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THE NEW VALUE ON PROVIDER "VALUE"

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The New Value on Provider "Value"

Efficient/efficiency:	*89*
Value/value-based:	*115*
Effective/effectiveness:	*146*
Quality:	*483*

The consolidated print of the Patient Protection and Affordable Care Act is 907 pages long. The first 216 pages are mostly about expanded insurance coverage. Beginning at page 216 to page 346 and then picking up again at page 387, the legislation sets forth a decidedly different vision for the delivery of American healthcare than has ever existed before. The tally above is how many times in the legislation the listed words appear. [1]

References to "quality" include the following phrases, repeatedly and throughout: high quality, quality improvement, quality reporting, quality measures, quality data, quality of care, quality performance. There are also more than 260 references to evaluations of programs by the Secretary or others. This law is -- in a very significant way-- about improving the quality of American healthcare, rewarding more efficient care, and eliminating wasteful spending. Although not the subject of this chapter, in the new mandates for health insurance, there are explicit references to consumers getting "value" for their health care premiums and how that will be measured.[2] The Medicare Advantage and Prescription Drug programs are similarly replete with references to improved value and measurement of performance.

The actual words 'value-based purchasing' appear only in specific sections, but the totality of the emphases in the many mandatory, pilot and demonstration programs which are relevant to providers, and even the voluntary opportunities like the Accountable Care Organization (ACO) 'shared savings program,' all reflect a new demand for 'value' – demonstrably improved quality with contained costs. The reality the law posits is one in which Medicare and Medicaid providers – facilities, health care systems, and physicians –will have to change their behavior to succeed and, indeed, survive.

_.1 The Past Is Not Prologue

While much of the health system response to the legislation has been for hospitals to become mired in strategies reminiscent of the mid 1990's[3], including an inexplicable fascination with becoming an ACO, mergers among hospitals[4] and the employment of

[1] I did not include in the word count provisions related to Medicare Advantage or Part D, the prescription drug program, focusing my attention on provisions relevant to providers, although they have similar references. This chapter is focused on how PPACA will affect providers.

[2] PL 111-148 and PL111-152 Consolidated Print (hereafter "HR") §1003

[3] Burns, Anderson and Shortell, "Hospital-Physician Relationships," Health Affairs (Fall 1993) pp.213-223.

[4] Pear, "Consumer Risks Feared as Health Law Spurs Mergers," NY Times, (Nov. 21, 2010) p. A1.

high priced specialists, the new reality is not what the last efforts at 'value purchasing' were about. Then, the concept of differentiating among vendors and purchasing healthcare of demonstrably better quality at a reasonable cost, was primarily initiated by employers in their relationship to managed care and health plans.

I first wrote about value purchasing in 1991[5] when the then nascent concepts of utilization management (as distinct from utilization review) and data dissemination associated with performance measurement were first being deployed to control costs in the private sector, with some attention to assuring that care was effective. I examined caselaw where payors were held liable for the consequences of denied care, employers struggled with containing costs, physicians were held liable for ineffective utilization review, and the like. The lack of sophistication in the techniques at work then is striking. Three years later, "on the verge of national health reform"(!), I looked at what then qualified as a sort of 'value purchasing' in Medicare, which I viewed as coming principally from a cost containment perspective. I focused on (1) the changing PRO program which had moved from an effort to safeguard against hospitals responding to the perverse incentives of the DRG payment system to a program to encourage improved care; (2) the development of the Medicare physician fee schedule based on the Resource-Based Relative Value System; (3) federal information, collection, data sharing and dissemination programs, (4) federal antifraud and abuse laws, and (5) the activities of the Agency for Health Care Policy and Research.[6] My view then was that federal policy followed a pattern which usually began with a focus on budgetary constraints which was only tempered after initial implementation with some attention to quality.

In the intervening years, Medicare policy has barely moved on the value front. There has been far more activity from private employers seeking to manage their health benefit expenditures. The National Committee on Quality Assurance (NCQA) was a very clear manifestation of this need, by making HEDIS a national quality measurement program, which gave employers information on which to select which health plans they would offer[7]. The Leapfrog Group began in 1998 as an effort through which large employers could leverage their purchasing power to propel hospitals to improve patient safety.[8]

Relatively recently, there have been more sorties in federal policy and legislation into the value-based arena. Beginning with what was first a voluntary hospital reporting program, Congress established that hospitals would have their Medicare payments reduced if they

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[5] Gosfield, "Value Purchasing and Effectiveness: Legal Implications", HEALTH LAW HANDBOOK, 1991 Ed, Gosfield Ed., Clark Boardman, NYC, 1991, p. 185-217

[6] Gosfield, "Value Purchasing in Medicare Law: Precursor to Health Reform", Am J. of Law and Med. Vol XX, pp 169-186 (1994)

[7] I served on the Board of NCQA for 12 years, from 1992-2003 and was Chairman of the Board for five years, from 1998-2002.

[8] www.leapfroggroup.org. 1206 hospitals now report their patient safety data to The Leapfrog Group.

did not report core measures[9]. A demonstration program with the Premier hospital network paid hospitals differentially based on quality performance with savings measured against other hospitals[10]. A Physician Group Practice Demonstration project for groups of more than 200 doctors tried a similar approach of improving quality, but provided no payment unless there was better economic performance against a comparison group of beneficiaries.[11] Beginning in 2008, following the lead of a number of commercial managed care plans, Medicare stopped paying for 'never events', such as wrong site surgeries, patient suicide, medication errors and more, whether by denial of payment or recoupment of monies already paid.[12] In addition, beginning in 2006, Medicare does not pay additional money on a hospital DRG for a hospital acquired condition, when in the past, such a condition could actually increase the amount of money the hospital was paid as a complication of care.[13] And Medicare has made available information about a wide variety of facilities' performance on their "Compare" websites, including hospitals, nursing homes, and home health agencies.[14]

But these initiatives do not begin to measure up to the breadth and number of new programs, pilots, boards, reports and websites that the health reform legislation will spawn in an effort to identify and apply techniques to contain costs while improving quality of care.[15] The need to "bend the cost curve"[16] while improving clinical performance is the major challenge. This is the value proposition of health reform. And the law is replete with new initiatives to support, bolster, facilitate, and reward good performance, with some penalties for sub-optimal performance.

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[9] See CMS "Hospital Quality Initiative Overview," (March 2005), http://www.cms.gov/HospQualInits/downloads/HospitalOverview.pdf. Mandated reporting was required by §501(b) of the Medicare Prescription Drug Improvement and Modernization Act of 2003. See CMS "Reporting Hospital Quality Data for Annual Payment Update" htt://www.cms.gov/HospitalQualityInits/08_HospitalRHQDAPN.asp.

