LEGAL MANDATES FOR PHYSICIAN QUALITY: BEYOND RISK MANAGEMENT

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At its best, health care in the United States is superb. Unfortunately, it is often not at its best. Problems in health care quality are serious and extensive; they occur in all delivery systems and financing mechanisms. Americans bear a great burden of harm because of these problems, a burden that is measured in lost lives, reduced functioning, and wasted resources. Collectively these problems call for urgent action.[1]

Leaders lead by channeling attention – it is time for healthcare leaders to channel attention towards our error-prone healthcare systems.[2]

I. INTRODUCTION

In the last few years, how to improve the quality of health care has become the subject of public policy attention as never before. In addition to Congress and state legislatures, numerous other bodies, including the National Forum for Health Care Quality Measurement and Reporting[3] -- a public-private partnership, the Leapfrog Group -- a major employer's coalition, the Institute of Medicine of the National Academy of Sciences, and the Agency for Healthcare Research and Quality – the resurrected and reinvigorated AHCPR -- are aiming their sights at this critical but traditionally elusive goal. Some of this new policy momentum has been stimulated paradoxically both by anxieties over service reduction in managed care and increasing availability of data about performance, which sometimes shows better results for managed care entities.

While the general public professes skepticism if not downright fear about quality in managed care, they also have often assumed that all doctors are equal in skill, performance and outcomes. Of course, neither the medical profession nor the industry in general has done much to counter these presumptions. Moreover, when such information, however limited, is made available, reportedly individuals rarely use it.[4] The common wisdom is that in those rare instances when things go wrong, patients redress their harm in malpractice lawsuits. In the context of managed care, this issue has become the subject of vicious legislative battles at state and federal levels over whether managed care entities can or should be held liable for poor quality outcomes in individual cases. From the implications of ERISA for this issue, to the use of civil RICO lawsuits by litigators who have fought tobacco companies, breast implant and pedicle screw manufacturers, this "patient's rights" debate is stratospheric in terms of how high

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[1] Chassin, Galvin et al, "The Urgent Need to Improve Heath Care Quality," 280 JAMA 1000 (Sept 16, 1998)

[2] Reinertsen, "Let's Talk About Error," 320 British Medical Journal 730 (March 18, 2000)

[3] See, Gosfield, "Health Care Report Cards: Quality in the Public's Cross Hairs", *Health Law Handbook, 2000 ed.*, WestGroup, pp. 501-542 for more information about this organization and others engaged in quality reporting exercises.

[4] See, Gosfield, supra n. 3, at 522-525

its profile. Nonetheless, it is only one aspect of the quality wrangles, and one which arguably misses the real point.[5]

Despite the maelstrom, data has shown that most errors do not get litigated.[6] Today, new attention to errors in health care generally is at the forefront of discussions of health care quality improvement overall. Discussion of error has been a longstanding taboo among physicians. As Reinertsen notes, "Clinicians prefer to talk about something else – almost anything else — than our errors. We don't talk much about errors because deep down we believe that individual diligence should prevent errors, and so the very existence of error damages our professional self image."[7] Whether physicians will have the chance to mold the dialogue away from the blame game to a less accusatory improvement process remains to be seen. That challenge will be met in the current context which has inaugurated policy discourse at a pitch not heard in health care quarters since the adoption of the Health Care Quality Improvement Act about whether to open the books on error and safety to those who could use such data against the subjects of the reports – namely trial lawyers suing physicians. Commentators today analogize to the airline industry and the necessity to learn from errors rather than punish them. These discussions are an attempt to bring the error debates under the umbrella of how to improve quality. [8]

Points of leverage over quality have been analyzed by many. The godfather of the modern quality evaluation era, Avedis Donabedian, concluded there were three points of delivery on which to focus: (1) structure or input – the setting for care including the physical environment, personal qualifications, and institutional organizational structure; (2) process – how care is delivered including technical competence and appropriateness of services to the condition; and (3) outcomes or end results – what happened to the patient as a result of care.[9] Today new concepts addressing performance measurement have entered the lexicon along with continuous quality improvement/total quality management theories imported from Japanese manufacturing principles popularized by Edward Deming.[10]

Existing strategies to improve quality have been categorized as (1) regulation; (2)

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[5] See Gosfield, "Liability for Quality: A Modest Proposal," 1 Managed Care & Cancer, Jan/Feb 2000, pp. 11-12

[6] Brennan et al, *Patients, Doctors and Lawyers: Medical Injury, Malpractice Litigation and Patient Compensation in New York*, A Report by the Harvard Medical Practice Study to the State of New York, 1990

[7] Reinertsen, supra n.2

[8] For advocates on these points, see Reinertsen, supra n.2, and Gosfield, supra n.5

[9] Donabedian, "Evaluating the Quality of Medical Care" XVIV Milbank Memorial Fund Quarterly (66 July 1966)

[10] For an insightful and interesting history of these developments see Millenson, *Demonstrating Medical Excellence*, University of Chicago Press, (1977)

competition (3) continuous quality improvement itself; and (4) financial incentives.[11] Each has been cited as well for its limitations. Regulation fails to accommodate subtle variations in the characteristics of patients, offers limited flexibility and stifles innovation. Competition depends on a theory of the marketplace which is distorted in healthcare and not operating freely in accordance with the theories upon which market based competition depends. Continuous quality improvement has spread slowly, finds its manifestations primarily in hospitals and has engaged far too few clinicians. As for financial incentives, here, "We have devoted remarkably little creative energy to designing and implementing payment systems that reward excellence in quality."[12]

For those who labor in the multiple vineyards of quality improvement, another major challenge has been how to make a business case for quality improvement when the folks who foot the bill –employers and individual consumers-- behave as if they believe that all health care providers are quality-equivalent and that the quality is good. To improve quality there must be acknowledgment that things can be better. This alone is threatening to many who would be asked to change. In a comparative, measurable world some comparisons will inevitably be invidious. Even in the Valhallas of academia, there is a bottom of the class. On the other hand some would argue that when it comes to errors there really is no top of the class since the subject has been avoided for so long. So, if there is nowhere to go but up for everyone, then the patient safety/error issues may offer a new, less threatening basis on which to invigorate the broader policy questions. A persistent dilemma remains for the business case though: whether improving quality ought be value added and therefore better care should be paid for on top of basic health care; or whether good quality must be inherent and therefore a moral obligation.

Against this background, the role of the law holds a special place. Historically, assessment of the law as a goad or impediment to quality improvement has been limited primarily to consideration of risk management efforts to prevent malpractice litigation. Malpractice case law itself provides some insight into generic standards of behavior. Risk managers look to case law in their work within those health care delivery organizations which have focused on this concern, including those malpractice insurers which reward with lowered premiums physicians who practice safety measures and other risk management techniques.[13]

As the temperature rises in the quality/error policy debates and new initiatives will undoubtedly materialize, some attention to existing legal mandates for quality is appropriate. To date, the policy discussions have rarely taken into account the multiple legal forces at work today to motivate physicians -- as distinct from other elements in the system -- to provide, assure and demonstrate the quality of the care they render. Statutes, regulations, and contract terms including those oriented around payment systems, are all sources for these legal demands. Still

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[11] Chassin, "Assessing Strategies for Quality Improvement," 16 Health Affairs 151 (May/June 1997

[12] Id., generally and at 158

[13] Crane, "Medical Mistakes: Must doctors take the rap?" 77 Medical Economics 108 (Nov. 20, 2000)

further, these legal influences are not focused exclusively in managed care settings, but include fee for service medicine. Some influences are direct and some, like anti-referral laws, quite indirect for quality purposes.

Many other laws focus on other elements of the industry and will not be considered here. Hospital conditions of participation under Medicare,[14] and laboratory compliance with the Clinical Laboratory Improvement Act,[15] for example, are oriented at specific non-physician targets. These requirements are far better known than those which drive physician behavior, despite the fact that the plenary legal authority of physicians to practice medicine is so significant that it dominates virtually all other aspects of care delivery. Some have observed that the most expensive piece of health care technology of the last fifty years has been the ballpoint pen which gives physicians the ability to write the orders which drive the behavior of others.

