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Overcoming Managed Care Regulatory Chaos Through A Restructured Federalism

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OVERCOMING MANAGED CARE REGULATORY CHAOS THROUGH A RESTRUCTURED FEDERALISM

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IN THE REALM OF CONSTITUTIONAL LAW, federalism can be classified as a perennial issue, its history predating the adoption of the constitution itself.[1] Federalism conveys both a sense of structure and a sense of mandate, and while it is not as constant a presence in constitutional jurisprudence as issues affecting individual rights, it is a concept, nevertheless, which is a deeply rooted one, fundamental to government operations. This article is written to reflect on federalism in health care, and to suggest that the balance between Washington and the states has been skewed in ways that are counter productive to effective governance of this sector, and that such imbalances must not be tolerated as the status quo. The core argument driving the analysis in this piece is that the current regulatory frenzy in managed care presents a picture of uncoordinated, and short sighted efforts, often motivated by political gains which only serve to proliferate intergovernmental conflict, duplication of efforts, spawn unnecessary costs, and move us further away from a coordinated vision of government health care policy. The constitutional purists of the world who may stumble across this article should recognize that it is written by a health law academic who believe that constitutional doctrine underpinning federalism is fungible doctrine that should be changed when it no longer serves the public interest, and that the first step in a journey of a thousand miles maybe a slippery one.

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[1] *See* EDWARD DUMBAULD, THE BILL OF RIGHTS AND WHAT IT MEANS TODAY 163-65 (1957); *see also* AKHIL REED AMAR, THE BILL OF RIGHTS: CREATION AND RECONSTRUCTION 123-24 (1998).

BACKGROUND

Health policy is a rather disparate enterprise in that it is composed of multiple actors pursuing a wide range of often-unrelated activities that are linked only by a generic goal of enhancing individual and collective health.[2] For purposes of this paper, health policy will be viewed more narrowly as those actions of government, at the state and federal levels, which are directed toward the oversight, management and delivery of health services. While many health policies have their origins in non-governmental settings, increasingly, governmental entities have become the primary actors in developing or adopting approaches to our health delivery, using their considerable funding and regulatory authority to dominate this sector.

The history of government health policy is one which reflects ongoing and evolving relationships between the respective levels of government.[3] Health in all its facets has never been the purview of one level of government, but rather is an enterprise characterized by the involvement of respective governmental units based on tradition, legal imperative, and practicality. The world of government health policy, which predates Medicare and Medicaid, is one in which states were guided by a sense of public interest, empowered by the rather vague mandate of the Tenth Amendment.[4] Throughout much of the 20th century, state governments were primarily responsible for public health issues, regulating professionals, and facilities, as well as maintaining a public health administrative and regulatory infrastructure, which often included the provision of services in some areas such as mental health.[5] This is not to say that the

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[2] *See* KEITH J. MUELLER, HEALTH CARE POLICY IN THE UNITED STATES 1-16 (1993) (demonstrating the range of political values within the context of public health).

[3] *See* Robert F. Rich & William D. White, *Health Care Policy and the American States: Issues of Federalism, in* HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES 3, 17-25 (Robert F. Rich & William D. White eds., 1996); *see also* Robert F. Rich & William D. White, *Federalism and Health Policy*, 1998 U. ILL. L. REV. 861 (1998). For an excellent discussion of federalism in public health, see James G. Hodge, Jr., *Implementing Modern Public Health Goals Through Government: An Examination of New Federalism and Public Health Law*, 14 J. CONTEMP. HEALTH L. & POL'Y 93 (1997).

[4] *See* Rich & White, *Health Care Policy and the American States: Issues of Federalism*, *supra* note 3, at 8-20; *see also* Hodge, *supra* note 3, at 100-06.

[5] *See* Rich & White, *Health Care Policy and the American States: Issues of Federalism*, *supra* note 3, at 16-25.

federal government did not play a role in health policy, but that role was restricted to discrete areas where national policies were required, and to the provision of financial support for medical research and grant programs to assist with the development of public health programs at the state level. There were times in the first half of the 20th century in which federal policy makers skirted with national health insurance as an outgrowth of Social Security, but that movement never came close enough to fruition to effect a serious consideration of how such a massive undertaking would impact questions of federalism.[6]

With the enactment of Medicare and Medicaid in 1965, the respective roles of federal and state governments were dramatically expanded and at both levels, government became a primary participant in the financing and administration of health services for large segments of the American population.[7] Through the Medicare program, the federal government was able to exert a profound influence on the delivery of medical care at the local level. While Medicare is offered in the private sector, and in turn, is dependent on states' regulatory infrastructure, its policies, particularly in areas of reimbursement, and to a lesser extent, quality assurance, have had a profound impact on the operations of the health system, and have been frequently replicated by states and the private sector.[8]