[10] See http:www.premierinc.com/quality-safety/tools-services/p4p/hq/index.jsp

[11] Trisolin et. al., "The Medicare Physician Group Practice Demonstration: Lessons Learned on Improving Quality and Efficiency in Health Care," (Feb 7, 2008), The Commonwealth Fund, http://www.comonwelathfund.org/Content/Publications/FundReports/2008/Feb/The-Medicare-Physician-Grou-Practice-Demonstration-Lessons-Learned-On-Improving-Quality-and-Effici.aspx

[12] O'Reilly, "No Pay for 'Never Event' Errors Becoming Standard," amednews.com, (Jan 7, 2008) http://www.ama-assn.org/amednews/2008/01/07/prsc0107.htm

[13] See McNair, Luft and Bindman, "Medicare's Policies Not to Pay for Treating Hospital-Acquired Conditions," Health Affairs 28 No.5 (2009) pp.1485-1493

[14] www.medicare.gov

[15] Fraud and abuse enforcement and control of waste through inspection by auditors, recoupment of dollars and keeping those with a propensity to do bad things out of the program are in a highly increased mode as a result of the legislation, including converting violations of Stark and antikickback into false claims as well as failure to return an overpayment within 60 days as a false claim. But these issues are not directly value-based, although they will undoubtedly save money for the public programs.

[16] Cutler, "How Health Care Reform Must Bend the Cost Curve," Health Affairs 1131-1135 (June 2010).

While there are aspects to the law which feel like "A Thousand Pilots Blooming," in fact, there are clear and repetitive themes. For providers these fall mainly into three general approaches in Medicare, which are, in large part, now mirrored in Medicaid: (1) new payment conditions and models; (2) quality improvement and measurement initiatives; and (3) provider reconfiguration and innovation in delivery. In addition, there is the anomalous Congressional take on comparative effectiveness, which demonstrates a real ambivalence about confronting thorny issues inherent in 'value' judgments. This chapter describes these approaches and their implications to providers.

_.2 Payment Changes and Foreshadowing

While the legislation did not offer wholesale provider payment reform, there are a host of provisions which will change some payments significantly. There are enhanced payments for services considered more highly valued than others, and reductions or denial of payment for services that are subpar. In addition, an infrastructure which is already funded has been constructed to support innovations in payment. The law manifests an acceptance that the traditional models in Medicare of fee-for-service and Diagnosis Related Group (DRG) payment have neither saved money, nor produced desired quality results. Providing new financial incentives to providers to change their behavior and testing new ideas are hallmarks of the new programs.

_.2.1 *Value-based Purchasing Modifiers: Hospitals and Physicians*

The hospital value-based purchasing program will begin in FY 2012 and is mandatory for Medicare hospitals.[17] The Secretary will select measures against which hospital performance will be assessed. The conditions to be taken into account in measurement must include at least acute myocardial infarction, heart failure, pneumonia, surgeries as measured by the Surgical Care Improvement Project, and healthcare associated infections. In addition, patient experience of care will be assessed using the Hospital Consumer Assessment of Healthcare Provider and Systems (HCAHPS) survey. These conditions are already subject to measurement[18]; and some of the hospital acquired conditions already have payment consequences associated with them.[19]

The real difference now is that for discharges occurring during fiscal year 2014, the Secretary must include efficiency measures, including measures of 'Medicare spending per beneficiary', adjusted by age, sex, race, severity of illness and other factors the Secretary may select. Efficiency is what services cost. In selecting measures, the Secretary is to take into account appropriate factors such as practical experience with the measures, including whether a significant proportion of hospitals failed to meet the

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[17] HR § 3001.

[18] CMS "Overview of Specifications of Measures Displayed on Hospital Compare as of Dec. 14, 2006, " http://www.cms.gov/HospitalQualityINits/downloads/HospitalOverviewofSpecs200512.pdf

[19] See n.12 and 13 supra.

performance standard during previous performance periods, historical performance standards, improvement rates and the opportunity for continued improvement. So it is clear that the Secretary is not starting with conditions where hospitals are performing well. Rather, entirely the opposite is the case.

The Secretary is to develop a methodology for assessment of the total performance of each hospital in order to develop the "hospital performance score" for each hospital for each established period. Hospitals are given at least a year's advance notice of what the measures will be. Interestingly, the methodology must provide that the hospital performance scores will be determined using the higher of its achievement or improvement score for each measure. This creates an incentive for hospitals to continue to improve, but also to reach even higher levels of performance. The application of the methodology must result in "an appropriate distribution of value-based incentive payments… among hospitals achieving different levels of hospital performance scores, with hospitals achieving the highest hospital performance scores receiving the largest value-based incentive payments."[20] The law specifically states that the Secretary may not set a minimum performance standard.

So what is the financial incentive? Hospitals that meet or exceed the performance standards for the performance period for a fiscal year, will have their base operating DRG payment amount increased by the product of the base operating DRG payment amount for the discharge and the value-based incentive payment percentage. The value based incentive percentage is based on the hospital performance score of the hospital and the total amount of value-based incentive payments to all hospitals. Does this require new dollars? No. In fact, the value-based payments will be funded by reduced payments for all hospitals at the rate of 1% for fiscal year 2013, 1.25% for 2014, 1.5% for 2015, 1.75% for 2016 and for 2017 and succeeding years, 2%.

In addition to the payment effects, the Secretary will make information available to the public regarding the performance of individual hospitals with respect to each measure that applies to it, the performance of the hospital with respect to each condition or procedure, and the hospital performance score assessing the total performance of the hospital. Such information will be posted on the Hospital Compare Internet Website. In addition, the Secretary will periodically post aggregate information on the program including the number of hospitals receiving value-based incentive payments, and the range and total amount of such payments, as well as the number of hospitals receiving less than the maximum value-based incentive payment available to the hospital for the year involved.

Hospitals will have the right to appeal the calculation of the hospital's performance assessment, but there is no appeal of the methodology used to determine the payment amount, the determination of the amount of funding available, the establishment of the performance standards and performance periods, the measures, the methodology to calculate the scores, or the validation methodology. The Secretary is expected to ensure

[20] HR § 3006(a)(5)(B)(i)

that the measures used under this section are coordinated and aligned with quality measures applicable to physicians and other providers. The GAO will issue a final report no later than July 1, 2017, about the effect of the program on quality of care, as will the Secretary of HHS. Value-based purchasing demonstration programs will further be established for in-patient critical access hospitals, hospitals excluded from value-based purchasing, and then further to skilled nursing facilities and home health agencies.[21]

A separate provision establishes a value-based payment modifier under the Medicare physician fee schedule to be implemented in the same timeframe as the hospital program. The Secretary will establish a payment modifier that provides for differential payment for a group of physicians based on the quality of care furnished compared to cost during a performance period.[22] To the extent practicable, quality of care will be based on a composite of measures, which are always more difficult to score well on than single measures. The measures are both to reflect health outcomes and be risk-adjusted as appropriate. With regard to costs, beginning in 2014, physicians will be evaluated also based on a composite of appropriate measures of cost established by the Secretary, taking into account risk factors such as socioeconomic and demographic characteristics, ethnicity and health status of individuals. The modifier is to be applied in a manner that promotes systems-based care and must take into account the special circumstances of physicians or groups of physicians in rural areas.