In quality discussions today there is also a new emphasis on organized delivery systems, recognizing the role of physicians as only one part, albeit major, of far larger and more complex mechanisms. Whether managed care or multi-hospital based, in these organized entities many players create a multi-factorial process which ultimately determines the care a single patient or a population will get. Still, in these settings too, there has not been much attention devoted to what the law does to physicians in terms of improving or assuring the quality of their care. As policymakers and regulators confront the significant challenge of quality improvement, an appreciation of the context today and whether existing legal mandates advance or thwart new policy goals is important. This article catalogues and explains some of the primary and lesser known legal mandates for quality which focus specifically on physicians and considers them in light of current concepts of quality.

To assess various legal demands for quality, it is useful to identify what leading thinkers are saying about today's changing view of quality problems while keeping in mind Donabedian's framework. In 1990, in developing an overall strategy for quality in Medicare, the Institute of Medicine defined quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[16] This definition is broad and goes well beyond physicians, but it certainly incorporates them in its ambit. Later that decade, these concepts were refined further. Failures of quality are seen as of three types: *Underuse* is the failure to provide a health care service when it would have produced a favorable outcome. *Overuse* occurs when a health care service is provided under circumstances in which its potential for harm exceeds its possible benefit. *Misuse* occurs when an appropriate service has been selected but a preventable complication occurs and the patient does not receive the full potential benefit of the service.[17] The

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[14] 42 CFR § 482 *et seq*

[15] 42 USC§ 263a

[16] Lohr et al, *Medicare: A Strategy for Quality Assurance,* National Academy Press, Wash. D.C. 1990

[17] Chassin and Galvin, supra n.1

surprisingly widespread prevalence of these three types of problems and their costs has also been noted.[18] Yet, these quality problems are distinct from errors. At the millennium, ten years after its Medicare quality strategy, the Institute of Medicine's Committee on Quality of Health Care In America took on the daunting task of examining the quality of health care in America generally and how to achieve a threshold change in quality. Although they began with medical errors, the Committee will next consider under and overuse, but the error issue captured headlines and commentary with astonishing force.

In a report which drew vast attention in the lay and academic press, the Committee defined *error* as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.[19] Not all errors in health care result in harm and not all harm is the result of errors; but the scope of the error problem identified by the study was staggering.

> When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results...imply that at least 44,000 Americans die each year as a result of medical errors. The results of the New York study suggest the number may be as high as 98,000...Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between $17 billion and $29 billion of which health care costs represent over half.[20]

The IOM recommended, among other things, developing protected systems to report errors found, learn from them and thereby prevent future errors. The new focus on patient safety, in response, is a major departure from the codes of silence, blame and fear which have characterized any considerations of the problems of medical errors. Even so, many criticized as hype and scare tactics the reported extent of the patient safety problem. Still others decried the expense that would be associated with fixing it.[21]

As the question of how much information about errors to make public became a hotspot in the ensuing brush fires, it recalled the fierce policy debates now renewed over whether the National Practitioner Data Bank ought be open to the public. As if this debate were not enough, HCFA has announced an intention to reverse fifteen years of policy by making physician identifiable PRO assessments public.[22] The Joint Commission also has announced the intention

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[18] Id.

[19] Kohn et al, *To Err is Human*, National Academy Press. Wash D.C., 1999

[20] Id. Executive Summary, at http://www.nap.edu/htmt/to_err_is_human/exec_summ.html

[21] See, Crane, supra n. 13

[22] PROs profile individual physicians under their contracts. Physician identifiable information has not been disclosable to the public since 1985. (42 CFR § 480.101(b)(1)). This policy is reportedly about to change. Now in response to a complaint in Florida, HCFA has said it is considering opening data regarding individual physician quality deviations. Pear, "Medicare Shift: Doctors' Errors To be

to make hospitals have their physicians disclose errors to patients.[23] The tendentiousness of these disclosure issues is only one example of the passion with which stakeholders have confronted a single component of a fulsome consideration of quality problems. Given the other problems which are up for grabs besides data disclosure, before we impose new requirements and incentives on physicians who are already struggling in an era of diminished payment, increased regulation and intensified accountability, let us consider what they face today.

II. FEDERAL MANDATES

A. PROs

In the absence of real conditions of participation for physicians analogous to facility requirements for entry into the Medicare reimbursement system, Utilization and Quality Control Peer Review Organizations ("PROs") remain the primary quality control mechanism to review physicians in Medicare.[24] Created initially in 1982 under the Tax Equity and Fiscal Responsibility Act, with the advent of the Prospective Payment reimbursement system ("PPS") for hospitals, the initial orientation of PROs was to act as a check and balance against the perverse incentive in PPS for hospitals to cut costs by underserving patients. Even while inpatient utilization was the PROs' initial focus, under PRO review, physicians remain at risk for significant penalties both for under and overuse of services. Moreover, the focus on hospital gaming of PPS is still part of the PRO Scope of Work today but has evolved considerably through the last twelve years to the current Sixth Scope of Work.[25] The new program reflects both an increasing emphasis on quality interventions for failed physician and institutional performance and a return to that PRO link to federal sanctions which led some to characterize PRO authority as "mini-field offices of the OIG."[26]

The fundamental review responsibility of the PRO, itself usually a physician organization contracted to conduct review in accordance with the Scope of Work, is to determine whether services are reasonable and medically necessary, whether they were provided with quality which meets professionally recognized standards of care and whether services and items proposed to be provided on an inpatient basis could effectively be provided on an outpatient basis or in an inpatient facility of a different type.[27] The PRO's determination on these issues is binding on the

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Disclosed," New York Times, January 2, 2001, p. A1.

[23] Lovern, "JCAHO's New Tell-All," Modern Healthcare, January, 2001, p. 2

[24] 42 USC§ 1320c-1 *et seq*

[25] PROs get their contracts from the government by proposing to implement the government's Scope of Work, which functions like a request for proposal.

[26] For more information about PROs generally see, Gosfield, "Utilization Management, Quality Assurance and Practice Guidelines" in American Health Lawyers Association ed., *Health Law Practice Guide*, Vol 2, Chapter 25, pp. 25-29 through 25-55

[27] 42 USC§ 1320c-3(a)(1)

Medicare carrier; and denied payment is the first weapon in its significant arsenal.[28]

In addition, PROs have been required since their inception to utilize norms, criteria and standards to make their review determinations.[29] They have been extremely variable in undertaking this activity. The power of these measures can be significant, though. To motivate physicians to conform with these analogues of clinical practice guidelines, there is a never-used statutory provision which protects from malpractice liability a physician who takes action in compliance with or reliance upon a PRO's norms, criteria and standards, provided he exercised due care in doing so.[30] To further stimulate physician participation in and adherence with the PRO program, the statute also offers its own immunity and confidentiality provisions -- peer review protection, if you will--for informants to its processes and participants in them, even going so far as to provide for government payment of any legal defense expenses incurred by any PRO, member or employee related to the performance of any duty or function authorized under the PRO's contract.[31]

Despite these minimal PRO carrots, the principal sticks they can wield against physicians come from their role in imposing "sanctions", exclusions from Medicare or Medicaid programs as well as civil money penalties for quality failures. It is noteworthy that while the regulations governing the PROs' sanction authority were originally published in 1985 with the other three sets of regulations which have remained in effect since then, the PRO sanction regulations have now been removed to become part of the other regulations under the authority of the Office of the Inspector General governing exclusions from Medicare and Medicaid.[32]

The statute provides that each practitioner is obligated by law to assure that "to the extent of their authority", services or items ordered or provided by them are provided economically and only when and to the extent medically necessary, are of a quality which meets professionally recognized standards and are supported by evidence of medical necessity in such form and fashion and at such time as the PRO may require.[33] There are two types of violations for which a physician can be cited: (1) "substantial violations" occur when the practitioner has failed in a substantial number of cases substantially to comply with any one or all of the obligations; (2) in a single instance a practitioner has placed a patient in imminent danger or unnecessarily high risk, a "gross and flagrant violation" may be found. Penalties are exclusion of the individual from Medicare for no less than a year, fines of up to $10,000 for each instance of improper care and or repayment or withholding of improperly paid amounts associated with the violating services.

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[28] 42 CFR§ 411.2; 466.86

[29] 42 CFR§ 466.100

[30] 42 USC§ 1320c-6(c)

[31] 42 USC§ 1320c-6(a), (b) and (d)

[32] See, 42 CFR§ 1004.10 *et seq*

[33] 42 USC§ 1320c-5

Since all forms of PRO review can generate a sanction, this authority is quite broad. The standard against which the clinician's behavior is evaluated is not always clear; and defending a physician against a sanction recommendation is much like defending a malpractice case, but with only thirty days to do so.