Medicaid, a structural outgrowth of prior public health programs, presents a more direct brand of federalism, as it was established as a dually administered operation between the federal and state governments.[9] While Medicaid affords states' discretion concerning the scope of benefits and administration of their

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[6] *See generally* Theodore R. Marmor, *Forecasting American Healthcare: How We Got Here and Where We Might Be Going*, 23 J. HEALTH POL. POL'Y & L. 551 (1998) (reviewing and predicting the changes in medicine and healthcare since World War II); Jerry L. Mashaw & Theodore R. Marmor, *The Case for Federalism and Health Care Reform*, 28 CONN. L. REV. 115 (1995) (discussing the role federalism can play in health care reform).

[7] *See generally* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 367-74 (1982) (describing the impact of redistributive governmental health care reform).

[8] *See generally* 42 U.S.C.A § 1396 (West 1992 & Supp. 2000) (appropriating federal money to states to enable them to administer programs of necessary medical assistance to low-income families).

[9] *See* John K. Iglehart, *The American Health Care System: Medicaid*, 340 NEW ENG. J. MED. 403, 403 (1999); *see also* Health Care Financing Admin. (HCFA), *Overview of the Medicaid Program* (visited Apr. 20, 2001) <http://www.hcfa.gov/medicaid/meligib.htm>.

respective programs, the program operates under federal oversight, and the history of this dually administered enterprise has been one of contention between the respective levels of government.[10] In particular, federal and state regulators most often disagree about funding, and over the years they have had a series of intergovernmental disputes related to joint financing responsibilities which have accelerated with heightened federal mandates being placed on state Medicaid programs. In spite of increased tensions which Medicaid sparked between the respective levels of government, a certain equilibrium developed in intergovernmental relations, and the parties were able to recognize the boundaries which separated their activities, and even adjust to the often Byzantine rules of dual coverage which characterized areas like long term care.[11]

While it is difficult to capsulize the respective roles of government during the period 1965 through 1990, it can be concluded that much of the focus of the regulatory enterprise was directed primarily at managing the costs of the two large public programs.[12] In turn, the fiscal pressures felt by government spilled over into the private sector and forced employer health benefit programs to adopt a more aggressive posture toward the purchasing and management of health care, resulting in the promotion of what is now collectively referred to as managed care.[13] The private sector's embrace of managed care spawned the expansion of publicly supported prepaid health in the late 1990s, far beyond the federal and state courtship with these delivery systems in the 1980s.[14] In fact, private sector managed care, promoted by large employers and government, has been

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[10] *See* Iglehart, *supra* note 9, 405-06.

[11] *See* U.S. General Accounting Office, No. GAO/T-HEHS-97-119, Medicare and Medicaid: Meeting Needs of Dual Eligibles Raises Difficult Cost and Care Issues, Hearings Before the Special Committee on Aging, U.S. Senate (1997) (testimony of William J. Scanlon, Director, Health Fin. & Sys. Issues).

[12] See MUELLER, *supra* note 2, at 67-99 (reviewing different attempts at controlling the cost of providing health care).

[13] *See generally* Michael J. Taylor, *The Employer's View of Managed Health Care: Show Me the Value*, *in* ESSENTIALS OF MANAGED HEALTH CARE 555, 555-65 (Peter R. Kongstvedt ed., 4th ed. 2001) (discussing trends in managed care affecting employers).

[14] *See id.* at 556-61.

the primary catalyst for the reorganization of local health care market places.[15]

Spurred largely by costs, the Clinton administration's health reform initiatives in the early 1990s was anchored by the notion of a competitive marketplace, so-called managed competition in which local health plans would be actively competing for business on the bases of both cost and quality. While the Clinton's massive federal initiative was stymied by politics, both the federal and state governments turned to managed care products as primary vehicles for the delivery of health services at reduced costs.[16] At the federal level, Congress through the Balanced Budget Act of 1997 initiated a strong new managed care option for Medicare, adding part C to the program, and in the process, broadening the options of enrollees to choose from a wider range of plan designs. While the expansion of managed care options has altered Medicare, the program has never undergone wide sweeping reform.[17] Recent talk of Medicare reform is often based on the adoption of the seemingly less complex Federal Employee Health Benefit program which depends heavily on the use of managed care plans.[18] At the state level, managed care has been pursued vigorously through waiver programs, as a vehicle to salvage ever costly and expanding state Medicaid budgets.[19] In some cases, such as Tennessee, entire Medicaid programs were converted into managed care based operations; the majority of states have actively pursued some

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[15] *See generally* James C. Robinson, *The Future of Managed Care Organization: Health Care May Be a Local Business, But Managed Care Is a National Enterprise*, HEALTH AFF., Mar.-Apr. 1999, at 7.

