



New York State Bar Association

Health Law Section

Summary Report on Healthcare Costs: Legal Issues, Barriers and Solutions

August, 2009

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Summary Report on Healthcare Costs: Legal Issues, Barriers and Solutions

The costs of the healthcare system are an ever increasing drain on the federal budget, the economy, and on employers, particularly small employers. Total health spending in the United States is currently 16 percent of gross domestic product (GDP), up from eight percent in 1975, and without changes, is projected to reach 25 percent by 2025.ⁱ Medicare and Medicaid comprise more than 25 percent of the federal budget. Medicaid alone comprised approximately 22 percent of total state spending in fiscal 2007, with a projected spending growth rate of eight percent annually for the next decade, according to a report released December 5, 2007 by the National Governors Association.ⁱⁱ Overall, states' single largest expenditure for fiscal 2007 was healthcare, accounting for on average nearly one-third of state spending.ⁱⁱⁱ

Healthcare costs also have social and public policy consequences. Insurance premiums increase every year, driving down the number of employers that offer health insurance to employees: 61% in 2007 versus 69% in 2000.^{iv} Uninsurance has costs: the uninsured delay seeking medical care and end up sicker when they do go for care; when hospitalized, the uninsured are likely to be in worse condition and die than the insured, and over half of all personal bankruptcy cases are due to medical bills.^v Increased costs have also been found to not result in better care, in fact, areas of the country with higher costs (due in large part to higher utilization) may have worse outcomes.^{vi} While we recognize the enormous achievements of the United States healthcare system, for example in prolonging healthy maturity through treatments for cancer, heart, and vascular disease, cost reduction is a clear priority in the current reform environment (to provide resources to support broader coverage) and opportunities for such cost reduction certainly appear to exist..

This report explores many of the legal issues involved with healthcare costs, how various laws and regulations stand in the way of reducing costs, and how the law may need to be changed to allow reduction to healthcare costs. It will discuss the components of the healthcare costs formula (units of services used, multiplied by price per unit, plus administrative costs), and discuss legal issues involved with each, including

- how the law affects efforts to reduce unnecessary utilization of goods and services
- legal difficulties involved with end-of-life care
- lack of payer incentives to promote appropriate utilization
- legal barriers to changing a healthcare payment system that rewards utilization
- how a change in the law may be considered to allow "quality performance payment programs" whereby hospitals may make payments to physicians for improvement in measured quality or sustained levels of quality
- comparative effectiveness research and clinical practice guidelines' role in preventing overutilization,
- legal concerns of providers leading to high "list prices" charged to the uninsured, and laws that cap charges by hospitals to the indigent
- legal barriers to transparency/sharing of healthcare providers' charges for services
- the role of statewide and regional health planning
- the high level of administrative costs in the U.S., and legal issues involved with mechanisms to reduce such
- the burden placed on providers by the multiple layers of applicable regulations
- the potential legal restrictions placed on medical homes by state insurance laws, and
- reducing political influence in making healthcare costs decisions.

A. Components of Healthcare Costs, and Potential Strategies to Reduce Costs

There are three components of the healthcare costs formula: (a) how many services of each type we use (i.e., utilization of care), multiplied by (b) how much we pay per unit of service, plus (c) the administrative

costs involved with the healthcare system, including payment of claims, profits, shareholder return, broker costs, ^{vi}litigation, and other factors.

The cost of care may be directly associated with the “business” of healthcare, largely unique to the United States (and perhaps recently to China). To quote the New England Journal of Medicine February 7, 2008, “the dominance of for-profit insurance and pharmaceutical companies, a new wave of investor-owned specialty hospitals, and profit-maximizing behavior even by nonprofit players raise costs and distort resource allocation.” To the extent that economic incentives are working in perverse ways, policy, legal and legislative changes may be in order. The commercialism of healthcare is strongly related to findings of the 2007 McKinsey study (“Accounting for the Cost of Healthcare in the US”) that the overriding cause of high US healthcare costs is the failure of the system to (a) provide sufficient incentives to consumers to be value conscious in their demand decisions, and (b) establish the necessary incentives or mandates to promote rational supply. Although maximization of profit may be standard practice on an institutional level, society as a whole bears the cost when applied to healthcare, because it is generally tied to higher overall costs.

Reduction in healthcare costs will only come about with a reduction in utilization, a decrease in price of services (perhaps through driving consumers to more efficient providers), and/or a reduction in administrative costs. Although opponents of reform attempt to scare the public with words such as “rationing care,” the reality is that healthcare dollars are not endless and choices must be made that will direct care to the activities that are the most effective. However, this paper will not discuss issues related to the overt rationing of care by government or private payers. Those policies may lower the costs a particular payer may bear, but they do not affect the cost of the service, and an argument exists that rationing already exists, albeit based on the ability to pay.

B. Legal Issues Involved with Reducing Healthcare Costs

Consideration of restructuring the healthcare system to provide appropriate incentives and reduce costs raises a large number of legal issues. Legal issues include statutory and regulatory limitations, creating legally allowable structures that provide appropriate incentives (e.g., the inability of hospitals to pay non-employed physicians for changes in utilization), rights under existing law, contractual obligations (e.g., confidentiality clauses in provider-payer contracts and effect on transparency), antitrust issues, ERISA, insurance rating systems, ability of payers and employers to change employee/subscriber behavior under existing law, and more. Legal options to address healthcare costs may include possible state and/or federal legislation to limit some of the administrative costs (e.g., establishing a brain-damaged baby fund similar to the national vaccine pool or having a single healthcare claims adjudicator), incentivizing insurers to keep subscribers healthy and manage care (not just costs) by requiring the insurers to be responsible for patients’ care over the long run, removing regulatory impediments to alignment of incentives among providers, payers and patients, and providing immunity to providers who follow certain delineated standards. Neutralizing the incentive of each player to protect their own position through lobbying and the political system may best occur through the establishment of a politically immune “healthcare board” similar to the Federal Reserve Board or the military’s base closing commission. The legal community can assist in formulating and structuring both healthcare system reform and payment reform.

Exploration of how the United States can reduce healthcare costs optimally involves trying to predict what challenges may be posed. Because affected groups will likely attempt to halt a reduction in healthcare costs that affects those groups’ profit margins (or, in the case of consumers, access to care), thought should be given to what legal issues are involved in strategies seeking to reduce healthcare costs. Consideration of the legal issues as part of the structuring of cost reduction strategies can minimize later challenges, and save time and resources.

This paper will discuss only those legal issues involved with healthcare reform that are targeted at healthcare costs. There have been and will continue to be many efforts at healthcare reform whose aim is different from reduction of healthcare costs, e.g., Massachusetts’ effort to reduce the number of uninsured. The goal of providing coverage to those without insurance, while admirable, is to be distinguished from

cost containment. Although conceptually there is an argument that providing insurance coverage to more people may reduce costs by allowing care to be received on a preventive basis rather than later in a disease process, the net effect may be more care provided to more people, which is a laudable but costly result. If the result is improved health, there is an obvious benefit to increased insurance coverage, but a reduction in healthcare costs should not be an expected benefit. Obviously, certain advocates disagree.

This paper will also not discuss the issues surrounding health information technology. The use of information technology in the healthcare system will likely expand given the financial incentives for such in the recently enacted American Recovery and Reinvestment Act (ARRA). Although health IT has long term benefits including (i) mistake reduction and (ii) reduced payment delays and lower administrative costs, at least one study found that health IT will add to costs in the short run.^{viii} Even the government's generous ARRA subsidies will not fund all of the costs, and use of alternative funding services will raise multiple legal issues, including Stark, anti-kickback, and privacy/HIPAA issues beyond the scope of this paper.

