Pre-Publication Draft

THE PROMETHEUS PAYMENT™ PROGRAM: A LEGAL BLUEPRINT

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Pro·me·the·an (prə-mē'thē-ən)
adj. defiantly original; so boldly creative as to have a life-giving quality

3 .1 Beyond Pay for Performance (P4P)

Pay for performance (P4P) programs are sweeping the country in both public and private health insurance. Responding to the Institute of Medicine's call for new payment models[1] to really advance quality, these initiatives are typically designed to motivate physicians to improve their care but increasingly they also address hospitals. While there is some data that shows that P4P payments produce changed physician behavior in some measure[2], there are many questions as to how P4P can be sustained as a payment model.

Against this background, a new payment model has been developed to (1) confront the toxicities to optimal quality which are found in fee for service (FFS) and capitation payment modes, (2) respond to the IOM's call for a new approach, and (3) tackle, with new thinking, the limitations of today's P4P. PROMETHEUS Payment™ is a model which has been two years in the initial design. **P**rovider payment **R**eform for **O**utcomes **M**argins **E**vidence **T**ransparency **H**assle-reduction **E**xcellence **U**nderstandability and **S**ustainability is expected to accomplish these goals by focusing on the values conveyed by its acronymic name. Pilot demonstrations will permit a practical analysis of both its limitations and pitfalls and what will make it better. To make PROMETHEUS Payment™ real, however, it will be necessary to create additional contractual relationships and a new legal context for its operation.

This chapter explains the limits of P4P, the tenets of PROMETHEUS Payment™, and elucidates the legal blueprint for its implementation, including contracts between providers and health plans, what is appealable and to whom, the role of independent service bureaus, and potential legal liabilities and opportunities the model will generate.

3.1.1 P4P Presence and Results

P4P programs are now omnipresent. By November, 2006, of 252 HMOs surveyed across the country, among the respondents, 81.3% in 41 metropolitan areas use pay for performance; 89.7% of the respondents incentivize physicians and 38.1% focus on hospitals.[3] For all of their claim to novelty, though, there are those who have observed that P4P programs have been on the health care scene for at least ten years in

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* Alice G. Gosfield is the first chairman of the board of PROMETHEUS Payment™ Inc. and has been an active member of the PROMETHEUS Payment™ Design Team.

[1] Corrigan et al, "CROSSING THE QUALITY CHASM", National Academy Press, 2001

[2] Rosenthal et al, "Early Experience With Pay For Performance," 294 JAMA 1788 (October 12, 2005)
[3] Rosenthal et al, "Pay for Performance in Commercial HMOs", NEJM 355: 18, (Nov 2, 2006)

the forms of bonuses and add-ons to the basic physician payment amount, linked to some measures of performance.[4]

Most P4P programs in their current iterations are of only a few years duration at most. Most are local in their impact. Even the CMS programs are primarily demonstration programs. Assessments and evaluations are only recently available. There is data that P4P does change physician and hospital behavior, but so far these changes are of small proportions although the scope of the endeavors are limited as well. In the Premier-CMS Hospital Quality Incentive Program, in the first year among the 260 hospitals participating, the top performers shared $8.85 million, with an average improvement of 6% on the five principal issues measured, for which between 27 and 52 hospitals shared between $1.13 million and $2.07 million per measure, for an average of $72,000 per hospital.[5] Early reports from commercial programs demonstrate that those physicians who were doing well before P4P do very well when additional payment becomes available; and they get more money without changing much in their behavior. The others alter their behavior only slightly.[6] In the United Kingdom, P4P was adopted nationally for primary care and the experience was similar --- those who were doing the right thing before the program's inception got more money; others changed their behavior marginally, and the performance levels were set so low that the pay outs far exceeded what had been planned.[7] Many of the P4P programs have intentionally incorporated relatively low levels of performance necessary to qualify for payment so as to gain provider acceptance. For physicians, CMS has begun with a voluntary reporting program for all physicians which initially offers no payment enhancement.[8] In oncology, additional Medicare payment is available to physicians for reporting care in relationship to guidelines, whether the care followed the guidelines or not,[9] but there are no results available yet.

3.1.2 P4P Pitfalls

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[4] Reschovsky and Hadley, "Physician financial incentives linked to quality: some growth in recent years, but productivity incentives still dominate", (forthcoming).

[5] CMS/Premier Health Quality Incentive Demonstration Project, "Project Overview and Findings From Year One", (April 13, 2006). http://www.premierinc.com/quality-safety/tools-services/p4p/hqi/hqi-whitepaper041306.pdf

[6] Rosenthal, supra n.2

[7] Galvin, "Pay for Performance: Too Much of a Good Thing? A Conversation with Martin Roland", Health Affairs, (Sept/Oct, 2006) pp. 412-419

[8] http://www.cms.hhs.gov/PVRP/

[9] http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=717

No matter the early returns, though, there are some features inherent in the design of almost all P4P programs which limit their potential shelf-life.[10] Almost all of the programs focus on paying extra for providers to do something. The earliest, therefore oldest P4P programs essentially addressed only under-use and nothing about overuse.[11] Recent changes have shifted more attention in P4P programs to overuse and misuse, but the fundamental dilemma with P4P is that these payments are small, incremental add-ons to the existing payment systems they complement, which payment systems drive towards different incentives. If fee for service and capitation actually motivated quality, P4P would not have arrived and PROMETHEUS Payment™ would not be a topic of conversation.

Most of the P4P metrics are focused on very discrete, condition-specific measures, including predominately diabetes and chronic cardiac conditions, although some are now using composite scores. Still, when all of the providers in the program have moved up to optimal levels on the diseases of focus, what happens next? Do the rewards for those programs get shifted to other conditions? Do we add more measures to be included in the same payments? No one has addressed these issues yet.

In almost none of these programs are there contract amendments which address the health plan's obligation to pay. Because there is no enforceable contract, other than as implied in the publicity around these programs, we have no data yet on what disputes, if any, will emerge when providers' revenue expectations are dashed.

To date, no one has addressed the fact that all of the contracts of the providers paid under these P4P programs already require them to comply with the plan's utilization management programs. In addition, plans often track provider use of laboratory and pharmacy benefits more than any other services because they can monitor laboratory and pharmacy costs more easily than other services since they are processed through separate payment and claims streams. If providers who seek to achieve better results for the P4P metrics, do so by prescribing more drugs and ordering more laboratory studies, how will those changes be addressed by the utilization management department when the physician's increased ordering behavior becomes known? In addition, there is now evidence that P4P programs themselves are adding to provider administrative burdens because of their custom-made nature reflecting the desire of plans using them to gain competitive advantage in their markets.[12] Despite the recognition that the need to

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[10] Gosfield, "P4P Transitional at Best", Managed Care, (Jan, 2005) http://www.managedcaremag.com/archives/0501/0501.p4p_gosfield.html
Gosfield, "P4P Contracting: Bold Leaps or Baby Steps", Patient Safety and Quality Healthcare, (Sept/Oct, 2004), http://www.psqh.com/octdec04/gosfield.html

[11] See Gosfield and Reinertsen, "Paying Physicians for High Quality Care", Letter To The Editor, 350 NEJM 1910 (April 29, 2004).

[12] Trude, Au, Christiansen, "Health Plan Pay-for-Performance Strategies", Am J. of Mgd Care. (Sept. 2006), pp.537-542

standardize common measures of quality is so great that it led to the creation of the National Quality Forum[13] that has not happened in P4P either.

A critical issue, both to motivate changed behavior as well as to sustain any such motivation, is what it costs providers to get the P4P payments --- in other words, where are the financial margins? Physicians tend to focus more on revenues than on margins, but even if it takes fifteen minutes to abstract a record to report to NCQA under Bridges To Excellence,[14] that time expenditure by some staff person represents a cost. So does the additional equipment and personnel to provide the additional services necessary to get the additional payments. Now, even hospitals are griping about the burdens associated with the reporting initiatives they are involved with as well,[15] and since the average payment to hospitals under the CMS-Premier Hospital Quality project was only $72,000, there is a real question as to whether what it takes to get the additional payments is enough to generate sustained responses, or even whether the measured change was the result of the enhanced payment.

Many of the P4P programs are associated with transparency initiatives. Every NCQA Diabetes Recognized Provider is listed on the NCQA website. This is a predicate to payment for diabetes care under Bridges to Excellence. Part of the purpose of transparency is to motivate patients to gravitate to the better quality providers by exercising choice. Where the brittle, complex diabetics make that very choice and present themselves to the better quality providers, if those physicians are paid capitation they will suffer serious adverse selection problems -- the actuaries who establish the capitation rates will not have taken into account the additional resources necessary to treat these patients in higher numbers than a typical primary care case mix would experience.

Taken together, while the jury is still out in terms of performance sustained over more than even just three years, there are a host of dilemmas in P4P; but the biggest problem of all is that these are incremental and small additions to fundamental payment models that cannot motivate quality generally and in many ways are toxic to our goals with respect to a more appropriate reimbursement system. A new payment model will be necessary to really change behavior in a manner that will improve quality on all three axes of underuse, overuse, and misuse and be durable over a longer time horizon.

3.2 PROMETHEUS Payment™: Differences and Intent

The primary purpose of the PROMETHEUS Payment™ program is to offer a sustainable payment model that will improve quality for patients, lower administrative

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[13] See, Gosfield, "The Performance Measures Ball: Too Many Tunes, Too Many Dancers?", Gosfield, ed, HEALTH LAW HANDBOOK, 2005 ed., pp. 227-283.

[14] The initial official estimate which is no longer on the website.

[15] Pham, Coughlan, O'Malley, "The Impact of Quality-Reporting Programs on Hospital Operations", Health Affairs (Sept/Oct 2006) pp 1412-1422

burden for providers and plans, pay fairly, and provide usable, transparent information to propel continuing improvement while it facilitates patient choice where it can be exercised. The Design Team[16] met every month for almost two years before a press release was even offered.[17] The first implementation of the model is not expected to occur until the second half of 2007. This has been a complex undertaking. Had it been easy it would have happened years ago.

To structure the design process, we employed a technique used by General Electric in their design of any new products or services called "Design for Six Sigma" which is a formal way to develop consensus among disparate stakeholders. We made several decisions which determined the boundaries of the design: we would design nothing which required legislation to implement; we would focus solely on provider payment and not on benefit design or how to make benefit design support the incentives of PROMETHEUS, although that work will be important and will strengthen the power of the model; the model would have to be as "plug and play" as possible for the plans if there was any realistic expectation of its use, meaning it could not require them to disrupt existing payment mechanisms or design new claims processing systems; until we had proof of concept we would not involve Medicare, so the initial populations of focus would be covered under commercial insurance, although Medicare has had a keen interest and a member of the Design Team worked for CMS. When we went public with our Press Release, Mark McClellan, then administrator of CMS, called us to offer a positive quote in support.