[16] *See generally* Robert E. Hurley & Stephen A. Somers, *Medicaid Managed Care, in* ESSENTIALS OF MANAGED HEALTH CARE 684, 684-701 (Peter R. Kongstvedt ed., 4th ed. 2001) (discussing how managed care emerged as a major Medicaid reform strategy).

[17] *See* U.S. General Accounting Office, No. GAO/T-HEHS/AIMD-00-103, Medicare Reform: Leading Proposals Lay Groundwork, While Design Decisions Lie Ahead, Testimony Before the Committee on Finance, U.S. Senate (2000) (testimony of David M. Walker, Comptroller General of the United States).

[18] *See generally* Harry P. Cain II, *Moving Medicare to the FEHBP Model, or How to Make an Elephant Fly: Can Medicare Really Be Modernized?*, HEALTH AFF. July-Aug. 1999, at 25.

[19] *See generally* BARRY R. FURROW ET AL., HEALTH LAW § 12-11, at 612-16 (2d ed. 2000) (describing the history of Medicaid managed care programs).

type of prepaid health care scheme for significant portions of their Medicaid population.[20]

MANAGED CARE: CONTROLLING THE NEW BEAST

Unquestionably managed care, in all its manifestations, has had a profound influence on federal and state health policy during the last ten years.[21] The movement toward managed care has changed the playing field of federalism, but in and of itself it does not encapsulize the entire story of intergovernmental health policy. Another key factor in recent health policy has been the push of federal legislators to fill the void left by the demise of the Clinton health reform initiative through the enactment of a series of coverage mandates to address short falls in the system. It has been suggested that the Clinton administration took an incremental approach to health legislation to achieve some of the goals they could not in their broader reform initiative, in addition to using executive power to fill in gaps in coverage and other policy areas. Federal legislation, such as the Health Insurance Portability and Accountability Act,[22] the Children's Health Insurance Program,[23] the Mental Health Parity Act,[24] and a number of smaller coverage mandates can be viewed collectively as an attempt to create a type of federal floor in the coverage area. The states, in their own right, stepped into the coverage void left by the failed federal health reform initiative, and they too enacted numerous coverage mandates affecting insurance plans under their respective control.[25]

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[20] *See* Marsha Gold, *Markets and Public Programs: Insights from Oregon and Tennessee*, 22 J. HEALTH POL., POL'Y & L. 633 (1997) (describing Tennessee's initiative to reconfigure its Medicaid program into a managed-care-based operation).

[21] *See generally* Marilyn Denny, *Managed Care: Increasing Inequality & Individualism*, 3 QUINNIPIAC HEALTH L.J. 59 (2000) (analyzing the impact of the growth of managed care on the poor and the elderly).

[22] Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 18, 26, 29, and 42 U.S.C.).

[23] State Children's Health Insurance Program, 42 U.S.C. §§ 1397aa–jj (Supp. IV 1998).

[24] The Mental Health Parity Act of 1996, 29 U.S.C.A. § 1185a (West 1999), 42 U.S.C.A. § 300gg-5 (West Supp. 2000).

[25] *See* Joel C. Cantor et al., *Challenges of State Health Reform: Variations in Ten States*, HEALTH AFF., Jan.-Feb. 1998, at 191, 191-92; *see also* Douglas A. Hastings, *Patient Rights Meet Managed Care: Understanding the Underlying Conflicts*, 31 J. HEALTH L. 241 (1998).

It is the combination of the large scale adoption of managed care, spawned in part by government, together with the surge in federal and state coverage mandates, which has set the stage for a realtered health care federalism. Managed care brought with it new rules for the provision of medical care that collectively ushered in rapid changes in the delivery of medical services, and raised the ire of patient and provider alike, quickly galvanizing the political community into action as managed care plans have become the pariahs of the early 21st century.[26] The same politicians who saw managed care as a vehicle to contain publicly supported health care programs became champions of protecting individual rights against their new enemies, the Managed Care Organizations. Fueled with negative anecdotes, legislators devised command and control strategies to restore the balance of power back to patients and physicians alike.[27] Solutions for the ills spread by managed care were sought in established consumer protection laws, as well as in the development of a new body of legislation and regulations which was directed toward banning overt abuses, and affording patients/providers with new rights.[28]

At both the federal and state levels of government there has been a rush to address the "managed care crisis" through a wide range of "patient protection" measures.[29] The Congress has attempted for several years to enact a patient bill of rights, and until recently politics has scuttled that goal, but administrative channels have been used to promote such policies.[30] For example, in the final years of the Clinton administration an initiative to extend patient protections to Medicare beneficiaries, federal employees and those enrolled in health plans regulated by the Department of Labor was launched. At the state level, there has been considerably more success in passing laws affecting managed care operations, as a host of new patient protection measures have been enacted into law.[31]

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[26] *See generally* Gregg Easterbrook, *Managing Fine*, NEW REPUBLIC, Mar. 20, 2000, at 21, 22 (discussing the impact of HMOs on health care).