Below is a discussion of each of the three components of healthcare costs (utilization, cost of goods and services, and administrative costs), various strategies that may be considered as part of any effort to reduce healthcare costs, legal challenges that may be asserted, and legal issues involved with such.

1. Use of Goods and Services, and Efforts to Reduce Unnecessary Utilization of Care

Utilization is the number of services of each type that we consume, whether hospital services, physician services, home care, drugs, imaging, etc. The significance of utilization as to costs is best illustrated by the Dartmouth-Atlas study, which explains the variation in Medicare costs per beneficiary in different areas of the country as due to differences in utilization of services.^{ix} Each of the parties in the healthcare equation (patients, providers/suppliers and payers) must be incentivized to utilize the "appropriate" number of services. (Of course, part of the problem is that there is no definition of what amount of services is "appropriate utilization," as addressed below.) Following is a discussion of the involvement of incentives on each of the parties driving healthcare costs, and the legal issues involved with such.

a. Patient Incentives to Utilize the "Appropriate" Number of Services

i. Incentives to Reward Patients/Health Insurance Beneficiaries for Healthy Behavior

Given that over seventy percent (70%) of healthcare costs are spent on chronic disease, promotion of behavior that reduces the incidence of obesity or other health conditions associated with chronic disease, can conceptually reduce health care costs. Healthy behavior may be encouraged by employer "wellness" programs, in which an employer provides a benefit to employees who, e.g., stop smoking or lose weight. However, there are several federal and state laws that limit an employer's ability to put into place a wellness program. For example, the Americans with Disabilities Act (ADA), which prohibits discrimination on the basis of a disability, restricts employers from inquiring about employees' medical conditions or requiring medical exams. Under the ADA, an employer may not take action against an employee (including with regards to health insurance or other benefits) that treats a disabled employee differently than other employees. Under Equal Employment Opportunity Commission (EEOC) guidelines, wellness programs may be part of an employer's *voluntary* wellness and health screening program, but a penalty may not be imposed for not participating. Thus, an employer may offer a weight reduction program, and if an employee is not able to participate because of a disability, the employer must make a reasonable accommodation to that employee so s/he is not penalized because of the employee's inability to participate.

In addition, under the federal Health Insurance Portability and Accountability Act (HIPAA), group health plans may not base eligibility for benefits on health status, medical condition (including physical and mental illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, or disability. A group health plan also may not require higher premiums on the basis of any "health related factor." However, discounts may be offered (or copays and deductibles adjusted) for employees who participate in a "bona fide wellness program." The requirements of a "bona fide wellness

program” are set forth in regulations jointly issued by the US Department of Labor, the Internal Revenue Service and the Centers for Medicare & Medicaid Services. These regulations allow differentiation of premiums and cost-sharing for employees who succeed in “wellness” programs such as smoking cessation or weight loss programs, only if the reward or penalty for success is limited.^x

Various state laws also protect against employment discrimination, or regulate benefit programs, and can be relevant to wellness programs. Legal analysis regarding an employer’s ability to institute a wellness program may also include review of a unionized employer’s collective bargaining agreement, pursuant to which an employer may be required to negotiate wellness programs with a union. This may be due to the employer’s agreement in its collective bargaining agreement to negotiate any changes in benefits, or a union’s position that the National Labor Relations Act’s requirement that employers bargain over “wages, hours, and other terms and conditions of employment” encompasses benefits (and wellness programs).

While the importance of not discriminating against the disabled must be recognized, also important is taking action to encourage prevention of those conditions leading to disabilities (and costs), to the extent such can be prevented or their incidence reduced. Another option to promote healthy behavior that may help avoid employment discrimination or risk-gaming by insurers is to distribute payments for healthy behavior through public health or other government entities. Mexico’s Oportunidades program, which Mayor Bloomberg has proposed emulating in New York City, provides a model.^{xi} If there is a Congressional commitment, however to give employers “sweeping new authority to reward employees for healthy behavior,” as reported in the New York Times on May 9, 2009, changes to the above regulations may need to be explored.

ii. High Deductible Health Plans

Another structure that incentivizes patients to be prudent purchasers is the High Deductible Health Plan. These plans set large deductibles, and can be used along with health savings accounts, which allow individuals to set aside monies pre-tax to pay healthcare expenses within the deductible amount. All savings (the difference between the amount so funded and expenditures) accrue to the insured, who thus has an incentive to limit expenditures. Although widely available since 2004, only approximately 8% of beneficiaries throughout the U. S. were covered by this form of health insurance as of September, 2008.^{xii} Although there are questions as to whether high deductible plans are workable for lower income individuals, these programs do not appear to raise material legal issues.

iii. Disease Management

Like wellness programs, disease management programs are often focused on encouraging patients to do the right things for themselves (e.g., diabetics losing weight and taking medication to control blood sugar). Behavior modification incentives are often crucial to success of disease management programs, but their use is very limited by the legal restrictions placed on such. Legal limitations exist not only with employer programs, but even more so with government sponsored wellness programs and disease management programs. Due to the near ban on financial incentives to encourage healthy behavior in Medicare and Medicaid beneficiaries, disease management providers have struggled even in attempting to encourage Medicaid patients to complete health assessments, the first step in managing chronic disease. A provider or plan may be subject to penalties for offering anything more than a nominal incentive to encourage individuals to control their disease better.

The limitations on providing incentives to Medicare and Medicaid patients are due in large part to the Civil Monetary Penalties (CMP) provisions in Section 1128A(a)(5) of the Social Security Act, which prohibits offering remuneration to a beneficiary that is likely to influence the patient to seek items or services from a particular provider, practitioner or supplier, for which payment may be made by Medicare or Medicaid. The OIG has interpreted this law as allowing only goods or services valued at less than \$10 per item and \$50 per patient in the aggregate on an annual basis.^{xiii}

In addition to the CMP, a disease management program may violate the anti-kickback statute, which makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce

referrals of items or services reimbursable by the federal health care programs. “Remuneration” includes anything of value.

As with wellness programs, any desire to encourage disease management programs will require review and revision of the above laws, unless the disease management process is moved to the public health arena and administered separately from the health financing system.

iv. End-of-life Care and Challenges to the Concept that Healthcare Dollars are Unending

Medicare spends 25 percent of its dollars on care of its approximately six percent of beneficiaries in the last year of life,^{xiv} due in large part to the high utilization of high-cost services (intensive care, drugs and technology) at the end-of-life. Although health care services overall may engender an attitude of “spare no cost” by those patients and family members whose health is at stake, this attitude can be particularly pronounced with end-of-life decisions.

The legal issues involved with end-of-life care often revolve around consent, and the intensity of services a patient would want utilized to prolong their life/death. Advance directives have been promoted as a mechanism to allow patients’ wishes to be expressed when the patient cannot do so personally, and may reduce costs through reducing utilization of services and technology. In the absence of a directive, family members often feel obliged (and providers can be required) to continue care despite its lack of long-term benefit, at least for some time. Only a small percentage of the US population have advance directives, and although work should occur to increase this number, efforts to reduce end-of-life costs must encompass more than promotion of advance directives. Options to reduce end-of-life costs must address legal and non-legal factors involved with utilization of end-of-life services and technology, including (i) discomfort of physicians and providers in discussing death with patients and/or family and offering the option of less aggressive end-of-life care, (ii) the absence of clear legal authority for family and friends to direct the withdrawal or withholding of life-sustaining treatment under appropriate circumstances, based on the reasonably known wishes or the best interests of a patient without capacity to consent, (iii) reluctance of providers to withhold or discontinue treatment that offers no real benefit to the dying patient, (iv) the low rate of hospice use among Americans in general, and certain minority groups in particular, (v) concern with legal liability, (vi) overuse of ICU beds, and (v) lack of standards as to treatment at the end-of-life.

