans that administer Medicare Part D programs are given an average of 12% more money than would be expended on the same patients in the "fee for service" program.

The question, then, is—how can we arrange the numerator so that we don't have to give back what we net from a relatively small volume of underwritten commercial insurance and from Part D? You might think that administrative cost would go down, so as to maximize that percentage of the premium dollar going to actual medical expenses. But you would be wrong. Since the passage of PPACA and the roll out of rules for the medical loss ratio, there has been an ongoing debate as to the definition of "medical loss ratio," as if it were a new or undefined concept.

The insurance brokers (acting through the National Association of Insurance Commissioners) put up a mighty battle to be included as part of the cost of doing business (the services to the patient!), or, in the alternative, to be excluded from the calculation altogether, so that their presence and work would not count against measurement of the loss ratio. They are acutely aware of the fact that the carriers have to give back amounts of money (and began to do so in 2012) represented by the "excess" of income over the 85% or 80% standard.

Other groups fast off the mark were the pharmaceutical manufacturers and the pharmacy benefit managers. The pharmacy benefit managers actually managed to have a portion of their *discounts* included in the numerator, a signal victory largely unnoted.

Now we have concerted efforts to put carrier utilization review, clinical guidelines, electronic record management and other expenses into the numerator, as if they were also medical expenses. It's all enough to make you ask, "What do you mean by medical expenses?"

Meaningful Use

The business of "meaningful use" is intended to incentivize physicians to adopt "certified" electronic medical record technologies that produce data which Congress in passing the American Recovery and Reinvestment Act thought to be "meaningful."

But meaningful to whom? Is not the physician, focused on the patient, in the best position to know what information is meaningful? If the government wants to pay physicians to adopt medical records, so be it, something good (stimulation of the information system industry, flat prior to the passage of the ARRA) may follow.

And, if physicians choose to go through this process, and to convert their practices, in response to federal incentives, why not?

The central issue is this: The incentives, coercion and fear all have no scientific basis, that is, there is nothing that indicates that the quality of medical care actually made available to the patient (as measured by outcomes) is in any way, shape or form dependent upon the information designated by CMS as "meaningful."

In the absence of that kind of nexus - - showing that a requirement for specific information to be collected yields a better quality - - why not drop this rock?

Treatment:

Repeal PL 111-5, Section 4101(a), 123 CFR 467-472.

Chapter II, The Changing Nature of Medical Practice

Presenting Complaint:

The challenge facing policy makers - - and explanation for the actions they have taken - - is as follows: how to ensure that the benefits of modern medical care are available to all of the population, on an equitable basis.

The immediate problem is this: the cost of delivering those medical services (including the services themselves, the overhead and bureaucracy, the "insurance" layer, both public and private) is formidable, sufficiently high that, were all members of the public to have access to those services on the basis now provider to most, the federal treasury, among others, would be bankrupt.

Moreover, the mechanism through which we would address the "revenue" side of the equation - - the avoidance of bankruptcy by raising revenue - - appears inadequate to levy on the public the tariffs that would be needed to bolster financial feasibility. Therefore, the "cost" side must be attacked; namely, the way in which we pay for medical care must be dramatically changed, in fact by $716 billion or more, during the next decade.

Other Signs and Symptoms: What is the likelihood that this will happen?

Likelihoods, probabilities and projections have had great attention in recent years, given our success in some areas (baseball) and dramatic failure in others (economic meltdown).

Nate Silver, in "The Signal and the Noise," observes that the promise of "big data" (see below) is much more likely to be just that, promise, rather than performance.[5] He says, "The numbers have no way of speaking for themselves. We speak for them…like Caesar; we may construe them in self-serving ways that are detached from objective reality." He goes on to observe, with regard to the global financial crisis, "Models, and our failure to realize how fragile they [models] were to our choice of assumptions, yielded disastrous results." Citing Toffler, a generation earlier, Silver writes, "He thought our defense mechanism would be to simplify the world in ways that confirmed our biases, even as the world itself was growing more diverse and more complex."

[5] Silver, N., The Signal and the Noise, page 11-12

In evaluating the alternative scenarios or "narratives" (see above), we should ask:

- What are the biases in the first narrative?
- What are the biases in the second narrative?
- How can we distinguish one set of biases from another, and give way to that which is deserving?

The biases in the first set of narratives are, most importantly, these: they are based entirely on projection into the future from limited models. Moreover, (see below, Congressional Budget Office Reports on Medicare payment incentive experiments), our experience to date is that each of the prior models, to which these are advances and modifications, have failed. That is, to the extent CMS has made a "prediction" in the past, based on a particular incentive or penalty reimbursement change, it has been in error, without effect, or, in some cases, with counter-effect, that is, moving backward from our goal (higher rates, more confusion, more employer stress = fewer employees covered with health insurance).

The record of CMS in supporting policy hypotheses in medical care should give pause, but, apparently, does not. To the contrary, our incapacity in the past to project the future consequences of our fragile economic models appears only to have emboldened those whose bias is in favor of the outcome.

What do we know about the bias in the alternative narrative, that of (many, perhaps most) independent practicing physicians? We know that is it borne of experience. That is, while the first narrative is a *projection*, dependent upon limited information and fragile models, the second narrative is a story based on experience.

How to articulate that story, how to bring together the various pieces and threads, how to appropriately label ("Top Ten Irritants") so as to make the story understandable and compelling - - that is a challenge.

What is not a challenge, however, is to verify the truthfulness of the second narrative, in that it either does or does not reflect the current *experience* of the independent practicing physician. We would know this (see below) by analysis of the behavior of the independent practitioner, in

(a) leaving private practice, to join higher reimbursed hospitals,

(b) taking "defensive" action with regard to reimbursement, that is, developing means of payment not entirely depending on fee-for-service medicine.

If the second narrative is "true," in other words, if, that is, it corresponds to objective reality (for Silver), then we would expect to see physicians behaving in a way which moves away from the hot burner on the stove.

If, arguably, the second narrative were not true, not corresponding to objective experience, we might find physicians coming out of residency training programs looking for associate, then partnership positions with fee-for-service practitioners. But, to the contrary, we see the new graduate interested in having a "job," with predictable hours, time off, thank you, and "shift-related" responsibilities, that is, the capacity to "hand off" responsibilities when necessary for personal convenience.

Clinical Quality Measures

In the end, and it is visible from where we are now, CMS intends to promote change in the process of diagnosing disease and medical and surgical treatment. In the 2014 Medicare EHR Incentive "Meaningful Use Program" CMS has announced the Clinical Quality Measures (CQMs). The CQMs begin in 2014, regardless of whether the physician is participating in Stage I or Stage II. Reporting on the CQMs to demonstrate meaningful use is a requirement. What are the CQMs?

In 2014, physicians will be required to submit nine of 64 approved CQMs from at least three of six so-called National Quality Strategy (NQS) domains, including clinical process/effectiveness, efficient use of health care resources, population and public health, care coordination, patient safety and patient and family engagement. The late starters, those for whom 2014 is the first year, have an even earlier deadline, having to submit CQM data by October 1, 2014.

The CQMs, to put it bluntly, are the acceptable algorithms for diagnosis and treatment of medical conditions (see **chart**, following page, excerpt, first three CQMs of 28 pages of CQMs published by CMS 11-2012.)

You can see the future from these pieces: First, we automate reporting, in prearranged and prescribed templates. We ensure compliance by incentives (the upside) and penalties (the downside), sometimes both. Then, we label the preferred outcomes to be higher quality, those that don't fit the mold lower quality. We compel the reporting of CQMs, in preparation for future decisions by the Patient Centered Outcome Research Institute and/or the Independent Payment Advisory Board (PCORI and IPAB) to "outlaw" the deviance.

CLINICAL QUALITY MEASURES FOR 2014 CMS EHR INCENTIVE PROGRAMS FOR ELIGIBLE PROFESSIONALS

CMS eMeasure ID	NQF #	Measure Title	Measure Description	Numerator Statement	Denominator Statement	Measure Steward	Link to NQF website
CMS146v1	0002	Appropriate Testing for Children with Pharyngitis	Percentage of children 2-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	Children with a group A streptococcus test in the 7-day period from 3 days prior through 3 days after the diagnosis of pharyngitis	Children age 2-18 years who had an outpatient or emergency department (ED) visit with a diagnosis of pharyngitis during the measurement period and an antibiotic ordered on or three days after the visit	National Committee for Quality Assurance	http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=370
CMS137v1	0004	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	Numerator 1: Patients who initiated treatment within 14 days of the diagnosis Numerator 2: Patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit	Patients age 13 years of age and older who were diagnosed with a new episode of alcohol or drug dependency during a visit in the first 11 months of the measurement period	National Committee for Quality Assurance	http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=1245
CMS165v1	0018	Controlling High Blood Pressure	Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	Patients whose most recent blood pressure is adequately controlled (systolic blood pressure < 140 mmHg and diastolic blood pressure < 90 mmHg) during the measurement period.	Patients 18-85 years of age who had a diagnosis of essential hypertension within the first six months of the measurement period or any time prior to the measurement period	National Committee for Quality Assurance	http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=1236#p=-1&s=n&so=a

Can you imagine lawyers putting up with this? First, lawyers who charge too much would have their clients told by the government that the lawyers are crooks, or at least inappropriately high priced. Then, the lawyer who took an hour, versus the one who took fifty minutes, would be sanctioned. Finally, there would be a prescribed algorithm for the conduct of "quality legal services," deviation from which might be labeled fraud, ultimately barring the lawyer from participating in legal care. We don't have this, of course, since most of the laws are written by lawyers, not by doctors. Inadvertently, perhaps without meaning to, the lawyers (and regulators who follow them) are changing the nature of medical care, away from the one patient-one physician model, and toward a more "efficient" (but arguable much less effective) set of approved practices.

Diagnosis

Therefore, the first narrative is doomed. To the extent the narrative is in place as a means of expanding access to medical services as we know them at an affordable cost, it has no history, and, to the extent its sponsors (CMS) have a history, it is one of inaccurate prediction and forecasting. What, then, will we have with the second narrative?

Given that the second narrative reflects today's reality, and, in all likelihood, tomorrow's, there are certain inevitable realities which will follow. There will be a "bifurcation" in medical care between that which can be afforded by public bodies and that which is available on a fee-for-service basis. This will mirror the medical care systems of other countries with central state planning of health care, that is, a "publicly available" level of medical care for most, a "privately available" level of medical care for some. The difference will be in the degree: The enormous wealth, prosperity and (remaining) entrepreneurial spirit of our country will ensure that our "publicly available" services are of a high or relatively high level, and therefore that our "privately available" services will not grow substantially, that is, there will be a minimal migration from the former to the latter.

Silver urges us to rely on reality, and to avoid bias, in the assessment of enormous amounts of information (noise) and the attempt to discern directions which are consistent with history and human nature (the signal).

Here is a beginning. For most of the past decade, CMS has been preoccupied with attempting to centralize measurement of "value" in hospital services. The CMS thesis in pursuit of value is that "best practices" lead to "best outcomes." This should mean that CMS efforts at rewarding hospitals on

"process of care" measurement (best practices) and "patient satisfaction" should lead to better outcomes (as initially measured by rates of readmission of patients within 30 days in a limited number of diagnoses). This is an arguable premise from the outset, illustrating, if nothing else, the crude nature of our attempts to measure value, at least in a central state planned mechanism.

In reviewing the "VBP" (Value Based Purchasing) and readmission outcomes, it has been noted that "Dozens of hospitals that got the highest marks for avoiding readmissions were heavily penalized for their performance on process and patient satisfaction, while dozens more that received the maximum penalty for high 30-day readmission rates got high marks on key processes and attention to patients."

By adding these two numbers, as indications of the capacity of the measured institutions to (a) deliver effective medical care or (b) fill out the boxes properly, or (c) both, results are as found on the **chart**, next page.

If you do this—that is, take into account the bonuses and penalties for the "Value-Based Purchasing" score (70% on twelve process measures, 30% on the "Hospital Consumer Assessment of Health Care Providers and Systems Survey") and the penalties for readmissions penalty (from 0 – 1%), eight of the top ten hospitals in the nation (of 3,429 listed by CMS) are partly or completely owned by physicians.

However, it would be politically inopportune to point this out, given that a key element (apparently) in our attempt to control the high cost of health care will be to favor the increasingly consolidated (too-big-to-fail) non-profit hospital systems at the expense of the physician-owned hospitals (a tiny number, slated, per Section 6001 of the Patient Protection and Affordable Care Act, to stay that way).

Finally, CMS has had to correct this calculation twice since initially made, the latest (in March 2013) affecting a total of 1,274 hospitals, albeit in minor amounts.

Follow on comments to the VBP business included "The science isn't quite there yet," and "There is limited evidence about the effect of treatment strategies for most acute care conditions" and, most telling, "It's time to move on." The last of these seems to say, "Notwithstanding our failed attempts to have central state planned measurement in the past, let's move on to bigger and more complex measurements."