In addition to the utilization and quality judgments made in their fundamental reviews of hospital outlier stays, hospital requested higher weighted DRG adjustments, and hospital and managed care plan-issued notices of non-coverage, there are links with other sanction based authorities which require medical input. PROs are required to review cases referred to them by Regional Offices of HCFA to determine the medical aspects of anti-dumping law violations,[34] namely whether patients are medically stable or in active labor. Under their contracts they review instances of beneficiary complaints about quality when these are referred by the Regional Office of HCFA or the Office of the Inspector General; and under the Fifth and Sixth Scopes of Work they are obligated to perform any other clinically relevant fraud and abuse referrals those offices may refer to them.

As for the quality orientation of PRO review and its effect on physicians, the Fifth Scope of Work (which still pertains to some PROs as they transition to the Sixth) was designed as part of a HCFA mission:

> "to promote the quality, effectiveness and efficiency of services to Medicare beneficiaries by strengthening the community of those committed to improving quality; monitoring and improving quality of care; communicating with beneficiaries and health care providers in order to promote informed health choices; protecting beneficiaries from poor care; and strengthening the infrastructure."[35]

The kinder, gentler PRO world was to be characterized by cooperative projects focused on improving care for patients with acute myocardial infarction or diabetes and improving preventive care in the form of flu vaccines and screening mammography. Improvement was to come from "Comprehensive Interventions" starting with communication with providers, then offering resources ranging from technical assistance in quality improvement techniques to literature review to limited data collection and analysis, to identifying and supporting critical personnel involved in quality improvement.

Between the lofty aims of the new approach and its more academic study techniques, one might be lulled into believing that its goals were purely educational. That would be a mistake. In fact, the PRO was still to engage in "surveillance analyses" using data to monitor patterns, trends and variations in care, to identify sentinel events, and to act upon opportunities for improvement. But still this data and all PRO review feeds into the sanctions processes. Physician profiling is part of the program; and coordination with other enforcement agencies at state and federal levels is still part of the PRO quality improvement strategies. For individual physicians, the PRO is

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[34] 42 USC§ 1320c-3(a)(16) see text at n. 60 *infra*

[35] Fifth Scope of Work at C-2

more stick than carrot.

The Sixth Scope of Work, which will eventually be in place for all PROs, reemphasizes the quality strategies of PROs. But here, the PROs are directed to initiate Payment Error Prevention Programs (PEPP) designed to reduce payment errors particularly in the inpatient setting. In this initiative PROs are to focus on unnecessary inpatient admissions (overuse) and miscoded DRG assignments, using traditional case review and data collection. Although HCFA states that the emphasis is to be primarily educational, where fraud is suspected referrals to enforcement agencies are expected. Of greater interest to this consideration, where quality of care issues are identified, the PROs are directed to steer cases to the PRO's own quality improvement staff to develop quality improvement projects or conduct mandatory review.

The Sixth Scope of Work continues the cooperative projects though with even greater specificity. HCFA has pledged in the Sixth Scope to provide greater support for the PROs' activities through Clinical Area Teams for each of the national clinical areas targeted for quality improvement. For each clinical area a Clinical Area Support PRO is to be contracted to support the PROs working on these projects. The targeted clinical issues include acute myocardial infarction, diabetes, heart failure, pneumonia, stroke/transient ischemic attack/atrial fibrillation and breast cancer. PROs are to initiate local quality improvement projects on other needs and issues of interest in their states. As for the six national clinical areas, PROs are to implement a quality improvement project in one of the following: skilled nursing facility, nursing home, dialysis facility, home health agency, hospice rehabilitation hospital, *physician's office* or another outpatient facility. This approach makes it clear that HCFA intends PROs to expand their focus to the broader continuum of care than the traditional inpatient hospital setting.

Taken together the PRO program has strongly enunciated a quality improvement orientation, but its statutory authority vis a vis physicians remains, as it always has been, one of payment denial and sanction recommendation. Physicians will be involved in the implementation of projects around the targeted clinical issues which can directly affect physician quality performance; but these efforts are not directed at physicians *per se* but at processes. Nonetheless, by linking much of its review to payment issues, a strong component of PRO review has always been focused on overuse. From the beginning, however, where PROs have used their sanction role, underuse and misuse have also been part of the program, but only in the most egregious circumstances. Even the nomenclature of sanctions emphasizes the drastic nature of the quality problems at issues, "failing in a substantial number of cases substantially to comply," or "gross and flagrant" violations. The new quality improvement focus of PROs is intended to make a difference before individual cases reach these dramatic levels of failed performance. Whether the new system is working, though, is hard to know at this writing since the data is not yet available about the impact of these cooperative programs.

B. Sanctions Based on Quality: Exclusions and CMPs

While PROs are an organized program of quality review which touches on overuse, underuse and misuse, they are embedded in a system of penalties and sanctions which has expanded both in scope and depth with each of the multiple iterations of the government's fraud and abuse authorities in health care. Little recognized is the extent to which these penalties are

focused on quality relevant issues. Punishing failure to provide 'medically necessary' services is the core aim of some of these authorities and further punishing providers of services of substandard 'quality' – undefined and open-ended – is the second.

The Secretary of HHS has the authority to exclude from all federal health care programs those individuals and entities which have engaged in certain activities, even without a prior conviction. These permissive exclusion authorities include any individual or entity which "has furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under Medicare or Medicaid) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care."[36] There are no standards propounded for these clinical judgments, either in the statute or implementing regulations.[37] Consequently these determinations are made by PROs or carriers in accordance with their general approach to review determinations. Individuals (including physicians) who may control organizations which have been excluded may also be excluded as individuals from the federal programs.[38]

Civil money penalties ("CMPs") may also be imposed in quality relevant instances. Any person who knowingly submits claims "for a pattern of medical or other items or services that a person knows or should know are not medically necessary"[39] is subject to a civil money penalty of not more than $10,000, in addition to any other penalties allowed under law. CMPs may also be imposed where any individual knowingly gives or causes to be given to any person information regarding coverage under Title XVIII for hospital inpatient admissions, that he knows or should know is false or misleading and that could reasonably be expected to influence the decision as to when to discharge the patient from the hospital.[40] Although the latter penalty, like much in PRO review, is aimed at safeguarding against the hospital incentive to discharge a patient early under the PPS system, it is also relevant to physicians who may be responding to financial incentives in managed care. Nonetheless, for neither of these situations in which stiff penalties may be imposed, are any standards set forth by which these judgments will be made.

Related provisions address two separate sources of authority governing financial inducements to physicians in Medicare and state health programs. Variously referred to as "gainsharing"[41] when the paying entity is a hospital and as a "physician incentive plan" when the payment is coming from a managed care organization. (1) Civil money penalties may be

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[36] 42 USC §1320a-7(b)(6)(B)

[37] See 42 CFR §1003.105

[38] 42 USC§1320a-7(b)(8)

[39] 42 USC§1320a-7a(a)(1)(E)

[40] 42 USC§1320a-7a(a)(3)

[41] See King and Louthian, "Gainsharing – Life Before and After the Bulletin," *Health Law Handbook* 2000 Edition, WestGroup, pp. 195-214

imposed where a hospital knowingly makes a payment, directly or indirectly, to a physician to induce him to reduce or limit services provided to individuals. The hospital itself is subject to a $2000 CMP for each such instance and the physician receiving the payment is also subject to a separate CMP of $2000.[42] (2) Where a Medicare or Medicaid paid managed care entity puts a physician group at substantial financial risk, certain safeguards must be in place to protect Medicare beneficiaries from risks of underservice.[43] The implications of this approach were so contentious that in the Health Insurance Portability and Accountability Act of 1996 Congress made the definition of "substantial financial risk" subject to a negotiated rulemaking. Those interim final regulations were published November 19, 1999[44] and harkened back to the earlier physician incentive plan regulations which offer now only one of four methodologies by which the extent of financial risk might be assessed. Without addressing the complexities of the risk calculations at issue under the regulations, nor the other aspects of their requirements, they target the financial incentives to underutilize in managed care arrangements.

Congress stimulated HCFA's attention to physician incentive plans under the anti-kickback statute in 1986[45] and then repealed and reinstituted authorities culminating in provisions in OBRA '90,[46] which were later joined by the specific additional prohibitions under Stark II in 1993,[47] which manifested increasingly wider concern for managed care driven underuse.