Some of the options that may address the above include:

- (i) promotion of clinical practice guidelines in end-of-life care, which may help to reduce long-term use of expensive modalities on patients whose benefit from such is questionable,
- (ii) comparative effectiveness research to determine whether certain expensive drugs and treatments used at the end-of-life provide more benefit than less expensive alternatives.
- (iii) clarifying and in some states broadening the authority of family members to authorize the withdrawal or withholding of end-of-life treatment for their loved ones;
- (iv) have a federal law similar to the law in Texas, which provides a process that hospitals may take if family members refuse to allow discontinuation of care which the hospital and physicians feel is extraordinary/non-beneficial, and recognize the right of healthcare providers not to participate in non-beneficial care^{xv}.
- (v) define treatment that provides no medical benefit other than prolonging death as “non-beneficial treatment;” avoid the terms “care” (all patients should receive care) or “futile care”; and provide immunity for ceasing non-beneficial treatment if approved by an ethics committee or other appropriate body, or if consistent with clinical practice guidelines issued by a specialty society or other nationally recognized body.

Of course, debate as to the above should also include considerations of patient autonomy, informed consent, and the value placed on the lives of the elderly and disabled.

b. Payer Incentives to Promote (pay for) Appropriate Utilization

Under the current system, payers' incentives are to reduce their financial responsibility for services, which lack of payment often reduces utilization. Patients/insureds often change insurance plans, and a payer likely will not have responsibility for a patient over an extended period of time. Therefore, the payer has no incentive to pay for services which may prevent long-term problems, because it is more likely than not that the payer will not be responsible for the individual in the long term when that problem arises.

In other countries such as the Netherlands, insurers are required to take responsibility for patients as long as the patient wishes to remain with that insurer. The benefit to this concept is that it truly "invests" the insurer in the patient, and motivates the insurer to keep the patient healthy so as to reduce the patient's long-term costs. Although making insurers responsible for patients potentially until such time as the patient is old enough to qualify for Medicare does not entirely abrogate a payer's incentive to deny care, it removes the incentive to deny care that will improve health over a period of time that may be longer than a one year subscriber contract. This concept legally may be strongest if enacted through an amendment to ERISA, as was COBRA, so as to maximize the number of health plans to which it applies.^{xvi}

c. Provider Incentives: Decreasing Unnecessary Utilization Through Changes in Payment Mechanisms
(a/k/a "follow the money")

One of the recognized impediments to a change in utilization of resources is the present payment system and the fact that physicians and many other providers are largely paid upon volume of services provided, inducing providers to offer more testing and procedures to compensate for an overall reduction over the past years in reimbursement for cognitive services. This was well illustrated in a July 2009 New Yorker article^{xvii} exploring how such incentives have resulted in utilization of services in McAllen, Texas that have caused McAllen to have the second highest per capita healthcare costs in the nation: \$15,000 each year per Medicare enrollee. Compared to El Paso, with a similar population, McAllen has sixty percent more stress tests with echocardiography, 200 percent more nerve conduction studies to diagnose carpal tunnel syndrome, and 550 percent more urine flow studies to diagnose prostate troubles, yet McAllen's hospitals ranked worse than El Paso's on most Medicare metrics of care. Noting the financial focus of healthcare providers in McAllen, the surgeon author diagnosed "the primary cause of McAllen's extreme costs [as] very simply, the across-the-board overuse of medicine."

Not only does the current payment system reward utilization, it creates a perverse incentive whereby hospitals and physicians are financially penalized for keeping patients healthy, because healthy patients have less need for medical services. Equally disturbing, the law as is creates substantial barriers to creating structures that can focus on quality rather than volume. Although Medicare and other payers are exploring other mechanisms of payment, e.g., for episodes of care, hospitals that are not in a demonstration project face legal burdens to attempting to structure arrangements that change the incentive for physicians to order more care and perform more procedures. These hurdles are largely due to restrictions set forth in (i) the physician self-referral (Stark) law, which prohibits physicians from referring to an entity in which they have a financial interest unless an exception exists (and no exception exists for rewarding physicians who decrease utilization), (ii) the anti-kickback law, which prohibits the offering or receipt of an inducement in return for referrals of patients or business paid for by Medicare or Medicaid, and (iii) the Civil Money Penalty statute ("CMP" law) at Section 1128A(b)(1) of the Social Security Act (42 USC Section 1320a-7a(b)(1)).

The purpose of these laws is to prevent financial considerations from interfering with patient care decision-making, and these laws are often necessary, given the dollars in the healthcare system. However, provision needs to be made for arrangements that allow doctors and hospitals to work together within certain guidelines to encourage quality, which promotes appropriate utilization. Although hospitals have some latitude with employed physicians under the Stark and anti-kickback laws, many hospitals do not have the financial resources to add numerous physicians to their payrolls, and there will always be independent attending (non-employed) physicians whose decisions as to patient care affect not only the patient, but impact on the hospital and overall healthcare costs.

The impact on healthcare costs of the relationship between hospitals and physicians can be seen from the Dartmouth Atlas study. The version of the study released in 2008 showed the difference in the number of

physician services received by patients whose care was through Mayo Clinic as compared to those patients whose care was through an academic medical center in New York City. Patients who received their end-of-life care through Mayo Clinic received during the last six months of their life, on average, 24 physician consults, whereas patients who received their end-of-life care through the New York City academic medical center received in the same time period on average 76 physician visits. The patients' outcomes or quality of care were not deemed changed by either practice.

Of the above three laws, the anti-kickback law may be the least worrisome for hospitals that wish to implement or participate in a gainsharing or quality improvement project, as this statute requires intent. However, the current exceptions under the Stark law allow hospitals extremely limited ability to formulate a structure that provides physicians with an incentive to achieve quality measures and cost efficiency. CMS proposed an exception for incentive payment and shared savings programs in the 2009 Medicare Physician Fee Schedule proposed rule ^{xviii}, but this was not finalized. In the final Medicare Physician Schedule for 2009, CMS posed fifty five (55) questions regarding shared savings programs and incentive payment plans and asked the industry for comment as to how such could be structured to allow flexibility without program abuse. One set of comments sent to CMS^{xix} promoted the concept of allowing "quality performance payment programs ("QPPP")," whereby hospitals may make payments to physicians for improvement in measured quality or sustained levels of quality, which measures are defined and applied through the term of the program. The comments suggested certain safeguards for a QPPP, including that it be based on a written document identifying the measures, payments, qualifications, baseline and targets; that the program be required to use measures substantially related to nationally recognized measures, that no physician be able to be paid based on volume or value of referrals, and that the hospital conduct ongoing monitoring of the program. An exception under the Stark law for QPPPs could potentially assist with not only an improvement in quality, but a decrease in costs, as ineffective or wasteful services are avoided.

Additionally, the CMP law has been widely interpreted to prohibit hospitals from trying to incentivize physicians to contain costs, as it subjects to civil monetary penalties and exclusion from Medicare/Medicaid a hospital that knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the physician's direct care. The OIG has taken interpreted this law very broadly, stating in a July 1999 Special Advisory Opinion that:

"The statutory prescription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or a reduction in medical necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute."