The PROMETHEUS Payment™ model is specifically designed both to reflect the STEEEP values promulgated by the Institute of Medicine in "Crossing The Quality Chasm" and to respond to the call for new payment models to enhance the likelihood of improved quality of care.[18] There is no question that there have been compromises in the design to accommodate the sometimes conflicting needs of multiple stakeholders. The goal has been to create something that can actually be implemented rather than to issue another set of design principles or goals. Although providers who perform better on PROMETHEUS-determined metrics will do better financially than those who do not score well, that is virtually the end of the similarities with P4P as it exists today or has existed in the past.

3.2.1 Evidence-informed Case Rates™

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[16] Alice G. Gosfield; Francois de Brantes of Bridges to Excellence; Elizabeth McGlynn of RAND; Meredith Rosenthal of the Harvard School of Public Health; Douglas Emery of eHealth Initiative; Michael Pine, M.D. of Michael Pine and Associates, Inc.; Jeffrey Levin-Scherz, M.D. of Partners Healthcare, Boston; James Bentley of the American Hospital Association; Craig Schneider of the Boston Regional Office of CMS; Daniel Roble of Ropes and Gray, LLP; Michael Taylor of Towers Perrin HR Services; and Toni Mills of The Blue Cross Blue Shield Association.

[17] Press release, Sept. 13, 2006, http://www.prometheuspament.org/assets/Documents/PROMETHEUSNewsReleasefinalforwire2.pdf

[18] Care should be safe, timely, effective, efficient, equitable and patient centered. Corrigan et al, supra n.1 at pp 44-55

The single biggest distinction between the PROMETHEUS Payment™ approach and any other form of payment of which the Design Team has been aware is that it begins with good clinical practice guidelines (CPGs) which state the science which should be brought to bear to treat a patient with a specific clinical condition. From the CPGs, an assessment is made as to the actual resources, including clinician time, which must be marshaled to make the continuum of care on the CPG happen, taking into account all the providers who will treat the patient on that CPG – hospitals, pharmacies, physicians, rehabilitation providers, imaging centers, laboratories, durable medical equipment suppliers and anyone else interacting with the patient clinically for that condition. The cost of those resources is accumulated to construct a case rate amount which functions as a big budget for the services to bring to bear these resources for the patient.

In the early descriptions of PROMETHEUS Payment™, the Design Team referred to the case rate as an "Evidence-based Case Rate™ (ECR™)". Based on conversations with physicians who consistently raised the fact that much of what PROMETHEUS will address has no pure, randomized controlled clinical trial evidence available in support, we changed the name to reflect that. Because the new payment system is designed explicitly to pay for the care that is truly clinically relevant and needed by the patient, a pure evidence-based model would not meet our design requirements. Consequently, we refer to the payment amount as an "Evidence-informed Case Rate™" (ECR™). This is intended specifically to demonstrate that case rates will include, in many instances, consensus based judgment as well as an empirical evidence base from observed performance with good results. There are many aspects of care delivery which are not explicitly enumerated in even good clinical practice guidelines that PROMETHEUS™ hopes to address. For example, infrastructure and organization of processes of care – e.g. use of non-physicians and care registries – have never been considered in clinical practice guidelines, but they are elements to be taken into account in designing the Evidence-informed Case Rates™.

In the first iterations of this program, in the absence of data with respect to the actual cost to providers of resources to deliver care, the Design Team has been forced to look at very large national databases reporting claims paid by Medicare and commercial programs for the cost of care which adheres to good guidelines as described in claims payment. We have been acutely aware of the limitations of these databases as accurate reflections either of all that was done for the patient or what it actually cost to render that care. Therefore, from that base, we have adjusted the "cost" calculation upward intentionally to build financial margins for providers into the payment to be made to them, while also accounting for the fact that claims payment data reflects distortions in the existing payment models. This is how the initial ECR™ budgets are constructed.[19]

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[19] The initial conditions modeled into PCRs™ are (1) preventive care – all the services mandated by the Preventive Health Services Task Force; (2) diabetes; (3) depression; (4) two cancers – lung and colon; (5) hip and knee joint replacement; and (6) three interventional cardiology conditions – non-ischemic congestive heart failure; ST elevated myocardial infarction; and mitral valve regurgitation. The conditions were selected based on a prevalence and cost in a commercial population, a broad scope of providers involved in the treatment, and availability of up-to-date widely accepted CPGs to use as the basis for rates. Working Groups of practicing physicians were convened to 'deconstruct' the CPGs to articulate the actual

Because patients do not always present with single conditions, ECRs™ are also condition modified to account for the additional services that greater complexity or acuity of a condition and co-morbidities would demand. There are a variety of ways in which this can happen. A simple condition modifier would occur where a patient with adult onset diabetes mellitus is also morbidly obese and has moderately severe dyslipidemia. A complication which "breaks" the base ECR™ would be where a patient being treated for moderately severe extrinsic asthma develops chronic obstructive bronchitis after a severe lower respiratory infection. Because the fundamental condition primarily driving the care is the COPD, the asthma may convert to a condition modifier on a COPD ECR™. If a patient with diabetes develops hypertension, hyperlipidemia, coronary artery disease and then develops congestive heart failure, each of these is a condition modification severity adjustor onto the base ECR™ amount to reflect the additional conditions and the commensurate appropriate additional services. If that patient further develops renal failure, then he is not being treated primarily for diabetes any longer; so the ECR™ would be "broken" in favor of payment on the renal failure ECR™. Once stabilized, the patient might well return to the diabetes ECR™ with extensive condition-modifiers, but if the patient becomes a chronic dialysis patient, then he would likely be followed under two related but separate ECRs™ - one for the dialysis and the other for the ongoing diabetes.

Depending on the patients' conditions, they might be treated on multiple unrelated ECRs™. The same diabetic patient might develop symptoms of a gastric ulcer which should appropriately be treated by a gastroenterologist quite apart from the diabetes, so an additional ECR™ for the GERD would be opened. If the patient has a hip replacement the rate would be calculated as a hip replacement ECR™.

The CPGs which are used to determine the ECR™, the condition modifiers, what triggers the ECR™, when it ends, and what would break it, are all based on open rules made known to all. Still further, there are some very simple conditions – like a chest cold or urinary tract infection -- for which this type of approach is far too complex to make sense. Even for patients whose care is otherwise paid on a ECR™, that simple care outside the ECR™ program would be paid fee for service.

Still further, there are combinations of problems for patients which are so complex, they cannot be managed or paid for in this way. For example, a paraplegic cancer patient who gets caught in a house fire will never have his care paid for on a ECR™. Therefore, even in the fullness of time, PROMETHEUS Payment™ compensation will not and ought not supplant all existing forms of payment. The Design Team believes that the model will work for about half of what is paid for today.

3.2.2 Who Plays and How?

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services necessary to deliver the care. Common co-morbidities were identified. Their analysis was tested against large national claims databases. Then the necessary constellation of services across providers was priced using that data as a base with an intentional increase in the prices to take into account perverse post debasements as well as to build in an intentional positive margin for providers.

Once the ECR™ budget is established, providers come forward in whatever configurations make sense to them, to negotiate to deliver whatever portion or all of the care that is within their expertise and the resources they have available to them. For example, some cardiology practices have high end imaging services and lower technology diagnostic services as well as a full clinical laboratory within their walls. Others do not. Each type of practice could 'bid' to provide differing parts of the ECR™ continuum. A fully integrated delivery system might negotiate to deliver the entire range of services in the case rate budget.

Other groups of clinicians and facilities might come together in idiosyncratic combinations that they believe will be able to best meet the patients' needs in terms of quality and efficiency. For example, a group of orthopedic surgeons might join with a hospital or ambulatory surgery center to bid together to provide a part of the CPG with or without the post-surgical rehab providers. If they wanted to create a formal network, like a PHO, to accept payment for all of the otherwise independent providers bidding together they can do so, but a bedrock principle of PROMETHEUS, in addition to transparency throughout, is that no one holds the money of any party unless they choose to be paid that way.

Providers can bid together but be paid separately. They need not form new legal structures. They take no insurance risk. They are at risk for their ability to manage the clinical delivery of care within the prices they negotiate under the ECR™ budget. Many of the problems of hidden bundling of services into CPT codes or idiosyncratic coding conventions used by managed care plans are eliminated with this model of payment.

Some have thought that the model is designed for fully integrated delivery systems, but that is inaccurate. What will be learned in implementation is whether integrated delivery systems offer competitive advantages in terms of better quality results and greater economic efficiency because of their relatively higher degree of structural and process organization. (On the other hand, we may learn they are top heavy in management and not efficient). Formally structured independent group practices might well perform better than solo physicians and smaller configurations of doctors.[20] But the payment model is applicable for all types of providers who know enough about what it costs them to treat patients in accordance with science that they can effectively bargain for the appropriate part of the ECR™. One of the goals of the program is to have all providers come to understand the economic value and rewards which lie in that knowledge.

3.2.3 The Scorecard and Its Incentives

The primary distinction in PROMETHEUS Payment™ is that it grounds payment on a CPG which is used to create a case rate. This decision reflects the expectation that this change would improve the likelihood that everything and just as much as a patient

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[20] Gosfield, "PROMETHEUS Payment: Getting Beyond P4P", Group Practice Journal (Oct. 2006) pp. 14-19

needs clinically will be appropriately provided, since all of what science dictates should be done is taken into account in the payment rate. But, the availability of a case rate alone does not establish incentives to change behavior, nor does it provide any guarantee that the provider will, in fact, deliver what he bargained to render. Still further, other administrative burdens which currently exist as safeguards against gaming (e.g., prior authorizations, concurrent review, utilization review, post-payment audits) are eliminated from the PROMETHEUS Payment™ system as time consuming and not quality-enhancing. Consequently, there has to be some way to assure that patients are getting what they should. Moreover, a patient-centric model of care, per the Institute of Medicare, requires availability of useful information regarding provider performance to improve the likelihood that patients would seek out efficient, higher quality providers. The Scorecard addresses all of these concerns.

The primary application of the Scorecard is in measuring whether, based on an evaluation of quality and efficiency scores, the provider will be paid all or only part of a Performance Contingency Fund --- a withhold of 10% of the agreed payments for chronic care and 20% for acute care. First of these scores is whether the provider delivered the salient elements of the CPG which he/it bargained to deliver. There is a quality threshold that must be met before any of the withheld pool of money will be paid at all. Then one half of that money (5% or 10%) is allocable to quality and the other half is allocable to the provider's relative efficiency, which is measured against average performance of other providers treating the same clinical condition under a ECR™ budget.