Congress began by targeting only Medicare and Medicaid risk arrangements, but the Stark statute went beyond that focus to all incentive plans. Still further, while the initial import of the Congressional provisions had been on the plans themselves, inclusion of physician incentive plans in Stark II made it clear that physician referrals that occurred under improper arrangements were punishable by separate civil money penalties of $15,000 for each improper referral.

C. Anti-referral: Stark and Kickbacks

The quality implications of anti-referral laws stem from the indirect efforts to control against overutilization. The two sources of authority, the Stark statute[48] and the anti-kickback statute[49] are intended to penalize any incentive to overutilize in a fee for service frame of

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[42] 42 USC§ 1320a-7a(b)

[43] See 60 Federal Register 13430 March 27, 1995, codifying provisions in 42 CFR§ 417.479 and 1003.100 *et seq*

[44] See 62 Federal Register 63503

[45] Section 9313(c) of the Omnibus Reconciliation Act of 1986, Public Law 99-509

[46] Section 4204(a)(2) of the Omnibus Reconciliation Act of 1990, P.L. 101-508

[47] Section 13562 of the Omnibus Reconciliation Act of 1993, P.L. 103-66

[48] 42 USC§ 1395nn *et seq*

[49] 42 USC§ 1320a-7b(b)

reference or to stimulate additional business which comes from certain financial relationships. One can argue whether the internecine analyses which must be engaged in to determine a Stark violation speak to the fundamental concerns that motivated the statutory provision: (1) whether we pay too much for services where physicians enter into joint ventures with entities that otherwise could provide the service themselves; (2) whether physicians by virtue of the incentive to refer to something with which they have a financial relationship are referring in instances where the provider does not meet quality standards; and (3) whether the services ordered for a specific patient at a specific point and time are medically necessary or appropriate. It hardly matters in light of the government's bi-polar insistence that it needs the statute which was drafted in a vastly different time on one hand, but the agency managed not to issue regulations for it for six years, on the other.

Stark's statutory focus is exclusively on physicians and exclusively oriented around Medicare and Medicaid patients. Stark isolates enumerated 'designated health services' for its prohibitions; and then excepts through extremely controlled qualifications certain specific financial relationships.[50] Ignoring the difficulties of utilizing a statute which became effective in 1995 but for which final regulations were still not issued as of December, 2000, the impact of the statute is primarily on utilization alone (overuse) and has essentially nothing to do with the quality of the service provider or the medical appropriateness of the service rendered.

The anti-kickback statute, in contrast, is not limited to physicians but implicates all players in the federal health care programs. The Stark statute is a strict liability statute which imposes CMPs on the physician who makes an improper referral and also on the entity which submits a claim pursuant to the improper referral irrespective of intent. On the other hand, the anti-kickback statute is an intent based statute. While Stark may have potential implication for false claims, the anti-kickback statute was, until the Balanced Budget Act of 1997, purely a criminal statute although entities can be excluded from Medicare and Medicaid for violating this statute without the necessity of a conviction.[51] Now, kickbacks, too, are punishable by a $50,000 CMP, which does not require a prior conviction.

The anti-kickback statute is intended to prohibit financial benefit from referrals, inducing referrals, or ordering, providing, leasing, furnishing, recommending or arranging for the provision of a service, item or good payable by a federal health care program. For physicians, the provision implicates joint ventures, relationships with hospitals and other entities to which they refer and with which they have business relationships. To the extent that the statutory provision is relevant to physician quality, again, that significance lies almost exclusively in the intent to mitigate the incentive to overutilize when a physician stands to benefit economically from the provision of a specific service by a vendor or entity with which he has a financial relationship.

These two types of laws are essentially misguided in terms of not only patient and public

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[50] For a discussion of Stark generally see, Teplitzky et al "1993-1994 Developments in Health Care Fraud and Abuse" in Gosfield ed. *Health Law Handbook*, 1995 edition, WestGroup, 1995, pp. 295-304

[51] 42 USC§ 1320a-7(b)(7)

fisc protection but also quality. The real question is whether a referred to provider is appropriately qualified to render the requested service and whether that patient clinically needs that service. Neither law really addresses either of those concerns. Both are aimed primarily at who will make money from the delivery of care. If the service is clinically appropriate, someone will benefit economically from its provision. If it is not appropriate, no one should benefit from it. Clinical practice guidelines as the basis for making these judgments would jointly advance the quality and economic agendas here.[52]

D. Carrier Review

The carriers which administer Part B payments to physicians are charged with the responsibility to conduct medical necessity reviews for payment purposes. These reviews are performed post-payment and more recently on a pre-payment basis. The results can be physician repayment of monies previously paid or carrier denial of payment in the first place. In especially problematic cases, referral may be made to the OIG or Department of Justice for false claims enforcement. In addition, pursuant to a specific provision in the Health Insurance Portability and Accountability Act ("HIPAA"), Program Integrity Contractors – "super-carriers" so to speak -- have been selected to perform reviews pertaining to medical necessity and patterns of care of substandard quality.

For many years carriers have had responsibility for post-payment review and utilization review generally. Until recently, to understand the boundaries and processes of these reviews one merely consulted the Carriers Manual at Section 7500.[53] Today, to do so refers you directly to the new Program Integrity Manual (PIM-83) which is published only online. All of the longstanding discussion pertaining to what triggers review, the differences between focused and comprehensive review and any clarity regarding these processes, has completely disappeared. Instead, pursuant to HIPAA provisions providing for such authority, HCFA has contracted with thirteen super carriers (Program Integrity Contractors also known as Program Safeguard Contractors) to perform utilization review and fraud review.[54] Today, it is almost impossible to cite with any certainty the bases upon which physicians are selected for review other than data aberrancies and beneficiary complaints, but the chilling effects of pre and post-payment review are considerable, as are the administrative burdens they impose on physicians, so much so that, the carriers are now advised to engage in progressive corrective action rather than overwhelm physicians immediately with the full brunt of their power.[55]

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[52] See Gosfield at n. 69 *infra*

[53] For a discussion of the purpose and approaches to utilization management in Medicare Part B physician fee for service payments, see Gosfield, "Is Less Really More? Utilization Management in the 1990's," in Gosfield, ed., *Health Law Handbook,* 1996 Ed, WestGroup, pp. 95-105

[54] "Fact Sheet: Fighting Fraud, Waste and Abuse in Medicare and Medicaid," HCFA, April 2000

[55] HCFA Program Memorandum, Intermediaries/Carriers Transmittal AB-00-72, August 7, 2000, "Medical Review Progressive Corrective Action"

Most of these activities are directed at cost containment. But utilization review is not based upon strict actuarial or statistical patterns or even just on normative patterns of behavior. The essence of much of the review involved in pre-payment and post-payment review is whether the claims meet the threshold statutory criterion of being reasonable and medically necessary.[56] As with many of the other authorities noted in this article, no guidelines, parameters, or standards are enunciated, yet there is a clear quality implication to this type of review. A judgment that services were not medically necessary at a minimum implicates overuse and may implicate misuse. Whether the deviations reviewed for payment are seen to be of sufficient concern as to trigger exclusion and false claims charges is yet to be seen. The requirement that physicians affix ICD-9 (diagnostic codes) to claims[57] is useful as a blunt claims screening mechanism -- rejecting a pregnancy test for a man, for example. But the clear implication over time has been that with more technical internal edits couched in terms of "correct coding,"[58] quality impacts will result.

In fact, it would be possible, through code linking (ICD-9 with CPT procedure codes) in connection with benchmarked clinical behavior based on evidence-based clinical practice guidelines to generate some meaningful, quality-relevant impact. This was actually part of the reason for the creation of the Agency for Health Care Policy and Research's national guidelines efforts.[59] But this clinical foundation for payment judgments has never been formally related to the fee for service payment system. There has not been any (at least as revealed to this author's research efforts) explication of these relationships, or even any clear connection between HCFA's correct coding initiative and the HIPAA provision addressing civil money penalties for claims for patterns of care not medically necessary. These multiple efforts have obvious quality implications but are not dealt with as such by the regulators, although physicians often perceive their ministerial requirements as directly counter to clinical quality, while merely adding to ever accreting administrative demands.

E. EMTALA

Another federal statute intended to confront quality and access issues was the Emergency Medical Treatment and Active Labor Act ("EMTALA")[60] which imposes on hospitals and physicians specific clinical responsibilities when patients present to their emergency departments

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[56] 42 USC§ 1395y(a)(1)

[57] 42 USC§ 1395u(p)

[58] See Carrier's Manual §4630 and 15068 for discussion of HCFA's correct coding initiative which rejects for payment code pairs that represent duplicative, unbundled or unlikely CPT code combinations.