According to the OIG, this law prohibits hospitals from implementing "gainsharing" arrangements, whereby the hospital shares with physicians part of the money that a hospital has been able to save due to, e.g., use by physicians of less expensive equipment or following certain guidelines.

The OIG in 2001 began issuing advisory opinions allowing specific gainsharing arrangements, and has issued 14 favorable opinions as of 2009. However, the OIG does not seem to have changed its view that the CMP law prohibits gainsharing, but instead in its advisory opinions has either found that certain elements of the proposed arrangement do not have clinical significance (and therefore do not implicate the CMP law), or do have clinical significance but do not pose a risk of abuse. A recent article in the March 6, 2009 American Health Lawyers Journal ^{xx} makes a very plausible argument that the CMP law was intended to prohibit only payment for reduction in *necessary* care, and that it does not clearly prohibit paying physician to refrain from furnishing *unnecessary* medical care or to use one clinically equivalent medical supply or device rather than another. CMS and the OIG certainly have the ability to take a fresh approach to the CMP statute to allow alignment of hospital and physician incentives to improve care and reduce costs.

d. Compare the Effectiveness of Care and Develop Clinical Practice Guidelines Against which Utilization of Services can be Measured

One reason for the large variations in utilization across the country is that there is no “standard” as to what amount of utilization is appropriate. Analysis of the “appropriateness” of treatment requires consideration of what treatments (or levels of treatment, or amounts of treatment) are most effective in achieving the goal of maximizing the patient’s health.

The 2009 American Reinvestment and Recovery Act included \$ 1.1 billion for comparative effectiveness research. Comparative effectiveness in and of itself is not designed to control costs, but is to compare the effectiveness of treatments, for the purpose of improving quality, reducing wasteful variation, and enhancing how taxpayer dollars are used when paying for medical care. The Congressional Budget Office, in a 2007 report, defines comparative effectiveness as “a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients.”^{xxi} This report suggested that comparative effectiveness research could reduce health spending in the long term, and the CBO in a later report stated that it could help ensure that costly services were used only when they offer a clinical benefit greater than the benefit offered by less costly services. Review of use of comparative effectiveness research by other countries shows that it is used not as a way to refuse to pay for a service or drug, but as a way to determine relative payment based upon how effective the modality is compared to others. For example, Britain has used “pay for performance” pricing whereby the government receives a rebate if a technology does not perform in accordance with manufacturers’ claims, or pays an enhanced price if greater effectiveness is demonstrated. Other countries such as France have used comparative effectiveness research to produce disease and product information for professionals and patients, allowing providers information from sources other than drug companies and device/technology vendors.^{xxii}

That certain treatments and drugs have been proven to be more effective than others does not guarantee that the more effective (or equally effective and less costly) treatments/drugs will be used by practitioners. Encouraging use of treatments or drugs whose comparative effectiveness has been shown may require a reason to use an equally effective drug or treatment. One reason may be the extent of coverage of each treatment or drug. As part of the need to look at whether this nation can continue to afford treatments whose clinical effectiveness is no greater than other, less expensive treatments, Congress may wish to consider specifically authorizing Medicare to exclude more expensive treatments or drugs from coverage when, based upon clinical effectiveness research, they are shown to be no more effective than less expensive treatments or drugs. Application on a going-forward basis could increase chances of withstanding legal challenges, so that patients are allowed to finish a course of treatment or medication that has already begun; obviously, a process that recognizes possible individual discrepancies in drug response – which may make some drugs non-comparable for a given patient, and/or an exception process for patients who have developed stable complex long standing drug regimens – would also enhance the litigation position and address some consumer advocacy concerns.

Comparative effectiveness could potentially be translated into clinical practice guidelines (CPGs). These evidence-based guidelines guide clinical decisions by providing guidelines and/or criteria for diagnosis and treatment of specific diseases and medical conditions. CPGs are intended to document the best medical and scientific evidence and standardize medical care. Use of CPGs can assist not only in payment, but can also reduce costs in other ways, including reducing utilization. For example,

(a) The Dartmouth Atlas study demonstrated how utilization of services differs in various areas of the country, illustrating how the “standard of care” can be flexible. Although flexibility can allow for patient preferences and patient response to treatment, lack of a standard of care can allow overutilization, e.g., with end-of-life care. Clinical practice guidelines for end-of-life care can help physicians discuss the use and benefit (or lack of benefit) of such in dying patients.

(b) Clinical practice guidelines can also be used to help to prevent overutilization by physicians who order tests and procedures to avoid allegations of malpractice. A November 2008 study by the Massachusetts Medical Society estimates that physicians’ ordering of unnecessary tests,

procedures, referrals and consultations because of their fear of being sued adds at least \$1.4 billion per year to healthcare costs in Massachusetts alone. The study reported that 83 percent of physicians surveyed admitting practicing “defensive medicine,” with an average of 18-28 percent of tests, procedures, referrals and consultations, and 13 percent of hospitalizations, ordered to avoid lawsuits. A physician who follows clinical practice guidelines could be allowed a rebuttable presumption in a malpractice suit that the legally expected standard of care was used in the care of that patient. Although not conclusive, because a plaintiff could rebut this presumption through use of other evidence, use of clinical practice guidelines in this fashion could reduce unnecessary utilization and potentially reduce non-meritorious lawsuits against physicians, as well as reduce unnecessary services.

Development of clinical practice guidelines may raise antitrust concerns, depending upon who sets the standards. If CPGs set a standard for a market, a decision has effectively been made for that market. The antitrust law as applied to standard setting focuses on ensuring that the standard setting organizations are not captured by one or two of the market players, and that the process by which standards are set is fair and is not slanted to favor a particular player or outcome. This was illustrated in a May 2008 settlement between the Connecticut Attorney General and the Infectious Diseases Society of American (IDSA) regarding the IDSA’s alleged anticompetitive behavior in development of clinical practice guidelines for diagnosis and treatment of Lyme’s disease. The IDSA guidelines concluded that there is no scientific basis for “chronic Lyme disease,”^{xxiii} that antibiotics beyond 30 days are not appropriate (despite other studies as to the effectiveness of long-term antibiotics) and that patients who fail to improve with the IDSA’s protocol have no treatment options other than palliative care.

The IDSA was alleged, in combination with members of its Lyme disease guidelines panel, to have engaged in an unlawful refusal to deal in, and monopolization of, the market for Lyme disease, by abusing the guideline development process. After the AG’s investigation found conflicts of interest with panel members, and refusal to appoint scientists with divergent views, the parties settled. The IDSA agreed to form a new panel to reassess the guidelines, appoint an ombudsman to ensure no conflicts of interest exist, and allow presentations by persons with different interests and views. These concerns are met in other countries by conflict of interest policies, careful composition of a panel reviewing specific effectiveness research, and engagement with stakeholders.^{xxiv}

The loudest objection to CPGs will be from technology, pharmaceutical and device providers/manufacturers/ suppliers whose technology or medications are not determined to be as clinically effective as another, or not superior in effectiveness to a lesser priced item. There will likely also be objections from practitioners who deride clinical guidelines as “cook-book medicine” that remove discretion to treat patients differently. The most effective objections to practice guidelines are likely to come from patient advocacy groups, who will resist any program that reduces patient choice of care modalities.