Parenthetically, Silver notes that a key element in the historic failure of the rating agencies to discern the true level of uncertainty (hence exposure to nearly unlimited risk) in collateralized debt obligations was

Provider Number	Hospital Name	City	State	ZIP Code	Hospital Referral Region	VBP Percent	Readmission Percent	Total Bonus/Penalty Percent
130063	TREASURE VALLEY HOSPITAL	BOISE	ID	83704	Boise, ID	0.83%	0.00%	0.83%
280127	LINCOLN SURGICAL HOSPITAL	LINCOLN	NE	68506	Lincoln, NE	0.78%	0.00%	0.78%
450883	BAYLOR MEDICAL CENTER AT TROPHY CLUB	TROPHY CLUB	TX	76262	Dallas, TX	0.78%	0.00%	0.78%
450774	TOPS SURGICAL SPECIALTY HOSPITAL	HOUSTON	TX	77090	Houston, TX	0.75%	0.00%	0.75%
420054	MARLBORO PARK HOSPITAL	BENNETTSVILLE	SC	29512	Florence, SC	0.74%	0.00%	0.74%
450422	BAYLOR MEDICAL CENTER AT UPTOWN	DALLAS	TX	75204	Dallas, TX	0.74%	0.00%	0.74%
450874	IRVING COPPELL SURGICAL HOSPITAL LLP	IRVING	TX	75063	Dallas, TX	0.73%	0.00%	0.73%
360352	SURGICAL HOSPITAL AT SOUTHWOODS	YOUNGSTOWN	OH	44512	Youngstown, OH	0.73%	0.00%	0.73%
150160	INDIANA ORTHOPAEDIC HOSPITAL LLC	INDIANAPOLIS	IN	46278	Indianapolis, IN	0.72%	0.00%	0.72%
450851	BAYLOR HEART AND VASCULAR HOSPITAL	DALLAS	TX	75226	Dallas, TX	0.72%	0.00%	0.72%
280131	MIDWEST SURGICAL HOSPITAL LLC	OMAHA	NE	68114	Omaha, NE	0.72%	0.00%	0.72%
670059	ST LUKES LAKESIDE HOSPITAL	THE WOODLANDS	TX	77384	Houston, TX	0.71%	0.00%	0.71%
670049	NORTH CENTRAL SURGICAL CENTER LLP	DALLAS	TX	75231	Dallas, TX	0.71%	0.00%	0.71%
460043	OREM COMMUNITY HOSPITAL	OREM	UT	84057	Provo, UT	0.70%	0.00%	0.70%
40152	PHYSICIANS' SPECIALTY HOSPITAL	FAYETTEVILLE	AR	72703	Springdale, AR	0.69%	0.00%	0.69%
370192	NORTHWEST SURGICAL HOSPITAL	OKLAHOMA CITY	OK	73120	Oklahoma City, OK	0.69%	0.00%	0.69%
170183	KANSAS SURGERY & RECOVERY CENTER	WICHITA	KS	67226	Wichita, KS	0.68%	0.00%	0.68%
100314	WEST KENDALL BAPTIST HOSPITAL	MIAMI	FL	33196	Miami, FL	0.68%	0.00%	0.68%
110200	HUGHSTON HOSPITAL	COLUMBUS	GA	31909	Columbus, GA	0.68%	0.00%	0.68%
190257	GREEN CLINIC SURGICAL HOSPITAL	RUSTON	LA	71270	Shreveport, LA	0.67%	0.00%	0.67%
390316	SURGICAL INSTITUTE OF READING	WYOMISSING	PA	19610	Reading, PA	0.67%	0.00%	0.67%
390322	BUCKS COUNTY SPECIALTY HOSPITAL	BENSALEM	PA	19020	Philadelphia, PA	0.67%	0.00%	0.67%
670008	HOUSTON PHYSICIANS' HOSPITAL	WEBSTER	TX	77598	Houston, TX	0.67%	0.00%	0.67%
260115	MISSOURI BAPTIST HOSPITAL SULLIVAN	SULLIVAN	MO	63080	St. Louis, MO	0.66%	0.00%	0.66%
450221	MOORE COUNTY HOSPITAL DISTRICT	DUMAS	TX	79029	Amarillo, TX	0.66%	0.00%	0.66%
450888	TEXAS HEALTH HARRIS METHODIST HOSPITAL SOUTHLAKE	SOUTHLAKE	TX	76092	Dallas, TX	0.66%	0.00%	0.66%
200041	INLAND HOSPITAL	WATERVILLE	ME	4901	Portland, ME	0.65%	0.00%	0.65%
390321	SURGICAL SPECIALTY CENTER AT COORDINATED HEALTH	ALLENTOWN	PA	18104	Allentown, PA	0.65%	0.00%	0.65%
370222	MCBRIDE CLINIC ORTHOPEDIC HOSPITAL, L L C	OKLAHOMA CITY	OK	73114	Oklahoma City, OK	0.65%	0.00%	0.65%
360263	INSTITUTE FOR ORTHOPEDIC SURGERY	LIMA	OH	45804	Dayton, OH	0.65%	0.00%	0.65%
340148	MEDICAL PARK HOSPITAL	WINSTON-SALEM	NC	27103	Winston-Salem, NC	0.64%	0.00%	0.64%
190201	WOMEN AND CHILDREN'S HOSPITAL AT LAKE CHARLES	LAKE CHARLES	LA	70605	Lake Charles, LA	0.64%	0.00%	0.64%
450780	METHODIST AMBULATORY SURGERY HOSPITAL NW	SAN ANTONIO	TX	78240	San Antonio, TX	0.64%	0.00%	0.64%
390314	COORDINATED HEALTH ORTHOPEDIC HOSPITAL	BETHLEHEM	PA	18017	Allentown, PA	0.64%	0.00%	0.64%
390323	ADVANCED SURGICAL HOSPITAL	WASHINGTON	PA	15301	Pittsburgh, PA	0.64%	0.00%	0.64%
450856	SOUTH TEXAS SPINE AND SURGICAL HOSPITAL	SAN ANTONIO	TX	78258	San Antonio, TX	0.64%	0.00%	0.64%
450886	SOUTHWEST SURGICAL HOSPITAL	HURST	TX	76054	Fort Worth, TX	0.64%	0.00%	0.64%
520194	ORTHOPAEDIC HSPTL OF WI	GLENDALE	WI	53212	Milwaukee, WI	0.64%	0.00%	0.64%
170109	MIAMI COUNTY MEDICAL CENTER	PAOLA	KS	66071	Kansas City, MO	0.63%	0.00%	0.63%
420037	HILLCREST MEMORIAL HOSPITAL	SIMPSONVILLE	SC	29681	Greenville, SC	0.63%	0.00%	0.63%
230072	HOLLAND COMMUNITY HOSPITAL	HOLLAND	MI	49423	Grand Rapids, MI	0.62%	0.00%	0.62%
170190	MANHATTAN SURGICAL HOSPITAL LLC	MANHATTAN	KS	66502	Topeka, KS	0.62%	0.00%	0.62%

an observation that “I don’t think they wanted the music to stop.” If your business is federally funded research into the measurement of quality, it may be indeed the time to move on, to seek new and more elaborate studies.

III. Automated Information Collection

Presenting Complaint: "This information system slows me down, and often asks questions having nothing to do with my patient's needs . . . "

Nobody denies that the amount of data in the American (and international) health systems is enormous, and, properly harnessed, could reveal patterns and insights now hidden. There is the clinical data of health care providers, for example, electronic medical records and images. There is the data on patient behavior, for example, spending and lifestyle. There is data on insurers' claims, for example, volumes, types of care and costs, and on pharmaceutical research and development data, for example, clinical trials.[6]

As described in a recent popular review, however, the data is "massive and messy," and while "harnessing vast troves of data is increasingly seen as the solution" (the problem of higher than expected health costs), we appear to be only at the outset of the use of these "predictive analytics" (see below) to move information forward in an orderly manner.

At a minimum, attempts to provide rewards and penalties would appear premature, until or unless we know what it is we are rewarding or penalizing, with some certainty, and the connection of those phenomena with the actual well-being of patients.

The problems presented by the federal initiatives in the promotion of information systems are as follows:

(1) The promotions focus almost entirely on "process" steps, this one's good idea, that one's recent paper. This has spawned the mini-industry of promoters, consultants and analysts, focused on PQRS (a change from PQRI!), the Physicians Quality Reporting System; HQID, PGPD; and the like.

(2) The "process" measure - - nearly always unarguable, in its general terms - - is spun out into extraordinary detail, attempts to control interactions a long distance from Washington, DC, and at variance with bureaucratic processes. The long reach is connected to an incentive (today) or a penalty (tomorrow), whether or not…

[6] Dembosky, April, "Data Prescription for Better Health Care," *Financial Times*, December 12, 2012

(3) It promotes "quality." Regrettably, many of the claims for the promotion of quality through electronic records are evidence-free (see below, especially Congressional Budget Office reports), that is, there is no link between "preexistent quality measures" and the process steps outlined in the CMS initiatives. Recently the "Pioneer Accountable Care Organizations" have stepped into a similar controversy, noting that the CMS "quality measures" against which their performance will be assayed are without foundation.

(4) The process measures will lead to lower cost. You might think this (cost, as opposed to quality) would be more readily measured. If so, see Medicare's treatment of the HQID program, below, and, of course, again, the CBO reports. Finally…

(5) There is a push - - when all evidence to support the cost decrease or quality improvement evaporates - - to spend more, in quixotic pursuit of a better result, if only more money is spent. For example, the Rand Corporation, in service to its sponsors, reported seven years ago that health IT could save the U.S. health care system $81 billion a year. (It passed general notice at the time, but not now, that the 2005 Rand report was paid for by a group of companies, including General Electric and Cerner Corporation, that sought to promote their electronic medical records products[7].) In the interim, unfortunately, annual health spending has increased from $2 trillion to $2.8 trillion.

(6) The failure of health IT[8],[9] to impact any of this is "not due to its lack of potential but to shortcomings in the design and implementation of health IT systems…"

In other words, if we only spent more time, had more disruption in the office and in the hospital, we would realize the lower cost or higher quality results.

The revisionist Rand report explains that "we've not achieved the productivity and quality benefits that *are unquestionably there for the taking.*" [Emphasis added]. This faith-based research flies in the face of the evidence: As Abelson notes, "There is increasing concern that electronic records have actually added to costs by making it easier to bill for more services," to say nothing of, as indicated elsewhere in this paper, the extraordinary expense.

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[7] Abelson, Reed, "In Second Look, Few Savings from Digital Health Records," *The New York Times*, January 10, 2013

[8] Terry, K., "Rand: Health IT No Bargain Yet," *Information Week*, January 8, 2013

[9] Kellerman, A.L., and Jones, S.S., "What it Will Take to Achieve the As-Yet-Unfulfilled Promises of Health Information Technology," *Health Affairs*, January, 2013

All of this, despite some twenty-two million patient records compromised by accidental disclosure since the Office of Civil Rights in HHS began keeping records of such disclosures in 2009.

Parenthetically, the observation concerning "easier to bill for more services" would look less self-serving if the very companies which sponsor and promote electronic medical records did not use that feature as a primary selling point to physicians. ("We know this is a pain, and expensive, but you will get the federal incentive money, and capturing more information will enable you to bill for services you are actually providing, Doctor.")

The regulator response, predictably, is that it was easier for "hospitals and doctors to bill for services they did not provide." But a reasonable hypothesis is this: the automated capture of information of peripheral importance does exactly what could have been predicted at the time - - ease billing for services that were provided, but which were previously difficult or time-consuming to document.

At the very highest level - - the information czar - - there is a partisan split as to which administration (Bush, which began this; Obama, which extended it) made the bigger mistakes. David J. Brailer, the first health information czar, under President Bush, said he "still believed" that "tens of billions of dollars could eventually be squeezed out of the health care system through the use of electronic records."[10] He thought the "colossal strategic error" was the incentive program - - "the vast sum of stimulus money flowing into health information technology created a single 'race to adopt' mentality - - buy the systems today to get government handouts, but figure out how to make them work tomorrow."

(7) This trajectory, entirely predictable, obscures the one finding which experience underlines: the effort has increased the cost, decreased the productivity and had an arguable effect (see below, the new distance between the patient and the doctor) against what most patients would understand to be "quality" in their medical care.

In other words, the belief supporting the hypothesis is sufficiently strong, augmented by research funded by sponsors of the hypotheses, that any alternative is not seriously pursued, and, at least amongst the academic students of the field, dismissed.

[10] Abelson, Reed, "In Second Look, Few Savings from Digital Health Records," *The New York Times*, January 10, 2013

There is nothing new about these observations, of course. Dr. Scot Silverstein has been at it since 1998, with a theme roughly summarized as this: it is impossible for medical professionals to be ready for a system that is not ready for them.[11] Silverstein, with a 20+ year history in medical informatics, says, "Physicians are largely pragmatists. They will adopt technology when it is clear to them that it is both safe and effective and might actually make their patient care better."

Silverstein notes the rush to implement meaningful use and grab the limited government incentive dollars being doled out by HHS. The rush includes measures to suppress reporting of bad outcomes, with gag clauses to mask defects in health IT, industry propaganda against "Luddites," numerous impediments to the flow of information and even hostile retaliation against physicians through sham peer review.

Efficiency and Effectiveness

The issues involved with automated information collection in the health field seem to fall into one of two categories: (a) is this an appropriate way for physicians (and other direct service professionals) to "relate" to patients, a question of "effectiveness"? And (b) how can we separate the "efficiency" of such information collection from its apparent propensity to foster fraud?

In the hospital world, the general issue of hospitals badgering physicians to admit patients, perform tests and the like is one of great interest.

One recent focus of media attention came via a "60 Minutes" investigation. A question of particular interest to "60 Minutes" was whether a hospital management company used an artificial software contrivance in their various hospital Emergency Departments (ED) to boost the probability that ED patients would be admitted, rather than logged in under the much lower paying "observation" status, or sent home.

The software worked something like a video game, in which the physician recorded one after another sign or symptom, generally in response to a programmed question, until the aggregate "value" of the inputs justified an admission.

[11] Mace, Scott, "Scot Silverstein's Good Health IT and Bad Health IT, *Health Leaders Media*, January 8, 2013

Two other hospital chains had previously sued one another over this business, each alleging fraud by their competitor.

The target of “60 Minutes” argued that their administrators have no influence on the admission of patients from the ED--it's them doctors that do it. This brought guffaws from the field, and, of course, you can see from the program what some of the doctors say. They were punished financially and threatened with dismissal if their “scores” did not produce the system-wide goal of a 20% conversion rate, that is, 20% of ED visits becoming inpatient admissions, with 50% the goal for Medicare patients, both of these goals in excess of national norms.

What is the issue applicable to over-regulation, the theme of this paper? That attempts to automate and systematize the collection of information which has inherent and substantial financial value to those setting or living with the rules is *not the same as automating information for the clinical benefit of the patient.* A simple point, no?

Other Signs and Symptoms: My productivity is down, the amount of "information" is up, the relevance of the "information" I receive is of questionable value for my patients.

An example of an issue on this list is the current controversy involving the evaluation and management (E&M) codes for office visits.

We know that a 99201 Common Procedural Terminology (CPT) office visit is problem-focused, straightforward in its medical decision-making for a new patient with a minor problem, and (somewhat controversially) that it takes ten minutes.

We know that a 99205, on the other hand, involves a comprehensive exam for a new patient, has high complexity in medical decision-making, has moderate-to-high severity in terms of the problem as presented, and takes, again controversially, sixty minutes or so to deliver.

The same categories involved in comparing these two CPT codes (range of activity, medical decision-making complexity, nature of the presenting problem and time) are also applied in other series of codes for office visits by established patients, for initial and subsequent hospital care, for emergency department services, for nursing facility care, and so forth.

Historically, a physician who has a 99201 or a 99211 (for an established patient) would deal with the issue presented. What would distinguish the 99201 from the 99202, 99203, 99204 or 99025? It would be whether or not "required key components" for billing such codes had been included, and what the resulting judgment was with regard to medical decision-making and involvement of other presenting problems.

With our "information system" limited to what the doctor could physically write or dictate him or herself, the results were fairly straightforward.

More recently, we have had policymakers urge (and reward) automation of our information collection, and, further, in clinical decision support, have decisions made with the aid (and by inference for the future, by requirement) of algorithms based on historical patterns. This ordering of information began with the work of Professor Larry Weed at Dartmouth in the 1970s with the problem-oriented medical record.

Automation in the collection of information has its precedents in manufacturing, retailing, transportation and other fields. What could we have learned from those other fields? We could have learned that there are patterns in the automated collection of information. For example,

(a) "Documentation by exception,"
(b) "Prefilled templates," and
(c) "Bringing forward" information (a step up from "copy and paste")

. . . are all known features in the automation of information systems that are the natural consequence of "sweeping" vast quantities of information.

We are on the verge of major investment by leadership of health systems in "big data" exercises, which will bring to the physician's attention even greater volumes (perhaps exponentially greater volumes) of information.

These known features of automated information systems generally will also, in the health field, increase reimbursement, by suggesting additional steps to be taken in examination of the patient, and documenting the results of those steps. These features help assure that physicians will "click on" necessary things to ensure optimal billing and payment.

So this - - the higher bill, reflecting more "work,"- - is an unintended consequence. With what result?