On the quality side, the Scorecard measures whether the elements of the CPG were delivered, the patient's experience of care and the outcomes of the care. The scores are based 70% on what the contracting provider does; but 30% of the score turns on what all the other providers treating the patient do, even those not paid as part of the ECR™ negotiating process. The intent is to create a real incentive for clinical collaboration among independent providers. Physicians who are managing a portion of the care under a ECR™ ("managing physicians") will do better in their payment if they refer to higher quality hospitals, consultants and rehab providers, for example. Still further, managing physicians have a good reason to have conversations with their consultants over where the optimal moment for referral is found. Still further, the clinicians have a good reason to have a common understanding, at a minimum, about whether the involvement of the consultant is merely a consult – providing information for the managing physician to use in caring for the patient --- or is better handled as a transfer of care for that component of the rate.

Where these decisions reflect optimal clinical choices for the patient, both providers will do better financially. The payment of the Contingency Fund is made pro rata; so once the provider exceeds the threshold, he can still be paid part of the Contingency Fund even if he doesn't qualify for all of it. Because it is expected that not all providers will qualify to have returned to them all of the Contingency Funds set aside for these quality assessments, there will be an excess pool of the remainders which will

accumulate. These monies will be available to pay additional bonuses to the top 25% of providers treating on that ECR™.

To qualify for any efficiency dollars, first the provider has to meet the minimum quality threshold. But a provider cannot get any monies for efficiency if he/it doesn't meet the quality threshold. This prevents any value in skimping on care. Then, there are two ways he can benefit financially: First, if the expenses for resources he uses to provide his care come in under the level contemplated for that portion of the ECR™ budget he has negotiated to provide, he will realize an improved financial margin, but that in and of itself is not related to the Scorecard. Second, if all the providers treating the patient are more efficient, measured against the average of all providers treating patients for that condition, the provider will be paid one half of the Contingency Fund pro rata, reflecting the total score as compared to the average. Different from the quality-determined Fund portions though, unused efficiency dollars are not returned to any of the providers, because others will exceed their budgets, generating expenses for the plan.

As care under the ECR™ is delivered, the program tracks the allocation of dollars and services among providers treating the patient, and reports that to them so they know where they are in terms of providing appropriate care. This tracking mechanism permits the providers treating the patient to pay attention to what the patient should be getting, and encourages them to deal with each other if scores are lagging to improve them. The Scorecard results are shared with patients and made public.

3.2.4 Distinctions from Other Payment Modes

It is a truism that fee for service motivates over-utilization at the perverse end of its incentives. The more you do, the more services you render, the more revenue you will get. Capitation incentivizes physicians in the opposite direction. Paid on a fixed basis irrespective of patients' needs or services rendered, the financial incentive motivates under-use. Since lowered expenses maximize profits, the less you do the more money you will make. For hospitals, Diagnosis-Related Group (DRG) payments and its outpatient analogue, Ambulatory Payment Classifications (APCs), establish fixed rates which reflect past resource use for specified groups of diagnoses and clinical conditions. Within the fixed rate, the hospital maximizes its financial incentives at the under-use end of the continuum because the payment is capped.

Payment rates such as capitation and percent of premium, both of which turn on actuarial principles, do not consider or reflect quality values. Generally speaking, actuarially based payment rates look at past utilization patterns and project them forward with some demographic assumptions about the incidence of disease in the expected patient population. These calculations are made without reference to adjustment for whether the prior quality was good, bad, indifferent or stellar. As a result, providers paid on this basis take insurance risk --- the risk that the projections of the incidence of disease were wrong, or the past patterns of resource consumption were inappropriate or distorted in some way.

In these models, in addition, providers are at risk for the marketing practices of the plan which can confound the appropriateness of the projections. For example, the Bridges to Excellence P4P program rewards Diabetes Recognized Providers with $100 more for each diabetic in their patient panel on top of their capitation rates. The P4P programs in California under the aegis of the Integrated Healthcare Association also reward appropriate diabetes care with additional payments above capitation. As the performance of the good diabetes providers is made known, though, more and sicker patients would be expected to seek them out. But this shift in behavior would, by definition, distort in reality the assumptions which were used in setting the payment rates, because the capitation did not anticipate the adverse selection of the providers having sicker patients than the payment rate contemplated. Actuarially established rates also expect cross-subsidization from healthier patients who need little care to sicker patients who need more care. This gives providers financial risk they have no way of managing. PROMETHEUS is intended to resolve these dilemmas. In the PROMETHEUS Payment™ program they do not take insurance risk. Rather, they are at risk for knowing what it costs them to deliver services so they can negotiate a good payment rate within the ECR™ budget. Then they are risk for managing the delivery of what they have agreed to provide the patient in an efficient manner, including collaborating effectively with the providers to whom they refer and from whom they accept referrals.

Case rates have existed in the past, but they have never been grounded on what science has said is necessary to treat a patient appropriately. Some have been essentially gainsharing programs around DRGs. Others used consensus judgments of expert panels. Both are distinct from the PROMETHEUS Payment™ model which starts with published, well established CPGs. The actual construction techniques used in prior case rates have rarely been elucidated. Oxford Health plan implemented a program for a list of a few conditions, but it ended after three years when the basic financial structure of Oxford collapsed for other reasons.[21]

Because the PROMETHEUS Payment™ system allocates additional payments to providers when acuity increases by the presence of co-morbidities, providers have no incentive to treat only healthier patients. When the complications increase to such a level that the patient is no longer really being treated for the condition which defined the base ECR™ amount, even with condition modifiers, then the ECR™ is 'broken' before it would be naturally concluded in accordance with the guidelines, and a different ECR™ defines the continuing treatment or the providers revert to traditional payment if no ECR™ is available or appropriate. These mechanisms (condition modifiers, the rules that break or add another ECR™) minimize insurance risk and prevent catastrophic losses to the providers.

Under the PROMETHEUS Payment™ model, it is expected that most providers will prefer to receive their payments prospectively. In other words, of the 80% or 90% of their ECR™ portion, they will want to be paid monthly in advance. This gives certainty

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[21] For a discussion of past initiatives around case rates see Emery, "Pricing Episodes of Care", (Feb, 2006) www.bridgestoexcellence.org/pdf/Episode%20Pricing%20Draft%202%20(z).pdf

in cash flow and obviates the need to track claims payment and EOBs. In that regard, the PROMETHEUS Payment™ mechanism will operate like capitation. If the patient leaves the plan midstream, or the ECR™ is "broken" before its natural conclusion, there will have to be a reconciliation to maintain equity in the payment amounts for both the provider and the plan.

Other providers will prefer to continue to be paid on a fee-for-service basis with a reconciliation at the conclusion of the ECR™ to the ECR™ bargain they have struck with the plan. In that respect, the payment process will function like fee for service with a bonus at the conclusion, but the regular cash flow will be diminished by the money withheld for the Performance Contingency Fund. If the payout to the provider FFS exceeds the ECR™ bargain then no Contingency Funds will be paid for efficiency, but if the quality scores are good, the provider can still get that portion of the Funds. If the patient leaves the plan midstream of the ECR™, then there would have to be a 'reconciliation' of a different type to give back the amounts withheld in the Contingency Funds that no longer would apply.

3.2.5 Benefits

PROMETHEUS Payment™ was designed to track as closely as possible to the STEEEP values promulgated by the Institute of Medicine.[22] Payment should encourage the likelihood that care will be safe, timely, effective, efficient, equitable and patient centered. Safety is part of what is scored in the Scorecard, particularly for facilities. Providers will do better financially to the extent the patients are diagnosed, treated and seen timely; it is expected that both the process and therefore the outcomes of care will be better than what would occur without the PROMETHEUS Payment™ model and patient experience of care will improve. In addition, timeliness is also addressed with attention in the design on elimination of administrative burden which wastes providers' time on non-patient centric, non-quality supportive demands.

A strong emphasis on effectiveness lies in the basic grounding of all payment on good clinical practice guidelines. For twenty years it has been acknowledged in public policy that a good clinical guideline stands for the outcomes it would claim for itself.[23] Efficiency is accounted for in the Scorecard metrics as well as in the inherent margins that can accrue from economically resourceful care, which is all the care that the patient needs, but only what the patient needs. The primary benefit, to physicians in particular, from the new model is that it tracks far more directly to the way physicians actually treat patients. It is logical to them and therefore more easily implemented by them. At the

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[22] Corrigan et al, supra n.1

[23] Field and Lohr, GUIDELINES FOR CLINICAL PRACTICE, National Academy Press, 1992, p.30 (regarding "validity")

same time, one of the basic values driving the program was reduction in administrative burden that impedes optimal care.[24]

Because there is a clear agreement in advance on the scope of the care each patient will receive from each provider as negotiated under the ECR™ budget, there is no need for the eternal reinspection process and payment safeguards that characterize FFS and capitation. In specific there is no need for prior authorization of hospitalization or other services in the ECR™; no need for concurrent review, post-payment audits, certificates of medical necessity, documentation of the medical necessity of services, nor of the scope of the visit as conveyed in the evaluation and management code bullet points. There is the potential to eliminate drug formularies. All of these have nothing to do with quality but merely assure the paying agent that the care paid for was rendered and medically necessary.

In the PROMETHEUS Payment™ system all of this is contained in the agreed upon CPG and need not be revalidated, because the Scorecard measures whether the salient elements of the CPG were delivered. There is no benefit to any provider to provide less than this 'incompressible zone' of basic services to deliver the contracted for bargain. Providers who will be found not to deliver basic levels of care under the ECR™ will be prevented by the plan from contracting on this basis going forward. Providers who are paid prospectively will appreciate a more reduced administrative burden, because they need not substantiate E&M visits, their claims are paid more quickly without going through normal claims processing and they have more certain cash flow than providers paid FFS. Those paid fee-for-service need not alter their administrative processes, but their cash flow is reduced because the amount paid on each claim is reduced by 10% or 20% to fund the Performance Contingency Fund.

The mechanism provides certainty to both plans and providers regarding the basic amounts they can be paid for their care as well as the maximum available for that care. It is true that the availability of additional bonuses from quality remainders is speculative and depends on the relative performance of other providers, but that is just an added bonus and not a basic motivator in the program.

The contracting process expects negotiation between plan and provider. This does not mean the plan has to recontract the network. Rather the approach for the applicable conditions is set forth in simple amendments, as described more fully below. (See 3.3.2). But the opportunity for providers and plans to have a meaningful conversation and agreement about the scope of services and a fair rate for them is a purposeful characteristic of PROMETHEUS, designed to move away from 'take it or leave it' contracting which characterizes much of the basic payment system today and almost all P4P programs.

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[24] See Gosfield and Reinertsen, "Doing Well by Doing Good: Improving The Business Case for Quality" (Jan. 2003), http://www.uft-a.com, and Gosfield, "The Doctor-Patient Relationship as the Business Case for quality", 37, J. Health Law (Spring 2004) pp.197-223.