While Congress and state legislatures would appear to have broad authority in the area (particularly when determining payments under public programs), many states (such as New York) afford State constitutional status to healthcare, which would be implicated in an extreme case. Moreover, Federal requirements that States must meet in operating Medicaid programs may further limit policy options in the area or require amendment. Challenges to federal or state administrative action creating such a program would be expected.

e. Allow Exploration of “Medical Homes”

Medical homes are models of care based on the concept that patients with a “medical home” will receive closer coordination of care that can prevent exacerbations of illness and unnecessary care (and cost). Most issues involved with medical homes are financial (compensating physicians for their time in coordinating care) or operational, rather than legal. However, to the extent that state insurance laws may prevent medical homes, the law is restricting use of a model that may be able to improve patient care and reduce costs. For example, an operator of a medical home in Seattle that requires patients to pay low monthly fees (\$39-79 depending upon age) but gives 24/7 access for all primary physician care has found that the people

who are attracted to them are the high utilizers. ^{xxv} Given that seventy percent of healthcare costs are spent on chronic disease, this model could conceivably reduce medical complications and attendant costs, while expanding access. However, in March 2009, the New York State Insurance Department stopped a physician from offering patients, including the uninsured, unlimited office care for \$79 per month plus a \$10 co-pay, claiming that the physician's fixed-rate plan was equivalent to an insurance policy. ^{xxvi}

2. Cost of Healthcare Goods and Services/Healthcare Consumer Protection

a. Limitation on Charges for Healthcare Services for the Uninsured/Underinsured

Overall healthcare costs are largely determined by the charges per unit of healthcare services, supplies, pharmaceuticals and goods provided by tax-exempt and for-profit hospitals, long-term care providers (some of which are large national chains), physicians, large pharmaceutical companies, and suppliers of various sorts. In a capitalist society, it is problematic to dictate what parties can charge (although charge limits are imposed by the Federal Government and some States as a condition of participation in Medicare). Instead, control is exerted over what the government or private payers pay for those goods and services. (For example, the debate on pharmaceutical pricing has primarily focused on the government acting as a purchaser for government labeled programs, and not on direct pricing controls.) However, parties without a contractual arrangement with a healthcare provider or supplier (such as an uninsured patient who doesn't have the benefit of a negotiated rate with a hospital or pharmaceutical supplier) can be charged almost an unlimited amount, and certainly an amount that is a multiple of what a well-positioned buyer of services pays. This was illustrated by the rash of lawsuits against hospitals in the mid-2000s, in which patients alleged that hospitals were abusing their tax exempt status by charging uninsured patients high list prices that far exceeded what Medicare or private payers pay. ^{xxvii} The courts generally dismissed these suits, acknowledging there is no legal limit on charges. ^{xxviii}

Some states such as New York and Illinois have passed legislation which caps the amounts (based upon Medicare payments) that hospitals may charge the indigent, and it may be appropriate to expand such legislation to include all persons without insurance (as well as potentially the underinsured), to apply to providers other than just hospitals, and to apply such on a federal level rather than have varied state laws. Alternatively, and perhaps preferably, thought might be given to ending the practice of maintaining a consistent charge for non-contracted patients and use by providers of a high "list price" charge unless financial need is demonstrated.

b. Price Transparency

If healthcare providers and suppliers can charge what the market will bear, then changes should be made to the healthcare market to have it function like other markets. Perhaps a reduction in the cost of healthcare goods and services could be achieved by making the cost of services transparent and allowing consumers to compare prices, which will hopefully drive consumers to more efficient and less costly providers. However, one reason that a "rational" market does not seem to exist with healthcare services is because there is no ready way for healthcare consumers to compare prices and make reasoned decisions based upon the cost of the contemplated service. Medicare has made attempts to provide information to Medicare beneficiaries as to the charges by various providers for certain services, and some managed care providers have formulated databases of charges by certain providers in their network, which database is available to subscribers in that health plan. However, there is no database that a patient without insurance (or a patient with a high deductible plan) can view of all e.g. providers in that locality who provide a certain type of service and their charges, so that a patient can compare charges in making a decision as to which services to purchase. ^{xxix}

Contracts between payers and hospitals, physicians or other providers generally contain confidentiality clauses, prohibiting the provider from disclosing the terms of the contract, including the payment terms. In addition, some payer contracts have "most favored nation" clauses, requiring the provider to give the payer the best rate that it gives to any other payer. Even without a most favored nation clause, providers are generally concerned that a payer that is aware that a lower price was offered to another plan will use such

as a reason to reduce payment to the provider. Therefore, any provider who lists its charges and who has any payer contracts would be unlikely to list less than (a) the provider's charges (which for most hospitals are unrealistic) or (b) the highest rate allowed under any of the provider's managed care contracts, to avoid any of its payers from attempting to negotiate a lower rate based on the lower "transparent rate." Congress could increase transparency by requiring that providers have available (e.g., on their websites) published prices for individual patients (i.e., those not covered by a third party payer). This would allow individuals to know and make decisions based on cost before a service is rendered.

Antitrust issues may also arise from making healthcare prices "transparent," as competitors' prices would be viewable by others, and competing providers may adjust their prices either to undercut their competitors, or to seek additional reimbursement if competitors' negotiated rates with payers are higher. Federal legislation exempting providers who post price information from antitrust liability may encourage such transparency.

c. Determine which Goods and Services Should not be Compensated at Current Prices or Compensated at all

Although Medicare has done much to reduce inequality of payments among providers (e.g., tying fees for surgery at ambulatory surgery centers to those paid to hospitals), some disparities still exist. In addition, there may be some services that are no more effective than a clinically equivalent service that is less expensive. If such determination is made (through a comparative effectiveness study), consideration should be given to payment by Medicare based on the "value" of that service, i.e., its clinical effectiveness. Lastly, federal law has already determined that situations exist where payment should not be made at all (e.g., for services referred by physicians to entities in which they have an ownership interest in violation of the Stark law), and it may be appropriate to review whether other such situations also exist, e.g., radiation oncology provided by urologists who refer and treat the patient.

d. Statewide and Regional Health Planning

Many states have used (and some continue to use) public allocation processes such as certificate of need (CON) laws to limit overutilization of tests and procedures by controlling the number of facilities and providers able to provide such. Although these laws have been repealed in many states, they can indeed be effective, as illustrated by the difference between New York and New Jersey in the number of ambulatory surgery centers (ASCs) in each state (New York requires certificate of need approval for establishment of ASCs, whereas New Jersey does not).^{xxx} Similarly, centralized planning and CON laws may also be utilized to allow certain "high need" hospitals, e.g., those serving a disproportionate share of the medically underserved, to obtain certain services that may not be approved for provision by other, wealthier providers in that region.