Here is the result: the Secretary of HHS and the Attorney General jointly held an "emergency" news conference, to denounce as outrageous the increased reimbursement going to hospitals and physician practices as a result of the efficiency of automated systems in collecting information.

An observation in "AHRQ Morbidity and Mortality" in July, 2012 noted that the solutions to this problem would probably include (a) harassment of sinners, (b) technology (disabling copy and paste functions), (c) education and mentoring, and/or (d) acceptance.

In the meantime, we are on the verge of criminalizing (as fraudulent billing) results which come naturally from the automated collection of information, prompting and the electronic systems that process that information into a bill.

Other Signs and Symptoms, e.g. ICD-10

A tsunami of diagnostic upcoding looms.

We have not yet recovered from MSDRGs, through which we found that the human body had evolved quickly between 1983 and 2008. After October 1, 2008, for example, that body no longer experienced plain old chronic obstructive pulmonary disease (DRG 88). COPD-MS was now MUCH more expensive, with appropriate medical severity lingo.

Well, here we go again, from 17,500 relatively stable ICD-9 diagnostic categories to 155,000 finely delineated differences in ICD-10. An unparalleled opportunity for mistake, scandal and, of course, cost increase without benefit to the patient.

More Signs and Symptoms

The latest "buzz phrase"/technology for CMS is predictive analytics. Widely heralded as a means of enabling CMS to "prevent" fraud, the Office of Inspector General now has the first report out, indicating that CMS's roll out of predictive analytics suffers from inconsistent data and flawed methodologies sufficiently severe to make it impossible to track inaccurate bills.

Among the OIG findings are these:

a. There is no requirement that the "contractors" track money recovered from following so-called Fraud Prevention System (FPS) initiatives;
b. There is no requirement that FPS be coordinated with law enforcement authorities;
c. The methodology for development of projected "savings" from "improper payment" does not account for the fact that not all of the claims that came from a former provider were necessarily false, and that some, if not many, (perhaps most) of such previously denied claims may eventually be paid;
d. Finally, there is no requirement for the calculation of costs to verify information associated with the fraud investigation.

CMS is the first federal government agency to use predictive analytic technology on a large scale in an attempt to identify fraud, as well as "waste and abuse," otherwise undefined.

The OIG report follows one by the General Accountability Office, chastising CMS for falling behind in integrating predictive modeling with payment processing. The GAO report blamed the lack of progress on the difficulty involved in developing the system in the abbreviated amount of time available. GAO indicated that CMS did not define or measure particular benefits or goals of the program. As a consequence, GAO pointed out, it is not possible to determine the extent to which the FPS is increasing CMS's ability to accomplish its goals.

One Senator, commenting on CMS's lack of progress, said that "GAO has found that even after spending $77 million on the program, CMS has no idea whether it is saving money or preventing fraud."

More Diagnosis . . .

"e-Iatrogenesis" has become a focus of health information literature.[12]

[12] Weiner, JP, "e-Iatrogenesis: The Most Critical Unintended Consequences of CPOE and Other HIT," *Journal of the American Medical Informatics Association*, 2007; 14:387-8.

The unintended consequences of computerized physician order entry and other elements involved in the "meaningful use" of electronic medical records highlight the importance of studied design, testing, revision and retesting in information systems.

Weiner notes that, "EHR-induced risks include use errors (an interaction between the user and the technology that is neither what the user expected nor what the designer intended), inefficiencies, miscommunication and work-arounds." He calls the widespread promulgation of EHRs "premature," spurred by "incentives." He predicts that most health care entities, lacking the knowledge or resources to evaluate electronic health records "will make uninformed purchase decisions favoring products promoting the capture of 'meaningful use' rather than usability or safety. Many will short-change the local customization required to make EHRs efficient, usable and safe."

Pressure on the physicians, support staff and hospitals generally will lead to unreported error. Governmental capacity for post-market surveillance, known to be deficient in pharmaceutical and device regulation, may also fail for health information technology. Taylor writes, "Because of the enormous and immediate financial incentives available to implement this plan, hospitals are rushing to initiate programs that are far from user-friendly or safe, often requiring physicians to beta-test EHRs being written even as they are being installed…" This might be forgivable if not for the serious risks EHRs pose to patients' health and safety, the very goals of the authors of these efforts.[13] Taylor continues, "In the Wild West of commercial EHRs, there is virtually no regulation of program content or sophistication."

Finally, at the end of the day, the ARRA incentives (all of the "meaningful use" business) doesn't make up for lost productivity, additional expense and, of course, the overload of irrelevant information. Now we have a study showing that a survey (which might have been done on a pilot program before all of this was rolled out) shows the average physician losing over $40,000, notwithstanding the meaningful use incentive.[14] And this in Massachusetts. The difference between the financial winners and losers "was the extent to which they used their EHRs to increase revenue," which might be more patients per day (one hypothesis) or few rejected claims (another hypothesis), or the most common practice, the upcoding for which physicians have been criticized.

[13] Taylor, R., Letter to the *New England Journal of Medicine*; December 2010
[14] Adler-Milstein, J., et al, " "A Survey Analysis Suggests That Electronic Health Records Will Yield Revenue Gains For Some Practices and Losses For Many," *Health Affairs*, March 2013

If the promoters of PPACA, publishing in *Health Affairs*, studying practices in Massachusetts, find (a) a few winners--the larger, better organized, hospital affiliated and more expensive physician groups, and (b) a lot of losers, this is probably the floor for what will be found among practicing physicians nationally. The ceiling will be physicians who lose a lot of money, a lot of productivity and, as the literature is now showing, are overwhelmed with data, underserved with information.

The dependence of medical information systems on political decisions may be a further source of disruption. For example, the Balanced Budget and Emergency Deficit Control Act (the sequester[15]) shows that there will be a 2% reduction in the electronic health record incentive payments under ARRA, hence an equation skewed further against the independent physician.

Theft of PHI

You might think that, given our aspirations to use lots of data (including Personal Health Information—our PHI!) to solve big problems, we could at least protect the data. The nature of electronic information—challenges with economical (yet accessible) storage, the (large) number of those who "need" access, etc.—virtually guarantees large-scale information theft, and an enormous increase of such theft and misuse over previous (non-electronic) medical record eras. In other words, and quite aside from the exotic manipulation of data, the promotion of questionable relationships between this number and that, and frequent lack of actuarial credibility, electronic automatic of information has also featured theft and misuse of information on a scale not contemplated prior to the passage of HITECH.

Section 13402(e) (4) of HITECH requires the Secretary of HHS to post a list of breaches of unsecured protected health information affecting 500 or more individuals. These breaches take place for all sorts of reasons, losses (TriCare losing nearly 5 million individual records, "We don't know how this happened") (HealthNet in California losing nearly 2 million records), outright theft (New York City Health and Hospitals Corporation losing 1.7 million records), a mixture of malice and incompetence involving many parties, more than 525, in fact, recorded on the HHS website.

Some of the most elegant names (Memorial Sloan-Kettering) show ongoing breaches, one lasting nearly three years, involving unauthorized access and disclosure.

[15] Zients, Jeffrey, Deputy Director for Management, OMB, Letter of March 1, 2013 to the Honorable John A. Boehner

There are also humorous pieces: recently the *Los Angeles Times* chronicled the story of an Indio, California couple who were paid by the Kaiser health system to store 300,000 of its hospital records. The couple kept the Kaiser records in a garage shared with a party rental business and in the man's Ford Mustang; in a dispute over payment, they complained to the state about Kaiser's lax habits in handling health data.

In fact, personal medical information of 21 million people (that we know about) has been improperly exposed in the past three years, according to federal reports.[16]

The lesson?

Not that we need to avoid electronic records. But, we need to proceed in a deliberative manner, to ensure that, with each step, we are not incurring (a) unnecessary cost, which (b) becomes part of the problem, raising costs and insurance rates still higher, and (c) doing harm to the patient in the process.

There is great pressure to demonstrate that automation of information will bring the cost of health care down. At this time, such a claim seems palpably false. Yes, we do have rapid transmission of legible data, albeit not between professionals in different health care settings. Also, this information is not necessarily in a format which would be of use to a practicing physician.

But the big push to show how such data can control cost, improve quality and the like trips over fundamentals—including whether or not we can even keep the information secure.

Who is Interested in Collecting (and Addressing) Problems with EHRs?

Apparently not the (ominously named) Office of the National Coordinator (ONC) for Health Information Technology, overseer of the implementation of electronic health records.

The ONC is issuing rules, announcing the results of self-sponsored research and in 2012 conducted a "contest," as follows: at the ONC Annual Meeting (held December 12, 2012) results of the contest could include:

[16] Terhune, C., "Vast Cache of Kaiser Patient Details Was Kept at Private Home," *Los Angeles Times*, January 5, 2013

a. “some of the amazing things you’re doing to employ health IT to help your patients’ quality of life…” or
b. meaningful use, or
c. using meaningful use to improve quality and efficiency, or
d. how health IT engaged patients, and
e. how you, as a provider, have made privacy and security a priority.”

Not included in the contest were possible responses to the multiple challenges of (a) the Congressional Budget Office, (b) the Office of Inspector General, (c) many of the peer reviewed articles published on the subject, and of course (d) objections from practicing physicians.

Treatment

Repeal 42 USC. §§300jj, §§17901.

IV. Quality: Who is to Say?

Presenting Complaint: "How can they determine quality? I think I give my patients quality medical care . . How does Washington know otherwise? "

My wife has (currently) three doctors. They have very different styles. Their styles will evoke sympathetic nods and responses from readers.

First, there is the thoughtful, well-respected primary care physician. He eschews automated medical records, preferring to keep his office a model of folders, stacks of folders, rows of folders, all accessible to his staff by diminutive wooden ladders, directly taken from a Norman Rockwell painting of medical care 50 years ago, circa the passage of Medicare.

This physician, well regarded by his peers, actually sits and talks with the patient. He thinks. He pauses. He's doing what physicians thought they would be paid for through adoption of the Resource-Based Relative Value Scale in 1991. This RBRVS adoption of Evaluation and Management (E&M) payment was recognition of the physician's thought process, bringing information together, producing insight, narrowing options, resulting in a diagnosis and appropriate therapy.

The American Society of Internal Medicine, in particular, sought adoption of E&M codes for this type of thoughtful analysis. Their acquiescence to these proposals at the time meant that the primary care physician, having no procedures or operations for which he might bill, would be brought up toward the higher level of reimbursement of the surgeons. Ironically, of course, the E&M Codes are now central in controversy about the "fraudulent" up-coding in medical examination. So my wife's primary care physician talks to her, thinks about what she says, gives his advice.

Then there is the orthopedic surgeon. He's in a rush, in the office. After all, no real money is made in the office, only in the operating room. Even in a rush, however, this surgeon, like many, adept at video games and smart tools, finds time to check the boxes, punching in the numbers on his electronic medical record, so that his practice management system can assimilate those numbers into a universal bill form and send it in the correct form to the third party payer. Punching in the numbers and checking the boxes frequently takes his already limited attention away from the patient. The mental picture of the physician with his or her back turned to the patient has become parody.

My wife's third doctor, an older surgeon, is known as a thoroughly skilled, even brilliant operator. When he has a scalpel in his hands, he's an artist. But, with an i-Pad in his hands, he fumbles, needing the medical equivalent of a seven year old to help him out. Are you the right patient? When was your visit? Oops, that's the wrong button.

From which (if any) of these physicians is my wife receiving "quality" medical service? Or is she receiving quality medical service from all of them? How do we know what quality medical service looks like?

Historically, of course, doctors knew who the good doctors were, and made appropriate referrals. Today, however, such behavior is rarely rewarded, sometimes punished. What we know, however, is that the quality of medical care is entirely unrelated to whether or not the records are electronic, the buttons are pressed, or the buttons are missed.

How do we know this? We know this because there is a body of literature (summarized below) which shows entirely equivocal results from automation of or access to information--there is no demonstrated relationship between any of these things and patient outcomes.

Other Signs and Symptoms: CMS, AHRQ and other HHS-sponsored "research" linking one or another aspect of medical practice to one or another index of "quality."

We have had multiple experiments involving government "awards" for higher quality of care, another common theme of PPACA.

An early award in the reform era was for "e-prescribing" under the PQRI (Physician Quality Reporting Initiative, now PQRS) program. In 2010, CMS's Office of Public Affairs released a report entitled "Medicare Demonstrations Illustrate Benefits in Paying for Quality Healthcare." The representation in this report was that three such demonstrations had provided "strong evidence that offering providers financial incentives for improving patient care increases quality of care and can reduce the growth in Medicare expenditures." Then-Director of CMS Dr. Berwick noted that these reports were "good news for all Americans with Medicare."

But today's incentive payment may become tomorrow's punishment - - that is, one purpose of these multiple incentive programs is to create new standards, deviation from which will result in financial punishment.

This is a hypothesis, supported by evidence such as this: first, the incentives in 2011-2013 for "meaningful use" of electronic health information turn to penalties in 2014 ff.; then, automation in the collection of health information, including response to programmed prompts, increases reimbursement, unless the results are labeled "fraud," which will increase punishment.

What is the record of CMS in sponsoring programs that lead to improvement of quality through rewards or punishment?

From the mid-1990s there have been a significant number of such programs. One such was the PQRS (Physician Quality Reporting System). Like other CMS experiments, this one began with incentives (fractions of a percent increase in payment for Medicare patients), and now has turned to penalties, all of this is the absence of any evidence that PQRS standards—met or not—lead to better outcomes for patients. Now we learn that 80% of America's physician practitioners will be penalized for failure to meet the goals of the Physician Quality Reporting System (PQRS).[17]

This Neiman Institute analysis focused specifically on radiologists, finding that only 24% qualified for PQRS incentives, and that, conversely, 76% will be eligible for penalties beginning in 2015, totaling $100 million in that specialty. The chief executive of Neiman indicated that "Although not a specific part of this analysis, penalties for non-radiologists could total well over $1 billion." Of particular concern, "performance" on the PQRS matters in 2013 will determine penalties for 2015.

So an initiative that has yet to demonstrate lower costs or higher quality will now be used to remove $1 billion in physician compensation from Medicare payments.

In addition to the PQRS (then PQRI), there was the Hospital Quality Incentive Demonstration (HQID). The HQID program had awarded nearly $50 million in its seven years, and another $50 million for studies in similar areas.

[17] Duszak, Richard, "Most Physicians Do Not Meet Medicare Quality Reporting Requirements," a publication of the Harvey L. Neiman Health Policy Institute, *Journal of the American College of Radiology*, January 8, 2013

CMS reported in 2010 on the HQID program, and included this finding: "An independent evaluation suggests the demonstration contributed to quality incentives. However, quality also increased substantially for similar hospitals that were not participating in this demonstration, but had reported information on Hospital Compare…." Even hospitals that received no incentive payments, "raised their quality score" and the hospitals that did not beat any benchmarks and did not receive any payments "also improved their quality average score by eighteen percentage points."

What do we learn from this?

a. First, we learn that the organization sponsoring this experiment was also responsible for reporting its success.

b. Second, we learn that the success takes place irrespective of the incentive payments.

c. Third, we know that Medicare - - for these programs alone - - was out $100 million.

d. Finally, we know that these three are a small fraction of the five dozen or so demonstration programs by CMS, going back to 1995, that have also escaped independent review.