The quality measures will be published no later than January 1, 2012 to be implemented for payment for the 2013 physician fee schedule. The program will be rolled out for specific physicians and groups of physicians, as the Secretary shall determine, beginning on January 1, 2015. But by January 1, 2017, the program will be mandatory with respect to all physicians and groups of physicians.

The costs that will be taken into account means "expenditures per individual as determined appropriate by the Secretary… taking into account the amount of growth and expenditures per individual for a physician compared to the amount of such growth for other physicians."[23] Moreover, the Secretary will coordinate the value-based payment modifier with the physician feedback program. (See Below).

The intersection of these two value-based programs is an enormously powerful motivation for hospitals to change their processes, for physicians to clinically integrate within their own groups, and for hospitals and physicians to work together on the same clinical conditions.[24] None of this requires that either own the other, nor that they be

[21] HR § 3006

[22] HR § 3007. How the "group" will be determined is not yet known. It may be self-selected based on the clinical conditions selected to measure.

[23] HR § 3007(p)(8)(A)

[24] Gosfield and Reinertsen, "Achieving Clinical Integration with Highly Engaged Physicians" (November, 2010) http://www.gosfield.com/pdf/ACI-fnl.1129.pdf

legally merged. It certainly does offer a goad to hospitals to pay attention to the performance of all the physicians they now employ!

_.2.2 *Hospital Acquired Conditions and Preventable Readmissions*

An additional incentive to reduce hospital acquired conditions will require a 1% reduction in the amount of payment that would otherwise apply to a hospital's discharges during fiscal year 2015.[25] This is actually a penalty because the top quartile of hospitals which reduce these conditions, by comparison with the national average, will be exempt from the payment reduction. A mirroring provision in Medicaid focuses more broadly on health care acquired conditions calling on the Secretary to identify state practices that already do this and apply them to Medicaid generally.[26]

A similar approach can be seen in the reduction in payment for hospital readmissions.[27] Here, for discharges occurring on or after October 1, 2012, the Secretary is to reduce payments that would otherwise be made to a hospital by an amount equal to the base operating DRG payment amount and the adjustment factor set forth in the statute for that year. The "adjustment factor" is equal to the greater of 1 minus the ratio of the aggregate payments for excess readmissions and the aggregate payments for all discharges with respect to such hospital or the "floor adjustment factor". The "floor adjustment factor" is .99 for fiscal year 2013, .98 for fiscal year 2014 and .97 for fiscal year 2015 and subsequent years. "Aggregate payments for excess readmissions" means the base operating DRG payment amount for such condition, the number of admissions for such condition, and the excess readmissions ratio minus one. The "excess readmission ratio" means the ratio of the risk adjusted readmissions based on actual readmissions (as determined consistent with the readmission measure methodology) to the risk adjusted expected readmissions for such hospital for such condition. The term "applicable condition" means a condition or procedure selected by the Secretary among conditions and procedures for which readmissions are high-volume or represent high expenditures and there are endorsed measures approving them[28] and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge, such as a planned readmission or transfer to another hospital.

Here, the Secretary is going to have to establish a readmission measure methodology, but the readmissions which are targeted are the admission of an individual to the same or another applicable hospital within a time period specified by the Secretary from the date

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[25] HR § 3008. This is on top of the policy of not paying for the additional costs of these conditions discussed at n.13.

[26] HR § 2702

[27] HR § 3025

[28] For a discussion of the National Quality Forum and the advent of endorsed consensus measures see Gosfield, "The Performance Measures Ball: Too Many Tunes, Too Many Dancers?" HEALTH LAW HANDBOOK, (2005 ed.) WestGroup pp.227-284

of such discharge. Information regarding readmission rates will be posted on the Hospital Compare Internet Website. There is no appeal of the determination of base operating DRG payment amounts, the methodology for determining the adjustment factor, the excess readmissions ratio, the aggregate payments for excess readmissions, aggregate payments for all discharges, and applicable periods and applicable conditions. In addition, there is no appeal of the measures of readmissions. The Hospital Compare Website will also display hospital specific all patient readmission rates which will be calculated based on data that hospitals will be required o submit in such form, manner, and time as specified by the Secretary.

The value proposition is to stimulate better coordination of care and better management of discharges. In addition to payment reductions as indicated, the statute also provides for hospitals, which the Secretary has determined have a high rate of risk adjusted readmissions, to participate in a program to improve their readmissions rates through the use of patient safety organizations.

Taken together, the value-based purchasing modifiers will coordinate measurement of hospitals and physicians. In addition, physicians are the providers who actually admit patients and re-admit them. These new programs create an enormous incentive for hospitals and physicians to work together in ways that will benefit both of them from a payment perspective. Some physicians will also get direct enhanced payment on their base payment amounts.

_.2.3 *Increased Primary Care Payment: Medicare and Medicaid*

A whole subtitle in the legislation is focused on strengthening primary care. The basic thrust is that primary care should be valued more than it has been previously. For the period of time between January 1, 2011 and January 1, 2016, primary care practitioners will be paid a 10% additional incentive for primary care services.[29] The primary care practitioners who are eligible include physicians with a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine, or a nurse practitioner, clinical nurse specialist, or physician assistant for whom primary care services accounted for at least 60% of the allowed charges under Medicare for such physician in a prior period as determined by the Secretary. The primary care services are designated by CPT codes as office visits, nursing facility visits, and home care visits. In addition, there is a 10% incentive payment for the same period of time for major surgical procedures furnished in health professional shortage areas for general surgeons, defined by specialty-type 62 for surgical procedures for which a 10-day or 90-day global period pertains. The Medicare Physician Fee Schedule for calendar year 2011 has incorporated this provision, including within the definition of primary care services, domiciliary, rest-home or custodial care evaluation and management services, domiciliary, rest-home (for example, an assisted living facility) or home-care plan oversight services and new and established patient home evaluation and management visits.[30] Medicaid has a mirroring

[29] HR § 5501

[30] 42 CFR §414.80

provision to identify current state practices which prohibit payment for healthcare acquired conditions, effective as of July 1, 2011[31]

In addition, in the Medicaid program, for primary care services furnished in 2013 and 2014, by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine, payment shall be made at a rate not less than 100% of the Medicare Fee Schedule amount. Not only are evaluation and management services included, but also services related to immunization administration for vaccines and toxoids.

Turning now from mandatory programs that reflect direct changes in payment amounts, we find Congress stepping into an arena that has been enormously contentious in the commercial world.