In addition to a bedrock value of transparency, in the PROMETHEUS Payment™ model no one holds the money of any party unless that party agrees. So a hospital cannot bargain to be paid for physicians who have not agreed that the hospital will be their agent in negotiation or to hold their money. Similarly, a physician group cannot seek to take the money to pay the hospital at a discount or otherwise, unless the hospital agrees. Prudent plans will require attestations that any such roles as an agent have been agreed to by all the providers involved.

The fundamental infrastructure to make the program work -- the development of the ECR™ budgets from the CPGs, the tracker to allocate the dollars in the ECR™ budget to the provider which rendered that portion of the services, and the Scorecard -- is complex. But it will be created before the program will even be piloted, and therefore is as "plug and play" as possible for the plans, minimizing disruption to them from system innovation. Moreover, the management of the core data elements in that infrastructure will be conducted by service bureaus contracting with the plans and not by the plans themselves. (See 3.3.4, below.) This lowers administrative burden to the plans and enhances the credibility of the critical data functions to providers because those functions are not housed in the same entity which pays the claims, thereby reducing concern that data might be manipulated to achieve financial goals.

Although there are complaints from some quarters that many of the CPGs available today to model ECRs™ represent idealized patients who are rarely seen in practice,[25] one of the dilemmas in the development and publication of CPGs has been a lack of clarity regarding their potential uses. The Design Team believes that the advent of this unambiguous payment application of CPGs can motivate the creation and articulation of more useful CPGs going forward.[26]

There is now evidence that physicians who fail to follow CPGs have a six-fold increased risk of being sued in malpractice.[27] The 100,000 Lives Campaign of the Institute for Healthcare Improvement brought so much attention to six specific bundles of processes to prevent needless deaths that it likely changed overnight the hospital standard of care.[28] The behaviors that the PROMETHEUS Payment™ system rewards are safety enhancing because the provider maximizes payment with safe, effective clinical processes. It is likely, therefore, that the PROMETHEUS Payment™ program not only can lower malpractice liability because more care will explicitly reflect the standard of

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[25] Brush et al, "Integrating Clinical Practice Guidelines Into the Routine of Everyday Practice", 4 Critical Pathways in Cardiology, 161 (Sept. 2005)

[26] See Gosfield and Reinertsen, "CPGs: Think Core Concept", Health Affairs (May/June 2005) pp. 885-886 and fn.31 infra.

[27] Ransom et al, "Reducing Medicare for Risk by Compliance with Obstetric Clinical Pathways: A Case Control Study." 10 Obstetrics and Gynecology 751 (2005)

[28] Gosfield and Reinertsen, "The 100,000 Lives Campaign: Crystallizing Standards of Care for Hospitals", Health Affairs (Nov/Dec, 2005) pp.1560-1570

care in legal terms, but the actual impact, it is hoped, will reduce the number of clinical misadventures that create lawsuits.

The goals and values of PROMETHEUS are contained in its name: **P**rovider payment **R**eform for **O**utcomes **M**argins **E**vidence **T**ransparency **H**assle-reduction **E**xcellence **U**nderstandability and **S**ustainability. The drive it is intended to motivate toward clinical collaboration among providers in meeting the patient's needs is unprecedented, since it does not require changed legal structures, or formal organizational change, but focuses attention on better, more effective clinical care paid for at an equitable rate. This author, with James L. Reinertsen, M.D., has propounded principles to impel significantly more movement along this pathway than has existed in the last thirty years. To make the health care system better we need to find more ways to (1) standardize to the science; (2) simplify the administrative chaos; (3) make everything in the system, and particularly payment for its services, more clinically relevant; (4) engage the patient actively as a partner in his care provided with these values; and then (5) fix accountability for the results of process change at the locus of control.[29] All of these are present in the PROMETHEUS Payment™ system. Still, the Design Team is aware of lurking pitfalls and criticisms.

3.2.6 Potential Pitfalls

In any new payment model, no matter the efforts to anticipate problems, there are potential pitfalls both in the design and operation. The Design Team has tried to anticipate and address many.[30]

As acknowledged above, the essence of the PROMETHEUS Payment™ model relies on the validity of clinical practice guidelines which are, admittedly, not perfect. Guidelines may be too broad or too narrow, resulting in incentives that are too diffuse on one hand or lead to more fragmentation of care on the other. In response, by testing the base-ECR™ against past claims payment patterns, major payment dislocation should be avoided. In the last analysis, though, claims data will, in the ideal version of PROMETHEUS Payment™, only be a test of the farthest reaches of a ECR™. Rather, the best data to establish ECRs™ would reflect actual resource consumption costs associated with delivering the care, but until providers have actual data on point, we are forced to use claims data as a surrogate, although its use is massaged to blunt its potential pernicious effect on equitable rates.

If the ECR™ does not appropriately capture a fair balance of services and their costs, the entire theory of the payment model will be at risk. If condition modifiers are not appropriately calibrated, the incentives may be blunted and the expenses may be higher than appropriate. The Design Team is well aware of the fact that simple

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[29] Gosfield and Reinertsen, supra n. 24

[30] See PROMETHEUS Payment™ White Paper, at pp.22-27 and FAQs both at http://www.prometheuspayment.org

cumulation of existing CPGs to adjust rates will not only be inappropriate, it could actually harm patients.[31]

The infrastructure that is necessary to make the PROMETHEUS Payment™ model work has had to be designed for this process. If the tracker engine, which establishes, monitors and allocates costs within the ECR™ budget, fails, cases could be triggered inappropriately and double payments could occur. The integration of the PROMETHEUS Payment™ infrastructure with existing plan payment processes is also a challenge.

The scope of the ECR™ budgets and their allocation offer more potential pitfalls where multiple treatments are appropriate as established in the evidence and the choice of care is particularly sensitive to patient preference. For example, a patient with low back pain may be treated either with conservative care or surgery. How providers respond to this accommodation in the ECR™ budget could prove problematic. But the risk of providers gaming the system is always present with innovations when increased revenues are available. Physicians may over-claim patient complexity to gain additional dollars from ECR™ condition modifiers.

On the other hand, a critical worry is whether there will be enough participation from plans to make the critical mass of patients whose care will be paid for on this basis viable for interested providers. The Design Team recognizes that there will inevitably be transitional costs, since in any market it is unlikely all the plans would participate. Providers will have to maintain parallel administrative systems, so whether there are enough patients in any program to make them interested will be important. Still further, whether the calculation of the 10% or 20% Performance Contingency Funds is high enough to motivate changed behavior is also not known.

The Scorecard presents its own lurking pitfalls, including whether the scores are reliably related to better care, and whether the scores accurately capture what the providers actually do. Still further, if the scores are not properly conveyed or understood by consumers it may motivate unexpected patterns of care or channel patients inappropriately to the wrong providers. Finally, there is a school of thought that attribution of outcomes to individual clinicians is virtually impossible[32], so it might be difficult to assign responsibility for results to the correct provider. But, the PROMETHEUS Payment™ model departs significantly from P4P attribution issues because the provider states which pieces of the ECR™ he will provide and therefore on which care he will be measured. Whether he was personally responsible for that care, or the patient's perception of the care experience, or even the outcomes, is irrelevant. The PROMETHEUS Payment™ system rewards the effect of the system of care and

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[31] Boyd et al, "Clinical Practice Guidelines and Quality of Care for Older Patients with Multiple Co Morbid Diseases," 294 JAMA 716 (Aug. 10, 2005); see deBrantes, Rosenthal, Gosfield, McGlynn and Levin-Scherz, Letter to the Editor, 295 JAMA 34 (Jan. 3, 2006)

[32] Pham, "How Many Doctors Does It Take To Treat A Patient?" PowerPoint, AMGA Results Based Payment Sharing Committee Meeting, September 27, 2006

specifically counts 30% of the scores based on all providers treating under the ECR™ budget.

Health plans fear that the cost of healthcare will continue to rise. In addition there is no basis to claim that the PROMETHEUS Payment™ program will be budget neutral. Unless elimination of overuse reduces by the same amount or more of what will be provided that is currently underused, there is no way the program can be budget neutral. Still further, if Americans are only getting 55% of the services science says they should,[33] then there is a 45% under-use problem today. To fix that, inevitably entails additional expense. That said, however, going forward, the effect of PROMETHEUS Payment™ structure ought be able to alleviate the upward trend in rapidly rising healthcare expenses by motivating appropriate and efficient resource consumption as reflected in what patients need in accordance with science. Administrative simplicity is also a critical concern of plans. They resist anything that imposes on their existing system designs. In PROMETHEUS, though, provided they do not try to tinker with the inner workings of the program, the system, as designed, incorporates most of the administrative components needed to make it real. Integrating the PROMETHEUS Payment™ components with the plan's existing systems is a potential pitfall, as is the relevant connection between the plan and the service bureaus that manage the data.

3.3 What is the Legal Infrastructure?

The Design Team explicitly chose to develop a program that did not require legislation to implement, nor the approval or involvement of Medicare. Still, even without legislative or regulatory mandate, the legal obligations in PROMETHEUS Payment™ relationships will be real. One of the fundamental problems with P4P programs is that almost none of them is documented in enforceable contract terms. We still do not know whether any disputes over P4P will be litigated and if so on what basis, since the aggrieved providers have no legal expectation of payment other than the plan holding itself out as engaging in such a program. In contrast, the PROMETHEUS Payment™ model does expect legally binding obligations to support it.

3.3.1 Plan-Provider Negotiations

The first issue between plan and provider is the negotiation over the scope of services on the CPG and within the ECR™ budget for which the provider will take responsibility. This will drive how his Scorecard will be constructed, because 70% of the scores turn on what the provider does and 30% on what the other providers treating the patient on that ECR™ do. There is a balance between the provider assuming direct responsibility to deliver pieces of the CPG and his becoming a 'managing physician' whose services trigger the initiation of the ECR™ budget for which he will be scored, in which status he can benefit more from effective, efficient referral practices that will affect 30% of his scores.

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[33] McGlynn et al, "The Quality of Health Care Delivered to Adults in the United States", 548 NEJM 2635 (Jan. 16, 2003)

Where providers come together for clinical collaborations and agree on what that means – when referral to a specialist is optimal, at which facilities the patient should be worked up, when the patient should be admitted and where, who can best perform the post-operative rehabilitation – they can bid together, in essence parsing out among them the clinical arrangements they believe to be best for the patient. They need not be paid together, nor do they need to reveal their decisions to the plan, other than as the decisions reflect which salient elements of the CPG they will be held responsible to deliver themselves.