3. Efforts to Reduce Administrative Costs, Including Shareholder Returns, costs of Processing and Administering Claims, Profits, Broker costs and Malpractice costs

There are a large number of administrative costs in the US healthcare system. Some estimates are that 31 percent of healthcare dollars are spent on administrative costs. Health administration costs total at least \$294.3 billion in the United States, or \$1,059 per capita, significantly more than other countries.^{xxxii} These include the cost of processing and administering claims, shareholder returns, executive compensation, profits, broker cost, and malpractice costs. Advocates of single payer systems argue that substantial savings can be achieved through eliminating multiple parties from the financing system,^{xxxiii} and quote as support a recent Urban Institute report commissioned by New York State to study the costs associated with various models that may be considered to expand coverage.^{xxxiii}

a. Malpractice Cost Reduction

Malpractice costs also contribute to the problem of healthcare costs, although the extent of that contribution is a matter of contention between the attorneys who bring malpractice suits and the insurance companies

that pay out on these claims. Even more expensive than the costs of defending and litigating malpractice cases, and paying out jury verdicts, are the costs associated with “defensive medicine,” i.e., physicians ordering tests or performing procedures whose primary purpose is their value in defending the doctor against a claim of medical negligence. A 2006 study by PriceWaterhouse Coopers attributed up to ten percent of the insurance premium dollar as due to a combination of the cost of litigation and defensive medicine.^{xxxiv}

If the federal government were to pass legislation restricting malpractice suits, a legal challenge might come in the form of the appropriate balance of state-federal power. Instead (or in addition to tort reform), an option could be removal of some of the most expensive malpractice cases (i.e., cases alleging brain injury in newborns) from the tort system through establishment of a compensation fund. There is both federal and state precedent for such action. In 1988, Congress passed the National Childhood Vaccine Injury Act of 196 (Public Law 99-660), creating the National Vaccine Injury Compensation Program (VICP). The VICP was established because of numerous lawsuits alleging injuries to children from vaccines, and the difficulty in obtaining insurance by vaccine manufacturers. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. Individuals who believe that they have been injured by a covered vaccine can file a claim against the US Department of Health and Human Services in the U.S. Court of Federal Claims, seeking compensation from the Vaccine Trust Fund. If found eligible, claimants can recover compensation for related medical and rehabilitative expenses, and in certain cases, may be awarded funds for pain and suffering and future lost earnings. More than 1,500 people have been paid, with awards averaging over \$800,000. Although an individual who is dissatisfied with the award may reject it and file a lawsuit in state or federal court, very few lawsuits have been filed since the program began.

State precedent also exists for special compensation funds. In response to increasing costs of claims against medical providers and medical malpractice insurance in the late 1980s, Virginia and Florida both created funds to compensate families whose babies are born with neurological impairments. Brain damaged baby claims were singled out because of the large awards that can result from these claims. A family that receives compensation from these funds does so in lieu of malpractice litigation. A family may receive compensation for medical, rehabilitative and custodial care, special equipment or facilities, and related travel, except to the extent these expenses have already been paid by insurance. Lost earnings are also available, although limited in Florida. In Virginia, the Workers’ Compensation Commission determines eligibility; in Florida, the State Management Department assigns an administrative law judge to resolve claims. In both states, annual assessments from physicians and hospitals capitalize the funds, both of which are currently actuarially sound.

Other malpractice reform initiatives could include increased disciplinary sanctions tied to a pattern of unexpected adverse outcomes, improved credentialing and licensing programs, and/or limiting certain forms of damages and mandating binding arbitration. A federal statute would likely be constitutional under the Commerce Clause.^{xxxv} State laws are subject to State constitutional law challenges

b. Payer Cost Limitations as a Percentage of Premiums

Some administrative costs are inevitable, but there are a number of methods that have been tried or considered in attempts to reduce administrative costs from the healthcare system. Some states require managed care companies to spend a minimum defined percentage of their revenue on medical care/costs rather than overhead and profits, although in some states the requirements are that managed care companies must spend as little as 60% of the premium paid by policyholders on medical costs. Although disliked by the managed care companies, these have generally not been challenged. However, such minimum percentage expenditure requirements may only increase the incentive to maximize premiums, and thereby, profit.

c. A Single Claims Adjudicator/claims efficiency

Another option to substantially reduce administrative costs of administering the healthcare claims and payment system is to change the claims administration system. In the present system, the same entities responsible for paying claims are responsible to make decisions as to whether the claims should be paid. A number of class action lawsuits have alleged that health plans delay and deny payment, through deeming claims not properly “authorized,” care not “medically necessary,” losing claims, and the like. A proposal from late 2007^{xxxvi} suggested formation of a unified health claim clearinghouse system to separate approval and payment of claims from the ownership of premium cash pools. This proposal would create an independent and electronic healthcare clearinghouse to coordinate the approval of and payment for covered services, and avoid the conflict that payers presently have in trying to maximize profits by denying claims and delaying payment. Given that Medicare’s administrative costs are roughly 5-6 percent, whereas private payers’ administrative costs fall between 8.9 and 16.7 percent (which does not include provider costs, which are substantial)^{xxxvii}, a proposal to restructure administration of claims payment to a system similar to Medicare could allow for substantial savings (although some of Medicare’s administrative costs are expensed elsewhere in the federal budget^{xxxviii}). Congress could pass such legislation under the Commerce Clause or potentially its spending power,^{xxxix} which should give authority against legal challenges by health insurers related to the displacement of part of their functions to an independent entity, and removal of their control of claims (a vast pool of money).

Other action can also be taken to reduce administrative overhead that is short of a single claim adjudicator, but that provides for more efficiency than the current decentralized system whose requirements vary depending upon the particular payer. Although HIPAA’s administrative simplification requirements and the Medicare National Provider Number (NPI) have helped somewhat to decrease the administrative burden on providers and patients, much more remains to be done. For example, (i) Benefit packages could be standardized, so that a provider does not have to ascertain whether a patient has 20 or 24 physical therapy visits and a \$10 or \$20 co-pay, (ii) payers could be required to set up electronic portals allowing providers to electronically check patient eligibility and benefits on a 24 hour basis, (iii) payers could be required to provide subscribers with ID cards that can be electronically “swiped” at a providers’ office with connectivity to a payer’s system, (iv) payers could be required to use a standard claims forms and codes. In fact, two states (Colorado and Texas) have mandated the use of standardized health insurance identification cards.^{xl}

d. Use of Standard Managed Care Contract Provider/Payer Interaction Terms

One reason that Medicare’s administrative costs may be lower is because it does not negotiate separate contract terms with its providers; the terms are uniformly prescribed in regulation and policy manuals. In contrast, commercial payers and providers expend enormous amounts of time and money negotiating contracts terms, such as coordination of benefit provisions, claims submission time periods and authorization requirements. Providers’ need to comply with multiple inconsistent plan provisions is burdensome and costly. One way to reduce administrative costs for both plans and providers, with no effect on quality or access, may be to enlist government to promote equitable routine provisions in provider-payer contracts.

e. Regulatory Reform

Lastly, the regulatory burdens on healthcare providers increase costs for healthcare services. Hospitals and healthcare providers are among the most highly regulated of businesses in the United States. Both federal and state laws and regulations contain a myriad of requirements regulating every area of a hospital’s practice, from how it can compensate its physicians, to the type of staff it must have, to how many hours its nurses can work. Although some degree of regulation is clearly necessary, over-regulation imposes layers of cost on an already expensive area. HIPAA, with the confusion as to whether providers are releasing too much or not enough information, is an example. News reports of families believing their loved ones have died because the hospital staff were concerned about releasing information about the patient’s transfer, demonstrate the confusion and questionable benefit of portions of this law.

Although excessive regulation can be beneficial to lawyers who practice in the field (as no one else can keep track of the regulations), the bar asks Congress to be wary of passing additional legislation and regulations imposing burdens on healthcare providers, which burdens simply add to the cost of the healthcare system. Congress may consider a cost benefit analysis be mandated before each new regulation is passed, and that the cost-benefit analysis be repeated after implementation to determine if the regulation is working as desired. It is interesting that part of the extensive regulation has come about as a punitive set of mechanisms to counteract the perverse incentives in the system that reward utilization. It has been estimated that at least three percent of healthcare claims are based upon fraud.^{xii} Revision of payment incentives to pay for efficient and effective health improvement, rather than units of service, may be most effective in reducing “fraud” in the system.