_.2.4 *Episode Grouper*

Episode groupers have been developed in the last few years as a basis upon which to bundle all of the services provided to the patient within an episode of care and calculate the expenditures associated with those episodes. These episode groupers have been used primarily by managed care plans to profile physicians. The two principal programs have been Medical Episode Grouper (MEG) and Episode Treatment Groups (ETGs), proprietary products, the first owned by Thomson Reuters and the second by Ingenix. Physicians have railed against their inaccuracy and unfair use for some time.[32] These matters got so heated that in 2007, then New York Attorney General, Andrew Cuomo investigated these programs, resulting in a settlement with CIGNA Healthcare as part of an industry-wide investigation. Under the settlement, CIGNA agreed to ensure that rankings for doctors would not be based solely on cost and would clearly identify, among other things, the degree to which any ranking was based on cost; would use established national standards to measure quality, including measures endorsed by the National Quality Forum; employ measures to foster more accurate physician comparisons including risk adjustment and valid sampling; disclose to consumers how the program is designed and how doctors are ranked; provide a consumer complaint and physician appeals process and use an independent ratings examiner.[33] In 2010, the RAND Corporation published a study that found that the episode groupers used for this profiling were deeply flawed and just as likely to say that a high cost physician was low cost and

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[31] HR § 2702

[32] Hussey, et. al., "Episode-Based Performance Measurement and Payment: Making It a Reality," Health Affairs 28: No. 5, (2009) pp.1406-1412.

[33] Guadagnino, "Physician Report Card Validity" Physicians New Digest, April 2008, http://www.physiciansnews.com/cover/408.html.

high quality as it was to state the obverse.[34] The point of these programs was to identify highly efficient, high value, high quality providers as contrasted with those who do not measure up. They have been suspect in part because of the "black box" nature of their methodologies.

Congress has stepped into the fray by requiring the Secretary to develop an episode grouper, itself, that combines separate but clinically related items and services into an episode of care for an individual as appropriate, to be developed by January 1, 2012. In contrast with the "black box" proprietary profiling programs currently in place, the details of the episode grouper must be made available to the public.[35] The program is to be used to provide additional feedback to physicians on their utilization of resources as part of the Physician Quality Reporting System (formerly the voluntary "Initiative").

While the Physician Quality Reporting Initiative has been voluntary and does not require that the actual quality of care be measured, even when it was initially announced, its purpose was to serve as a foundation to transition to a program that would eventually pay differentially for quality (which the value-based payment modifier will do). Much like the once voluntary hospital reporting initiative, now if eligible professionals do not satisfactorily submit data on quality measures for covered professional services for the quality reporting year, beginning in 2015, the fee schedule amount for such services furnished by such professional during the year will be reduced in 2015 to 98.5% of what he or she would have gotten and for 2016 and subsequent years, 98%.[36] As part of this initiative, there will be an integration of physician quality reporting and meaningful use EHR reporting.[37] The episode grouper relates to the PQRS Program by its link to the physician feedback program. This already existing program, which has had some considerable difficulties, uses claims data to provide confidential reports to physicians that measure the resources involved in furnishing care to individuals. The PQRS information will be used to create, for the first time, a Physician Compare program.[38] This emphasis on public transparency of quality and efficiency performance is also extended under the Health Reform legislation to long-term care hospitals, rehabilitation hospitals, and hospice[39]; PPS-exempt cancer hospitals[40]; and psychiatric hospitals.[41]

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[34] Adams, Mehrotra, Thomas, and McGlynn, "Physician Cost Profiling – Reliability and Risk of Misclassification," RAND Corporation, 2010 http://www.rand.org/pubs/technical_reports/2010/RAND_TR799.PDF

[35] HR § 3003(a)(9)

[36] HR §3002

[37] Id. at (d).

[38] HR § 10331

[39] HR § 3004

[40] HR § 3005

[41] HR § 10322

_.2.5 *Payment Bundling Pilot*

Related to the concept of episode grouping, by January 1, 2013, the Secretary is to implement a national pilot program on payment bundling. Integration of care around an episode of hospitalization is intended to enhance coordination, quality and efficiency of healthcare services. The Secretary is to select one or more of ten "applicable conditions" to include a mix of chronic and acute conditions, surgical and medical conditions, at least one for which there is evidence of an opportunity for providers of services and suppliers to improve the quality of care while reducing total expenditures – to enhance value; where there is significant variation in the number of readmissions and the amount of expenditures for post-acute care spending under Medicare and whether a condition is high volume and has high post-acute care expenditures under the title. The Secretary is to determine which conditions are most amenable to bundling across the spectrum of given care.[42]

The bundled payment is to include acute care inpatient services, physicians' services delivered in and outside of an acute care hospital setting; outpatient hospital services, including emergency department services, post-acute care services including home health, skilled nursing care, inpatient rehabilitation and inpatient hospital services furnished by a long-term care hospital as well as other services as the Secretary shall determine appropriate. The episode for which payment will be bundled includes three days prior the admission of the patient to the hospital, the length of stay of the beneficiary in the hospital, and 30 days following the discharge. In connection with the bundled payment pilot, the Secretary is to determine which payment assessment instrument shall be used under the program to evaluate the condition of the beneficiary for purposes of determining the most clinically appropriate site for the provision of post-acute services. In addition, the Secretary, in consultation with the Agency for Healthcare Research and Quality, is to develop quality measures for an episode of care and for post-acute care. The Secretary has the authority to extend the pilot program to a mandatory program after 2016.

Payment will be made to an entity comprised of providers of services and suppliers, including a hospital, physician group, skilled nursing facility, and a home health agency, who are otherwise participating in Medicare. The Secretary will develop the relevant payment methods and accept bids from entities to participate. The program must be budget neutral and not result in spending more for the entity than would otherwise be spent if the pilot program were not implemented. The payment methodology is to include payment for the furnishing of applicable services and other related activities such as care coordination, medication reconciliation, discharge planning, traditional care services, and other patient centered activities. The bundled payment itself under the program shall be comprehensive, covering the costs of applicable services, and be made "to the entity" which is participating in a pilot program.

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[42] HR § 3023 as revised by § 10308(b)(1)

This program assumes that one actual payment will be made to a single entity. This is as distinct from the PROMETHEUS Payment Model[43], for example, which creates the same financial incentive around care coordination, but uses a bundled budget with separate payments to be made, if providers are independent. The Secretary is to establish quality measures addressing process, outcome and structure, to assess functional status improvement, reducing rates of avoidable hospital readmission; rates of discharge to the community; rates of admission to an emergency room after the hospitalization; incidents of healthcare acquired infection; efficiency measures; measures of patient-centeredness of care; measures of patient perception of care, and any other measures. The contracted entities will submit data to the Secretary on all of those quality measures.