[59] See Gosfield, "Clinical Practice Guidelines and the Law: Applications and Implications," in Gosfield ed. *Health Law Handbook*, 1994 Edition, WestGroup pp. 65-99 and Gosfield, "Measuring Performance and Quality: The State of the Art and Legal Concerns," in Gosfield ed. *Health Law Handbook*, 1995 edition, WestGroup, pp.55-59

[60] 42 USC§ 1395dd *et seq*

("ER") seeking care. A patient presenting to an emergency department must be evaluated by an appropriately qualified individual, through an "appropriate medical screening" examination. The patient may not be transferred to another facility if the patient is not stable or is in active labor. While mandating that screening and triage be performed by qualified individuals, the initial import of the statute was to prevent patient dumping – transferring or refusing care to patients with bad or no insurance with the intent to "dump" them to another institution. The statute operates through both regulatory requirements and big civil money penalties of $50,000 for each failure by either a physician or a hospital to meet their obligations.

The breadth of the statute as it applies to physicians is not well appreciated by the physician consultants who may be summoned to treat an ER patient as part of their on call responsibilities as members of the hospital medical staff. Emergency department physicians have come to understand the intricacies of EMTALA very well. Given, however, the increasingly broader sweep of the courts' interpretation of the statute, it represents a significant piece of the fraud and abuse weaponry brought to bear on quality issues.[61]

When an unstable patient is going to be transferred, after all the appropriate evaluations have been made, a physician must certify the medical necessity of the transfer.[62] HCFA's interpretive guidelines establish a range of conditions which pertain to these judgments including that the clinical outcome of an individual's condition is not a proper basis for determining whether an appropriate screening was provided or whether an individual transferred was stabilized. Settlements involving physicians have increased over time. "In 1999, HHS/OIG entered 61 settlement agreements with hospitals and physicians and collected civil monetary penalties of $1.7 million. This is an increase from the previous high of 53 settlements in 1998, and reflects the commitment of both HCFA and HHS/OIG to ensure patient access to appropriate emergency medical services."[63] PROs make the judgments as to whether the clinical conditions have been met, but the penalties are imposed by the Office of the Inspector General.

F. Health Care Quality Improvement Act

The Health Care Quality Improvement Act[64] is a direct control on quality by protecting the activities of physicians in peer review contexts from antitrust and other liabilities when these

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[61] For a recent consideration of the developing context of EMTALA, see, Williams, "Recent Case Law Decisions and Interpretive Guidelines Expand the Scope of EMTALA Obligations", Gosfield, ed., *Health Law Handbook,* 2000 Edition, WestGroup, pp. 279-315

[62] 42 USC§ 1395dd(e)(4)

[63] Department of Health and Human Services and Department of Justice Health Care Fraud and Abuse Control Program, Annual Report for Fiscal Year 1999, January 2000, http://www.oig.hhs.gov/press/hipaa2.htm

[64] 42 USC§ 11101 *et seq*

activities are oriented around quality judgments. Offering immunity for those who implement these peer review programs effectively, confidentiality for an informant to these procedures, and due process protections for the individual who is subject to the procedures, the statute is aimed at fostering both a more complete evaluation of quality and a resulting discipline system for physicians who have not met appropriate quality standards. The statutory provisions dealing with what activity qualifies for the various protections targets explicitly those areas where judgements are made regarding a physician's quality performance, whether on an initial application to join a hospital medical staff, HMO or another entity with a formal peer review program which also provides care, or during his tenure with such an entity.

The statute is intended to influence those physicians who are engaged in peer review to be more aggressive than they would be if they feared for their own liability as individuals or as medical staff organization members, when they evaluate their peers' quality. Through the impact of the National Practitioner Data Bank ("NPDB") in providing information to other players in the system regarding the quality of physicians reviewed, the statute was also intended to have a chilling effect on physicians who might otherwise engage in improper behavior that would be punished and the punishment reported to the NPDB and thereafter follow them throughout their careers. It is also a warning system to other players who might affiliate with those on whom reports are made.

The NPDB arguably has within it, data regarding extremely egregious fact patterns in which physicians may have lost their licenses or been suspended from practice as well as other lesser quality related issues that have been judged by peers in hospitals, HMOs, and medical groups throughout the country. There is extraordinary dispute over the quality of the data in the NPDB even making it so far into the lay press as to appear on the first page of USA Today in December, 2000,[65] based on a General Accounting Office report.[66]

The practical implications of this initiative for actually improved quality, given the history of the NPDB, are quite questionable. Yet the creation of a data clearinghouse to gather together purportedly quality relevant information was the last major Congressional undertaking intended to change the way physicians confront quality failures of their peers. This clearinghouse has now been joined by the National Health Care Integrity Data Bank[67] which reports on physicians who have been sanctioned by the federal programs and health plans. Together they constitute the primary national repositories of data about which information can be obtained regarding physician quality. Both remain non-public and their significance is under attack.

G. Antitrust and Clinical Integration

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[65] Davis, "Data on Disciplined Docs Flawed Report Critical of Record Keeping" USA Today, December 1, 2000, pg. 01.A.

[66] "Major Improvements are Needed to Enhance Data Bank's Reliability" GAO-01-130, November 2000.

[67] 45 CFR § 61.1 *et seq*

Although indirectly a control on quality, under the antitrust laws, the Department of Justice and the Federal Trade Commission have issued "safety zones" which describe those activities for which they would be unlikely to prosecute absent some information under a "rule of reason" analysis which would indicate protection ought not be afforded.[68]

Through 1993 and 1994 the essential safety zones applicable to physicians struggling to engage in concerted action against insurers rested on financial integration of a group of otherwise competing physicians. Integration meant a fully merged single practice or significant, joint financial risk taking. The requirement focused on the physicians' financial interrelationships and proved a barrier to the formation of groups of otherwise competing physicians into entities that could engage in joint bargaining, particularly with managed care entities. Most physicians are so fiercely individualistic that combinations of them which are financially integrated but otherwise independent are difficult to create.

In establishing its various safety zones, the regulators do not enumerate those activities that need be present to assure safety. Rather, through the postulation of hypothetical circumstances, the indicia of clinical integration are elucidated. In their description of a "physician network joint venture involving clinical integration" the regulators allow for joint activity among otherwise competing physicians who would not be financially integrated and would be paid on a fee for service basis.

Operating through an IPA, the hypothetical physician group would implement systems to establish goals relating to quality and appropriate utilization of services by the IPA physicians. Regular evaluation of individual participants and the network's aggregate performance, combined with modification of actual practices where necessary based on these evaluations are the factors deemed important to demonstrate integration. Case management, preauthorization of some services and concurrent and retrospective review of inpatient stays are a part of the fact pattern. Most critically for the discussion of quality, the hypothetical IPA would develop "practice standards and protocols to govern treatment and utilization of services... and ... will actively review the care rendered by each doctor in light of these standards and protocols."[69]

Although the fact pattern makes reference to "a significant investment of capital to purchase the information systems necessary to gather aggregate and individual data on the cost, quantity and nature of services provided or ordered by the IPA physicians,"[70] the fundamental activities involved do not necessarily entail capital expenditures. The hypothetical IPA would hire a medical director to perform the relevant functions and some of the investment creating the

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[68] "Statements of Antitrust Enforcement Policy in Health Care" Issued by the Justice Department and Federal Trade Commission, August 28, 1996, 5 BNA HLR 1295, (8/29/96)

[69] Id., For a discussion of other legal benefits from using clinical practice guidelines see Gosfield, "Integrating Clinical Guidelines into Administrative Processes Can Lower Risk" 1 Journal of Health Care Compliance, Oct. 1999, pp. 9-15

[70] Id.

integration comes from the sweat equity of the physicians who would have invested appreciable time in developing the practice standards and protocols and would continue to monitor care.

The postulated IPA represents 25% of the primary care group practices in the area and a number of specialists to whom the primary physicians refer. They constitute from 20-35% of the specialists in each relevant market depending on the specialty. Physician participation in this model IPA would be nonexclusive.