On the other hand, although regulation of providers is myriad, regulation of other parties in the healthcare system may be appropriate for review and enhancement, including, e.g., requirements that payers implement claims efficiencies such as setting up electronic portals allowing providers to electronically check subscriber/patient eligibility and benefits twenty four hours a day, and use a standard claims form and codes.

C. Reducing Political Influence in Making Healthcare Costs Decisions

Healthcare is a segment of the economy in which multiple players attempt to profit, from pharmaceutical companies and managed care companies to medical device manufacturers and durable medical equipment manufacturers, to hospitals and physicians. Although a part of capitalism, the desire to protect profit has caused various constituencies to attempt to avoid regulation or cost containment, often through political means, resulting in decisions skewed by politics, and the use of “healthcare dollars” on lobbying activities. One of the mechanisms that has been used in other political arenas to attempt to remove decision-making from the political process has been appointment of a neutral commission or body to make certain decisions. Recent examples include the federal base closing commission, and the New York State Commission on Health Care Facilities in the 21st Century (the “Berger Commission”) used by New York State to make recommendations on closing hospitals in New York State.^{xiii}

A number of challenges were brought by governors and senators in states containing bases recommended for closure or realignment by BRAC. Similar challenges had been raised under the 1990 BRAC Act. In these challenges, the US Supreme Court precluded judicial review under the Administrative Procedure Act of the President’s discretionary decisions to close certain military installations, noting “longstanding authority holds that such review is not available when the statute in question commits the decision to the discretion of the President.”^{xiiii}

It may be most effective to follow a similar process in the healthcare field to make decisions as to e.g. funding or reimbursement.

D. Conclusion

In summary, changing the incentives that drive up healthcare costs requires consideration of changes in the law to (among other things): (i) allow incentives to be used as a part of wellness and disease management programs, (ii) promote use of clinical guidelines, (iii) allow providers (including hospitals) to refuse to participate in (and discontinue if appropriate) non-beneficial treatment after a process including family discussion and ethics committee review; (iv) allow hospitals to act as “accountable care organizations” and reward non-employed physicians based upon achievement of defined quality measures; (v) tie hospital charges to the uninsured to Medicare rates, (vi) reduce malpractice costs; (vii) require that cost implications be considered prior to further regulation of providers, and (viii) allow exploration of medical homes without restrictions of state insurance laws. Other actions that can be taken that may involve legal action (but not necessarily a change in the law) include setting up a healthcare claims processing clearinghouse to reduce administrative costs involved in processing healthcare claims, prescribing uniform terms in provider-payer contracts, and appointing a neutral commission or body to make certain healthcare costs

decisions and reduce the political influence on cost decision-making. To the extent that the healthcare bar can be of service it is ready to do so. The bar calls on its members, Congress and all members of the extended healthcare community (including patients, payers, and providers/suppliers) to work together and put aside self-interest to decrease healthcare costs and strengthen our healthcare system.

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Note: The Health Law Section of the New York State Bar Association includes a wide range of perspectives, including advocates for physicians, other healthcare providers, hospitals, health plans, regulators and consumers. Some members believe that some important policy alternatives to control costs (e.g., a single payer plan) should be included in any analysis, and that there should also be deliberate consideration of policy arguments concerning such matters as consumer protections in discussion of some of the measures analyzed in the report. It should be noted that the report does not advocate adoption of any particular policy alternative.

ⁱ Congressional Budget Office, *The Long-Term Outlook for Healthcare Spending* (November 2007).

ⁱⁱ The Fiscal Survey of States, December 2007, National Governors Association, National Association of State Budget Officers.

ⁱⁱⁱ *Id.*

^{iv} The Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits, 2007 Summary of Findings* (2007).

^v David U. Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Study*, THE AMERICAN JOURNAL OF MEDICINE (2009), http://pnhp.org/new_bankruptcy_study/Bankruptcy-2009.pdf.

^{vi} National Coalition on Health Care, *Health care Quality, 2009* (2009).

^{vii} As cited in the Commonwealth Fund's July 2009 Issue Brief, "How Health Care Reform can Lower the Costs of Insurance Administration," by Collins, et al., the costs of broker commissions alone in the small-group market, where brokers play a key role in identifying pertinent insurance policies, run from 4 percent to 11 percent of premiums.

^{viii} Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Cost*, 24(5) HEALTH AFFAIRS 1103, (2005).

^{ix} John E. Wennberg et al., *Tracking the Care of Patients with Severe Chronic Illness*, DARTMOUTH ATLAS OF HEALTH CARE (2008).

^x See 71 Fed. Reg. 239 (Dec. 13, 2006); see also 26 C.F.R. § 54 (for the IRS regulations); 29 C.F.R § 2590 (for the Employee Benefits Security Administration regulations); 45 C.F.R § 146 (for the CMS regulations). The reward for the wellness program, coupled with the reward for other wellness programs, may not exceed 20 percent of the cost of the employee-only coverage under the plan. A reward can be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.

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- ^{xi} Mexico's Oportunidades program offers families a monthly payment, free or low-price medical services, and scholarships in exchange for their participation in health, nutrition and education programs. See Theresa Braine, *Reaching Mexico's Poorest*, BULLETIN OF THE WORLD HEALTH ORGANIZATION (2009).
- ^{xii} Employer Health Benefits, 2007 Annual Survey, Kaiser Family Foundation, 2007-09-11.
- ^{xiii} See Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55855 (August 30, 2002); see also Op. OIG No. 02-14 (2002).
- ^{xiv} Melinda Beeuwkes Buntin & Haiden Huskamp, *What is Known about the Economics of End-of-life Care for Medicare Beneficiaries?* THE GERONTOLOGIST 42:40-408 (2002), http://gerontologist.gerontologyjournals.org/cgi/content/abstract/42/suppl_3/40.
- ^{xv} A recent case in NJ, *Betancourt v Trinitas Hosp.*, Docket No. C-12-09, Superior Court of New Jersey, March 4, 2009, illustrated the need for recognition of healthcare providers' rights not to participate in non-beneficial care, which the court stated was an issue of first impression in New Jersey, did not recognize such, and appointed as decision-maker the patient's daughter, who desired continued maximal efforts in a patient for whom physicians agreed care was non-beneficial (and who had also indicated intent to bring a lawsuit against the hospital and therefore had another potential motive for delaying the patient's demise).
- ^{xvi} COBRA, at 29 USC 1162 et seq., was enacted in 1986 (effective 1986) as an amendment to ERISA.
- ^{xvii} Atul Gawande, *The Cost Conundrum: What a Texas Town can Teach us about Health Care*, THE NEW YORKER, July 1, 2009.
- ^{xviii} 73 Fed. Reg. 38502 (July 7, 2008).
- ^{xix} See December 12, 2008 letter by Alice G. Gosfield and Associates, P.C.
- ^{xx} Donald H. Romano, *A Fresh Look at the CMP Statute: It May Not be as Proscriptive for Gainsharing Arrangements as the OIG Believes*, HEALTH LAWYERS WEEKLY (2009), http://www.arentfox.com/email/romano/Don%20Romano%20HLW_article.pdf.
- ^{xxi} Congressional Budget Office, *Research on the Comparative Effectiveness of Medical Treatments* (2007).
- ^{xxii} Kalipso Chalkidou et al., *Comparative Effectiveness Research and Evidence-Based Health Policy: Experience From Four Countries*, 87(2) THE MILBANK QUARTERLY 339 (2009).
- ^{xxiii} Chronic lyme disease is a situation in which patients suffer ill effects after a tick bite for months or years, and the guidelines allowing antibiotics for only 30 days is based on a conclusion that the spirochete that carries the disease does not live in the body long-term
- ^{xxiv} Kalipso Chalkidou et al., *Comparative Effectiveness Research and Evidence-Based Health Policy: Experience From Four Countries*, 87(2) THE MILBANK QUARTERLY 339 (2009).
- ^{xxv} John Commins, *Direct Medical Home Offers Healthcare Without Insurers*, HEALTHLEADERS MEDIA, July 13, 2009, http://www.healthleadersmedia.com/content/235830/topic/WS_HLM2_PHY/Direct-Medical-Home-Offers-Healthcare-Without-Insurers.html.
- ^{xxvi} VOSIZNEIAS, STATE BUREAUCRATS FIGHT DOCTORS' \$79 FLAT FEE FOR UNINSURED, (2009), <http://www.vosizneias.com/28392/2009/03/04/new-york-ny-doctor-trying-to-help-uninsured-patients-with-annual-low-fee-is-being-fought-by-state-bureaucrats>.
- ^{xxvii} See e.g., *Galvan v. Northwestern Mem'l Hosp.*, 382 Ill.App.3d 259, 888 N.E.2d 529, 321 I.L.Dec. 10 (2008); *Cox v. Athens Reg'l Med. Ctr.*, 279 Ga.App. 586, 631 S.E.2d 792 (2006); *Pitts v. Phoebe Putney Mem'l Hosp.*, 279 Ga.App. 637, 631 S.E.2d 830, cert. denied October 16, 2006; *Urquhart v. Manatee Mem'l Hosp.*, 2007 WL 781738 (M.D.Fla. (2007)); *Colomar v. Mercy Hosp. & Catholic Health E.*, 461 F. Supp.2d 1265 (S.D. Fla. 2006).
- ^{xxviii} Physicians also typically have a list of charges, which also are used as the basis for payment by patients whose insurance doesn't contract with that physician, at all or for a particular service. Physicians and other providers who participate with a third party payer (and are part of that payer's network) get paid either according to that payer's fee schedule, or a negotiated rate.
- ^{xxix} Complicating the lack of a database of local providers and their charges is the fact that the issue of "quality" is also important in medical care, and considered in choice of a health care provider. Consumers now have significantly more quality information than ever before with the various "Compare" databases from Medicare (e.g., Hospital Compare and Nursing Home Compare), and services such as Health Grades.
- ^{xxx} New York has 0.45 ambulatory surgery centers per 100,000 people, and New Jersey has 2.31 ambulatory surgery centers per 100,000 people, according to statistics from the Ambulatory Surgery Center Association cited in "Ambulatory Surgery: National and State Environments and Key Policy