This program is one of the major demonstrations of Congress's belief that bundled payment will shift the incentives currently present in Medicare to higher value delivery by putting providers at risk with each other, since only one payment will be made. This is a completely separate proposition from the accountable care organization opportunity which is discussed below in _.4.1.

A similar project is to be implemented for a Medicaid global payment system focused around "safety net hospitals".[44] In the Medicaid model, however, the payment model is explicitly stated to be global capitation, and the program will operate from fiscal year 2010 to 2012. No more than 5 states will be able to participate in the demonstration. That program is to be established by the Center for Medicare and Medicaid Innovation.

_.2.6 *Center for Medicare and Medicaid Innovation*

This Center, which has already been funded with $10 billion and was launched in November, 2010, has extraordinary flexibility to implement a wide range of tests and demonstrations explicitly focused on testing innovative payment and service delivery models to reduce program expenditures.[45] Preference is to be given to models that improve the coordination, quality and efficiency of healthcare services. In essence, this is the "let's test for value" office. Here, the legislation explicitly addresses promoting broad payment and practice reform in primary care, including patient-centered medical home, models for high-need individuals, women's unique healthcare needs and initiatives that transition primary care practices away from fee-for-service based reimbursement towards comprehensive payment or salary-based payment.

The Center has the authority to contract directly with groups of providers to promote innovative care delivery models. Care coordination programs are part of its mission. Among its many authorities, Congress explicitly assigned to it the job to vary payment to

[43] The PROMETHEUS Payment® Model is being tested in the first grants that have been made to develop the episode grouper.

[44] HR § 2705

[45] HR § 3021

physicians who order advanced diagnostic services according to their adherence to appropriateness criteria, and to pay providers of services and suppliers for using patient decision support tools to improve applicable individual and caregiver understanding of medical treatment options. The Center is authorized to allow states to test and evaluate systems of all-payor payment reform for dual eligible patients (Medicaid patients eligible for Medicare in the state). It is to align nationally recognized evidence-based guidelines of cancer care with payment incentives in the areas of treatment planning and follow-up care planning. It is to improve post-acute care, fund home health providers who offer chronic care management services, promote improved quality and reduced cost by developing a collaborative of high quality low cost healthcare institution responsible for developing, documenting and disseminating best practices and improving care methods; implementing such best practices and improving care methods and providing assistance to other healthcare institutions on how best to employ such best practices and proven care methods. The Center is to promote greater efficiency and timely access to outpatient services through models that do not require a physician or other healthcare professional to refer for the service, even as it facilitates inpatient care, including intensive care of hospitalized patients at their local hospital through the use of electronic monitoring by specialists. The Center is even allowed to establish comprehensive payments to Healthcare Innovation Zones consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities that, through their joint activities, deliver a full spectrum of integrated and comprehensive healthcare services while incorporating innovative methods for clinical training for future healthcare professionals.

Taken together, quite a departure from the regulatory emphasis of the Center for Medicare and Medicaid Services (CMS), this office reads like a combination of the RAND Corporation and the Harvard School of Public Health. Its first program is already announced: the inaugural initiative is to evaluate the effectiveness of doctors and other health professionals across the health system, working in a more integrated fashion and receiving more coordinated payment from Medicare, Medicaid, and private health plans. Eight states[46] will participate in the Multi-Payor Advanced Primary Care Practice Demonstration that will ultimately include over 1200 medical homes serving almost one million Medicare beneficiaries. The Center has established a Federally Qualified Health Center Advanced Primary Care Practice Demonstration to provide patient centered coordinated care to approximately 195,000 individuals with Medicare.[47] The Center is housed within CMS, which is itself a payment agency for Medicare and Medicaid. The legislation, has reached far more broadly than money in much of its emphasis on quality.

_.3 Quality Improvement and Measurement

The statute enacted sweeping provisions with regard to quality improvement and measurement generally. These programs will provide foundational data on which to

[46] Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan and Minnesota

[47] "CMS Introduces New Center for Medicare and Medicaid Innovation, Initiatives to Better Coordinate Care" http://innovations.cms.gov/innovations/pressreleases/pr110910.shtml

assess, evaluate, and take further action to drive continued improvement. It is a statement of fact that no value judgments or comparisons can be made without data reporting performance. The purpose of measure development is to further the work of comparing performance. The implications to providers are full of portent. Much more of what they do will be measured; and, inevitably more programs of consequences from measures – whether in payment reduction or enhancement, or assistance to improve, or exclusion from other programs -- will emerge. Measurement drives behavior.[48] And that is part of the point.

_.3.1 *National Strategy for Quality Improvement*

By January 1, 2011, the Secretary was to have announced a national strategy for quality improvement in healthcare. Going beyond Medicare and Medicaid, the identification of priorities are to be those with the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of healthcare for all populations, including children and vulnerable populations. Strategies to identify areas in the delivery of healthcare services that have the potential for rapid improvement in quality and efficiency in patient care while addressing gaps in quality, efficiency, comparative effectiveness information and health outcomes measures as well as data aggregation techniques. Broadly, the strategy is to improve federal payment policy to emphasize quality and efficiency; enhance the use of healthcare data to improve quality; address healthcare provided to patients with high cost chronic diseases; improve research and dissemination of strategies and best practices and to improve patient safety and reduce medical errors, preventable admission and readmissions, and healthcare associated infections. Value. Value. Value.

The comprehensive strategic plan to achieve these priorities must be coordinated with state agencies with a focus on minimizing duplication of effort using common quality measures where possible. Agency-specific strategic plans are to be established with each agency to achieve its priorities. A process for regular reporting on implementation and strategies to align public and private payors with regard to quality and patient safety efforts is part of the approach. Consistent with all of the other emphases on transparency, there is to be an internet website to make public information regarding the national priorities and agency-specific strategic plans. A very broad panoply of federal agencies is to be included in the coordination of this work.[49] **[Something will have to be inserted here when strategy is announced]**

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[48] Asch, McGlynn, et al., "Comparison of Quality of Care in the Veterans Health Administration and Patients in a National Sample," Ann. Of Int. Med., Vol. 141, No. 12, Dec. 21, 2004, pp 938-945.

49 HR § 3012, DHHS; CMS; NIH; CDC; FDA; Health Resources and Services Administration; AHRQ; Office of the National Coordinator for HIT; Substance Abuse and Mental Health Services Administration; Administration for Children and Families; Department of Commerce; OMB; United States Coast Guard; Federal Bureau of Prisons; National Highway Traffic Safety Administration; the FTC; SSA; Department of Labor; US Office of Personnel Management; Department of Defense; Department of Education; Department of Veteran's Affairs; Veteran's Health Administration; any other agencies identified by the Secretary.