In evaluating the competitive implications of this arrangement, the regulators focused on the following:

> "Prior to contracting on behalf of competing doctors, the IPA will develop and invest in mechanisms to provide cost-effective quality care, including standards and protocols to govern treatment and utilization of services, information systems to measure and monitor individual physician and aggregate network performance, and procedures to monitor physician behavior and assure adherence to network standards and protocols. The network is structured to achieve its efficiencies through a high degree of interdependence and cooperation among its physician participants. The price agreement, under these circumstances is subordinate to and reasonable necessary to achieve these objective."[71]

Taken together, this model and the implications for quality are astounding. In fact, by utilizing this safety zone, the law explicitly motivates physicians to engage in quality improvement behavior, while controlling costs, and simultaneously creating data that can give them the ability to negotiate more effectively over fees. To do all of this in a frame of reference that would otherwise be per se collusive (since the physicians are otherwise competing physicians of similar specialties) is a profound yet apparently elusively subtle direct legal influence on quality. This safety zone has barely been noted or described in the physician-oriented literature. The potential power of this safety zone is alluring, to say the least. It certainly calls into question the need for any kind of physician unionization, since through this vehicle, physicians could do the right thing, improve quality and advance their financial agendas as well. The lack of publicity and support for this potentially important boon to physician quality is indeed puzzling.

The federal legal armamentarium for controlling, influencing or affecting physician quality performance ranges from slingshots to heat seeking missiles pointed at egregious departures from desired behavior. Most efforts stem from Medicare payment. Some laws look more like Rube Goldberg contraptions in their capacity to generate positive outcomes. Still others, seem more obviously relevant but have not been used in a way that would confirm that analysis. The state level landscape is similar but with even greater disparity.

III. STATE REGULATION

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[71] Id.

Under the police powers, the states have the authority to control health care within their borders. Consequently, physician licensure is the classic state regulatory threshold to practice. Of course, the qualifications for licensure are so minimal that the nexus with quality in the terms considered here is weak at best. However, some new and developing areas in licensure are, in fact, more quality relevant than they have been. For example, anti-abandonment provisions which control how physicians terminate their doctor-patient relationship, requiring that accommodation for transfer of care be assured, is one example.[72] Specific regulations to facilitate transfer of medical records,[73] is another. Both address continuity of care.

States that include the corporate practice of medicine in their authorized forms of physician practice do so on the principle that the essence of employment is control by the employer over the employee. To have non-licensed individuals employing physicians would compromise their clinical judgement, a fairly blunt guarantee of quality. Similarly, some states have looked at the issue of ownership of various kinds of health care businesses and required supervision and control by physicians. For example, in New Jersey, a diagnostic center which is not otherwise regulated by the state must be owned, controlled, and supervised by a physician licensed in the state of New Jersey.[74]

State Peer Review Protection Acts[75] which were the precursors to the Health Care Quality Improvement Act are also intended to foster broader physician dialogue on quality issues in the evaluation of physicians for hospital clinical privileges. Traditional immunity and confidentiality protections to the participants and informants to these programs are their hallmarks. The fact that most were enacted during the malpractice crises of the mid-1970s creates the loop between peer review protection and risk management. These state laws, reflecting the raging battles at the federal level, have also now been criticized from both ends of the policy spectrum as undermining quality rather than supporting it. Provider advocates argue that these laws do not protect enough and therefore diminish truly aggressive efforts to improve quality.[76] Trial lawyers argue that their presence impedes malpractice litigation which regulates quality in the market.[77] Of course, preventing litigation over the process of peer review was part of the point of these laws; so limiting access to information about the findings of these processes supports the goals of the protection itself.

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[72] See 49 Pa. Code 16.61(17)

[73] See 49 Pa. Code 16.61(18)

[74] NJAC 13:35-2-5

[75] For a list of all peer review protection acts see, http://www.hortyspringor.com/PeerReview.html

[76] Scheutzow, "State Medical Peer Review: High Cost But No Benefit – Is It Time for a Change?" 25 AJLM 7 (1999).

[77] Beustring, "An Epidemic with Justice for Few":, Advocate, Ok. Trial Lawyers Association, http://www.otla.org/Advocate/Advocate 1988/2ndQ/MedNeg.htm

Many states have adopted anti-referral laws that are intended to prevent overutilization of services much like the federal Stark and anti-kickback statutes. Some flat out prohibit physician ownership of entities to which they refer for specific services.[78] Others require only prior disclosure of the physician's relationship,[79] while others grandfather otherwise violative relationships merely because they were in place during a prior period of time.[80] These laws vary in terms of the types of services where financial relationships are proscribed. Some vary by payor imposing, for example, anti-referral prohibitions under Workers Compensation, but not otherwise.[81]

State managed care reform has fostered its own series of quality oriented controls. Many of these do not focus directly on physicians, but rather prohibit or mandate certain actions by managed care entities. More than twenty-one states have adopted provisions in the nature of free speech guarantees for physicians. These laws are predicated on the notion that quality is impinged when patients are not offered all options for treatment whether or not their insurance will cover them for the recommended services. Often referred to as "anti-gag clause" provisions, these laws variably prohibit MCOs from restricting the information physicians provide to patients about treatment options and payment arrangements, and often further prohibit plans from retaliating against physicians who appeal utilization management decisions or otherwise advocate for their patients.[82]

Permitting patients to have direct access to certain kinds of specialists has been another type of state law purportedly driving towards better quality in that those who are more highly trained and focused in a clinical discipline are seen as more likely to provide more appropriate service. By prohibiting mandated managed care gatekeeping in certain instances, these laws are intended to decrease the risk that a non-specialist will not authorize necessary services. Direct access to obstetrician/gynecologists is the most typical. In Florida and Georgia direct access is provided to dermatologists.[83]

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[78] Florida Statutes 455.701, for example

[79] 35 PS 449.22

[80] NJ Stat § 45:9-22.5

[81] §306(f.1)(3)(iii)of Act 44 Amending 77 P.S. §1 *et seq*

[82] See for example, Alaska: AS 21.07.010(a)(5); Arizona: ARS 20-118B; Minnesota: MSA 62J.71; Maine: 24-A MRSA 4303 (3); Florida: FL St 636.035 (10); Delaware: 18 Del C 3303; Connecticut: CGSA 38a-478k; DC Code: 35-4506(h); New Jersey: NJSA26:29:2S-9; Nebraska: Neb. Rev. St 44-7106(i) and (o); Iowa: ICA 514C.15; Kansas: KSA 40-4604; Kentucky: KRS 304.17A-530; California: Cal,. Bus and Prof Code 2056.1(b); Michigan: MCLA 333.21052a; Maryland: AnnCode MD 15-116(b); Louisiana: LSA-RS22:215.18; Indiana: IC 27-8-11-4.5(a); Hawaii: HRS 432E-4(d)

[83] For surveys of state law actions on direct access to specialists see, http://www.aaos.org/wordhtml/bulletin/oct97/ban.htm and http://www.findarticles.com/m0903/n2_v16/20420603/p1/article.jhtml

Physician profiling and public reports on physicians is another attempt to create a quality oriented market. In Massachusetts and Florida, state government publishes physician specific report cards.[84] In Pennsylvania, the Health Care Cost Containment Counsel publishes data specifically about surgical procedures as performed by certain physicians. This data offers cost and quality information.[85] Physician report cards or other performance data does not control physician behavior itself. Rather such regulatory schemes can improve physician behavior because of the risk to physicians of bad scores and therefore a bad reputation or loss of business.

Whether state government report cards can improve quality is not yet known.[86] Time lags in production of the data and concern about its validity are also issues. While there is some positive judgment on the effect of public data in changing hospital performance in California, Missouri, Pennsylvania and New York,[87] the relative dearth of physician focused data does not permit similarly sanguine conclusions there. Still, some commercial physician report card efforts have shown a strong correlation between the number of 'best practices' designations for network medical groups and increased enrollment for patients in those groups,[88] offering at least an initial business case for quality for physicians in those networks.

Not surprisingly state laws present a crazy quilt of physician quality control efforts both within their borders and by comparison with each other. Looking at private contract provisions drills even deeper on the issues of legal influences on physician quality.

IV. MCO CONTRACT PROVISIONS[89]

While regulatory controls are intended to motivate physician behavior primarily through negative sanctions ("if you don't behave, we will punish you") managed care contracts represent a different major legal influence on physicians. Here, because the managed care organizations ("MCOs") are themselves subject both to regulation and market forces that drive toward their ability to demonstrate quality performance, they in turn impose on physicians through their participation agreements, multiple legal obligations that are intended to directly influence the quality of care and overall physician performance. The threat of loss of income from contract termination is the primary motivator of this system.