The scope of the base services in the ECR™ budget itself is not negotiable. That is established by the PROMETHEUS Payment™ model which is maintained by PROMETHEUS Payment™ Inc. (PPI), the not-for-profit organization which holds the PROMETHEUS Payment™ intellectual property and trademarks. What is negotiable is the rate the plan will pay to the provider or combination of providers, to deliver the specified elements of the ECR™ which they would claim as their responsibility.

PPI establishes the scope of the full ECR™ and the basic services, below which the case rate would not qualify as an Evidence-informed Case Rate™. Still further, although the plan establishes the dollar amount associated with that case rate, reflecting regional variations and local issues, the budget must be large enough to reflect what the cumulative fee for service fee schedules as of the date of PROMETHEUS implementation would reflect for the estimated set of what will qualify as the basic services. PPI, however, does not establish the price itself.

To the extent providers believe the basic services defined by the ECR™ scope are not broad enough, those matters are only challengeable as design issues to be brought to PPI for change. (See 3.4.1 below.) When CPGs change or when new technologies become available and the CPG which formed the basis for the ECR™ budget has not yet been updated, these matters would also be brought to PPI for modification. Between the plan and provider, the negotiation is for the price of the applicable piece of the ECR™.

The plan has the burden of determining how to allocate the totality of the payments it will make within the ECR™ budget. If, for joint replacement, the plan negotiates a price with the surgeons and the hospital so that there is not enough money left in the budget for the rehabilitation provider to provide all the services the ECR™ calls for, the plan will not have safeguarded the integrity of the ECR™ construct which would be a violation of its arrangements with PPI. (See 3.3.4 below) Managing the negotiation around the dollars to be paid to each set of providers to meet the patient's needs is one of the most critical functions the plan plays in this model of payment.

There are inherent tensions among providers seeking to maximize their margins in this model, although they have an incentive not to bargain to deliver more than they can, because if they do, their scores will fall. There is no incentive to a plan to 'low ball' the rates to providers because it must be able to demonstrate to PPI as a condition of its trademark license, that it adequately supports the delivery of the full base ECR™ services

budget, the scope of which the plan both does not establish and must agree to in order to be able to claim it is operating a PROMETHEUS Payment™ program.

For the providers, the most critical challenge in the negotiation is their knowing what it literally costs them to care for a patient with the condition addressed in the ECR™. Few providers have such data today, despite the fact that if they had been working on this issue over the years, they would have been in a better position to manage their margins and lower their expenses in the delivery of care, while assuring that the patient receives the services which science says he should get for his condition.

In PROMETHEUS Payment™ the need to understand actual resource costs is very much heightened. It is the expectation of the Design Team that over time the ECRs™ will be established, not by looking at normative claims data which has inherent distortions in it, reflecting the perversities in current payment models, but by engaging in a more active negotiation between plan and provider based on real information about real costs. This is one of many instances in which the short-term practicalities of making PROMETHEUS Payment™ real today are different from the idealized long-term potential of the program.

3.3.2 Plan-Provider Agreements

Plans seek to avoid recontracting the network at almost all cost. This payment model allows existing credentialing and participation mechanisms to endure, along with the payment structure and rates to which plan and provider have already agreed for everything they do not address under PROMETHEUS Payment.™

Once the provider's price for it's components of the ECR™ has been established, though, that rate will be documented in an amendment to the existing participation agreement with the plan. This contractual obligation to pay the agreed upon amount is essential. When and how payments are made must also be documented, including that interest which accrues on the Performance Contingency Funds pending their payout is included pro rata in the payments to providers. Some providers will want their payment to be made prospectively, parceled out monthly from the full portion of the ECR™ they will provide. Other providers will want their payments made fee-for-service with a reconciliation or settle up at the end of the ECR™. Either method can be accommodated, but both direct differing contractual provisions in the amendment.

How the Scorecard is applied and the method and timing of the payouts, if any, from the Performance Contingency Funds, also must be documented in the amendment, although the functionality of the payment can be set forth in a policy manual. But the issues which otherwise pertain in the contract regarding post-payment audit must also be carved out in the amendment since, once the Scorecard metrics have been applied, and payment made, other than subject to the appeals processes, (See 3.4 below) the payment process is concluded for that care.

Interestingly, in light of all the policy lamentations about the failure of existing managed care programs to generate optimal quality, in fact, there are a host of typical provisions in managed care contracts, many purportedly addressing quality, which must be addressed in amendments to make PROMETHEUS Payment™ viable. Many must be carved out from the basic contract, blunting their impact on cases for which PROMETHEUS Payment™ applies. First among these is elimination of inapplicable provisions, including requirements to adhere to the plan's utilization management, medical management and claims documentation requirements which are not necessary for PROMETHEUS-compensated care. If such carve-outs are not put in place, then physicians will continue to be burdened by such documentation requirements as the E & M bullet points, prior authorizations for their own care as well as for other providers, and more which plans obligate them to, as a way of assuring they adhere to the gross incentives in the plan's medical management programs. PROMETHEUS Payment™ is intended to change medical management by clinicians measured in a Scorecard. Duplicative or redundant plan requirements would impair its fundamental design.

Restrictions on which personnel may perform services may also be problematic and should be prevented from applying to care provided under PROMETHEUS Payment™. The new payment model encourages team treatment of patients using all clinicians at their highest and best use. The model is indifferent to whether a physician, a nurse practitioner or a physician's assistant rendered a specific service -- as long as all who treat the patient act within the scope of their licenses, and the patient is safe and receives the services science recommends in the CPG. Contractual restrictions on the use of non-physician practitioners, whom health plans may not individually credential or recognize as separately participating providers, ought be carved out from the otherwise applicable provisions of the contract or the existing limits will act as a barrier to the fundamental principles of efficiency, safety and quality which PROMETHEUS supports.

There are specific appeals mechanisms which will pertain to PROMETHEUS Payment™ decisions (See 3.4 below) and these must be referenced in the contract amendment as applicable and superseding of other appeals processes to which providers must otherwise adhere.

Termination clauses will have to deal with a failure of a provider to implement PROMETHEUS Payment™ effectively. In other words, it can be expected that some providers, despite good intentions or not, may fail to provide to patients the care which they bargained to provide, not even becoming eligible to receive any monies in the Performance Contingency Funds. When their care consistently falls below the 'incompressible zone', they no longer ought to be eligible to be paid in this way. That does not mean they need be terminated as participating in the plan's network, but that they no longer will receive PROMETHEUS Payment™. Similarly, failure to provide data required to populate the Scorecard, or knowingly providing inaccurate or false data for the Scorecard are a separate grounds for termination from PROMETHEUS Payment™. The triggers for termination from PROMETHEUS Payment™, notice regarding it, and appeals rights with respect to it, must be documented in the amendment.

These are the broad and typical areas in most managed care contracts which would be at cross purposes with PROMETHEUS Payment™ and will have to be addressed in amendments while the basic contract remains in place for care not provided pursuant to PROMETHEUS Payment™. It is possible that plans may have other idiosyncratic provisions reflecting other home-grown initiatives or philosophies which would be inimical to the inner workings and full potential benefit of PROMETHEUS Payment™ .

Each managed care participation agreement into which PROMETHEUS will have to fit, will have to be reviewed carefully both by plans and providers, who, together, should have a common purpose to maximize the potential of the program while assuring that it is appropriately implemented in the interests of patients. To give the plan adequate assurance that it will get what it is paying for without unduly burdening the providers is the tension that will inure in this process. Another challenge will be how providers come together or organize themselves to maximize their opportunities in this program.

3.3.3 Provider-Provider Arrangements – Clinical Integration

Many providers who are interested in this model may find that there is a real advantage in formalizing their clinical understandings with each other. They may form virtual networks to coordinate their clinical care without creating legally organized entities such as IPAs and PHOs. Others may find it useful to actually create real corporate entities for these purposes. In addition, there may be an advantage, particularly for smaller physician group configurations, to join with other similar groups in more homogeneous aggregations of like specialists to achieve economies of scale in the costs of infrastructure as well as to learn from similar clinicians how to improve delivery of care both on quality and efficiency. Because PROMETHEUS Payment™ does not mandate any legal configuration of clinicians, the antitrust principles of 'clinical integration'are particularly relevant.

"Clinical integration" has meaning apart from, but completely consistent with, the position of the antitrust regulators in making it available as a vehicle for cooperative clinical behavior and collective bargaining with plans over rates. Clinical integration has been described as the coordination of patient care services across people, functions, activities, sites and time.[34]

> It involves coordinating inputs (equipment, supplies, human resources, information and technology) and intermediate outputs (preventive, diagnostic, acute, chronic and rehabilitative services) to achieve the primary goals of improving the quality, reducing the cost, and thereby increasing the value of patient care services.[35]

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[34] See Beck, Roblin and Selby, "Clinical Integration at the Service Delivery Level", (May 2001) http://depts.washington.edu/chmr/public/p0017/p0017_paper_h1_2001_Beck.pdf

[35] Id at 1, quoting Conrad

Surveying the range of initiatives involved in clinically integrating care, examples include the use of multidisciplinary health care teams of professionals (including primary care teams, hospitalist teams, and specialty care teams); integration in the context of chronic disease management including of diabetes, asthma, congestive heart failure, coronary artery disease and hypertension, and arthritis with the use of multidisciplinary care teams organized by clinical condition, using case management, self-care programs and patient education; primary care-specialty care interface with special attention to transition and referral among clinicians by means of restructured visits (e.g., mini-clinics, cooperative health care clinics, drop-in medical group appointments, enhanced specialist access through cellphone use); and integration by means of enhanced information technology.[36] All of these will enhance the chances of financial success under PROMETHEUS Payment™.

The antitrust enforcers, though, have focused on specific aspects of cross-provider clinical integration as worthy of protection under the antitrust laws. Fee bargaining behavior which would be per se violative of naked price fixing prohibitions is permissible when otherwise competing clinicians come together in the interests of clinical integration.[37] Published more as a statement of opportunity rather than a clear safety zone, the FTC and DOJ enunciated characteristics of a physician network that would not be per se violative of the rules against collusive fee bargaining if they engaged in certain behaviors including (1) the explicit use of protocols, guidelines or pathways; (2) utilization management and/or review programs to evaluate claims prior to submission; (3) going to the expense of developing or buying the infrastructure to permit these reviews to occur; (4) profiling the clinicians to identify those who were not measuring up; (5) taking action with respect to those who did not meet the network's standards; and (6) sharing data with payors.[38] A network of physicians with a hospital or hospitals also is explicitly acknowledged as legitimate when they are engaged in such activities.