_.3.2 *Quality Measure Development*

For any of the value-based programs to succeed, there have to be sufficient quality measures to evaluate the care provided. Several truisms from the world of quality measurement include "you can not improve what you can not measure", "what gets measured gets done" and "so be careful what you measure". The selection of quality measures will drive the essential features of the payment-based programs, as well as the judgment of success of any innovations. Under the legislation, the Secretary, in consultation with the director of the Agency for Healthcare Research and Quality and the administrator of CMS is to identify no less often than every 3 years, gaps where no quality measures exist and existing quality measures need improvement, updating, or expansion consistent with the national quality strategy.[50] The Secretary is to make grants or contracts for quality measure development.

_.3.3 *Development of Outcome Measures*

The legislation establishes the priorities for this work, including development of quality measures that allow the assessment of health outcomes and functional status of patients; management and coordination of healthcare across episodes of care and care transitions of patients across the continuum of providers, healthcare settings and health plans; the experience, quality, and use of information provided to and used by patients, caregivers, and authorized representatives to inform decision making about treatment; meaningful use of health information technology; safety effectiveness, patient centeredness, appropriateness and timeliness of care; efficiency of care; equity of health services and health disparity; patient experience and satisfaction; and use of innovative strategies and methodologies.

In connection with these measures, no less often than every 3 years, the Secretary shall develop and periodically update provider level outcome measures for hospitals and physicians. These must include outcome measurement for acute and chronic diseases, including, to the extent feasible, the 5 most prevalent and resource intensive acute and chronic measurement conditions, an outcome measurement for primary and preventive care, including measurements that cover provision of care for distinct patient populations (such as healthy children, chronically ill adults or infirm or elderly individuals). No later than 2 years after March, 2010, the Secretary shall develop not less than 10 measures for acute and chronic disease; and no later than 3 years after March, 2010, the Secretary shall develop not less than 10 measures for primary and preventive care. The reconciliation provisions of the act[51] substituted "quality and efficiency" for quality. Similar changes were made in the headings of the other quality measurement sections of the legislation.

[50] HR § 931

[51] HR § 10304

The legislation specifically establishes new duties for entities like the National Quality Forum. Moving from quality alone, the NQF and other similar consensus based entities[52] are expected to convene multi-stakeholder groups to provide input on selecting quality and efficiency measures. Throughout the legislation, no measures may be used that have not been endorsed by these organizations. Recognizing the enormous power of these measures, the statute requires transparency in the process of selecting them. Re-emphasizing the necessity to analyze data to be able to do any of this work, the statute establishes a significant authority for the Secretary to collect and aggregate data on quality and resource use measures.[53] Entities receiving grants for such activities must be multi-stakeholder entities that coordinate the development of methods and implementation plans for the consistent reporting of summary, quality and cost information with the capability to submit summary data for particular population and providers, such as a disease registry, regional collaboration, health plan collaboration or other population-wide source. The purpose is to promote the use of systems that provide data to improve and coordinate patient care and support the provision of timely, consistent, and resource use information to healthcare providers and other groups and organizations with an opportunity for providers to correct inaccurate measures. There is to be public reporting of performance information through standardized internet websites responsive to the differing needs of hospitals and other healthcare providers, physicians, and other clinicians, patients, consumers, researchers, policy-makers, states and other stakeholders.

_.3.4 *Medicaid Measures*

For the Medicaid program specifically, the legislation calls for the development of a core set of healthcare quality measures for adults eligible for benefits under Medicaid[54] and a core set of child health quality measures to be implemented in 2012. No later than January 1, 2013, the Secretary, in consultation with the states shall develop a standardized format for reporting information based on the initial core set of quality measures and create procedures to encourage states to use such measures to voluntarily report such information regarding the quality of healthcare for Medicaid eligible adults. No more than a year after the release of the recommended core set of adult health quality measures, the Secretary shall establish a Medicaid Quality Measurement Program in the same manner that it establishes a Pediatric Quality Measures Program. The law calls for revising, strengthening and improving initial core measures over time and expects state specific quality of care reports.

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[52] See n. 28, supra.

[53] HR § 3015 and § 10303. In considering the development of efficiency measures, one would think some of the controversies associated with comparative effectiveness would arise. (See _.5 below). Perhaps it is Congress's faith in consensus, which leads to the expectation of no major conflagrations over measuring efficiency.

[54] HR § 2701

When I first started working on health law as a summer student in The War on Poverty in 1972, it would have been hard to imagine an organized federal approach to measurement of Medicaid quality with public reporting. The original Professional Standards Review Organization program, which later became PROs and now QIOs, was created to use common measures between Medicare and Medicaid for the medical necessity, quality and appropriateness of medical care.[55] States however, did not follow through despite enhanced federal financial participation for doing so. No longer mandatory, today the state Medicaid plan may provide for the review of Medicaid services through a contract with a QIO, but there is enormous flexibility.[56]

The health reform legislation describes a program in which Medicaid will begin to mirror the initiatives that have long been in effect for Medicare. By measuring performance in the Medicaid program, there can not help but be improvement in both the value and quality of services providers will render. To succeed both under the significantly increased measurement programs in Medicare as well as Medicaid, providers are expected to reorganize in a variety of ways.

_.4 Provider Reorganization/Innovative Delivery

The Center for Medicare and Medicaid Innovation is created within Part D, Subpart 3 of the legislation referred to as "Encouraging Development of New Patient Care Models". The Center has considerable flexibility to contract directly with providers as well as to test and evaluate innovative delivery systems which may or may not be tied to new payment models. Against that background of significant flexibility, the legislation also offers its own tests of changed delivery models, expected to produce higher value. For reasons that are entirely unclear to me, the single most talked about aspect of provider implications from health reform has been the opportunity to apply to be an Accountable Care Organization.

_.4.1 *Accountable Care Organizations (ACOs)*

There appears to be enormous confusion over what this Medicare program is about. Not later than January 1, 2012, the Secretary is to establish a "shared savings program" that promotes accountability for a patient population and coordinates items and services under Parts A and B and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.[57] This is not a pilot program, a demonstration project, or anything other than a voluntary opportunity to participate in a program which has not only very little detail, but enormous challenges in its implementation. Although the types of entities that may qualify as ACOs are flexible, whoever participates must have the ability to take Part A and Part B money and allocate it

[55] Gosfield, PSROS: THE LAW AND THE HEALTH CONSUMER, Ballinger Press, Philadelphia (1975).