[27] *See, e.g.*, Hastings, *supra* note 25.

[28] *See id.*

[29] *See id.* at 245-46 (discussing "anti-managed care" efforts).

[30] *See* Office of Personnel Management, *Patients' Bill of Rights and the Federal Employees Health Benefits Program* (visited Apr. 3, 2001) <http://www.opm.gov/insure/html/billrights.html>.

[31] *See* Hastings, *supra* note 25, at 245-54.

The patient protection area is illustrative of the imbalance that currently characterizes health care federalism. Curiously enough, it is not a battle over content that is being waged, rather there appears to be a general consensus about the nature of the safeguards that ought to be enacted.[32] Typically patient protection measures include informational requirements, third party appeals, timely access to care, access to specialists, availability of emergency care based on a prudent layperson standard, etc.[33] The movement to create patients' rights in managed care is still ongoing, but the interim results present a panoply of related, but scattered state laws and federal initiatives. It seems clear that the federal government will pass some type of patient protection legislation as public sentiment for it remains strong, and even though the area is marked by political ambivalence, failure to act here would serve to underscore the weakness of Congressional governance, and would reflect poorly on the abilities of the new Bush administration to usher in compromise.[34] With a federal patient bill of right, a series of pro-patient provisions, similar to those already enacted in the states, will be applied to enrollees in individual and group health care coverage programs, and the federal rights provisions will form a floor on which states may add their own provisions. Whatever final version of federal patient protection emerges, it is safe to conclude that the role of the Health Care Financing Administration for regulating the behavior of individual health plans will only be expanded.

WELL, WHAT'S YOUR POINT ?

At first blush, it appears that the duplication of regulatory efforts in managed care is only destined to increase, and that federalism in this area could spin out of control. The reality of federalism in MCO regulation can, however, be viewed in calmer terms, and the emerging chaos can be attributed in large part to the odd situation created by the Employee Retirement and Income Security Act (ERISA).[35] Under the ERISA regulatory scheme, qualified plans are exempt from state regulation,

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[32] *See id.* at 245-51 (discussing areas of general consensus).

[33] *See id.*

[34] *See generally* John McCain & John Edwards, *Patients' Rights: Let's See Some Bipartisanship*, WASH. POST, Feb. 8, 2001, at A23 (discussing several patients' rights bills that have been before Congress).

[35] 29 U.S.C.A. § 1132(a)(1)(B) (West 1999).

and are governed by a series of statutory principles and regulations developed by the U.S. Department of Labor.[36] The preemption section of ERISA truncates the ability of states to regulate all private health insurance vehicles, as this law exempts self funded health plans from state regulations, and creates a dual system of health plan regulation. Also the enrollees who participate in ERISA governed plans are severely limited in the types of legal remedies they may avail themselves of in disputes against their respective plans.[37] Thus, the federal government, as a result of the ERISA preemption, must act to fill in the gaps created by this curious health benefit regulatory structure. Additionally, regardless of the avalanche of state laws affecting patients and provider rights, and the coverage mandates, so-called, "body parts" legislation, states have not always developed a noteworthy track record in health insurance regulation. Serious problems have existed in individual and group health insurance market regulation, prompting Washington to enact HIPAA in 1996 and for the first time, enter into the business of regulating private insurance markets, an area of traditional state regulation.[38]

It can be argued that while there has been a certain duplication of efforts in state and federal managed care (health insurance) regulation, the sum total of federalism affecting MCO issues, is a regulatory structure in which eventually a balance will emerge. The states will continue to be leaders in regulating private health insurance, and will press for comprehensive controls over MCOs, addressing fundamental structural and operational issues, such as scope of benefits, capitalization, and risk bearing policies to be applied to fluid models in this area.[39] In turn, Washington will provide guidance for developing managed care policies, and will work with the states to operationalize these policies, particularly in quality of care, and access areas, using ERISA as a primary lever. The federal authorities will utilize their power over Medicare, and their leverage over Medicaid, as a way to promote progressive MCO operational policies, and

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[36] *See* FURROW ET AL., *supra* note 19, § 8-2, at 420.

[37] *See generally id.* § 8-6, at 445-47 (describing differences between ERISA benefit determinations and typical health insurance claim denial cases).

[38] *See generally id.* § 9-7, at 489-92 (discussing provisions of HIPAA).