One should at least hypothesize a Hawthorne Effect, after the observation of researchers interested in changing work conditions in the Hawthorne Works plant, a Western Electric factory near Chicago. This phrase is used to describe situations in which productivity improves simply as the subjects' response to being studied, not to the specific changes implemented by the researchers.

The Congressional Budget Office took a more comprehensive look at this phenomenon - - that is, CMS' evaluation of its various incentive programs - - publishing the results of its study of Medicare incentive payment programs in January of 2012.

CBO found that none of the major experiments or demonstrations of alternative payment undertaken by CMS during this time period (essentially the mid-1990s to the present) produced any significant savings. There is no dishonor, of course, in entertaining ambiguity on this topic: "What is the relationship between quality and cost in the provision of health services?" An up-to-date systematic review[18] discusses

[18] Hussey, P., Wertheimer, S. and Mehrotra, A., The Association Between Healthcare Quality and Cost: A Systematic Review, *Annals of Internal Medicine*, January 1, 2013; 158(1):27-34

the fact that while cost containment and quality improvement are both important subjects, "The association between cost and quality is poorly understood."

The authors conducted a literature search of all of the major databases for U.S.-based studies published between 1990 and 2012, a comprehensive list. Two reviewers independently took data from these studies, including level of analysis, type of quality measure, type of cost measure and method of addressing confounding variables.

The authors found 61 comprehensive studies, showing these results:

(a) One-third showed a positive or mixed positive association (higher cost associated with higher quality);
(b) One-third reported a negative or mixed negative association, and
(c) One-third reported no difference.

Moreover, the "associations" of cost and quality - - even when found - - were of "low to moderate clinical significance in many studies."

The authors conclude, "Evidence of the direction of association between health care costs and quality is inconsistent." They add that "Most studies have found that the association between cost and quality is small to moderate, regardless of whether the direction is positive or negative."

We can't, to put it bluntly, even determine the "direction," much less the magnitude, of this association.

The Patient "Experience"

Of course, hospitals have this problem - - the disconnect between that which is measured and rewarded, and any evidence that the measurement implies quality - - already. For example, patients' reports of their health care "experiences." (Big health often adopts big business phrases, such as customer experience, sometime after the phrases have proven less meaningful than first thought for big business.) Would anyone seriously think that there was a direct correlation between the patient "experience" (in a setting such as a hospital which is frequently filled with tragedy, pain and stress) and quality? Apparently, this disconnect is news, however, to the academy. "Indeed, as physician and hospital compensation becomes

increasingly tied to patient feedback, health care providers and academics are raising strong objections to the use of patient-experience surveys."[19]

Manary and colleagues go on to write, "These views are fueled by studies indicating that patient-experience measures at best have no relation to the quality of care delivered and at worst are associated with poorer patient outcomes." But Manary asserts that, "When designed and administered appropriately, patient experience surveys provide robust measures of quality," which appears to be more "doubling down" and "faith-based" policy development. The central problem is not whether these are good researchers or naïve. It is whether entirely ambiguous and possibly counterintuitive conclusions should be the basis for compensation incentives designed to transform a field accounting for one-sixth of the gross domestic product.

Why should we worry about the indiscretions of CMS in promoting (made up news releases, evidence-free claims, funding of "academic" research to support policy initiatives, etc.) various representations concerning cost and quality?

For this simple reason: Medicare represents the law, whereas the ambiguous and confusing direction of policy studies are merely advice, which physicians may choose to take or not.

Is our belief in the direction and amplitude of an association between cost and quality sufficiently great that we should compel ophthalmologists to ask their patients' weight at every office visit?

Is our belief in the positive (as opposed to the demonstrated negative) impact of electronic automated information system collection sufficiently strong that we can decide whom to reward, and how much, and whom to penalize, based on what they use and what they record?

Are these questions not better left, at this stage of our knowledge, to academic debate, even that funded directly by CMS, rather than the whirling gears of legislation and regulation to compel hierarchy and orthodoxy, at the risk of autonomy?

[19] Manary, Matthew, et al, "The Patient Experience and Health Outcomes," *New England Journal of Medicine*, January 17, 2013, page 201

CMS, AHRQ and others sponsored by them announce relationships (for example, between new "ACA" initiatives and quality) with force and abandon. Minor qualifying notes appear subsequently, or in smaller type, or both, indicating that there is some margin of error, some uncertainty, some fuzziness. It is a "child's public health adage," that correlation is not causality.

Treatment

Repeal PL 111-148, Section 3041, especially Section 1890(b)(7)(B)(i)(l)

V. The Site of Service(s)

Presenting Complaint: "All of my friends are selling out to the hospital . . maybe I should join them . . ."

The situation was summarized nicely in a Bloomberg report in November 2012[20]. "Under hospital employment, physicians can earn up to three times more for the same tests and procedures they performed in private practice. Hospital-owned practices also enjoy more bargaining power with private payers."[21]

According to the American College of Cardiology, cited in the Bloomberg article, private practice cardiologists constitute 11% of the total number of practicing cardiologists, down from 62% five years ago.

Nationwide, for all practices, hospital employment of physicians has tripled from 8% five years ago to 24% in 2012 while physician-owned practices dropped from 73% in 2007 to 60% now.

The differential in payment for physician services between the physician office and the hospital applies even to new practitioners in their first year of professional work, following residency.

For example the "Medical Group Management Association Physician Placement Starting Salary Survey: 2012 Report Based on 2011 Data,"[22]shows that a family medicine physician, in his or her first year of practice, would receive average compensation of $164,890 in a solo practice. In a hospital, on the other hand, the same physician would receive $183,999, nearly $20,000 more.

The hospital's capacity to pay this $20,000 differential, and to absorb the expenses associated with practice management, is dependent, as noted above, on the "site of service" differential which MedPAC has previously targeted.

Recently, MedPAC has shown signs of movement to resolve this issue, as described in this report from InsideHealthPolicy.com, March 8, 2013:

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[20] Pettypiece, S., Hospital Medicare Cash Lures Doctors as Costs Increase, *Bloomberg*, Nov. 19, 2012
[21]Caramenico, A., Docs Join Hospitals for Higher Medicare Payments, *FierceHealthcare*, November 20, 2012
[22] MGMA *Connexion*, November–December 2012, page 10

The committee [MedPAC, chartered to give advice to Congress on Medicare] considered aligning payment rates between different settings for 66 different procedures and services, equalizing payments across settings for 24 and narrowing the payment differences for 42. Staff said the result would reduce Medicare spending and beneficiary costs by $900 million. It would also reduce overall hospital revenue for hospitals by 0.6 percent, and outpatient revenue by 2.7 percent. When combined with evaluation and management cuts recommended by MedPAC last March, the cuts would reduce overall hospital revenue by 1.2 percent and outpatient revenue by 5.4 percent with a greater impact on rural, teaching and government hospitals.

Patients should have access to settings that provide appropriate levels of care, but a prudent purchaser should not pay more for a service in one setting than another, MedPAC staff said. If the current shift to hospital outpatient departments continues at the current rate, MedPAC staff said, Medicare spending on evaluation and management visits would be $1.2 billion higher per year by 2021 due to shifts in where patients receive care. Beneficiaries would likely pay $310 million more. Medicare spending on echocardiograms and nuclear cardiology studies would be $1.1 billion higher per year by 2021, and cost sharing would be $285 million higher.

If the relative prices are skewed and sending distorted signals, we are influencing behavior, Hackbarth said, which can be seen now. It will continue the longer Medicare sticks with a structure that pays different rates for the same service based on location, he added.

Treatment

Implement MedPAC staff recommendation, March, 2013. This will reduce the "slush funds" with which hospitals have been purchasing physician practices, reducing what MedPAC Chairman Hackbarth calls the influence of such differential prices on behavior.

VI. DOC on the RAC (Today's Incentive, Tomorrow's Fraud)

Presenting Complaint: "If I check the wrong box, I will be labeled a fraud . . The government looks like it is balancing the books on my back, and using fear to do so . . . "

There is a growing body of legislative and regulatory activity at the federal level which seeks to criminalize mistakes made in the physician's office.

Two decades of "Stark Law" (42 U.S.C., Section 1395nn) prohibitions on physician management of specialized diagnostic and therapeutic facilities have been fruitless.

First, studies that purport to demonstrate higher utilization of such resources by physician owners have been unable to distinguish utilization necessary for more efficient or effective patient care from those merely producing more revenue.

Second, the Stark Law's strict liability scheme, with extreme penalties, threatens physicians who participate in Medicare and Medicaid with difficult and onerous sanctions. (Strict liability means that, notwithstanding the intention of those who make referrals which may violate Stark prohibitions, even in emergency situations, intent is irrelevant.) The sanctions include payment denial, civil penalties, even larger civil penalties for attempts to "circumvent" Stark, and exclusion from the federally sponsored health care programs. (42 U.S.C., §§1395nn (g)).

Oddly, there are no similar prohibitions in any other part of the health field, for example, in hospitals. How many boards of non-profit hospitals or health systems reward chief executives for growth, that is, for the development of services which promote higher top line revenue?

With Representative Stark no longer a Member of Congress, there may be an opportunity for a rational approach to physician-owned services.

Now we have the RAC.

Originally a study program, in 2003, the National Recovery Audit Contractor (RAC) program was "permanently" authorized under the Tax Relief and Health Care Act of 2006 and began in full force January 1, 2010.

The goal of the RAC program was to identify improper payments made on claims for services provided to Medicare beneficiaries, overpayments or underpayments.

We haven't heard a lot about underpayments since the original announcement of the program. Periodic reports (such as, for example, the report to Congress for FY2010, the MLN Matters Update, even the December 17, 2012 extraordinary publication entitled "Medicare Fee For Service Recovery Audit Program Myths") don't mention the underpayment business.

So let's assume, as common sense would dictate, the purpose of the program is to cut down on overpayments, that is, to ensure that the only payments are those in accord with Medicare management's understanding of appropriate payments.

The problems created in the RAC program are threefold.

First, the program doesn't work. Even at the highest amounts claimed by CMS for success, the total is far less than $1 billion, or about a quarter of a percentage point of total Medicare payments. That total claimed has to be "netted against" the appeals (to date from hospitals) which are successful, namely more than half of the total denials.

So we can assume that managerial capability is involved here somewhere.

We know, for example, that Medicare has a hard time maintaining an appropriate log of eligible providers, and of paying for eligible services. Even a task as seemingly straightforward as maintaining a list of physicians is difficult: the so-called PECOS system, for example, the "Provider Enrollment, Chain, and Ownership System," - - an acronym chosen apparently for its echoes of geography, rather than an explanation of function - - is the national database of enrolled physicians. Each year between 20,000 and 30,000 physicians find themselves suddenly dis-enrolled, for no apparent reason, with intermittent but frequently long delays in becoming re-enrolled.

The second problem is that the private contractors that CMS has chosen to pursue these false claims are paid on a contingency basis, surely an invitation for over-enthusiastic judgment against the "targets."

The contingency fees[23] paid to RAC auditors have ranged from 9 – 12.5%. There is, theoretically, a requirement for the RAC to return the fee if the overpayment is overturned on appeal. In other words, having failed to organize the payment system from the beginning, Medicare has superimposed a "chase and deny" policy, with retroactive review, recovery and penalties.

The third problem, however, and most important, is that the type of "error" identified by the RACs is overwhelmingly error in payment for procedures which were "medically unnecessary." (Other types of error could include (a) insufficient or no documentation or (b) incorrect coding.) But the largest category of "overpayment" is that for which services to the Medicare beneficiary is medically unnecessary, in the judgment of CMS, the RAC, or both.

Equally threatening, the potential "recovery period" in this process has just been extended. In the "fiscal cliff" patches to cover the cost of a one-year repair for the Sustainable Growth Rate, Congress extended provider exposure and liability for up to five years. The government's overpayment recovery period had been three years. CMS recommended this inclusion, expected to save the government $500 million in previously uncollected overpayments.

Therefore, Recovery Audit Contractors (RAC) will go back five years when looking at potential overpayments. Two alternative hypotheses present themselves as rationale for this expansion of RAC activity. First, the Office of Inspector General (which recommended the provision) believes they will actually collect $500 million (or some significant number) more. Second, whether or not OIG or the Congress believe this, the "patch" impact of $500 million was welcome as a low-hanging offset for the SGR fix, avoiding debate on larger issues, kicking one more can down the road.

What is likely to happen?

The most likely outcome is that the number of appeals from RAC decisions will increase, as the number of claims from which contractors can recover alleged overpayment also increases. The American Hospital Association conducts a survey of hospitals and RAC audits; thus far, hospitals have been nearly the exclusive focus of RAC audits. The "RACTrac" shows 58% of hospitals spending more than $10,000 managing the RAC process in the third quarter of 2012. However, hospitals are currently only appealing approximately 40% of RAC decisions. The hospital association has said they will encourage hospitals to appeal every denial, henceforth.

[23] Medicare Fee For Service Recovery Audit Program Myths, December 17, 2012, CMS

Moreover, there appears to be a significant backlog building at the second and third level of appeals, "partially due to an exponential increase of RAC appeals, as a result CMS has experienced difficulty meeting deadlines for hearing cases."[24]

Inevitably, failure at the front door (as in, for example, revenue cycle management) complicates management (and significantly increases the expense) at the back. This retroactive collection machine will shortly turn in the direction of physicians. Of course, the chance of a given physician being chosen may be small. But the consequence for individual physicians, when chosen, like the consequences for a diagnosis of rare but severe or fatal illness, is 100%. Fear of those consequences may be expected to shape the behavior of all who might be affected. It being unlikely the physicians who are employees of hospitals will feel affected, disproportionate impact will fall on the independent practitioner. The choices facing that practitioner (lawyers with expensive niche skills, consultants, additional credit) will all add to office expense.

The practicing physician has to ask, "Medically unnecessary according to whom?" Well, CMS is at lengths to indicate that the RAC contractor must have certified coders, nurses, therapists and a physician.

It is the "physician" that may frequently be the problem, since a clinician at the distal end of the information chain, long after the patient has been seen, is being asked to second-guess (or validate another staffer's second-guessing) the application of Medicare's complex and arcane rules of payment for a particular service.

Moreover, pointing out these problems has had no apparent effect. At the end of 2012 we had yet another Inspector General's report on the RAC program. The report noted that the RAC contractor program had "morphed into a complicated labyrinth, with one set of contractors paying claims and another combing through these claims in an effort to stop an estimated $60 billion a year in fraud." The OIG report indicated that the "repeated problems among the fraud contractors" had lasted more than a decade.

Among the further points made in the OIG report:

(a) CMS and HHS officials ignored whether contractors were opening any investigations at all;

(b) Contractors were reporting progress in different ways;

[24] Stein, M., Providers Face More Overpayment Recoveries, InsideHealthPolicy.com, January 14, 2013

(c) Information turned over to CMS officials reflected that performance was frequently inaccurate.