[56] 42 CFR §431.630

[57] HR § 3022

among providers. Beneficiaries are assigned to the program by a methodology yet to be determined, although they will not know they have been asigned. Quality standards apply and reporting to the Secretary is required. At the end of 3 years (the mandatory participation term) the ACO will share in savings it has generated only when it exceeds results by comparison with the expenditures that were made for the assigned beneficiaries in the 3 years prior to their assignment to the ACO. There is a pediatric ACO demonstration project in the Medicaid provisions with even less specificity.[58]

This methodology was fundamentally the type of approach that was used in the Physician Group Practice Demonstration project. Rather than measuring the expenditures by dollars paid for those beneficiaries, in the Group Practice Demonstration, physician group practices had to save more than 2% over a comparison population derived from each physician groups' local market area. The ten groups which participated (each had to have more than 200 physicians to qualify), are some of the same groups that were identified as high value, high quality providers during the health reform debates (e.g. Billings Clinic, Everett Clinic, Geisinger Health System, Park Nicollet, and more). In the first year, only two groups shared in savings for improving overall efficiency of care. In the second year four groups shared in savings for improving overall efficiency of care. By the end of year three, five physician groups shared in savings.[59] All of the groups improved quality, but the relevant Medicare fact sheets do not indicate what it cost them to achieve these results, when they did not share in any savings in the long run.

While the Medicare shared savings program details are still in development, in the commercial environment and under state health reform, similar initiatives of creating accountable care organizations have emerged. The Vermont Accountable Care Organization Pilot is operating under the auspices of the Vermont Health Care Reform Commission. Recommendations have been published regarding various aspects of implementation, but generally speaking they have found that an ACO's success depends on "committed leadership from physicians and other key stakeholders, multi-payor participation, a patient-centered primary care model, and robust IT support and reporting," and these programs are barely operational at this writing.[60]

The Medicare legislation does not specify how much savings will be shared or even what the payment methodology will be. Although the entities involved must be able to accept Part A and Part B payment, it is not clear that this payment must explicitly be bundled,

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[58] HR § 2706

[59] https://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Fact_Sheet.pdf. For another assessment of the implications of this demonstration for ACOs see Iglehart, "Assessing on ACO Prototype – Medicare's Physician Group 'Practice Demonstration,'" NEJM (Dec. 22, 2010) 10.1056/NEJMp1013896 raising issues as to whether hospitals controlled anything during the demo as well as the problem of no contemporaneous feedback to the physicians regarding performance.

[60] Hester, Lewis and McKethan "The Vermont Accountable Care Organization Pilot: A Community Health System to Control Total Medical Costs and Improve Patient Population" (May 2010), pg. vii http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2010/May/The-Vermont-Accountable-Care-Organization-Pilot-A-Community-Health-System-to-Control.aspx

although the ACO opportunity is separate from the payment bundling pilot. Many assume the payment model will be global capitation for which there is zero evidence of any quality effect.

There is considerable skepticism around these programs despite all of the activity they have generated. If the participants in the Physician Group Practice Demonstrations, most of which would likely be able to qualify as ACOs, had less than glorious results in terms of financial benefit to them, why would this purportedly new ACO model be any different? Some have described the program as "not ready for primetime"[61] or "HMOs in drag"[62]. Given the prerequisites for the success of any of these organizations, their applicability in most American healthcare systems or even large physician groups throughout the country is highly questionable. I am of the opinion that being an ACO will not necessarily improve or change anything regarding quality, will require an enormous amount of time and money in their formation, distracting organizations from real, necessary change. The real key to value is clinical process redesign to improve care and reduce waste. This work should start now and should be focused around the value based purchasing modifier, hospital acquired conditions and preventable hospital readmissions which will be mandatory for all Medicare physicians and all Medicare hospitals.

_.4.2 *Independence at Home/PCMH Support Demos*

The Independence at Home medical practice demonstration is intended to test a payment incentive and service delivery model that uses physicians and nurse practitioners to deliver home-based primary care to lower hospitalizations, readmissions, emergency room visits, improve efficiency, lowers duplication of testing and reduces cost while increasing patient and caregiver satisfaction.[63] Qualifying entities who may participate in the demonstration must be a legal entity comprised of an individual physician or nurse practitioner groups that provide care as part of a team, are experienced in providing home care 24/7, with demonstrated experience in doing this for high cost chronically ill Medicare beneficiaries. Each demonstration must provide services to at least 200 beneficiaries during each year using electronic health records, remote monitoring and mobile diagnostic technology.

In terms of the value proposition, the Secretary is to establish a target spending level on a per capita basis. The incentive payment will be the amount by which actual expenditures are less than what would have been the rate without the demonstration. Unlike the ACO model where beneficiaries are assigned, here beneficiaries get to choose to enroll. The program incorporates evaluation, monitoring and reporting.

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[61] Goldsmith, "The Accountable Care Organization: Not Ready for Prime Time," Health Affairs blog (Aug 17, 2009)

[62] Personal Communication, James L. Reinertsen, MD, October 29, 2010

[63] HR §3024

The Patient-Centered Medical Home (PCMH) Support demonstration project will offer grants or contracts for community based interdisciplinary inter-professional teams to support primary care practices within hospital service areas of the eligible entities. Capitated payments will be made to primary care physicians but this is a support project to help those patient centered medical home primary care practices. The support entities will engage in coordination, facilitation and reporting. Physicians contracting with them must provide a care plan to them, access to the health records of participants and meet regularly with the care team.

_.4.3 *Medicaid Health Homes and Integrated Care around Hospitalization*

There is a state option provided in the legislation to create "health homes" for enrollees with chronic conditions around a team of health care professionals. A health home can be a physician. Innovative payment may be used and it is not limited to capitation.

Another demonstration project in Medicaid will evaluate integrated care around a hospitalization beginning in January 1, 2012. This is the Medicaid version of the bundled payment for an episode of care associated with a hospitalization including physician services. States will be selected to specify one or more episodes involving safety net hospitals.

The themes around these changes are (1) vastly increased measurement, (2) a high degree of transparency, and (3) significant financial and other consequences for performing well or not measuring up. There is a clearly developing imperative for providers to get beyond incremental quality improvement to far more transformational clinical process redesign to succeed in the new environment. This demand for higher value performance from providers will inevitably be influenced in part by an anomalous program for which there has been general agreement we have need, but the specifics of the adoption by Congress points to the refusal of politicians to really confront the implications of what we should be paying for in healthcare.

_.5 Comparative Effectiveness

> *"A fundamental building block of any high-performance health system is reliable information about the effectiveness of care, including benefits, risks, and costs of alternative technologies and services."*[64]

The call for the creation of some national mechanism, vehicle or institute to conduct comparative effectiveness research has been persistent for many years. The absence of adequate data on which to determine what services, technology and products should be provided to which patients and what should be paid for has been the subject of numerous considerations.[65] Many experts declaim the fact that we simply do not have enough

[64] O'Kane, et. al., "Crossroads in Quality," Vol. 27, No. 3 Health Affairs, 749-758 (May/June 2008).