[39] *See* Thomas G. Goddard, *Managed Care and the Regulatory Arena, in* MANAGED CARE: INTEGRATING THE DELIVERY AND FINANCING OF HEALTH CARE: PART C 19 (1998) (noting horizontal and vertical regulatory structures in the health care arena).

those policies will impact the MCO field generally. A foray into patient protection will expand federal authority in the MCO area, but the states will realistically still play a key enforcement role in the area. This period of evolving MCO regulation can be seen as one of inevitable imbalance, driven by complex changes in our delivery system which are being assimilated into an already intricate structure of health care federalism, which in spite of constant political and economic wrangling seems to eventually achieve a balanced approach to regulation.

There is, however, another more critical perspective on managed care regulation and federalism that sees these developments as the triumph of politics, and legally driven consumerism, challenging the conclusion that federalism is an exercise in achieving horizontal balances that follow cyclical patterns. The current status of managed care regulation can be viewed as occurring because of a void in national, and states' vision concerning what the structure of American health care should be. At best, there exists only a muddled public view of the specific goals for our health system. Like other areas of domestic policy, government has been willing to turn to the private sector to meet public responsibility and in the process endorse a vision crafted in the marketplace. But for all their abilities to innovate and harness new technologies, private health care markets are driven by agendas that do not often mesh with necessary public needs. Managed care plans are creatures of the market, and while they may contain costs, and service most needs of their enrolled populations, they have yet to prove that these plans can function in ways that address the larger societal questions of access, and respond to the needs for accountability and quality. Perhaps there has never been a time in the public forum in which a broad consensus about health policy and the structure of our delivery system existed, but the rapidity of change toward a culture managed care has dramatically illustrated the flaws in American public health policy, and has further served to underscore how counterproductive our system of federalism is in this arena has been.

In the context of federalism, a harsher view of managed care regulation will no doubt be meet by arguments that innovation in American health policy does not flow out of centralized consensus. Innovations in regulation are the result of 50 states and the federal government pursuing conflicting agendas which play themselves out in a sort of Darwinian process, in

which the most viable regulatory approaches survive. Viability in such a context demands varied approaches to regulation which resonate politically, legally and economically in desirable ways within different jurisdictions. The words of Justice Brandeis are often paraphrased, that states are the laboratories of the federal government, so instead of recoiling at the idea of duplication and inconsistency, we tend to embrace a process of parallel regulatory efforts, and see such efforts as a chance to innovate, and thus elevate such innovations, duplicative or not, to expressions of democracy in action.[40] While the regulatory status quo which buttresses state power may be laudable, it must be justified at some point by the results it achieves, and by the cost/ benefits it produces. Solving ever pressing health care issues of cost, quality and access problems just might require a new approach to policy making. Startling statistics in the health arena abound, but few are more compelling than those which document the growing numbers of uninsured in America, or the cost statistics which points out that half of the global expenditures in health can be attributed to the American trillion dollar health enterprise.[41] Simply put, the costs in health care are too high, and access and quality too vulnerable, for us as a society to indefinitely tolerate the awkward ways in which this sector is regulated.

One approach which has been used by federal policy makers in meshing national and state policies has been to treat federal initiatives as regulatory floors on which states can build their own mandates. The most current example of the "federal floor" approach is seen in the HIPAA privacy regulations in which a detailed set of requirements has been issued on the federal level which in turn allows states to add their own requirements.[42] Such a policy is a reflection of a political compromise which is a Washington concession to state governments' traditional role in privacy, and while it may have appeal on this level, it is an invitation to chaos. What HIPAA privacy rules have done is to allow disparate regulatory treatment of patient data from state to state, and in the process create logistical di-

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[40] *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (cautioning the Court in its limitation of state experimentation).

[41] *See* Barry R. Bloom, *The Future of Public Health*, HARV. PUB. HEALTH REV., Fall 2000, at 4.

[42] *See* Standards for the Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (2000) (to be codified at 42 C.F.R. pts. 160 & 164).

lemmas for information which should be able to cross jurisdictional lines without such impediments.[43] It is likely that HIPAA federalism issues will necessitate the creation of a separate office within HHS to unbundle and referee the inevitable disputes. Federal regulatory policies should have unitary effects, and while allowing states to add on to federal regulations may have political appeal, it is not wise public policy.

IS THERE A CURE?