More than ten years ago, the Inspector General (in 2001) testified that CMS was not doing a good job of holding contractors (a different set of acronyms at the time) accountable. Many of the problems, in fact, began with CMS, in delayed and inaccurate information forwarded to the contractor, frequently with missing pieces. One contractor was reported to have had absolutely no access to data prior to the time their contract actually ended.

Treatment

Repeal RAC provisions of Tax Relief and Health Care Act of 2006, expanded by Section 6411(b) of PL111-148 and 111-152 (PPACA).

VII. Sustainable for Whom?

Presenting Complaint: "Why can't they figure out how to pay me for services to Medicare patients? This seems to go on every year!"

Payments for physician services[25] are made by Medicare based on a fee schedule which has "relative values" assigned to the various services provided by a physician: office visits, injections, surgery, everything a physician does.

This has been the case since 1991, when CMS (then HCFA) adopted the work of Harvard Professor William Hsiao, which was, in turn, based on the evolution of relative value scale payments in the California workers' compensation program. This work produced the Resource Based Relative Value Scale (RBRVS) for payment of services to patients covered by Medicare.

The relative values are meant to reflect three components, the physician work, the practice expense and the malpractice expense. The physician work is the key element, the practice expense somewhat less so. The last of these is relatively small, of psychological import, given the size of malpractice insurance, compared to other office expenses. Then these relative values are modified for geographic variation (GPCI).

Finally, there is a "conversion factor" each year. In theory, avoiding the details, once you have the relative value set, adjusted for geography, you multiply by the conversion factor to produce a dollar result. This is the payment the physician can expect for a specific service described in a Common Procedure Terminology (CPT) code associated with a certain RBRVS value.

Each year the conversion factor is updated. The update percentage is the so-called Medicare Economic Index (MEI). Application of the MEI takes place under the auspices of MedPAC, a high level congressionally chartered group whose members are nominated by the head of the General Accountability Office.

However, this MEI process was "adjusted" after 1997 to match the cumulative impact of spending on physician services to a "sustainable growth rate" (SGR), paragraph (1)(A) of the Balanced Budget Act.

[25] Congressional Research Service, "Medicare Payment Updates on Payment Rates," September 27, 2012, page CRS-21

The SGR has no relationship to the cost of medical practice, to physician incomes or to any other factor associated with medical field productivity, except indirectly as it relates to changes in the gross domestic product per capita. The conversion factor is therefore adjusted so that spending will equal the "sustainable" spending by the end of the year.

Until the superimposition of the SGR "cap," this process sounds pretty straightforward, with a professional methodology, so to speak. Multiplying the RVU times the conversion factor would yield the actual compensation, that is, the payment the physician would receive for the service classified under a particular code. Of course, given the complexity of medical care, and of the bureaucratic process, and of the run up to the actual recommendations (including the work of the Relative Value Update Committee or RUC, overseen by the American Medical Association), the actual output is mind-numbingly complex, even without the SGR.

One expert, widely respected, Frank Cohen, summarizes the RBRVS analysis he has made for 2013 (net of the SGR, sequestration or any other "big" adjustment) as follows:

> In summary, both total non-facility and facility RVU values saw a decrease, when weighted by line, of -0.56% and -0.20% respectively. Work RVUs and Malpractice RVUs were about the same with a slight increase of 0.2% while Practice Expense RVUs drove the overall impact with decreases of -1.26% for non-facility and -0.53% for facility RVU values. So, in addition to the injury of the 26.5% reduction in the conversion factor, we add the insult of an overall reduction in the value of the RVUs.
>
> Work RVUs reported 42 procedure codes with a negative change (meaning that the 2013 values are less than the 2012 values) and no codes with a positive change. For the Practice Expense component, non-facility reported 3,198 with a negative change and five with a positive change while for facility, there were 3,438 with a negative change and 4 with a positive change. For the Malpractice component there were 35 with a negative change and none with a positive change. There were 3,201 codes that reported a negative change for the total facility RVU and 3,437 codes that reported a negative change for the total non-facility RVU value. The positive changes were four and two, respectively.[26]

[26] Support@FrankCohenGroup.com, RBRVS Analysis 2012 vs. 2013, November 29, 2012

But all of this - - the complex annual update process - - now is subject to the overall "Sustainable Growth Rate" (SGR) legislation passed as part of the Balanced Budget Act of 1997, and the dreaded paragraph (1)(A) noted above.

The general idea was that, as part of welfare reform, physician compensation would be treated as one more form of social welfare, and made subject to an overall limit of what was "sustainable" for the government. The RBRVS would be multiplied by the conversion factor, all developed in accord with appropriate studies of expense, malpractice cost and new technologies, but would then be "capped" by what CMS felt was "sustainable."

The dilemma the federal government faced, of course, was entirely predictable. Candidates who became public officials had promised the aged (and, parenthetically, the medically indigent) that they would no longer (after 1965) face the challenges of health care alone, that is, they would not be both sick and poor at the same time. Medicare, to avoid the stigma of welfare, was presented as a "pay as you go" program. However, while the average couple on Medicare pays about $109,000 in, they get (today's expenses) about $343,000 out, per the Urban Institute. The disposition of legislators to raise the contributions necessary to make it a "pay-as-you-go" program has not kept up with the inclination of entrepreneurs to develop new services and new technology, the latter, for the most part, for the good of patients.

So the Sustainable Growth Rate was meant to cap what otherwise had developed as a fairly rational process, at least one which had some order to it. Prior to the SGR, the CMS annual process had the effect of predicting for physicians what their reimbursement from the single most important third party (Medicare) would be for the coming year.

The Sustainable Growth Rate, however, intervened in that system, creating confusion and discord with each successive year. Only in 2002 was the reduction in rates actually implemented. For fifteen years, the climate for physician reimbursement by Medicare has grown progressively more sour.

Each year's performance mimics a "Perils of Pauline" drama, with threatened reductions, controversy, dire predictions and warnings, and last minute resolution. Moreover, the stakes rise each year, as the dreaded paragraph (1) (A) appears cumulative - - that is, failure to reduce the growth rate artificially the previous year makes the calculation to "fix" the SGR for the subsequent year that much larger. Because the cost of "fixing" the SGR rises each year, Congress is presented with a larger and larger tab. It is not a

stretch to argue each year that if the size of the tab for fixing the 1997 mistake is unacceptably high, the threat should roll forward.

No actual reduction took place from 1998 to 2002, or thereafter. The reduction in 2002 apparently had a sobering effect on all parties. But we now have fifteen years of experience with the sustainable growth rate, and another "Perils of Pauline" episode just concluded.

The opacity and cant which generally surround defenses of health care pricing has recently been examined in the longest essay in the history of Time magazine[27]. Generally some outrage (familial, collegial) leads authors not otherwise involved in the health field to examine this pricing business. Here, a distinguished entrepreneur (The American Lawyer, Court TV, Clear) takes a look at this business, and finds the following: everyone along the supply chain – from hospital administrators (who enjoy multi-million-dollar salaries) to the salesmen, executives and shareholders of drug and equipment makers – was reaping bonanza. The only exceptions were those actually treating the patients - - the nurses and doctors.

Other Signs and Symptoms

Even more important is this: what Medicare pays the doctor is extremely important for medical practice. We know that hospitals, for example, are paid through Diagnosis-Related Groups (now MS-DRGs, medical severity DRGs, with additional adjustments from the most effective lobby of hospital sub-groups). More often than not, however, the private health insurance companies do not follow the DRG system in paying for hospital services.[28] Some health insurers have their own modification of the Medicare payment scheme for hospital payment. Other insurers pay on a "per diem" (total cost per day) or on a "discounted" basis, the discount being from list prices, known in the health services business as "charges." In any event, the hospital that is underpaid by Medicare and Medicaid is at least theoretically in a position to "shift" its cost so that it recovers the difference from the private payers (Aetna, Blue Cross, United and the like).

Members of the academy don't like the phrase "cost shifting" and search relentlessly for evidence to demonstrate that it doesn't exist. I suppose that if "cost shifting" could not be disproven, it would be more obvious to all that the private sector is subsidizing the public.

[27] Brill, Steven, "Bitter Pill: Why Medical Bills are Killing Us," *Time Magazine*, February 20, 2013
[28] Ginsburg, Paul, "Wide Variation in Hospital and Physician Payment Rates Evidence of Provider Market Power," Center for Studying Health System Change, No. 16, November 2010

Of course, there is nothing inherently wrong in such subsidies, if that is what elected officials intend, and if they keep getting elected holding those views. But it is a mark of the current high temperature in all discussions of health policy that deviation must be subdued, even at the price of common sense.

Everyone in the field knows that cost shifting exists, namely, you levy the private payer with the difference between what the government is willing to pay and what you need to sustain operations. You have an expense budget. The expense budget has to be met by revenues.

The "profit margin" of most hospitals (even when derived from multiple types of reimbursement) is remarkably small, negative in some years, positive in others, only infrequently very positive. For the most part, hospitals are service maximizers, not profit maximizers, not a business that can sustain major year-to-year revenue changes. (In part, this is due to the extraordinarily high degree of leverage in this field, where 90% of capital formation is from debt. The risk of default on this debt is generally overlooked, the assumption being that volume and payment for services will be adequate to cover very high debt service. Only through debt could hospitals afford to spend as much as they do for facilities, technology and supplies.)

So the revenues need to be there to meet the expenses, in this highly leveraged enterprise. Otherwise short-term "cost cutting" steps (laying off employees, outsourcing functions that shouldn't be outsourced, cutting back on physical plant renewal or maintenance) take place, generally to the detriment of the overall quality of hospital services. How is the revenue to be recovered when Medicare reimbursement shrinks? Let's call it "revenue shifting" so as not to offend those who are "cost shifting" deniers. But your own common sense will tell you that the difference must be made up.

Payment for physicians, on the other hand, by the private commercial insurance plans, generally uses the same methodology as Medicare. In other words, the "technology" behind the Medicare physician fee schedule is extremely important, as it guides much of commercial third party payment. One exception is Medicaid, the struggling state-federal programs, where many state Medicaid programs have made up entirely new schemes in an attempt to keep state budgets upright. Also, the individual commercial plans, while preserving the proportionality of CMS payment, may disguise the actual amount they pay, so as to avoid direct comparison with rival carriers.

So what Medicare decides with physician fees has a multiplier effect, not necessarily linear, but palpable.

Congress clearly wants to keep the practicing physician in the Medicare program. The most recent demonstration is the following: In Title VI of the "Medicare and other health extensions" section of HR8, the "American Tax Payer Relief Act of 2012," the rope to keep the country from falling off the "fiscal cliff," the very first provision (Section 601) is the Medicare Physician Payment Update. (See **chart** on the following page.)

In the middle of one of the (arguably) most difficult and contentious political and economic challenges in modern American history, the very first provision in the non-tax-related portions of this "last minute" temporary legislative relief involves a fix to the "Sustainable Growth Rate" controversy involving payment to practicing physicians for professional services for Medicare beneficiaries.

What was promised by Congress to the practicing physician? A big increase in fees? More freedom to practice in accord with patient needs? A decrease in the "hassle factors" of excessive regulation? Actually, the legislation provides for a "0%" update, nothing specific about freedom, and certainly nothing about hassle factors.

It isn't the 0%, however, which is of concern to the practicing physician. Most would readily accept the "0%," notwithstanding (a) the (previously discussed) 50% increase in back office expenses during the past decade, (b) the increased clinical complexity of practice, (c) the headaches of compliance with regulatory constraint, (e) the additional expenses and lost productivity associated with electronic medical records, even (f) the cost of living.

That isn't the problem. The problem is Section 1848(d) of the Social Security Act (48 U.S.C. 1395w-4(d)), and particularly paragraph (1)(A). This legislation says that "the conversion factor," in this last minute legislation, "Shall be computed" "as if subparagraph (A) "had never applied." That is, the "fix" which is the highest Congressional priority is to "un-do" (for one year!) the effect of the 1997 SGR legislation.

What effect has all of this had on the practicing physician?

We went on a cruise. The first person we met, in the small world category, was an interventional cardiologist from New York City, a man of significant clinical accomplishment and reputation. Professional small talk ensued.

Congressional Budget Office **January 1, 2013**

Detail on Estimated Budgetary Effects of Title VI (Medicare and Other Health Extensions) of H.R. 8, the American Taxpayer Relief Act of 2012, as passed by the Senate on January 1, 2013

(Billions of dollars, by fiscal year)		2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2013-2017	2013-2022
	CHANGES IN DIRECT SPENDING												
Subtitle A–Medicare Extensions													
601.	(a) Medicare physician payment update	10.6	6.7	1.3	1.3	1.2	1.0	0.8	0.7	0.7	0.8	21.1	25.2
	(b) Advancement of clinical data registries to improve the quality of health care	0	*	*	*	*	*	*	*	*	*	0.1	0.1
602.	Work geographic adjustment	0.3	0.2	0	0	0	0	0	0	0	0	0.5	0.5
603.	Payment for outpatient therapy services	0.7	0.2	0	0	0	0	0	0	0	0	1.0	1.0
604.	Ambulance add-on payments	0.1	*	0	0	0	0	0	0	0	0	0.1	0.1
605.	Extension of Medicare inpatient hospital payment adjustment for low-volume hospitals	0.3	*	0	0	0	0	0	0	0	0	0.3	0.3
606.	Extension of the Medicare-dependent hospital program	0.1	*	0	0	0	0	0	0	0	0	0.1	0.1
607.	Extension for specialized Medicare Advantage plans for special needs individuals	0	0.2	0.1	0	0	0	0	0	0	0	0.3	0.3
608.	Extension of Medicare reasonable cost contracts	0	*	*	0	0	0	0	0	0	0	*	*
609.	Performance improvement	*	0	0	0	0	0	0	0	0	0	*	*
610.	Extension of funding outreach and assistance for low-income programs	*	0	0	0	0	0	0	0	0	0	*	*
Subtitle B–Other Health Extensions													
621.	Extension of the qualifying individual program	0.6	0.2	0	0	0	0	0	0	0	0	0.8	0.8
622.	Extension of Transitional Medical Assistance	0.4	0.5	-0.3	*	0	0	0	0	0	0	0.6	0.6
623.	Extension of Medicaid and CHIP Express Lane option	0	*	0	0	0	0	0	0	0	0	*	*
624.	Extension of family-to-family information centers	*	*	0	0	0	0	0	0	0	0	*	*
625.	Extension of Special Diabetes Program for Type I diabetes and for Indians	0	0.3	*	*	0	0	0	0	0	0	0.3	0.3
Subtitle C–Other Health Provisions													
631.	IPPS documentation and coding adjustment for implementation of MS-DRGs	0	-2.0	-2.4	-2.8	-3.0	-0.3	0	0	0	0	-10.2	-10.5
632.	Revisions to the Medicare ESRD bundled payment system to reflect findings in the GAO report	0	-0.2	-0.2	-0.5	-0.6	-0.6	-0.6	-0.7	-0.7	-0.7	-1.5	-4.9
633.	Treatment of multiple service payment policies for therapy services	*	-0.1	-0.1	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.7	-1.8
634.	Payment for certain radiology services furnished under the Medicare hospital outpatient department prospective payment system	*	*	*	*	*	*	-0.1	-0.1	-0.1	-0.1	-0.1	-0.4
635.	Adjustment of equipment utilization rate for advanced imaging services	0	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.3	-0.8

Continued

We asked, “How are you doing with Medicare?” Well, he didn’t participate in Medicare, and had decided to drop out for reasons related to the confusion associated with what he might actually be paid for his services.