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[84] See http://www.docboard.org/ma/ma_home.htm and http://www.doh.state.fl.us/MQA/profiling/home.htm.

[85] See Gosfield, supra n. 3 at 518-522.

[86] See, Gosfield, supra n. 3 generally for a discussion of the impact of report cards whether commercial or government based.

[87] Id. at 520-21.

[88] Id. at 524

[89] For a broad consideration of the law and quality in managed care, see Gosfield *Guide to the Key Legal Issues in Managed Care Quality*, Faulkner and Gray, New York, 1996

MCOs are responsible in a number of ways for the quality of care they provide. Whether in Medicare+Choice programs where regulators control for managed care quality directly[90] or through market demands by employers who require demonstrated quality performance, or under certain state regulatory schemes which may require external quality review or plan accreditation, managed care entities have no ability to guarantee their position in the market in the absence of physician performance to meet their needs. MCOs, therefore, work to screen out bad physicians, require baseline behaviors from their participants to assure quality on an on-going basis, and make physicians stand good for their quality failures. By contract, physicians who breach these obligations can be terminated as participating providers, thereby cutting them off from significant income. A survey of some of these contractual provisions paints a more detailed picture of the physician's legal context for quality.

A. Input Controls

A primary control on quality in the contract is the way in which the MCO manages the credentialing process. In addition to the information requested in the application to be a participating provider, physicians are often asked to represent and warrant various threshold issues intended to weed out potential miscreants. Typical representations include those regarding current licensure, board certification, narcotics prescription authority, and clinical privileges at a participating hospital. The latter has been the topic of some confusion in the industry since some MCOs take the position that NCQA, the National Committee for Quality Assurance, requires clinical privileges at a hospital in its accreditation standards for managed care entities. This is inaccurate. In fact, for many years NCQA required that the MCO assure that if the physician has hospital clinical privileges that he or she maintain them in good standing. Today, NCQA merely requires review of the physician's history of loss of privileges.[91]

For other MCOs, reliance upon the fact of hospital clinical privileges has been a safeguard to the MCOs since hospitals were seen traditionally as having vetted the physicians through their own credentialing procedures thereby easing the burden on the MCO. The fallacy of this measure of quality however, is that much in managed care is performed on an outpatient basis or in physician offices where hospitals typically have little mechanism to review physician behavior. Still further, many physicians never set foot in the hospital, particularly in the new era of "hospitalists," so if hospitals purport to have reviewed these physicians, that review has often been extremely limited.

Other measures to bar entry to poor quality risks include representations regarding maintenance of malpractice insurance and history of malpractice experience-- arguably redundant since HMOs are specifically included in the ambit of the Health Care Quality Improvement Act and therefore often access and report to the National Practitioner Data Bank. For PPOs and

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[90] See discussions of HCFA's Quality Improvement System for Managed Care (QISMC) in Gosfield supra n. 3 at 525-531 and Krasner, "Medicare+Choice: Swamped by Regulation?" in Gosfield ed. *Health Law Handbook*, 2000 edition, WestGroup, pp. 479-497)

[91] NCQA, CR 4.4, Standards for Accreditation of Managed Care Organizations, Washington D.C., 2000

IPAs, however, Data Bank access is not such a clear issue. Since the statute permits access to organizations which provide care and engage in formal peer review of applicants and provider members, some PPOs choose not to access the Data Bank, since they want to be able to argue that they do not "provide" care.

A similar problem exists where MCOs request representations regarding the fact that the physician is not a "sanctioned person" or subject to an investigation which could make him a sanctioned person. This requirement is also potentially redundant now that the National Practitioner Integrity Data Bank exists.[92] These threshold inquiries relate to quality in the due diligence of barring those physicians who have been found by another party to have had quality problems. Similarly, some MCOs require physicians to represent and warrant the licensure and qualifications of the ancillary personnel to whom they delegate functions under the contract.

A different quality control exists where MCOs retain in their provider agreements the right to summarily terminate a physician's participation agreement if it is found that the physician misrepresented or omitted information from the application. This mechanism reflects the common assumption that a physician who will dissemble on an application manifests sufficient concerns over his integrity as to call into question his clinical judgment too.

B. Continuity of Care

Principal obligations of physicians to provide continuity of care rest in the requirement to provide coverage twenty four hours a day, seven days a week. MCOs differ in their control of how a physician may arrange coverage when he is not available. Some allow only other participating physicians who have themselves been credentialed by the MCO. Others allow substitute physicians who have been reviewed, but less vigorously, by the MCO. Still others allow any physician to provide coverage, but if the covering physician is not participating, they hold the covered physician responsible for the actions of the covering physician, thereby imposing a requirement on the covered physician to stand good for his delegee's performance in accordance with the MCO's mandates.

Access and availability of care is assured through the contractual obligations associated with maintaining specified office hours and office locations. Some MCOs require prior notification if the physician moves his offices or even if he retires. Others specify the time frames within which routine, urgent and emergent office visits will be scheduled. Still others limit the number of patients who can be assigned to a physician's panel to assure that timeliness of appointments and care can be maintained.

Requirements regarding medical records maintenance both as to form and content is another factor relevant to quality and continuity of care. These clauses also facilitate other activities in which the MCO may be engaged. In addition to the basic need for the medical record to permit others treating the patient to understand what is happening in the course of treatment, MCOs impose record keeping requirements so that the MCO can get data it needs for

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[92] See text at n. 67 *supra.*

its purposes – whether to report to others, to demonstrate that preventive services have been provided, or to facilitate communication among practitioners treating a patient. Some impose obligations on physicians regarding timeliness of reporting results of tests and consultations to referring physicians.

Gatekeeping and prior authorizations relate to overuse in MCOs by requiring evaluation of care before it is provided. While this arguably is principally a cost control technique, one of the quality arguments around gatekeeping which has not been very persuasively argued by the managed care industry is the basic continuity of care that is created when one clinician is assigned responsibility for coordinating all other care and maintaining a unified record of what is happening to the patient.

On the back end of the relationship, most MCOs impose on physicians a post-termination obligation to continue to treat patients to assure limited disruption in the availability of physicians to MCO patients. The simplest of these requirements merely mirrors statutes and case law which prohibit physician abandonment of their patients by requiring physicians to continue to treat those members who were patients in the hospital when the agreement terminated. Others go so far as to require physicians to continue to treat patients who were under their care (or even assigned to their panels) for so long as the MCO maintains its contractual relationship which creates the beneficiary status of the patient. Intermediate positions require the terminating physician to continue to treat patients until transfer can be effected, with an outside time limit beyond which the treatment obligation does not extend.

These clauses usually are used where the physician seeks to terminate rather than where the MCO terminates the physician for cause. Still, they are even used where the MCO has had problems with the physician but will have worse problems transferring his panel of patients to someone else. While these post termination obligations relate to continuity of care for the patients, one can question how supportive of quality they are. Why would an MCO want to continue to require a disgruntled physician to treat patients, particularly in bad payment situations, as where a capitated physician has his healthy patients transferred quickly but his sicker patients remain behind, now paid for at distinctly disadvantageous rates?

C. Direct Quality Controls

Stemming from the early days of MCOs when some physicians would segregate their patient populations, or by responding to MCO financial incentives would not provide all the care they usually ordered or provided for their fee for service patients, most MCOs even today maintain anti-discrimination clauses which forbid physicians from differentiating in their treatment of patients based on source of payment. Whether this provision is necessary or even desirable today is questionable.

The very essence of managed care was to change physician behavior through the use of different financial incentives and contractual obligations. If the need for managed care emanated, in part, from the fee for service response to the perverse incentive to overutilize, the point of

managed care relationships was for physicians to treat people differently. This essential feature has been recognized by the courts most recently in Pegram v. Herdrich[93] which explicitly noted that part of the point of managed care would result in some rationing of care. These anti-discrimination clauses began as a way of assuring quality to MCO patients, but may no longer be appropriate. Of far greater import in discussions of MCOs and quality are their direct influences over clinical behavior through their quality assurance and utilization management programs and their financial incentives.

Many HMOs and now PPOs are required to, or voluntarily choose to, be accredited by the National Committee for Quality Assurance. NCQA imposes requirements on plans which they, in turn, devolve onto physicians as appropriate with respect to quality improvement including problem identification and resolution, credentialing, utilization management, members' rights, and other issues. Today, part of the accreditation decision rests not only on NCQA's review of internal quality processes, but also on the plan's scores on certain HEDIS measures -- clinical performance outcomes data. As a result, these MCOs are keenly interested in performing well and scoring well, but they must rely on physicians to do so. Therefore, they impose a variety of obligations on physicians to accomplish their purpose.