[65] See Atkins, et. al., "Making Policy When the Evidence is in Dispute," Vol. 24, No. 1 Health Affairs, 102-113 (January/February 2005).

information about what health care works and for whom. Section 1013 of the Medicare Modernization Act authorized $50 million and appropriated $15 million in fiscal year 2004 for the Agency for Healthcare Research and Quality (AHRQ) to conduct research and set priorities related to improving outcomes as well as the clinical effectiveness and appropriateness of health services, including prescription drugs.[66] Comparative effectiveness research, generally speaking, compares two or more medical or public health interventions to measure their relative benefits or harms. Even back in 2003 when AHRQ was given the responsibility for conducting research, Congress prohibited them from mandating "national standards of clinical practice or quality healthcare standards and directed them to take into account variances among patient subpopulations as well as patient and physician preferences."[67] When AHRQ eventually established its effective healthcare program to conduct this research, money was not made available until fiscal year 2005 with a $15 million appropriation which was increased in fiscal year 2008 to $30 million.

When the Stimulus Act was enacted, several comparative effectiveness research initiatives were funded: at AHRQ for $300 million, the National Institutes for Health for $400 million and HHS with $400 million.[68] At the same time, Congress created a federal coordinating council and asked the Institute of Medicine to prepare a report recommending national priorities for spending the monies allocated to DHHS. Those reports were submitted in June 2009. With the adoption of PPACA, a different tack was taken providing for the establishment of a Patient-Centered Outcomes Research Institute. It is neither an agency, nor establishment of the United States government, but is intended to advance quality and relevance of evidence, including evidence that considers variations in patient subpopulations about the relative health outcomes, clinical effectiveness, and appropriateness of healthcare interventions.[69]

While establishing slotted stakeholder positions on the board, by law, Congress further adopted a Russian doll nesting set of relationships by giving to this private entity the responsibility to identify priorities (despite the earlier identification of priorities in 2009) and further suggested that in entering into research contracts, preference was to be given to AHRQ and NIH, although the Institute may contract with other federal agencies, academic research centers, and study-conducting entities.

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[66] Wilensky, "Developing a Center for Comparative Effectiveness Information," Vol. 25, No. 6 Health Affairs, (2006). http://content.healthaffairs.org/cgi/content/abstract/25/6/w572.

[67] Miller, "The Patient Centered Outcomes Research Institute" J. Health & Life Sci. L., October 2010, Vol. 4; at 4. http://www.healthlawyers.org/JHLSL

[68] American Recovery and Reinvestment Act of 2009 (ARRA) Pub. L. No. 111-5 11th Cong., 1st Session, 123 STAT 115, 176-177.

[69] HR § 6301

Although there are formidable challenges in (1) the determination of appropriate methodologies, (2) monitoring research as it is conducted, and (3) evaluating the evidence at hand, one of the most contentious issues has been the extent to which costs may be taken into account, and most specifically, whether a methodology used by virtually every other country that engages in this kind of activity, namely, "Quality Adjusted Life Years" (QALYs) may be utilized.

> *"QALYs represent health over time as a series of 'preference-weighted' health states, where the quality weights reflect the desirability of living in the state, typically from 'perfect' health (weighted 1.0) to death (weighted 0.0). Once the weights are obtained for each state, they are multiplied by the time spent in the state; these products are summed to obtain the QALYs."*[70]

There are, apparently, many arguments over whose preferences are to predominate in the weighting for QALY estimates. Some argue that this should be based on the members of the general public, on the basis that societal resource allocation should reflect some normative values. Others argue for using patients' preferences since the values of the people who have the condition are the most relevant. Studies now show that Americans are deeply suspicious of evidence based medicine judgments, presumably because they believe they smack of "rationing".[71] Although there has been enormous controversy surrounding purported "death panels" in the legislation which, of course, never existed, in a diametrically opposite position, the law explicitly forbids the use of cost per QALY as a threshold. Those who argue in favor of QALYs take the position that they are misinterpreted and misunderstood.[72] Congress has emphatically rejected using cost effectiveness analyses to aid Medicare coverage and reimbursement decisions. The government is also forbidden from making decisions on "coverage, reimbursement or incentive programs" under Medicare "in a manner that treats extending the life of an elderly, disabled or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill."[73] Despite this preclusion, Medicare is not prohibited from using research that shows a "difference in the effectiveness of alternative treatments" based on the age, disability, or health of different persons.

These prohibitions call into question the extent to which the value of interventions addressed in all of the measures which DHHS will be developing and supporting will

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[70] Neumann and Greenberg, "Is The United States Ready for QALYs?" Vol. 28, No. 5 Health Affairs, 1366-1371 (September/October 2009).

[71] Gerber, et. al., "A National Survey Reveals Public Skepticism About Research-Based Treatment Guidelines," Health Affairs (Oct. 2010) pp.1882-1884.

[72] Neumann and Weinstein, "Legislating Against Use of Cost Effectiveness Information" 363 NEJM No. 16, October 14, 2010, Pgs 1495-1497.

[73] HR § 6301(c) amending new § 1182 of the Social Security Act

really speak to the issue of "bending the cost curve". Which treatments are appropriate for which kinds of populations has been essentially absent from the American healthcare market place, and now truly comparative judgments related to whether an intervention is worth what it costs are precluded in the publicly funded programs. What, if anything, will emerge in the commercial sector is largely unclear.[74]

_.6 Conclusion

The issue of the value of provider performance has been debated since the advent of public financing for healthcare. The extent to which physicians would be free to exercise their own professional judgment at taxpayers' expense was recognized in 1966 in the still standing provision in Medicare which is the opening statement in the law:

> *"Nothing in this sub-chapter shall be construed to authorize any federal office or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control of the administration or operation of any such institution, agency, or person."*[75]

As the stakes have grown higher in health care in terms of quality performance and cost control, generally, and stakeholders solidify their positions, "value is emerging as a concept – perhaps the only concept – that all stakeholders in healthcare embrace."[76] The challenges of delivering value are considerable. Measuring performance is an essential first step to improving it; and it is not just the measurement of care delivered, but rather the outcomes and effects on patients that are now the essential focus. A new "value framework" has been proposed to provide structure to how we assess performance.[77] The debates will continue, for sure. But from emerging payment models to profiling of providers, it is increasingly clear that collaboration and "team" accountability will be critical to arriving at better results on most metrics.

The health reform legislation is a remarkable step forward in creating an environment in which providers – especially physicians and hospitals – will want to change their behavior to the new value paradigm, because now there are real consequences from not doing so. Whatever the outcomes of the constitutional challenges to the legislation, the new value mandate will not change because we can not afford the status quo. The message to providers is crystal clear. Start to change how you work, now.

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[74] For a brief review of the policy controversies in this arena see "Comparative Effectiveness Research" Health Policy Brief, Health Affairs (October 5, 2010) http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=27.

[75] 42 USC §1395.

[76] Lee, "Putting a Value Framework to Work," NEJM, December 8, 2010.

[77] Porter, "What is Value in Healthcare?" NEJM, December 8, 2010