We wondered, “How was that working for him?” It turns out to have worked fine, until his father needed a neurosurgeon. None of the cardiologist’s neurosurgeon friends participated in Medicare, either. He went from one to another, without result. Finally, he exercised personal and professional persuasion to get one neurosurgeon he knew to accept a discount from charges.

How would this work out for other Americans? Do we all have neurosurgical friends we can approach? Do we have parents who might need a neurosurgeon?

This result isn’t limited to one cardiologist and one father needing a neurosurgeon.

An online survey conducted by the American Medical Association in the spring of 2010 showed one in five physicians restricting the number of new Medicare patients added to their practice, because payments were too low, or because the ongoing threat of future payment cuts made Medicare an unreliable payor, or both.

For primary care physicians, on whom many expectations of PPACA now rely, one-third restrict the number of Medicare patients in their practice, for the same two reasons. Looking to the future, the same survey found 60% or so of physicians looking into opting out of Medicare, and treating their older patients through the “private contracting option.”

In compensation for low and unpredictable Medicare payment, some physicians reported delaying payments for supplies, taking out a loan or line of credit, holding up paychecks or dismissing staff, canceling or postponing services to Medicare patients or temporarily closing their practice to new appointments with Medicare patients.

The effect of the SGR, and of irresolution in “fixing” the SGR, has been to drive physicians away from participating in Medicare or from accepting new patients who are enrolled in the Medicare program. Rather than maintaining a steady cadre of physicians to serve the elderly, the spectacle of annual discord and controversy in the program has persuaded some to drop out, and has also persuaded many to take an alternative which is pervasive, namely to limit access by Medicare patients.

The new patient calls up the doctor's office. "I'm a new Medicare patient, and would like to see Dr. So-and-so." Well, Dr. So-and-So can either fit you in next week, or he can fit you in a couple of months from now. What makes the difference between ready and delayed access? Hopefully, it will always be the patient's needs. Realistically, especially in smaller practices, some patients will be directed to other resources, especially when there is a well-known alternative, such as a local hospital emergency room. (Ironically, of course, the hospital will be paid more for the use of its emergency room for primary care services than the physician could ever hope to receive for the same services).

So the consequence - - the disaffection of the practicing physician from Medicare, the alienation of some, the exit of others - - takes place, irrespective of the annual, last-minute saving grace.

Treatment

Amend section 1848(d) of 42 U.S.C. 1395w-4(d) to disregard par (1) (A) for all subsequent years.

VIII. PCORI—IPAB Lite

Presenting Complaint: What is 'comparative effectiveness' going to do? Am I going to be punished for going with what I think my patients need?

The origin and development (in the U.S.) of comparative effectiveness research (CER, beginning roughly in 1992) has led to the growth of guidelines and consensus panels with varying degrees of methodological rigor. Also varying are the capabilities for managing conflicts of interest, with many of the guideline or consensus groups staffed, supported or populated by representatives of one or another commercial interest in health care.

By 2008, more than 350 groups had created several thousand practice guidelines.[29] This chaos - - an invitation for conflict and confusion - - led to a congressionally mandated Institute of Medicine study. The study, at the end, found that "In a recent evaluation of 114 randomly chosen guidelines, researchers found poor adherence to the IOM standards, raising questions about the best approach to use guidelines as a benchmark of excellent care."[30]

Given the infancy of the clinical guideline business, and uncertainty as to whether following such guidelines will improve outcomes, how much better off would we be to defer comparative effectiveness research, PCORI and IPAB - - at least defer enfranchising the results in law - - for a future generation's review?

PCORI

The work of the Patient-Centered Outcomes Research Institute (PCORI), a major initiative in the Patient Protection and Affordable Care Act, may be summarized as follows: to apply the findings of comparative effectiveness research, as well as the results of the application of clinical guidelines, to promote effective and discourage ineffective medical care.

[29] Ransohoff, David, et al, "How to Decide Whether a Clinical Practice Guideline is Trustworthy," *JAMA*, January 9, 2013

[30] Kung, J., et al, "Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards: Two More Decades of Little, If Any, Progress," *Archives of Internal Medicine*, 2012, pages 1628-33

In some ways, although unspoken, PCORI is "IPAB-lite," that is, it's the "Independent Payment Advisory Board" in somewhat more democratic clothing.

What initiatives are PCORI likely to promote, that is, what medical care will it encourage, and what will it discourage? This body appears to be moving forward to recommend (and subsequently require) adherence to clinical guidelines which may, or may not, be appropriate for an individual patient.

For example, the always difficult area of screening. Is screening the detection of disease, which results in an earlier therapy and longer lifespan for the patient? Or is screening merely case-finding, with resulting increase in the overuse of therapeutic interventions?

Urologists all over the country are in an uproar over recommendations of the United States Preventive Task Force that asymptomatic men not be screened for prostate cancer.

A similar uproars might follow new findings that, for example, screening mammography has resulted in the over-diagnosis of breast cancer in 1.3 million women in the United States in the past 30 years.

We can expect that PCORI will erect another substantial administrative budget for our research and policy universe, supporting new projections of positive benefit in the absence of realities of negative cost.

Even an informal "projection" would be too rough to estimate what additional overall administrative costs would be hardened into the federal budget (with new spending constituencies). Then there is the expense to be borne by medical practitioners to keep up, as they attempt to demonstrate the "actual effectiveness" of a particular treatment not included in CER.

PCORI's particular spin on this is emphasis on "patient engagement." On its web site, PCORI wants patients to be involved in every step of building a national infrastructure because getting patients involved increases the chances that patients will use the research results in their decisions.

How accurate is any of this, and how desirable?

What is beyond question is that patients will seek the services they regard as most important for their health, irrespective of price or other barriers. There is no evidence that patient involvement in the development of a national database will somehow lead to their use of the "research results in their

decisions," or their participation in clinical trials or their contribution of data to the system, however desirable (if they are desirable) these goals might be.

PCORI, in other words, is a new, expensive, study group. It appears ready to ramp up continued representations that the pursuit of broadly stated egalitarian goals will lead to higher quality or lower cost or both in the delivery of health services.

IPAB

The Independent Payment Advisory Board (IPAB) has attracted notoriety.[31] IPAB is established in PPACA as a 15-person board, charged with the task of recommending cuts in Medicare, to the extent that Medicare expenditures grow beyond an index level, namely when the Medicare Chief Actuary forecasts the program's expenses growing at a full percentage point (or more) faster than the Gross Domestic Product.

PPACA, in fact, attempts to entrench "IPAB behind bullet proof glass," with provisions unknown in any other federal legislation in the health field, including:

> Instructions to the Majority Leader of the House and the Senate to introduce any legislative proposals "on a day on which a proposal is submitted" by IPAB ;
>
> Related rules that prevent legislators from changing IPAB recommendations;
>
> Rules limiting the length of debate on any IPAB recommendations;
>
> A provision attempting to estop repeal of IPAB, with language that it "shall not be in order" to "repeal or otherwise change this subsection." In the footnoted *Washington Post* story, it was reported that "IPAB's supporters" are not concerned with attempts to modify the House rules concerning debate on IPAB, since the "cuts become automatic if Congress does not pass an alternative plan to reduce costs."

[31] Kliff, S., "Republicans Can't Stop IPAB. But They Might Slow it Down," WashingtonPost.com, January 8, 2013

Still to come, a process perhaps as contentious as the nomination of Supreme Court Justices, namely accommodating and confirming the members of the IPAB Board, beyond conflict, but knowledgeable, willing to set rules for Medicare's 50 million-plus beneficiaries and the doctors who treat them.
Given that IPAB will be a focus of contention, and may well be constrained, the shorter-term spotlight should be on PCORI, less attended to, less contentious, but with, in the end, the same goal: altering the way physicians practice medicine, in order to constrain costs, without blame falling on any elected officials.

Treatment

Repeal of Section 6301, amendment to Title XI, 43 USC 1301, Part D.

IX. The Cost of All This

Presenting Complaint: "My costs continue to climb, for paperwork, not for clinical work . . . "

How do we reckon the cost (to the medical practitioner, to say nothing of real cost to the federal treasury) of the simultaneous moving parts associated with "reform" of the health care industry?

Overhead expense climbs both in management and in labor. By that I mean that the cost of "management" goes up as measured by loss of physician productivity (the doctor who has to spend time "managing" the regulatory environment in an independent practice).

For the hospital-hired or hospital-based physician, there is the cost of additional administrators for the management of outpatient practices.

The costs increase at the "top" of the pay scale, in other words, just as the costs increase for the receptionist, the medical secretaries, medical assistants, coders, billers and miscellaneous staff associated with the "back office" of modern practice management.

My back office expenses are up 50% in the past decade. How am I supposed to recover these expenses?

In general, we understand assignments in the doctor's office: there are people at the front desk, people involved in the clinical care of the patient (the nurse, the medical assistant), and people at the back end (coding and billing, managing accounts receivable, overall administration). Without detail, however, it might be difficult for the reader to comprehend the significance of these larger and somewhat abstract elements of medical office expense.

Take a single example: The annual process of updating the codes (known as "CPT" codes for the Common Procedural Terminology which is the formal name for the identification of services provided by physicians under a process developed by CMS and the American Medical Association, in response to government requirements).

The annual update involves as many as a half dozen new publications for taxonomy and administration of the code-based billing process in the physician's office. For example, there is a 900+ page new edition of

the CPT code book. There are specialty code books, for example, the CPT reference guide for cardiovascular coding. There are online services (CPT changes online, CPT assistant online). There are packages of publications for the working physicians, for hospitals, for billers and coders.

However, it is not the hundreds of dollars (thousands for a medium sized office) worth of publications that is of issue; rather, it is the time (down time, training time, problem solving time) of the office staff associated with the assimilation of new information every year, for this process.

Coming along is an even more difficult mountain, namely the transition from the International Classification of Diseases 9th Edition, to the 10th edition, the "ICD-10." The draft code set for implementation of this new methodology for diagnostic codes (ICD 9-10-CM-2013) is 1,156 pages. The "best practices" for documentation and compliance are described in a publication which is another 440 pages, while the "advanced anatomy and physiology for ICD-10-CM/PCS" is another 542 pages. You want to link your ICD-9 to the currently (draft) valid ICD-10 alternative measures? That's another publication, at 1,088 pages. You want "cliff notes" - - short cuts, reference cards? These are available also in the thirteen different specialized areas.

Commentators, polemicists and scholars alike frequently fault the U.S. for being a laggard in the adoption of serial ICD versions (sponsored by the World Health Organization). Uniquely, however, the U.S. uses the ICD categorizations to determine payment for services in a fee-for-service environment, not for refinement of diagnostic precision, public health studies or the like. The ICD document becomes (in this country) a "link" between categorization and reimbursement which unleashes the commercial forces behind our $2.8 trillion industry.

What will society get for the transition to ICD-10?

Third parties, students of the field, and regulators feel that they will have a better "handle" on the diagnoses for which payments are being made. Perhaps so, at least they will have a bigger handle. The transition from roughly 17,500 ICD-9 codes to roughly 155,000 ICD-10 codes has already been subject to parody (see, for example, *The Wall Street Journal*, September 13, 2011[32], "walked into lamppost, initial encounter," "walked into a lamppost, subsequent encounter.")

[32] Mathews, A., "New Medical Codes Provide Precision," *The Wall Street Journal*, September 13, 2011

Whether deserved or not, the humor fades in this light: this massive, nearly ten-fold upgrade in available diagnostic codes is a unique, unparalleled opportunity for gaming, upcoding and outright fraud. Based on the history of federally-sponsored coding change, this fraud will unfold over a five- to ten-year period, detected and pursued more or less at the end of that period, by which time there will have been a blurring between the diagnosis for legitimate medical care and the criminal misuse of these new and expanded categories.

What will the physician be paid for this annual update, training of the staff, the enormous expense of transition to ICD-10, and the inevitable third party glitches stretching accounts receivable?

Nothing. There is "zero" on the horizon for reimbursement associated with these "back office" changes. Likewise, there has been "zero" additional update (except insofar as taken into account in the MEI overseen by MedPAC, see above) for the past decade, during which office expenses have risen an estimated 50%. Productivity has improved, making up for nearly zero increase in fees: the five-year trend for total physician compensation appears to be about 3% a year, 13% for internal medicine, 11% for general surgery, 14% for non-invasive cardiology, for example[33], all or almost all due to productivity increases, that is, more work.

Once again, it is difficult (even impossible) to deny the laudable goals associated with the creation of more refined information. At the same time, it is inconceivable that these "policy" goals will not provide extraordinary opportunity for waste and unreimbursed growth in administrative expense to the practicing physician.

Other Signs and Symptoms

To estimate the cost of regulation in the physician's office, we rely on surveys, an uncertain proxy. These surveys depend on voluntary participation. Many of the management participants are interested in salary or compensation information, and not in the burden of regulatory compliance on the physician's pocketbook. The best of these surveys is the Medical Group Management Association's annual survey on production and expense, from which these observations are taken:

Let's assume that 50% of the net revenue is the staff, and that 20% of that number (or about 10% of the overall net revenue) is the front desk/registration, billing, coding and practice management expense. The

[33] MGMA Physician Compensation Survey: 2012 Report Based on 2011 Data

numbers are slightly more favorable to the physician in physician-owned multi-specialty practices, where total general operating cost per patient is a little short of $140, while physician compensation and benefits per patient is $178.[34]

How much has all of that gone up? In the past decade, administrative expenses in the field have risen faster than physician income, and are generally estimated to have increased by 25%. How much of that 25% increase was avoidable? Again, a judgment call, but given the issues discussed above (unanticipated expense associated with information systems, complexity of relations with managed care companies, growth of the uninsured), let's say a quarter of that increase has been associated with issues that can be characterized as avoidable.

This results in a number somewhere in the $100 to $200 million range, probably $150 million of so worth of unnecessary expense. Should we alter our march forward (an arguable thesis) in honor of $150 million?

The expense of administrative complexity to the physician may be annoying and avoidable, but is primarily important only to the physician paying the bills. The question is, "How does that physician respond to these rising costs?"

Here is one way of thinking about the "real" cost. By intimidating the practicing physician with (a) the prospect of higher and higher administrative cost, (b) more complexity, (c) more "work-arounds" in order to get through the day, and (d) the prospect of "poor quality" labeling for failure to check the boxes, the federal regulatory apparatus is essentially chasing the independent practitioner into larger business units.

This results in merging physician practices (with the resulting uptick in leverage those practices have over managed care companies), and, at the most expensive level, sending the physician into the arms of hospitals and health systems.

See our chapter on "Site of Service," but consider this: no professional raised and trained for 7 to 15 years wants to work in an environment in which clinical decisions are secondary to organizational and administrative decisions.