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[36] For this discussion we are focusing solely on cross-provider integration although other initiatives around clinical integration which are also effective and relevant to the quality and efficiency goals of PROMETHEUS Payment™ include integration within a single organizational structure such as Virginia Mason Medical Center's restructuring of hyperbaric oxygen therapy, among other services, in terms of location of services and facilities within the hospital to facilitate improved clinical interactions among providers. http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/ImprovementStories/VirginiaMasonMedicalCenter/ImplementsLeanManagementPrinciplesTo DireveOutWaste.htm Other healthcare systems are using similar principles to consolidate and integrate services. (Bazzoli, "Pulling the Pieces Together: Consolidation and Integration in Health Care Systems", (June, 2005) http://www.washington.edu/public/p0044/

[37] For an excellent elucidation of the development and purposes of clinical integration, see Leibenluft and Weir, "Clinical Integration: Assessing The Antitrust Risks," in Gosfield, ed., HEALTH LAW HANDBOOK, 2004 Edition, WestGroup, pp. 1-47.

[38] Federal Trade Commission and Department of Justice, "Statements of Antitrust Enforcement Policy in Health Care", Aug. 28, 1996 at Statements 8 and 9, http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm

Because as prosecutors, the enforcers do not want to offer unintentional protection to activities they do not understand well, they have been unwilling to provide any greater definition of what qualifies as integration. They also take the position that they do not want to stifle innovation by providing what would be perceived as directive guidance as to what constitutes legally sanctioned clinical integration. They have issued only one advisory opinion that approved a network as likely to be considered integrated, even while holding out the right to enforce if the physicians did not act as they described their plans.[39]

By June 2006, more than nine years after the initial statements offering clinical integration to physicians were made, the FTC had taken action against 22 IPAs and seven PHOs for price fixing, with almost all of the action occurring after 2002.[40] In all of these, clinical integration was offered as the opportunity the networks had missed; in other words, had they been sufficiently clinically integrated, there would have been no enforcement and no settlement.

There has been considerable speculation about why this significant opportunity for physicians to improve quality while they bargain collectively over rates has been so little used. Prime among these is the continued fragmentation of physicians into very small practices: 75% of physicians are still in groups or eight or fewer and 53% work in groups of 1-3.[41] Although risk contracts which can meet the standards for the financial integration safety zone have been fading fast, many IPAs, it is believed, are negotiating some level of risk and engaging in some level of messenger model arrangements, taking the chance that they will not be enforced against. Paradoxically, lack of clarity of what constitutes clinical integration has contributed to physician reluctance to even attempt something which does not fall squarely into a safety zone. When enforcement comes, it is an expensive proposition to negotiate a settlement and get out from the enforcers' scrutiny. There have been few obvious financial incentives as perceived by physicians, who approach managed care contracting with fear and dread given what they see as the far stronger negotiating power of the plan. Yet, as Casalino has observed, there are significant ways in which clinical integration can increase physician revenues:

> (1) by providing a safety zone for the negotiation of non-risk contracts at higher rates than the physicians would otherwise receive; (2) by improving the IPA's scores on quality (and/or cost control) measures in contexts where health plan pay-for-performance programs reward better scores; (3) by reducing administrative costs of the IPA and/or its physicians, and (4)

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[39] Letter from Jeffrey Brennan to John J. Miles (Feb. 19, 2002). http://www.ftc.gov/bc/adops/medsouth.html

[40] For an excellent consideration of the policy issues in the creation of and use of the clinical integration antitrust 'standards' see, Casalino, "The Federal Trade Commission, Clinical Integration and The Organization of Physician Practice," 31 J. Health Pol. Pol'y & L 569 (June 2006).

[41] Id at 571

> by increasing the volume of visits and/or procedures provided by the organization's physicians.[42]

In the context of PROMETHEUS Payment™ though, the virtues of clinical integration are inescapable. The payment model itself directly rewards clinical collaboration for efficiency and quality. The organization of clinical processes to achieve the best financial result drives directly to the principles of clinical integration to improve quality; and, as required by the FTC/DOJ Statements, the fee bargain (the agreement on the specific dollar amount for the services) is ancillary to the organizational mandate to change behavior in this way. PROMETHEUS Payment™ does what all the prior forms of payment have not been able to do -- at its core and as one of its primary principles it is designed to motivate clinical collaboration by otherwise independent clinicians.

Given the parameters of safety under the antitrust laws for clinical integration, documentation of the function and process of clinical integration of providers under the PROMETHEUS Payment™ model, in formal contracts, may not only facilitate recognition by enforcers of what clinicians do as qualifying as true clinical integration, but such organization may itself actually improve the quality and efficiency of care by the physicians who come together. Generally it would be recommended that the agreements among the parties who claim to be clinically integrated should be documented in formal contracts, although that is not a requirement of the mechanism. Those principles of engagement would have to address the payment arrangements – either all clinicians bill and collect independently or one entity takes the money and distributes it to others. Both models would be consistent with clinical integration. In the latter context, however, how monies are allocated is critical since squabbles over which piece of the monies paid belongs to whom contributed to the downfall of many of the failed PHOs of the early 1990s. PROMETHEUS Payment™ provides far greater clarity regarding which provider should be paid for what by grounding payment on the CPG. Who renders the service in the CPG provides an easy basis for such allocation. In clinically integrated structures, the corporate entity which may take payment for others to distribute to them in essence functions in place of the plan in allocating the dollars in accordance with how the CPG was provided.

The bases for corrective actions for those not measuring up would have to be stated in the organizing documents so the parties understand that more intense review and monitoring of care, refusal to submit claims which are deemed inappropriate, and potentially terminating the lagging provider from the network would be relevant to the success of the undertaking of all. These are not the only actions which might be taken but they are implied in the relatively limited guidance available.

Mechanisms to share data among the participating providers to obtain the full advantage of learning from those who are particularly successful would have to be addressed, consistent with HIPAA provisions pertaining to organized health care

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[42] Id at 575

arrangements (OHCAs). (See 3.5.1 below). How data will be reported to payors and when is important and, consequently so is it important to address the rights of the participating providers in reviewing and assuring the accuracy of data maintained and provided to others about them. Moving from the provider side of PROMETHEUS Payment™, how the program is implemented by plans and others also entails legal concerns.

3.3.4 PPI Relationships with Plans and Service Bureaus

PROMETHEUS Payment™ is a health insurance plan-based payment model. It requires a health plan to implement it since it addresses how providers are paid to deliver services to patients. We know that plans are loathe to change their internal mechanisms; and many are wedded to legacy information systems. To gain plan acceptance, the Design Team made the program as 'plug and play' as possible, so that the software "engine" required to allocate dollars among participating providers, track whether they have kept within their budgets when they are paid fee-for-service, give providers actionable information about their progress along their portion of the ECR, and gather data and analyze it within the Scorecard, which is then reported publicly, all resides within proprietary software that will be licensed to service bureaus --- separate corporate entities who may perform this function for multiple health plans. How data flows between the plan and the service bureaus will be the principal operational challenge for the plans who implement PROMETHEUS Payment™.

The Design Team also understands that with a new program of this kind there will be uncertainty as to its impact. Although there can be no claims made regarding true 'budget neutrality', plans will be concerned that implementation may increase their costs, despite the fact that by eliminating many medical management programs they use today, their administrative burdens will be reduced along with the reduction to the providers. While the plans will fear providers gaming the system, plans may have an incentive to add their own fillips to the basic PROMETHEUS Payment™ system. Some of these needs can certainly be accommodated, but others will fall into the arena of violating some of the basic tenets of the program. Plans will, therefore, be required to adhere to quality controls associated with the PROMETHEUS Payment™ trademarks.

Some of these include the requirement to use PPI-approved, endorsed or created ECRs™ as the basis for payment. Homegrown ECRs™ based on idiosyncracies are unacceptable as PROMETHEAN. There will be a process for others, outside of PPI, to submit case rates for adoption by PPI, but all must be consistent with the tenets of creation expounded by the Design Team. Plans must use only endorsed and approved service bureaus and must adopt the program in its totality for the conditions they are paying in this way. They may not pick and choose among the design elements they like. This is an all or nothing proposition for the conditions they include.

The plan must offer a real opportunity for negotiation with the provider regarding the portion of the ECR™ he or it seeks to provide. Many providers may choose simply to accept the portion of the ECR™ which was estimated to be relevant to their provider type

when the ECR™ was constructed, but the plan cannot insist on that approach only. Providers vary so widely, even within the same specialty, with regard to the resources they have available that it would be impossible for a plan to prejudge this. For example, cardiology groups vary in whether they have interventionalists within the group, clinical laboratory and imaging services in-house or even cardiac rehab as part of their practices. A twenty physician group will have different capacities to render care than a three person group. Physicians who have joined in clinically integrated networks may approach these issues differently from those who remain completely independent. For all of these reasons, provider groups will approach the ECR™ in different ways. This is one of the essential principles of equity – paying a fair amount for the constellation of services the specific provider configuration will bring to bear to deliver a portion of the ECR™.

Plans must offer complete transparency of all features of the program. They may not use black boxes in their dealings with patients, consumers or providers. This means that pricing, scores, appeals mechanisms, CPGs, and ECRs™ based on them must all be made known, publicly, prior to their use in any way in the program. Some of these principles of complete transparency will be more difficult for some stakeholders to accept than others. Plans have traditionally been reluctant to share information about the inner workings of medical management programs which they believe give them a market advantage. Providers, on the other hand, are wary of publicly reported data unless they can be assured of its accuracy and that the manner in which it is reported protects against misinterpretation. There will be a process available to providers to challenge inaccurate data which is populating the Scorecard, but once those matters are addressed, the data and the prices will be made public.

Although it is possible based on pilots, that we will find that the Performance Contingency Funds initially established at 10% on chronic care and 20% on acute care will have to be altered to have a stronger effect, there are limits below which the basic concept that the provider is being paid a fair price for all the services science says he should deliver to the patient would be violated. Some might argue that any withhold disadvantages the provider by denying him full payment for what he must deliver. The Scorecard, though, measures whether the salient features of the CPG were provided. If they were not, and as a result, the provider is not paid the full quality withhold, neither did the provider incur the expenses associated with providing the undelivered service, so he is not really disadvantaged. To go below the established withholds, however, could produce the feared effect. Therefore, plans will not be allowed to alter these withholds without some approval from PPI to assure that this basic tenet is in place.

All of the appeals processes which pertain in the overall design of the program must be made available in a meaningful way. By the same token, the decision of the service bureaus regarding the matters within their purview, may not be revisited or overridden by the plan. As it always does, the plan will manage co-pays, benefit design, coverage and enrollment of patients and subscribers as well as whether a provider is eligible for PROMETHEUS Payment™ or will be terminated once in the program. The plan actually pays the providers. But the allocation of the dollars among the providers

treating within the ECR™, the calculation of the scores, and the production of the Scorecards are all within the authority of the service bureaus.