Considerations,” presented to the Public Health Council, New York State Department of Health, January 23, 2009.

^{xxxix} Steffie Woolhandler et al., *Costs of Healthcare Administration in the United States and Canada*, 349(8) N. Engl. J. Med. 768-775 (2003).

^{xl} The Lewin Group estimates that if a single payer system were implemented with other major features of a reform plan – such as an employer requirement to offer coverage, expanded eligibility for Medicaid, a standard benefit package, and premium subsidies, that more than \$200 billion could be realized in administrative cost savings during 2010-2019. See Sara R. Collins et al., *How Health Care Reform Can Lower the Costs of Insurance Administration*, 57 THE COMMONWEALTH FUND pub. 12299 (2009).

^{xli} The Urban Institute, *Achieving Quality, Affordable Health Insurance for All New Yorkers: An Analysis of Reform Options* (2009), http://www.health.state.ny.us/health_care/reports/docs/2009-07-17_analysis_of_reform_options.pdf (prepared for the New York State Department of Health and the New York State Department of Insurance).

^{xlii} PriceWaterhouse Coopers, *The Factors Fueling Rising Healthcare Costs 2006, Prepared for America's Health Insurance Plans* (2006), <http://www.ahip.org/redirect/PwCCostOfHC2006.pdf>.

^{xliii} The Commerce Power of the United States Constitution, US CONST. art. 1, Section 8, cl. 3, in pertinent part, provides that Congress shall have the power “[t]o regular commerce . . . among the several states.” The Supreme, in *United States v. Lopez*, 514 U.S. 549 (1995) held that this power grants Congress authority to regulate activities having a substantial impact or relation to interstate commerce. Most health insurers conduct business across state lines. However, these regulations must be specifically directed at health insurers, as a statute requiring or compelling states to regulate insurers themselves will be considered a violation of the Tenth Amendment and not upheld, as decided in *New York v. United States*, 505 U.S. 144 (1992).

^{xliiii} Edward S. Kornreich et al., *The Unified Health Claims Clearinghouse: A Prescription to Simplify and Save on Health Care Services*, 14(1) NYSBA Health Law Journal 29 (2009)..

^{xliiii} A recent national study found that US physicians spent an average of \$68,274 per physician per year interacting with health plans, for a total \$31 billion annually, according to “What Does It Cost Physician Practices to Interact With Health Insurance Plans?,” Casalino, Nicholson, Gans, Hammons, Morra, Karrison and Levinson, Health Affairs Web Exclusive May 14, 2009.

^{xliiii} William G. Schiffbauer, *The Level Playing Field Myth: Comparing Administrative Costs for Public, Private Health Insurance*, BNA'S MEDICARE REPORT, April 24, 2009.

^{xliiii} Under Article 1, Section 8 of the U.S. Constitution, “Congress shall have the power to lay and collect taxes, duties, imposts and excises to pay the debts and provide for the common defense and general welfare of the United States. The U.S. Supreme Court in *South Dakota v. Dole*, 483 U.S. 203 (1987) validated Congressional conditioning of federal funding/spending on states’ compliance with the demands of the federal government (in *Dole*, to change the drinking age to 21), even if Congress does not have the constitutional power to regulate it in the first place. With health care, Congress could potentially invoke the Spending Power of the Constitution to induce all states to require private health insurers, conducting business in their respective states, to participate in the unified clearinghouse. This could be accomplished through conditioning federal funding related to healthcare (conditioning of 5% of funds was upheld in *Dole*) upon meeting such requirement.

^{xli} 8 TEX. INS. CODE ANN. § 1660 (2007), and 10 COLO. REV. STAT. ANN. § 16-135 (2009).

^{xli} Anti-Fraud Resource Center, *The Problem of Health Care Fraud*, NATIONAL HEALTH CARE ANTI-FRAUD ASSOCIATION, http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_cent&wpscode=TheProblemOfHCFraud.

^{xliii} For example, the Base Closure and Realignment Act of 2000, 104 Stat. 1808 as amended, following Title 20 U.S.C. Section 2687 (the “BRAC Act”) was passed in 2000 to set forth the process by which military bases in the United States and its territories were identified for closure and realignment, to avoid objections of politicians to closure of bases in their states or legislative areas. Pursuant to the BRAC Act, a process was set up whereby the Secretary of Defense was authorized to make recommendations for the closure and realignment of military bases in the U.S. to the BRAC Commission. The Commission then forwarded this recommendation to the President of the United States, who was required to either approve or disapprove the recommendations in the report in their entirety. See BRAC Act 2914(e)(1). The law

provided that if the President approved either the original or revised recommendations, he was required to send the approved list and a certification of approval to Congress. *Id.* at 2914(e)(3). Unless Congress enacted a resolution disapproving the approved recommendations within 45 days after receiving the President's certification of approval, the Secretary was required to carry out all of the recommendations. *Id.* at 2904(e).

^{xliii} Dalton v. Spector, 511 U.S. 462, 474 (1994).