Assuming the reader has not discarded this article as utter nonsense, or the harmless ranting of some obscure academic, the question arises about how our regulatory process in health care can be fixed, and a healthy balance created between Washington and the states. More specifically, can any changes be made in the framework of our system of federalism so that our nation does not have to continue with this current, inefficient process of crafting duplicative regulatory policies in areas like managed care. The fact is, managed care is just a current example of strained federalism, and that whatever health care system follows the present one, it too will be buffeted on the shoals of federalism. It may be tempting to recommend wholesale alteration of our federal system, but such recommendations are too devoid of reality to be worth considering. What would make some sense, however, is a reexamination, and a rational reordering, of regulatory responsibilities in American health care which could serve the respective levels of government as guideposts for formulating new regulatory strategies. It is, however, not an easy task to identify lines of demarcation in health regulation that could be widely agreed upon, as the roots of federal and state interests in this area run deep, and refocusing divisions of authority would open impassioned legal and political battles.

Undoubtedly there are many different approaches which could be postulated that would be helpful to the development of a new regulatory structure for health care federalism. There are also general principles for guiding a new health care regulatory structure that would arouse universal support, but may not have value in a practical sense. For example, few would argue that all Americans should not have access to high quality medical care, but such an aspiration does not serve as an operational guide-

[43] *See id.* at 82,463 (discussing state-specific health privacy protections).

post in realtering the federal/state regulatory processes in an operational sense. Still, recognizing the practical barriers, and more specifically, those of a legal and political nature, it appears that considering a basic set of recommendations for reformatting intergovernmental health regulation in managed care and beyond is needed, and the exercise of attempting to articulate such recommendations, in and of itself, has merit.

This essay will offer six basic recommendations directed toward refocusing health care regulation, and in the process reorienting health care federalism. Four of the recommendations will expand the roles of federal regulators, and the other two will serve to affirm state regulatory powers. The first broad recommendation for redefining health care federalism is that discrepancies in health care coverage across state lines should not be tolerated. There is no sound public policy reason why either government sponsored or private plans should vary in terms of core health benefits covered from state to state. Designing a standard core benefit package, no doubt, will be challenging, but it is an issue which has been confronted by all payers, public and private and the experiences of Oregon Medicaid should be particularly helpful. Inherent in a federal role in benefit design will be the responsibility of Washington to take the lead in assessing new technologies, including pharmaceuticals, to determine whether or not insurance coverage shall be provided.[44] Undoubtedly, placing coverage decisions in federal hands will require changes in law, but such changes should be made to address the chaotic patchwork which now exists in the coverage area, as the health system is in dire need of consensus on what it is that the system should actually cover.[45]

The second recommendation concerning federalism is that questions of reimbursement and distribution of resources should be made at the federal level. Sound public policy demands that discrepancies in reimbursement policies in the same geographical area, from payer to payer, should not exist. Medicare should take the lead, and be used as a national model for all health care payment programs, and its policies in fraud and abuse should be applied to all payers. Cross subsidization should no longer be seen as the way to equalize payment levels, but the federal gov-

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[44] *See generally* Joe Paduda, *Health Care Industry Needs to Refocus*, BUS. INS., Feb. 26, 2001, at 12 (noting the industry-wide problems involved in the provision of health care benefits to employees).

[45] *See generally id.*

ernment should design payment policies which are realistic, and place all health care coverage programs on equal footing. In the area of resources the goal of the federal regulators should be the creation of a delivery system, providing services which are uniformly available. States should not be able to interfere in national schemes to distribute resources equally. For example, the efforts of a state to safeguards harvested organs within its borders, and prevent those organs from being transported across state lines, should not be tolerated.[46] Like core coverage and reimbursement policies, the goal of Washington should be equity in the availability of covered services and states must yield in this area to federal authority, in order to meet broader public policy goals to achieve a more uniformly available set of services.

The third recommendation that will alter federalism is that the federal government should be primarily responsible to review and endorse medical standards and guidelines concerning the practice of medicine.[47] Undoubtedly some will argue that government at any level should not be involved in making decisions about medical practice, and that such matters are the sole purview of the health professions. This argument, however, fails to take into account the reality that the federal government through its financial and regulatory roles is already far too embroiled in the health delivery system not to be making decisions about the processes used in delivering medical care. While the government may not develop the specific processes for delivering care, it certainly has a responsibility to examine the safety and efficacy of treatments and demand clinicians support their conduct with conclusive outcome data. These evaluations should serve as the bases for coverage and reimbursement policies.

The need to evaluate medical care process and efficacy will only expand with the explosion in biological knowledge, the growth of bioinformatics and the continued popularity of alternative treatments. Aside from the goal of achieving some broader basis of uniformity in medical care delivery, government in its health services research role will be called on to

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[46] *See Organ Transplants: Wisconsin to Lead Multistate Lawsuit to Block New Federal Organ Allocation*, Health Care Daily (BNA) (Mar. 16, 2000).