Physicians must cooperate with the MCO's utilization and quality review programs. They must allow access to their records pertaining to members of the plan. They are often profiled and evaluated to determine whether they are effectively conforming with these dictates, including those with regard to customer satisfaction. Physicians are obligated to respond to patient grievances which can implicate customer satisfaction measures, a new way of looking at quality from a patient-centric perspective. Typically, physicians are obligated to cooperate with those external review organizations which accredit the plan, even allowing their representatives to come into the physician offices to look at medical records and evaluate the physical environment in which the care is being provided.

Some MCOs in their contracts reserve the right to terminate physician participation if they fall below thresholds for performance which are incorporated into the credentialing standards of the MCO. These provisions further implicate and motivate physician performance since termination of an MCO contract for quality reasons is often reportable to the NPDB. Physicians with quality problems would often rather be terminated without cause, since that is not reportable to the NPDB. Although resignation to avoid corrective action which would be reported is itself reportable, the HMO's termination without cause is not. On the other hand, given the procedural requirements imposed on HMOs to avail themselves of the HCQIA's protections, they often would rather take the "without cause" route. Of course, these below the radar approaches undermine the reliability of the information in the NPDB, since quality problems may not be reported because the parties choose these paths of lesser resistance.

Some MCOs lower reimbursement or payment for quality failures while still others are beginning to increase payment for higher quality performance. It is well beyond the scope of this consideration to discuss the many complexities and variations in financial incentive models

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[93] No 98-1949 US Sup Ct (6/12/00)

which are intended to drive physician behavior. Here, however, the clashes between control of costs and potential for underuse are increasingly fierce and contentious. These tensions are exacerbated further by the typical contract provision which states that regardless of the MCO's coverage, he must use his own independent medical judgment and treat the patient regardless of the payment implications of his doing so. Ignoring for the moment the disconnect between the obligation to adhere to the utilization management dictates of the MCO and this requirement, it is usually coupled with a disclaimer regarding the MCO practicing medicine as a way to bolster the MCO's avoidance of liability for poor quality outcomes in individual cases which might be litigated in a malpractice case.

A related contract clause often requires the physician to indemnify the MCO for any costs or losses it may incur as a result of the physician's negligence in treating patients. This type of provision is likely covered under the physician's malpractice coverage. But many of these clauses are far broader and require the physician to indemnify the MCO for any losses it incurs "on account of" or "arising out of" the relationship with the MCO. Most physician liability coverage excludes such contractual liability. From a quality perspective, these clauses are intended to hold the physician's feet to the fire in terms of his performance. They are the polar opposite of the enterprise liability theories that were circulating in discussions of Clinton Health Reform, which proposals would have prohibited direct liability to be imposed on the physician and would have moved the liability to the managed care plan which contracted with him. Whether these clauses have any real quality effect, they have been outlawed in some states.[94] Still further, they may not even be necessary given common law rights of contribution which have been construed to pertain in this setting.[95]

The power of contracts lies in the willingness of the parties to abide by their terms or run the risk of the other party's enforcement. In the world of managed care, one of the fundamental principles of contract law -- free negotiation between the parties -- has been tempered by regulatory intrusions aimed explicitly at safeguarding patients' rights, professional rights or perceived unfettered incentives to poor quality. Still, as with most private contracts, physicians and MCOs on one hand, and subscribers or patients and MCOs on the other hand, end up in disputes over provisions which case law construes. Other contracts are then altered or negotiated differently in response. Contracts, therefore, emerge as a significant force in the physician's legal context for quality.

V. CONCLUSION

Public policy concerns over both quality failures and errors as a subset of such failures is with us in force. What will be done is not yet clear. Whatever initiatives emerge from the current cacophony, it is clear that the efforts to date to influence physician behavior to improve quality, as manifested only in legal demands, is hardly a coordinated strategy. The survey presented here of three major sources of legal mandates is not exhaustive. Nor does it represent all the quality-

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[94] California: Health and Safety Code §1361.2; Louisiana: LSA RS 22:21518G; Alaska: AS 21.01.010(c)

[95] See Dunn v. Praiss, 139 NJ 564, 656 A2d 413 (1995) and Gosfield supra n.89 at 41-42

relevant legal undertakings at work today on the other sectors of the health care industry. It does show, however, that the law evolves by fits and starts in response to multiple pressures -- whether emanating from research, anecdote, speculation or lobbying. As a result, physicians face a noteworthy array of pitfalls related to quality. Unfortunately, as incentives go, most of what the law provides today is grounded in sanctions oriented around Medicare fraud and abuse with draconian punitive impacts. Although these laws do address the basic quality issues of misuse, underuse and overuse, in the absence of clinically relevant review parameters, they can only affect behavior at the most extreme margins where there is no dispute regarding quality failures.

The two most significant current federal schemes with potential positive influence on physicians have either been limited in their attention to physicians specifically (the quality improvement initiatives of PROs) or have received virtually no attention in those quarters where they might be most warmly received (the clinical integration safety zone). The last major federal attempt to stimulate aggressive, physician-focused quality dialogues (the HCQIA) is now facing more intense scrutiny and one of its major components (the NPDB) is criticized by players at every point along the policy spectrum. Other federal initiatives – carrier review, EMTALA and all other aspects of PRO review – offer little guidance to motivate physician quality and ultimately feed into the sanctions systems.

One is left with the inevitable conclusion that there is in the law not only no unified federal quality strategy regarding physicians, but despite longstanding research and policy pronouncements on the subject, there is neither a common legal definition of quality behavior nor even an agreed upon process by which to determine if it exists. It may be that the further work of the Institute of Medicine on quality including designing the health care system for the 21st century will accelerate the resolution of these matters. Until then, the objects of the regulatory exercises noted here -- physicians -- can hardly be held wanting for failing to respond to existing legal mandates when they can not know the standards against which they will be judged, because there aren't any.

At the state level, most of the action has been either a pale but confused shadow of the federal fraud and abuse controls, or, couched in the context of managed care reform has redressed some provider and patient complaints about managed care processes. In essence, state law merely reflects the same federal disorganization at local levels.

Private contracts present their own weaknesses in this realm. The sad part here, though, is that managed care purported to offer a better mousetrap. In its new approaches to insurer-physician-patient relationships there really has been a significant opportunity to directly influence physician quality, not just through obligations physicians must meet or be terminated, but through the creation of an environment in which physician quality improvement would be a hallmark value which would flourish. Although some MCOs have made strides in this direction, the typical legal manifestation of the MCO-physician relationship is a far cry from such a reality. Still, when compared with the legal context of the un-managed world, it would probably surprise many who decry managed care's blunt incentives to underuse to recognize the extent to which typical physician managed care contracts actually do provide inducements to address quality.

Whether today's legitimate questions about quality and errors will find quick and

meaningful, organized legal strategies in answer is unlikely, especially if left to the political process alone. Whether there is value in those most affected to step up and mold the coming era of quality regulation seems unassailable. The law will be called into play in the name of quality and patient safety no matter what policy path is chosen. The pace at which this happens is not yet known. It seems that the patient safety issue is propelling the debates in a way that provides an opportunity to revisit what the law is doing to physicians today.

As legislators have imposed on MCOs accountability for their processes, they themselves ought consider the wide-ranging dictates they have crafted which relate to physician quality. Policymakers, legislators, regulators and contract drafters ought to contemplate if not actively adopt better uses of legal mechanisms to affect physician quality, avoiding the deficiencies of the current mechanisms which have only been touched on here.

Physicians should lead the way in pointing out these dilemmas. To do so, they will have to abandon the paralyzing anxieties Reinertsen observes and step up to serve as the leaders they can be. They are currently at unappreciated risk from the definition-less, blunt force trauma of the provisions cited here. Even if enforcement under these mechanisms is rare, where enforcement occurs it is a hammer. The basic framework does not create an environment that encourages positive response.

To truly influence the developing legal environment physicians ought to embrace quality demands and vociferously endorse those regulatory efforts that can improve quality and simultaneously permit physicians to act accountably within their sphere of expertise (clinical integration under the antitrust safety zones). They should push for more clinically meaningful legal vehicles, while seeking to eliminate the redundancy and undue hazards posed by the existing panoply of legal mandates, both public and private. The result can only be more positive for them and the public.