The tri-partite structure that will make PROMETHEUS Payment™ work must be consistent with its design tenets. This will require a contract to license the trademarks and program from PPI to the plan for a fee and also from PPI to the service bureau at no charge, since the plan pays the service bureau for the data services it provides. Closing the loop, there will be another agreement between the plan and the service bureau documenting the allocation of responsibilities and authorities and how the service bureau is paid, all consistent with the design principles.

3.3.5 Other Trademark and Intellectual Property Licenses

The work of creating PROMETHEUS Payment™ has been performed by a Design Team of volunteers who have worked at monthly meetings for no compensation including all the work between the meetings. For two years, there has been no staff. There is only the Design Team. There will be additional conceptualization that will be necessary as the program unfolds; and the point of the pilot projects will be to learn how to improve the program based on real life experience.

The initial ECRs™ focus around five clinical areas: (1) preventive health --- all of the services recommended by the United States Preventive Health Services Task Force will be in one case rate;[43] (2) cancer care, modeling lung and colon cancer; (3) interventional cardiology, modeling non-ischemic congestive heart failure, ST elevated myocardial infarction, and mitral valve regurgitation; (3) primary care focusing on diabetes and depression; (5) knee and hip joint replacement. While these were selected for their prevalence in the commercial population, the availability of good, current CPGs addressing them, and their sweep and scope in terms of types of providers involved in rendering the care in multiple settings, they hardly represent the bulk of what is eligible for payment on this model.

The mechanism that was used to construct the initial ECRs™ will have to be scaled up for the program to be widely applied. This means that others will have to conduct some of the work. The methods used by the Design Team, while copyrighted in terms of their description, are open and available for others to apply. Should the original approaches merit change, they will have to be adopted as PROMETHEUS Payment™ methods to maintain consistency in trademark control. To the extent any others would seek to participate in this work and use the intellectual property created so far, they will have to sign intellectual property licenses with PPI to do so.

The members of the Design Team have been working under confidentiality agreements which have prevented the release of information until it was ready for primetime, but there has also been a recognition that at least two critical members of the Design Team will also have a role to play in the actual implementation of the program

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[43] USPHSTF, "Guide to Clinical Preventive Services, 2006", http://www.ahrq.gov/clinic/pocketgd.htm

going forward. Michael A. Pine and Associates, Inc. was engaged as a vendor to develop both the early components of the Engine to create ECRs™ from CPGs and the mechanism by which they will be allocated to treating providers. The RAND Corporation, through Beth McGlynn, is involved in the development of the Scorecard. They will license their intellectual property to PPI but will also have licenses back to do their work both in furtherance of the payment model itself and commercially with those who would adopt the program.

If others in the field develop work that will advance the diffusion and implementation of PROMETHEUS Payment™, if they seek to claim involvement with the brand, they will be subject to the trademark controls and licenses. If they come forward with work product -- like new ECRs™ -- they would seek to have branded with the trademarks, those will be subject to licenses too.

A model for the type of approach PPI will take is that of the National Comprehensive Cancer Network®, a coalition of 20 of the leading cancer centers around the country. They have developed clinical practice guidelines which are widely available at no charge for application in clinical settings in the treatment of patients. They are available on the web. They are published in the Journal of the NCCN. They are discussed at length at annual and regional meetings about them. They have been distributed throughout the country on CD-ROM. They have been translated into multiple foreign languages and for use by consumers. All of this has been made available to the public, plan and provider communities at no charge because of the generosity of those pharmaceutical companies and others who contribute to the tax exempt purposes of NCCN®. The guidelines themselves are, however, copyrighted and subject to all the traditional protections of copyright to maintain and assure the intellectual integrity of their science.

Similarly, providers who seek to position themselves for PROMETHEUS Payment™ are certainly free to do so without any license or other authorization from PPI. Plans, on the other hand, will have to pay royalty fees to PPI for the use of the brand and the infrastructure, as implemented by the service bureaus. This will finance the on-going work of the not-for-profit entity PPI which will be considerable, including with regard to appeals of various aspects of the program design.

3.4 Appeals and Potential Disputes

Any payment model where the total payment amount varies in accordance with some judgment cannot help but create points for potential dispute. Some of these disputes may turn on philosophical differences with the design of the program. Some may turn on the application of design components to a specific provider; still others will turn on whether a specific judgment was made effectively. The range of the issues likely to arise are, indeed, fairly wide. The Design Team has confronted a host of these, although others which are not anticipated are also likely.

3.4.1 Design Problems

There are some significant potentially contentious issues embedded in the operation of PROMETHEUS Payment™ which are beyond the scope of a consideration of this kind. For example, the Design Team has taken the position that no one will be paid for care that is associated with a "never" event as defined by the National Quality Forum[44] including everyone involved in the delivery of that care. For example, if the surgeon operates on the wrong leg, neither the hospital, the surgeon, nor the anesthesiologist involved in the "never" event will be paid for their care in creating the 'never event'. The referring physician, however, would be paid. The physical therapist rehabilitating the patient subsequent to the event would also be paid. PPI recognizes that plans may choose to pay for these "never" events, rather than risk provider appeals and provider relations problems. That certainly is a plan decision about which PPI would not mandate a policy. The Design Team strongly recommends that "never" events should not be rewarded, but plans could choose to do otherwise.

Similarly, the program will not pay for hospital readmissions caused by a premature discharge. To address this problem, when a patient is readmitted within 14 days of a previous discharge, it will be presumed that the second admission related to the first and therefore the entire cost associated with that care will be counted as one admission. Any disputes with these basic design principles would fall into the category of matters to be raised to PROMETHEUS Payment™, Inc. to be considered for design reform. Similar issues would include the choice of CPGs on which ECRs™ are based and, whether any ECR™ has been defined appropriately. The definitions of the condition-modifying circumstances and the scope of those condition modifiers would all be addressed to PROMETHEUS Payment, Inc. ™ and not in the context of payment to individual providers.

New technologies, drugs and procedures may arise subsequent to the selection of clinical guidelines. PROMETHEUS Payment™ will make determinations as to how to revise the scope of the ECRs™ based on information presented to it around those matters, since the argument for the addition of new technologies or procedures in a ECR™ is really the suggestion for use of a different, better clinical practice guideline.

The following issues are not appealable by individual providers but only with regard to the design of the program: the scope of the ECR™; the definition of the scope of the portion of the ECR™ for which the provider will be paid (since that is the subject of negotiation and will be documented in the contract amendment between plan and provider); the rules pertaining to when an ECR™ is triggered, broken, condition modified or concluded. That said, there are inevitable issues that will be appealed and the balance as to whether they are appealed directly to the plan under its ordinary appeals mechanisms, or to the service bureaus under appeals mechanisms to be provided there, is another matter of consideration.

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[44] "Serious Reportable Events in Healthcare: 2005-2006" http://216.122.138.39/projects/completed/sre/index.asp

3.4.2 Service Bureau Appeals

The service bureaus which manage the data that is the foundation for the PROMETHEUS Payment™ model are the appropriate locus to review whether the application of the PROMETHEUS Payment™ principles has been proper in a specific case. The first obvious issue of this type is whether the ECR™ was triggered at all. Since this turns on the relevant ICD-9 codes submitted by a physician in a claim, whether the right codes were submitted and when the ECR™ was triggered will be a matter over which there might be some dispute. As a matter of fact, we anticipate that one of the disputes may be around which physician becomes the "managing physician" whose claim submission triggered the establishment of the ECR™. There is no major significance to this acknowledgement except that by the inherent operation of the model, the 'managing physician' has some greater control over his financial risk for the behavior of other providers because his referrals drive those selections. He need not be a primary care physician. He is not a gatekeeper and is not paid any more or less than what the overall principles would generate; but someone triggers the ECR™. Then, there may be instances when two physicians may want to claim the same portion of a ECR™. For example, both a family physician and a cardiologist might have contracted to deliver the same piece of an ECR™. Since patients may go to either or both, both might think they are managing that piece of the ECR™. Because the basic incentive of PROMETHEUS Payment™ is to motivate clinical collaboration, if two physicians seek to be the managing physician, triggering the ECR™ and driving many of the resulting referrals, the service bureau will notify the two physicians and give them the option of determining who will be the managing physician and who the consultant. If they cannot agree, the ECR™ will be broken and they both will get paid fee-for-service, or under whatever other payment rules would govern their behavior in the absence of PROMETHEUS Payment™.

The issues which turn on data in claims are appealable for review by the service bureau. These include when a ECR™ was triggered, concluded or broken, the specific allocation of payments among providers, and whether condition modifiers apply in a specific clinical situation. Issues associated with the Scorecard are appealed to the service bureau which maintains the data and reporting of the Scorecard. Providers will be given the opportunity to review data before it is made public and to offer clarifying statements like the opportunities credit bureaus offer to the subjects of their reports. Whether a provider qualifies for payments out of the Performance Contingency Funds turns on the Scorecard, so these issues would be raised to the service bureau, since they involve data concerns. Determining the portion of the Funds for which a provider qualifies as determined by the pro rata calculation resides with the service bureau. In contrast, the actual money issues are lodged with the plan as they always have been.

3.4.3 Appeals to Plan

The plans actually pay the dollars driven by the model. Disputes regarding whether the dollars paid correspond to the data generated by the service bureau are appealed to the plan. Issues associated with fee for service claims paid and their

reconciliation to the ECR™ portion negotiated by the provider is appealed to the plan when there are disputes over the amounts paid in the reconciliation. The reconciliations of the Performance Funds against the services actually provided which reflects the translation of the scores in the Scorecard into actual pro rata dollars, are all matters which are appealed to the plan which is paying the provider.

When the provider is terminated from the PROMETHEUS Payment™ program on account of consistently not providing the minimum threshold of services, that appeal would be made to the plan. Whether a provider can be eligible to participate in a plan sponsored implementation of PROMETHEUS Payment™ would be appealed to the plan.

3.5 Legal Issues

One of the overarching concerns of many of the providers who get referrals from physicians from the operation of PROMETHEUS, where their economic fates are tied together in the Scorecard payment, would be whether the model would implicate the anti-kickback or Stark statutes. Happily, since the first iterations of PROMETHEUS Payment™ pilots will be commercial only, those statutes are not called into play. Nonetheless, even if this were applied in Medicare or Medicaid, the beauty of PROMETHEUS Payment™ though, is that it does not involve gainsharing as the OIG has addressed it, nor any payments for referrals. Each participant is paid an amount that reflects his own money and not money paid for referrals or for ordering, providing, furnishing, recommending, leasing or arranging for the provision of any service, item or good. There ought not be any liability under any of these statutes which reflect the problems created by other payment models.

In addition to the now virtually traditional contractual issues that arise between providers and plans in managed care, the contracts which support PROMETHEUS Payment™ are as likely subject to claims of breach as any other contract. In addition there are other potential bases for legal claims.