[47] *See generally* Alice G. Gosfield, *Who Is Holding Whom Accountable for Quality?*, HEALTH AFF., May-June 1997, at 26 (explaining the current state of the health care industry as related to regulation and consumer expectations).

safeguard the public against an onslaught of global health information and new treatment options. States simply lack the resources for the future evaluative tasks that will be required. Even now, the state agencies which have grappled with assessing the viability of medical procedures for purposes of coverage can only perform such a function in a very limited manner, and the public benefits of such decision making at the state level, beyond individual case coverage, is uncertain at best.

The fourth recommendation to guide the revamping of health care federalism concerns patients and their individual rights. While states need to be involved in the enforcement of patient rights, there should be a set of uniform rights afforded patients across the country, and as such, policies in this area must be made at the federal level.[48] By tradition, patient rights issues have been the purview of state government from both a common and statutory point of view. The federal government, however, has made inroads into this area, using its administrative authority (and to a lesser extent legislative) to promote patient right protections through various administrative initiatives.[49] As pointed out earlier in this article, states have been rushing into legislative forays to enact a whole series of patient protections, motivated by concerns about managed care abuses and concern over Washington's inaction. In the long run, having each state promote separate patient right policies only leads to a confused and disjointed situation, and just as discrepancies in coverage and reimbursement should not be tolerated, so too discrepancies affecting individual rights ought not exist.

The fifth recommendation in federal/state health policy relations is one that recognizes a central role for the states. The delivery of medical care is primarily a local enterprise, so regulations of facilities and health professional are best left in the hands of the states. State regulators have traditionally taken the lead in protecting the public health in their respective jurisdictions, and such a role should be continued, and if necessary

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[48] *See generally* Robert J. Blendon et al., *Health Care in the Upcoming 2000 Election*, HEALTH AFF., July-Aug. 2000, at 210 (explaining key voter concerns regarding health care and how these concerns relate to the presidential candidates' health plans).

[49] *See Children's Health: HHS Releases Proposed CHIP Rule; Administration Stresses Patient Protections*, Health Care Daily (BNA) (Nov. 2, 1999).

expanded.[50] For example, it should be a state's decision to explore the competitive viability of local health markets, and determinations of the appropriateness of market alterations should remain the purview of state attorneys general. In situations where the delivery system is not bounded by state borders such as the case of the emerging area of telemedicine and e-health, states must yield to federal authority, or develop a uniform compact for assuring that the issue will be handled in similar fashion across the country.[51]

Incorporated into the regulation of the delivery system, there should be a responsibility on the part of states to manage health care reimbursement systems, and states should be delegated to be involved in local fraud and abuse investigations. While overall reimbursement policies ought to be created at the federal level, the operational side of reimbursement should be turned over to the states. Public and private reimbursement dollars should flow through a central state authority, and where local cost variables need to be recognized, such judgements should be made by state reimbursement authorities, based upon application of federal guidelines.

The final recommendation for a revised federalism in health policy concerns a revision of an old idea, health planning. Since the heyday of the 1970s the notion of mandated statewide health planning document has hardly been in vogue.[52] Still the processes involved in a public assessment of the health delivery system in a particular jurisdiction, and the development of goals, and a plan of action for health policies, could be extremely helpful. Clearly there exist numerous plans concerning health care, including federal agency plans, as well as national and state public health plans, Medicaid plans, and a host of other lesser programmatic planning documents. In a restructured

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[50] *See* Eleanor D. Kinney, *Clearing the Way for an Effective Federal-State Partnership in Health Reform*, 32 U. MICH J.L. REFORM 899, 912-16 (1999) (detailing state involvement in public health policy-making).

[51] *See* Federation of State Medical Boards, *A Model Act to Regulate the Practice of Medicine Across State Lines: An Introduction and Rationale*, (visited Apr. 12, 2001) <http://www.fsmb.org/telemed.htm>.

[52] *See generally* Thaddeus J. Nodzenski, *Regulating Managed Care Coverage: A New Direction for Health-Planning Agencies*, 7 ANNALS HEALTH L. 1 (1998) (highlighting necessary changes that health planning agencies must make to regulate managed care programs); Bruce Spitz, *The Elusive New Federalism*, HEALTH AFF., Nov.–Dec. 1998, at 150 (discussing the relationship between federal and state approaches to meeting citizens' health care needs).

federalism arrangement, it would be very helpful for states to develop an annual health plan that would clearly spell out goals and objectives in health policy and regulation, and lay out a plan of action for a particular year. The planning document would need to be reviewed and commented upon by a federal authority, and it would become a type of contract between the branches of government, providing a record which articulates the boundaries of governmental authority and responsibilities in the health sector. A state's failure to adhere to the particulars of their plan would result in reductions in federal funding, or in an increase in federal involvement in state affairs. Presently individual entities have been given authority to act as they see fit, driven by a need to succeed in competitive markets, and not by a sense of creating a sound public health system.