[34] MGMA Physician Compensation Survey: 2012 Report Based on 2011 Data

But we aren't concerned about the doctor's feelings here; rather, we are concerned about the cost to the public. We discovered in the "site of service" differential that the difference in professional service costs is roughly two to three times the cost of those services. That is, for a patient seen in the hospital, or in an office owned by a hospital, the doctor's services cost 2x to 3x the cost of those services in an independent physician's office. When the doctor flees the playing field, in other words, we all bear the cost.

How much is that cost?

Well, we have a dramatic decrease in the number of independent physicians, that is, medical practitioners who are no longer "freestanding" as described in the literature, who are now in practices owned by hospitals and health systems, or have in fact become employees of those hospitals and health systems.

In cardiology, a meeting of the American College of Cardiologists at the end of 2012 revealed that while 70% of cardiologists five years ago were independent, now only 30% are. The numbers are, even if not precisely measurable, enormous.

Let's say, for the sake of argument, that 100,000 practitioners have moved from independent status to hospital-based status since the beginning of 2000. In fact, this seems to be a pretty good guess (see **chart**, following page).

The motive of a physician is clear - - he or she is under relentless regulatory attack. The financial means for hospital "rescue" of that physician are also clear: we pay hospitals more than we would pay a physician to deliver the same service. And the opportunity is there: the hospitals are only too happy to acquire the presence and loyalty of physicians who no longer have options with regard to the referral of their patients for lucrative specialty diagnostic studies, outpatient activity or inpatient admissions.

If we've moved 100,000 practitioners in the course of this endeavor and we've increased the total billings only by one-fold, we've done $25 billion worth of damage to the system per year, that is, we have the same services, with much greater expense. Two fold, as some of the evidence shows? Fifty billion, per year. It doesn't take too many years of buying the same services—but in a more expensive setting—to get to real money.

You might say, well, the increased "efficiency" or "accountability" associated with "alignment of the financial interests" of the hospital and physician will obviate the impact of that $25 billion per year

Year	Practicing Physicians	Percent Independent	Estimated Count of Independent Physicians
2000	682,470	57%	389,008
2001	690,369	55%	381,228
2002	698,359	53%	373,603
2003	706,441	52%	366,131
2004	714,617	50%	358,809
2005	722,888	49%	351,632
2006	731,254	47%	344,600
2007	739,718	46%	337,708
2008	748,279	44%	330,954
2009	756,939	43%	324,334
2010	765,700	42%	317,848
2011	774,562	41%	313,703
2012	783,526	39%	305,575
2013*	792,594	36%	289,127

*Projected

Source: *American Medical News* , 11-19-12

movement. Your premise would be that, doctors and hospitals working together, the total expense will go down. Unfortunately, there is no evidence to support this contention—none. Now you are prepared to consider this: we have another 300,000 physicians not yet in the employ of hospitals who we can scare into institutional safe houses.

All told, we will have repositioned as much as $100 billion per year worth of expenditure which now becomes baked in to larger, more powerful organizations, organizations which are too big in their own regions to fail, and too powerful in the aggregate to allow public officials to institute effective cost controls.

Between 1983, the beginning of DRGs, and the present, we have lost about 20% of our independent community hospitals, with 4,800 or so inpatient general medical/surgical hospitals left. Most of the proprietors of the big systems (the ones who get invited to national conferences and whose voices are heard in the national debate) see only more of the same, and of course will benefit from that direction, as well.

The Chairman of the Federal Trade Commission opined in 2012 that, if you wish to do something about the rising cost of hospital care, these hospital consolidations should be stopped, and many broken up. A future FTC Chair can only wonder how we pushed 650,000 independent doctors into the most expensive setting possible.

Other costs of implementing PPACA

The cost of implementation of the Patient Protection and Affordable Care Act continues to unfold in ways that may not have been entirely anticipated in that Act's passage.

Here are expenses that have been announced in 2012:

1. Health Insurance Exchange: At the end of November 2012 the Administration announced that it would charge insurance companies to allow them to sell health insurance to the millions of new participants in the markets to be run by the federal government. These user fees were estimated by the Administration at 3.5% of premiums for private health plans. Since we can estimate the individual costs (let's say, $4,000 all in for an individual) for that percentage of the 16 million who are going to be in the states that do not run their own insurance plan (let's say 2 million

citizens), we have added $280 million to the national tab borne by employers for health insurance.

2. The blue states: What about the states that do not have the federal government running their exchange? Well, they are supposed to be financially self-sustaining after the year 2014. They also can charge fees to insurers. By establishing 3.5% as a premium tax, however, the federal government essentially has set a standard (or provided cover) for the states.

   This means that the tab for tax on insurance plans looks more like $2.5 billion than $280 million. In making the announcement, the spokesperson for the Department of Health and Human Services "predicted that insurers would not raise prices."[35] As with so many parts of the health reform movement, however, the cost is certain (the premium, already announced), while the benefits are uncertain. More disturbing, the benefits are predicted in the absence of any evidence, and, in many cases, in the face of evidence to the contrary.

3. In addition to the health insurance exchanges, the federal government - - again, under PPACA - - will run an insurance company.

Here is a safe prediction: No insurance company is going to be able to participate in the health insurance exchanges (websites available to bypass brokers and support "official" - - that is, officially vetted - - commercial insurance plans available to individuals and smaller employers) without raising rates to accommodate the additional administrative, legal and accounting expense.

You ask how we know that in advance? On November 30, 2012, the new Federal Register contained a 373-page notice of proposed rule-making for health insurance exchange regulation by HHS of risk adjustment, cost-sharing and user fees. The same publication (keep in mind this is eight point font) contained a 122-page Office of Personnel Management proposed rule which spells out guidelines for the so-called Multi-State Plan Program. Not enough? The same issue had the Internal Revenue Service propose a 42-page rule on the Medicare payroll tax, to be charged to higher income earners to pay for all of this. Of course, it has become commonplace to observe that these regulatory tsunamis have waited until after election day, the delay compromising the job of state insurance commissioners in attempting to prepare for enrollment of 16 million additional insured beneficiaries.

[35] Pear, Robert, "Health Insurers Will be Charged to Use New Exchanges," *The New York Times*, November 30, 2012

In fact, as we write, in California, so often our leading edge, Anthem Blue Cross had just proposed a 26% rate hike, Aetna a 22% and Blue Shield of California a 20% increase for some policy holders.[36] The interpretation of these increases (for those adhering to the first narrative) is this: "The cost of health insurance would have gone up even more without PPACA." Here, again, we have laudable motives, expressed without credible evidence. Our "predictions" are based on "policy models" from economics, not from history, or from current reality.

We should remember that we have PPACA, in part, and perhaps at all, because of Anthem Blue Cross. It was WellPoint's former president, Angela Braly, who announced a 39% rate increase for individual and small group health insurance coverage in March of 2010.[37] At the time of Ms. Braly's announcement, PPACA was lying dead on the legislative cutting room floor. The President moved quickly to denounce the increase. The denunciation of a common "enemy" galvanized the bill's proponents. An outsider might have suspected something more than just fortuitous timing in this announcement. There is the dependency (see above) of the commercial insurance industry on federal largesse, and, of course the assumed intelligence of a CEO compensated at more than $10 million per year. In any event, action was taken, and on March 23rd we had PPACA.

At least the insurers are now ready to acknowledge that regulatory overload has (and will increasingly) inflated the price of their product. On December 21, 2012, America's Health Insurance Plans (some 2.5 years after passage of the legislation causing the problem described) wrote to the Deputy Administrator of HHS responsible for the insurance regulations, indicating that it would be impossible for an insurer to meet the mandates in the "health reform" law and still provide affordable family coverage. "The requirement that all policies cover ten categories of coverage, many of which are not included in some policies today, will require millions of people to buy coverage that is more comprehensive - - but also more costly - - than the coverage they currently have."[38]

In fact, the IT and labor costs for compliance with the rules noted above - - for rate filing and data submission - - will be significantly higher than estimated by HHS, according to the AHIP. The cost of filing was estimated at $4,300, with the number of filings per plan growing from 2 or 3 to as many as 40 per plan. Under current rules, such filings are required for small group and individual plans with annual premiums that go up by 10% or more. The new rules require filings for reports that stay the same or that

[36] Abelson, Reed, "Health Insurers Raise Some Rates by Double Digits," *The New York Times*, January 6, 2013
[37] Pear, Robert, "Health Executive Defends Premiums," *The New York Times*, February 25, 2010
[38] *Crain's Health Pulse*, ACA Benefits Ruling Helps Employers, January 7, 2013

go down. Naturally enough, the IT system used by HHS (the Health Insurance Oversight System) has different requirements than the data submission systems used by the states (the System for Electronic Rate and Form Filing, or SERFF, maintained by the National Association of Insurance Commissioners). (Traditionally, insurance has been regulated by the states under the Depression-era McCarran-Ferguson Act. PPACA, however, without much public notice, has moved nearly the entirety of health insurance regulation to the federal arena.)

In sum, the data collection process, based on the health plans' estimates, will have a system-wide cost well over $1 billion, about equal to the amount returned to individuals and groups under the medical loss ratio "savings" prominently announced in 2012.[39]

Most importantly, the rules issued so far are not the end of the story, in fact, not even close. Most of these new rules will not be tried out in a limited geographic experiment. Rather, they will be rolled out, if the past is prologue, without involvement - - among others - - of representatives of the practicing medical community.

Physicians, smart people, trained and motivated, will attempt to find workarounds to those rules which are averse to patient interest, or to the financial integrity of their practice. Years of contest will follow. The number of federal employees necessary to "monitor" the rules will grow. The setbacks (see above, hospital appeals of RAC audits, for example) will grow. At the end, it is highly likely that, without regulatory relief, the expenditures in our field will continue to grow disproportionate to the value of those expenditures, since so many of our new expenditures will be the direct result of untried regulation.

A recent poignant story in *The New York Times* told of an experienced business journalist, attempting to find out how much his life saving drug for multiple myeloma would cost in 2013. The patient/journalist needed this information before the December 7, 2012 deadline for choosing a Medicare Advantage program. His inquiries yielded a series of inaccurate and misleading communications from the various parties associated with his decision, different companies, plan representatives, brokers, and providers. This would be one of those comical "different answers from different IRS offices" stories, but for the impact on the individual. At the end of the day, the best advice he received was to file a claim, and see how much would be paid. It would be too late, however, to change his Medicare Advantage plan, once that "answer" had been found.

[39] Hall, Susan, "IT, Labor Costs to Drive up Rate-Submission Compliance Costs, Insurers Say," *Fierce Health IT*, January 7, 2013

This was all reminiscent of the leading legislator who, when asked what was actually in the then-2000 plus page draft of PPACA, said that they would have to pass it to find out. The difficulty in comprehending the end product—the regulations resulting from that legislation, the rules and communications—is many fold greater. In some important ways, you have to be there (in the doctor's office) to see.

We conclude this: so many of the results we fear are—counter-intuitive or not—the very result of our "reforms" in pursuit of realization of the first narrative, the hopeful one, the one which says we can make medical care available to all, without additional payment. The very mechanisms proposed for this effort are either without evidence, or contrary to the evidence. The reality, which will continue to unfold, is that central state planning, administered prices, regulatory overload, will combine to propel cost upward. Availability of the goods, therefore, will depend more on subsidy, scarcity and tiering based on patient resources.

How Much Will Be Saved Through Innovative Payment Experiments--$716 Billion?

Physician Reaction

It would be no exaggeration to say this: when practicing physicians understand the antics behind one or another CMS "cost saving" claim, they are furious. The "fury" stems from understanding that the public is being manipulated, at substantial expense, using federal funds to support the "studies" that support the very same funding agency's theories and policies.

These feelings may echo those of legislators who discovered that, toward the conclusion of the process of passing PPACA, a leading MIT economist who had aggressively promoted the bill was, at the same time, recipient of an $800,000 federal grant to study its provisions.

Of course, it would be unwise to ignore the difficulty facing all researchers—those now on the federal dollar, and those hoping to be—in bucking orthodoxy, that is, the current "health reform" agenda. A century ago Upton Sinclair put his finger on the problem: "It is difficult to get a man to understand something, when his salary depends upon his not understanding it!"

One example—another of the experiments in cost savings and cost containment, widely promoted, was the Medicare Physician Group Practice Demonstration (PGPD). The Congressional Budget Office concluded[40] that the experiment had "little or no effect on Medicare expenditures."

In the experiment, Medicare payments to PGPD sites were compared to total Medicare payments to control hospitals. Woolhandler and Himmelstein noted[41] that an evaluation meant to supplement that of the CBO excluded some Medicare payments to PGPD but not payments to control sites, resulting in partial Medicare payments to the PGPD sites compared to total payments to control hospitals. Even after excluding these bonus payments, the follow up report failed to show savings for the primary outcome, which was spending for the average patient.

Subsequent to the CBO reports, other payment initiatives have failed. For example, it has become obvious that the elimination of consultation payments for specialists - - based on a passing hypothesis, evidence-free, implemented nationally before local trials - - has led to a counter-intuitive result, namely a net increase in spending on both primary care physicians and specialist.[42] The background in this: in January of 2010, Medicare eliminated consultation payments for specialist physician office visits, and increased fees for the general office visits. This was supposed to move money from specialty to primary care. As with many of the CMS experiments criticized by CBO, the effects have not been those anticipated by the sponsor; instead, they have led to a 6.5% increase in physician compensation per beneficiary.

Again, as noted by Woolhandler and Himmelstein, a "risk adjustment" meant to correct for this matter "used diagnoses coded by PGPD sites that had enhanced incentives to upcode."

"The Congressional Budget Office noted that several PGPD sites reported that they had begun encouraging physicians to code more diligently to maximize risk scores and hence reimbursement," they wrote. Their conclusion? "A full accounting of the PGPD results suggest that it produced upcoding but no savings."

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[40] Nelson, L., Lessons from Medicare's demonstration projects on value-based payment. http://www.cbo.gov/sites/default/files/cbotiles/attachments/WP2012-02_Nelson_MedicareVBP_Demonstrations.pdf

[41] Woolhandler, S. and Himmelstein, D., Letter to the Editors, *JAMA*, January 2, 2013, pages 30-31

[42] Song, Z., et al, "Unintended Consequences of Eliminating Medicare Payments for Consultations," *JAMA Internal Medicine,* 2013;173(1):15-21

Inasmuch as the PGPD was an important early test of the Accountable Care Organization (ACO) strategy, Woolhandler and Himmelstein conclude that "Belief that ACOs will curtail medical costs rests on faith, not evidence."

So the problem described by Silver - - that "evidence" of the type used in predictions that have proven faulty may have been faith based, not evidence based - - is an enormous challenge, especially when the largest purses are available to support faith based research.

Proponents of our first narrative ("Reformers") will be promoting a point of view which can be roughly summarized as follows: The experiments undertaken by Medicare to date, while unsuccessful, might be recharacterized as successful with some modest change in assumptions, giving hope for still larger experiments with still larger stakes in the future.