3.5.1 Regulation – Managed Care and HIPAA

The first regulatory issue surrounding the implementation of PROMETHEUS Payment™ is state regulation of managed care plans. In many states, in the era of so-called "anti-managed care laws",[45] legislation pertaining to prompt payment, patient access to providers and provider dissatisfactions with plan payment procedures were addressed with regulatory mandates. There is little in PROMETHEUS Payment™ to raise concerns with regard to these issues, even though the program is primarily oriented around how to pay providers. Regulation regarding the providers' right to appeal the plan's payment to them will be relevant. But since under PROMETHEUS Payment™ the plans continue to pay either prospectively on a monthly basis like capitation or post-service delivery fee-for-service with a reconciliation afterwards, there should be no

[45] See, for example, Platt and Stream, "Dispelling the Negative Myths of Managed Care: An Analysis of Anti-Managed Care Provided by Health Maintenance Organizations", 23 Fla. St. U.L Rev 489 (1995).

disruption in the qualification of the plans implementing PROMETHEUS Payment™ with respect to their regulatory obligations under state law. The role of the service bureaus ought not represent any complication since they administer data but do not pay claims. Still, it is always possible an aggrieved provider may raise the role of the service bureau in a complaint regarding the plan's payment to him/it.

From a different perspective, there might be concern with regard to the data demands of PROMETHEUS Payment™ implementation. One of the critical features of PROMETHEUS Payment™ is the application of the Scorecard. Without it, the administrative burden reduction cannot be accomplished and the allocation of dollars which create the incentives which will improve the quality of care will not have much impact. Therefore, any legal barriers to the easy accumulation and analysis of data within the Scorecard would be problematic. It almost goes without saying that Health Insurance Portability and Accountability Act privacy rules are applicable. Fortunately, the PROMETHEUS Payment™ model appears to track directly to the relatively vague concept of "organized health care arrangements" (OHCA) where otherwise covered entities come together in common clinical purpose. Where an organized healthcare arrangement exists, the covered entities can (1) exchange protected health information about an individual for any healthcare operations activity of the OHCA; and (2) they can utilize a single joint notice of privacy practices. A joint notice would feed nicely into the spirit of administrative burden reduction that is one of the guiding principles of PROMETHEUS Payment™.

The OHCA concept was created in the final privacy rule, "to describe certain arrangements in which participants need to share protected health information about their patients to manage and benefit the common enterprise."[46] Among the described arrangements are those entailing a clinically integrated setting in which individuals receive healthcare from more than one healthcare provider; and an organized system of healthcare in which more than one covered entity participates, and in which the participating covered entities (a) hold themselves out to the public as participating in a joint arrangement; and (b) participate in joint activities that include utilization review, quality assessment and improvement activities, or payment activities. The fundamental nature of the OHCA lies in the perceptions of the individuals who obtain services from the OHCA leading to an expectation that the arrangements are integrated and that the collaborators will jointly manage their operations. Given the common enterprise of clinical collaboration and the Scorecard impact of the care rendered by all of the providers treating the patient, to the extent that protected health information (PHI) must be shared among them, the PROMETHEUS transactions should meet these definitions.

Whether the providers will want to avail themselves of the OHCA opportunity is not clear. Although activist lawyers may create burdens in this process in any event, the ability to use a joint notice of privacy practices among all of the providers treating the patient under PROMETHEUS Payment™ on a single or multiple ECRs™ would simplify administrative burdens otherwise associated with those notifications.

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[46] 65 Fed Reg 82494 (Dec. 28, 2000)

If the PROMETHEUS Payment™ participants choose to utilize a joint notice, they all must agree to abide by the terms of the joint notice with respect to PHI created by each of them, as part of their participation in the joint enterprise.[47] A joint notice of privacy practices may not be useful, though, and could be redundant, since there is a considerable range of activity of the providers-- with other payors and on other care even with the same payor -- that will not fall under the PROMETHEUS Payment™ rubric. It is more likely that providers who might otherwise qualify under the OHCA provisions will choose to keep their own notice of privacy practices.

The role of the service bureau is as a business associate to the plan, aggregating data and producing Scorecards and reviewing appeals and complaints to it regarding those determinations. The Scorecard reveals data including clearly protected health information among the providers treating the patients, even when those providers may not explicitly collaborate with each other. These activities are also protected as health plan operations. Finally, there are some who have speculated that the "holding out" of providers as being engaged in a "joint enterprise" as an OHCA could create liability issues that otherwise would not exist. However, under PROMETHEUS Payment™, there are some liability issues that will arise under any circumstances.

3.5.2 Liability

Some of the potential liability concerns in PROMETHEUS Payment™ will turn on the model's foundation of payment on clinical practice guidelines. Throughout the history of health policy regarding standardization of clinical care to science, there has been anxiety about whether the use of guidelines will adversely heighten the legal standard of care. The swift adoption by many hospitals of the goals of the Institute for Healthcare Improvement in the 100,000 Lives Campaign, has been seen to have altered the standard of care for them.[48] Some have argued that the performance standards associated with the purchasing principles of The Leapfrog Group also create potential liabilities.[49]

To the extent that there are these anxieties, they have long been in existence and there is little reason for more fear from PROMETHEUS Payment™ implementation. Most clinical practice guidelines represent what is already seen as the standard of care and therefore failure to deliver the guideline does not exacerbate liability since the liability existed anyway. Rather, it is hoped that with PROMETHEUS Payment's™ incentives, by the application of a payment model that is far more consistent with the delivery of science-based medicine, the frequency of delivering the standard of care will

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[47] 45 CFR §164.520 (d)(1)

[48] Gosfield and Reinertsen, supra n. 28

[49] Mello, Studdert and Brennan, "The Leapfrog Standard: Ready to Jump from Marketplace to Cartoon?" Health Affairs (March/April 2003) pp.46-59

increase, thereby diminishing the number of mistakes and failures of care which lead to lawsuits.

That said, there is the potential for some additional implications to be drawn from the payment model in that the minimum quality threshold for Performance Contingency Fund eligibility establishes one level of performance, whereas the pro rata payment for "partial" quality is evidence both of the expectation that not everyone will score 100 in every instance as well as of the "failure" in specific cases to provide everything. Since the aggregate scores will be made public, the extent to which providers meet these guidelines and principles would presumably be admissible in a court of law. The real question is, what would that be admissible to prove.

Where providers bargain to deliver care and fail to provide what they have bargained for, there are potential contract theories of liability. Some have recently postulated that the intersection of these contract claims with tort claims have created a new concept of "contort".[50] The real issue for tort liability is a harm to the patient and its causation. PROMETHEUS Payment™ essentially supports the delivery of a standard of care which may only be partially delivered. Unless the patient can demonstrate a nexus between the harm and the failure to fully deliver care, though, the case will not succeed. The system does not create additional tort liability but merely data potentially relevant to the claim.

On the contract side, the typical damages for a contractual breach are *quantum meruit,* the value of what was not provided. So, one might imagine a patient suing a plan to get a service or procedure encompassed in an ECR™ budget which was not provided; but since PROMETHEUS is a payment model, and it lives between the plan and provider, the patient is the incidental beneficiary of that payment relationship. Still, there is at least one similar high profile managed care case in the era when there was burgeoning litigation over the incentives in managed care and control of utilization, when most cases against plans failed because of ERISA preemption. A suit for damages was postured with the novel argument that the failure to provide a blood test was not malpractice but a failure to supervise the providers rendering the care. The intent was to avoid the problem of the ERISA pre-emption bar to plan liability. The argument succeeded on that score.[51]

Some providers might look at these potential liabilities and decide that the risk of malpractice liability from failure to deliver what good guidelines would call for is too great. They may take the view that because the PROMETHEUS Payment™ system will create data regarding patterns of behavior, they do not want to implicate themselves if they consistently fail to perform effectively or deliver everything the ECR™ budget provides for. Providers with those anxieties already must be paralyzed with fear since all

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[50] Morreim, "High Deductible Health Plans: New Twists on Old Challenges from Tort and Contract", 59 Vanderbilt (2006) pp.1207-1261

[51] Dukes v. US Healthcare, 1995 WL 361723 (3d Cir., PA)

of the new efforts regarding transparency, performance measurement and scorecards contain precisely the same dangers. Publicly reported measurement per force entails comparison.[52] This entire movement will create invidious comparisons for those who do not measure up. That is the point. Measurement and transparency do not create liability. Liability lies in negligence of clinical processes. One of the major purposes of PROMETHEUS Payment's™ incentives is to make it easier for providers to do the right thing for their patients and be paid fairly for their work.

Still, the transparency in the operation of the PROMETHEUS Payment™ program will provide more information which could be drawn into malpractice litigation. Plaintiffs' lawyers have been able to use data developed for performance measurement and report card purposes to imply invidious comparisons between high scoring care within a single institution versus its own low scoring care as bolstering evidence of a failure to perform effectively. Still, for all the potential anxiety around liability, the liability is not created by the data. The liability is created when a patient suffers an injury where there was a duty to the patient that was breached. The data merely acts as a bulwark to the plaintiff's claims, but provides no new cause of action.

In addition, to the matters noted, above, the potential uses of PROMETHEUS Payment™ Scorecard data are virtually unimaginable in scope. Patients might claim that they were misled by high scores to seek out practitioners who subsequently harmed them. The plans could be sued for implying the providers were of higher quality than what the patient experienced. In the last analysis, these concerns are misplaced, since the entire purpose of changing to the PROMETHEUS Payment™ model is to provide an environment in which improved healthcare quality will thrive and providers will find good reason besides their moral obligations and strong sense of professionalism to provide patients what science says they need for their medical conditions.

3.6 Conclusion

The PROMETHEUS Payment™ model represents the potential for significant change in the payment context within which providers interact with patients. Its goals are those which have been long sought but persistently elusive in the American healthcare system. The widespread failure to provide optimal quality is in no small part related to the countervailing forces of the existing payment systems. To make PROMETHEUS Payment™ a practical solution on the ground, its surrounding legal context and the contracts which will create it will be important. Undoubtedly there will be problems, disputes and anticipatory negotiations associated with its application. As with the rest of the program, much will be learned in pilots; but, as with all similar contractual undertakings, the bulk of the liabilities and disputes that will arise will not be known until the program has been in place for some time. Today, familiarity with the concepts of PROMETHEUS™ Payment and the legal construct that will create it will help attorneys for plans and providers to assist their clients in fulfilling the moral obligations of their

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[52] For a discussion of the fast burgeoning world of performance measurement and its liabilities see Gosfield, "The Performance Measures Ball: Too Many Tunes, Too Many Dancers?", in HEALTH LAW HANDBOOK, 2005 edition. WestGroup, pp. 227-283

roles in the American healthcare system.