The proponents of the second narrative ("Traditionalists") might see this work summarized differently, as follows: "Researchers" supported by federal grants will attempt to create "evidence" to support federal policy. Failure to find such support will only lead to escalation, as with current attempts to eliminate fee-for-service medical care altogether. Reasoning for this last argument might be seen as follows: we don't want to pay for expansion of benefits under the medical care model Americans currently have, because the voters would not re-elect us; we can't demonstrate that change in that model (that $716 billion in savings) will come about as we predicted; therefore we have to change what Americans understand as the model of medical care.

Treatment

Amend section 1848(d) of 42 U.S.C. 1395w-4(d) as above.

X. Summary

Presenting Complaint: "I'm growing distant from my patients . . . I don't see a way to continue to treat them (or any new patients) as I do now . . . "

We began by asking why an ophthalmologist would be required or "incentivized" to weigh his or her patients. We talked about a variety of requirements associated with federal, state and even private commercial third parties. These requirements—for information, for limitation on diagnosis or treatment, for compliance—may or may not be of use to the patient or to the physician.

These requirements, however, are levied in pursuit of one or another theory of how officials involved in the levying (those at CMS, state health departments, managed care companies) might practice medicine more efficiently, were they to practice medicine.

These requirements grow in accord with the attempt to centrally plan the delivery of health services. The central planning, in turn, in response to political interest or necessity, is supported by "research" showing the efficacy of the newly levied requirement. The practicing physician, in the end, intuits that all of this is "meaningless work" - - not "meaningful use" of automated information. Historically, if a physician thought that a patient's weight was pertinent to his or her medical challenge, weight was taken. All over America, now, scales are appearing in doctors' offices, in an attempt to pick the "low hanging fruit" associated with extra payment for weighing patients, whether or not the patient's weight has any clinical relevance.

Then we turned toward "box checking" - - a process which appears to be changing medical practice from a professional service into a commodity. Attracted by the safety record of air traffic - - much achieved through standardized box checking - - the doctor is, accidentally, distracted from the patient, instead treating the chart. At some point in our evolution as a species, "big data" may be available to substitute for the human intelligence and the seven to fifteen years of training of that intelligence which prepares a medical professional to treat patients. Are we there? Central state planning assumes we are, and that the checked box is evidence of the quality of medical care.

Aside from distracting the physician, the requirements of automated information systems often slow him or her down. The amount of data gathered, in other words, is up, while the relevance of that data and its translation into information of use to the physician is down.

Not only is the data gathered for automation frequently unhelpful, its use may determine whether or not the physician is judged to be a "quality" provider. This fourth irritant stems from the extraordinary funding by CMS, AHRQ and other HHS-sponsored organizations (now PCORI, perhaps in the future, IPAB) linking one or another aspect of medical practice to one or another index of "quality." "Lower cost, higher quality" is the representation of initiatives and studies sponsored for at least fifteen years by CMS. The bottom line, however, as studied by the Congressional Budget Office, is that few, if any, of the initiatives brought forward by CMS have done either - - that is, have improved the actual outcome for patients, or contained the cost in providing services.

All of these—the requirements of central planning, the box checking, turning toward a manufacturing process—are followed by a judgment that the physician is a high or low quality provider. Inevitably, the physician thinks about his or her friends in medical practice. Some of them have sold out to the local hospital or health system. They seem to have achieved some peace of mind, certainly have found relief from the burden of practice expenses, and appear to have stability in their personal income, as well.

The government pays the hospital more for my friend's service than it would pay my friend. This is the "site of service" differential which is responsible for chasing us into the arms of the hospital. We know what to find there - - we've been through this before. We know there is a cost of central hierarchy and autarchy, and that the cost is both direct and not. The direct cost is that the hospital overhead is greater than that of the physician, its collection of bills not as efficient, its decision-making not directly focused on the individual patient. But we also know that the hospital's concentration of resources will make it - - if it is not already so - - "too big to fail."

Not only is my income at risk, as well as the care of my patients, but I might be labeled a fraud. I've heard of the Recovery Audit Contractors. I know that they have been after the hospitals. I also know that three-quarters of their decisions against hospitals have been overturned. However, I don't have as much money as the hospitals to fight these people. Apparently they get paid for making mistakes, whether or not those mistakes are subsequently corrected. So I am going to suffer a number of irritants in my attempt to take care of the patient, be labeled as high or low quality depending upon evidence which is at best unclear, watch my friends "sell out" to the hospital, and, when the government needs to ramp up the revenue or intimidate the remaining independent physicians, be in danger of being labeled a fraud.

On top of these, and my seventh irritant, is that the rules seem to change every year. The government claims that they want to pay me rates that are "sustainable" but, I have to ask, sustainable for whom? If

the government makes promises to expand the availability of my services, don't they consider whether those promises are "sustainable" at the time originally made? I am supposed to put up with less money per patient, as more patients are attracted to my practice. Does the mechanic reduce the price of auto repairs when the quality of his or her work attracts more cars to his shop? It feels like I am being used to balance the federal budget.

Finally, I can hear the gears of the future grinding. One gear, the Patient-Centered Outcomes Research Institute, appears to be a somewhat lighter version of the Independent Payment Advisory Board. This is going to require that I adhere to "clinical guidelines" which may, or may not, be appropriate for my patient. I see this is already present in the "clinical quality measures" which are "high hanging" fruit in Stage 3 of the so-called "meaningful use" incentives. I can just imagine the future progress: first the guidelines; then, failure to adhere to the guidelines is adjudged not reimbursable; finally, not adhering to the guidelines becomes "fraud."

Of course, my back office expenses - - the people I count on to deal with all of this stuff on a daily basis, while I am trying to see patients - - are up 50% in the past decade, while, temporizing on the sustainable growth rate notwithstanding, my dollar adjusted reimbursement from Medicare is down more than 15%.

I thought I was entering a professional field. However, the field has become impersonal, even threatening. How can I preserve my sense of being a professional?

All of the above (the irritants) put a wedge between the doctor and his or her patient. The government has to pretend that the doctor is inefficient, fraudulent, delivers poor quality care or all of these to "justify" the government's limitations on payment. The limitations on payment, in turn, are necessary, since the government cannot otherwise fulfill promises made to expand health insurance coverage.

This series of unintended consequences, faith-based evidence, conclusions projected from minimal correlations, shows the practicing physician that the federal government is willing to squander billions on theories, and unable to correct course when the theories prove incorrect.

Top Themes

Three basic themes emerge in examination of the "top ten irritants."

First, the automation of the medical care process is producing a backlash.[43]

At a recent conference on "e-Health Initiatives," panelists noted the "significant backlash" in promotion of the use of health information technologies. One panelist observed that the "workflows" and "pathways" have to "look more and more like manufacturing." The panelist noted that the "mindset" of a manufacturing organization would enable physicians to "use their skills in combination with data at the point of care." It isn't clear, however, that physicians would like to be part of a manufacturing process, or, even if they were, that such a process would be as effective in patient care as the more traditional doctor-patient relationship.

Second, however, beyond the automation and impersonality, physicians sense that the most important issues are being overlooked. How do we properly fund benefits? How do we ensure that our safety net is intact? If, at the end of the day, we no longer have 50 million previously uninsured citizens, but have only reduced that number to 25 or 30 million uninsured citizens, have we gotten our money's worth? And if automation and the substitution of "big data" for individual physician judgment doesn't pan out, what then?

Finally, there is a profound sense that the process is dishonest. Claims of quality are everywhere, rarely in the better journals, seldom holding up under scrutiny, quickly forgotten. That one or another federal initiative has "bent the cost curve" is an equally common claim, again with minimal evidence.

So, automation, inattention to fundamental issues and dishonesty in promoting the results is a potent combination, alienating the practicing physician from government-sponsored programs.

How to Make Change?

The relative ease with which significant changes were made in the Patient Protection and Affordable Care Act during the course of "negotiation" over the American Tax Payer Relief Act (the "fiscal cliff" solution enacted at the beginning of 2013), may be a model for further legislative initiative.

For example, nearly half of a slush fund aimed at establishing cooperative health plans was excised, a saving to the Federal Treasury of $1.9 billion. This will also save the down-stream subsidies that would

[43] McNickel, Michelle, "Doctors push back against health IT's workflow demands," *Information Week*, 2-14-13

have been necessary to support start-up health exchange cooperatives obtaining this free federal money. This might be a model for addressing the "top ten irritants" and thereby reducing the alienation of physicians from Medicare and Medicaid.

Authority and Objectivity

Who would oversee any such changes in our policy - - for example, "defunding" one or another part of PPACA? An academy awash in grant largesse? Foundations eager to be in the mainstream? Hospital systems up to their ears in federal subsidy?

One nominee would be the Office of the Actuary in CMS. Among the responsibilities of the Chief Actuary are the evaluation of the financial status of the Medicare program, the provision of budget projections for Medicare and Medicaid, and predicting the financial effects of proposed health care legislation.

Oddly, neither the Chief Actuary, the Congressional Budget Office, nor the General Accountability Office were prominent in the evaluating the theories which shaped either HITECH or the Patient Protection and Affordable Care Act.[44] CBO found itself, from time to time, used as an "authority" on this or that projection during debates on PPACA, increasing or decreasing the deficit.

Ordinarily, in the field of health services and health policy, Members of Congress, observers, participants and potential beneficiaries (or targets) would consult the health policy literature, referred to above and more broadly as the "academy." Regrettably, much of the work of the academy has been, in the years leading up to and subsequent to passage of PPACA, subsidized by CMS, by AHRQ, or by other federal agencies interested in promotion.

It is difficult—especially when reviewing the post-mortems of the CBO or GAO, and the cost projections of the Chief Actuary—to believe CMS leaders were concerned about the strength of evidence behind their proposals for "cost cutting" or "quality enhancing"; the assignment, after all, was to find that wasted $716 billion, and to cut it out.

Those Members of Congress interested in avoiding repetition of past overly optimistic policy experiments should move to guarantee the independence of this office, to ensure that political appointees cannot

[44] McDonough, Inside National Health Reform, University of California Press, 2011

constrain, discipline or dismiss whomever is in the unfortunate position of having to project the actual (as opposed to the desired) outcome of federal initiatives.

Exit, Voice, and Loyalty

The recent passing of Albert Hirschman, author of "Exit, Voice, and Loyalty: Responses to Decline in Firms, Organizations and States," may help focus our attention on the consequences of these "regulatory irritants."

In his most famous work, Hirschman[45] presented this point of view: there are at least two different ways of responding to stress and disappointment with an organization. Individuals can vote with their feet (exit), or they can complain (voice).

Schumpeter in *The Economist* wrote,

> Exit has always been the default position in the United States: Americans are known as being quick to pick up sticks and move. It is also the default position in the economics profession.

The downside of exit, of course, as summarized by Schumpeter, is that monopolies have an easier life if their disaffected customers find alternatives. This reinforces a downward cycle, as summarized by Hirschman, in which a "moderate amount" of exit might produce "an oppression of the weak by the incompetent and an exploitation of the poor by the lazy…"

What does this alienation of independent physicians from the Medicare program mean to their patients, and to the American medical system? Is this a financial issue? An organizational issue? Or even a spiritual issue—leading to loss and exit?

[45] Schumpeter, Exit Albert Hirschman, *The Economist*, December 22, 2012

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XII. Appendices

Chart, Top Ten Irritants

Author profile

Top 10 Regulatory Irritants Driving Physicians Out of Independent Medical Practice

Top 10	Diagnosis	Presenting Complaint	Other Signs and Symptoms	Treatment
1	Meaningless Work	**"I am an ophthalmologist. Why do I need to weigh this patient?"**	A variety of requirements associated with federal, state (and private commercial) third parties which may or may not be of use to the patient or physician, but which inevitably add to the cost of delivering services.	Repeal PL 111-5, Section 4101(a), 123 C.F.R. 467-472.
2	Medical Practice is Changing from a Professional Service to a Commodity	**"I am turning into a box checker . . . "**	Why did I go through 7 - 15 years of training, so that my judgment about my patients' needs is second guessed in Washington?	Repeal Title IV of Division B, ARRA of 2009, 42 USC. §§300jj, §§17901.
3	Automated Information Collection	**"This information system slows me down, and often asks questions having nothing to do with my patient's needs . . . "**	My productivity is down, the amount of "information" is up, the relevance of the "information" I receive is of questionable value for my patients.	Repeal 42 USC. §§300jj, §§17901.
4	Quality, Who Is to Say?	**"How can they determine quality? I think I give my patients quality medical care . . How does Washington know otherwise? . . "**	CMS, AHRQ and other HHS-sponsored "research" linking one or another aspect of medical practice to one or another index of "quality."	Repeal PL 111-148, Section 3041, especially Section 1890(b)(7)(B)(i)(l).
5	The Site of Service	**"All of my friends are selling out to the hospital . . Maybe I should join them . . . "**	My friends who have sold their practice to a hospital achieved (a) peace of mind, (b) relief from practice expenses, and (c) stability in their income. I recognize that the cost to the patient and society is much greater, but what can I do?	Congress to implement February 2013 MedPAC staff recommendations to reduce or eliminate site of service payment differential.
6	DOC on the RAC	**"If I check the wrong box, I will be labeled a fraud . . The government looks like it is balancing the books on my back, and using fear to do so . . . "**	This Recovery Audit Contractor stuff does nothing but inspire fear - - I see that even the hospitals are powerless to get the RAC auditors to admit mistakes. Apparently, the RAC auditors are paid for their mistakes, whether or not subsequently corrected.	Repeal RAC provisions of Tax Relief and Health Care Act of 2006, expanded by Section 6411(b) of PL111-148 and 111-152 (PPACA).
7	Sustainable for Whom?	**"Why can't they figure out how to pay me for services to Medicare patients? This seems to go on every year!"**	What is this "sustainable growth rate" business? Does the grocer reduce the price of milk when more people buy milk? Does the mechanic reduce the price of auto repairs when more cars come into the shop? It feels like I am being used to balance the federal budget.	Section 601, amend section 1848(d) of 42 U.S.C. 1395w-4(d) to disregard par (1)(A) for 2014 and all subsequent years.
8	PCORI, the IPAB-Lite	**What is 'comparative effectiveness' going to do? Am I going to be punished for going with what I think my patients need?**	An enormous new and costly establishment, the "Patient Centered Outcome Research Institute," is moving forward to recommend (and subsequently require) adherence to clinical guidelines which may, or may not, be appropriate for my patient.	Repeal of Section 6301, amendment to Title XI, 43 USC 1301, Part D.
9	The Cost of All This	**"My costs continue to climb, for paperwork, not for clinical work . . . "**	My back office expenses are up 50% in the past decade. How am I supposed to recover these expenses?	Amend section 1848(d) of 42 U.S.C. 1395w-4(d) as above.
10	Central State Planning Will Increase All Costs and May, Inadvertently, Interfere with Effective Medical Practice	**"I'm growing distant from my patients . . I don't see a way to continue to treat them (or any new patients) as I do now . . . "**	What was a professional endeavor has become impersonal, even threatening, for the professional. What am I to do to preserve my sense of being a professional?	See text, oversight and limitations. Compel CMS to provide peer-reviewed evidence for reimbursement policies.

Fred Hyde is an independent consultant, with hospitals, physicians and community organizations as his clients. During the course of a four-decade career, Dr. Hyde has served as chief executive of hospitals, physician practices, an HMO and an ambulatory surgery center.

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