A CONSTITUTIONAL WAKE-UP CALL

Undoubtedly a reader with a passing familiarity with health policy will realize that each of the six principles posited for a realtered health care federalism are fraught with legal and political pitfalls. Even the most seemingly benign changes in the federal/ state relation in health policy will be fought vigorously. The uncertainties in health regulation and the lack of regulatory vision exists because any meaningful change in government health policy is now excruciatingly difficult to achieve, and must be sparked by a major crisis. Clearly any of the six principles enunciated in this essay would be battered on the reefs of politics, and both federal and state politicians will be equally vehement in opposition to changes in current operations which they perceive as diminishing their power in any way. But there is always a possibility that fundamental change could occur, and certainly there is a great deal to recommend a dramatic alteration of the status quo in health policy.

As this article is contained in a health law journal, perhaps the objections that will be voiced most vigorously will come from legal minds who will question whether the author has any clue that the pendulum of federalism is clearly moving away from regulatory dominance by Washington.[53] Based on recent U.S. Supreme Court decisions, there is a growing sense that the

[53] *See generally* MICHAEL S. GREVE, REAL FEDERALISM: WHY IT MATTERS, HOW IT COULD HAPPEN (1999) (describing the evolution of federalism) (summary discussion <http://www.federalismproject.org/library/books/realfederalism.htm>).

integrity of states must be protected against federal dominance. To ignore the realities of current constitutional law trends in considering fundamental changes in regulatory policies is no doubt foolhardy. Questions involving the division of government power are deeply rooted in constitutional jurisprudence, and have a long and tangled history in the courts, with roots that trace back to our founding fathers. It is the curious nature of the American Constitution, with its artful placing of limitations on government power, that has given us a system in which two separate government structures, federal and state, have authority over identical matters, thus leading to the ongoing concerns that frame federalism questions. Grapplings with the demarcations of government power have their origins in early American history, and represent ongoing disputes over the role of federal regulation, the scope of state authority, and the rights of citizens to be free from unwarranted government control at any level.[54] Federalism, sparks consideration of multiple concepts such the doctrines of preemption, enumerated powers, police power, the Commerce Clause, etc. and touches on jurisprudence underlying the Ninth, Tenth, Eleventh, and Fourteenth Amendments.[55] For purposes of this analysis, the consideration of the extensive body of constitutional jurisprudence which addresses these multifaceted matters will be limited to reflections on the recent U.S. Supreme Court opinions concerning federalism, and to a review of the Clinton Executive Orders which deals with federalism as a broader analysis of this area exceeds the scope of this essay.

While legal scholars and state rights advocates have always had a fascination with federalism, it seems to be more of an academic and theoretical concern, in that the 20th century was one in which the federal government consistently amassed greater power. In particular, under the auspices of the Commerce Clause virtually all domestic endeavors appear to fall within the ambit of Congressional authority. The power of the states has been eroded through the use of federal preemption, and even more so by a seemingly endless stream of laws which have created a type of quid pro quo in which states obtain federal funds in return for loss of control over the endeavor in

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[54] *See* DUMBAULD, *supra* note 1, at 140-56 (discussing the value of the Bill of Rights to modern society).

[55] *See id.* at 127-39 (discussing the heightened constitutional value of the Bill of Rights and its ties to the Fourteenth Amendment).

question.[56] Even a program like Medicaid in which states also are very involved in funding is dominated by Washington control because more than half of program's financing is national.[57]

While legislation and politics lie at the heart of the intergovernmental relationship, the position of the courts in deciphering the balance between the states and the federal government is critical. There has been a dramatic change at the U.S. Supreme Court in how the majority of the Court views the issue of federalism, and a seemingly insurmountable body of pro-federal government case law has been replaced by a new jurisprudence of state's rights.[58] In a series of recent decisions the Court has seemed to restore the Tenth Amendment power of the states, and has given states legal deference in areas of traditional state based regulation.[59] In a widely cited environmental law case, *New York v. United States*,[60] the Court ruled that the Congress had exceeded its authority in the Low-Level Radioactive Waste Policy Amendments of 1985, by mandating certain state actions. Justice O'Connor noted that: "States are not mere political subdivisions of the United States. State governments are neither regional offices nor administrative agencies...."[61] In addition to reaffirming the states unique role in governance under the Tenth Amendment, the Court has also focused on the Commerce Clause and has acted on the notion that Congressional power under the clause is not absolute.[62]

The best known of the recent Commerce Clause rulings is the case of *United States v. Lopez*[63] in which the Court found the Gun-Free School Zones Act of 1990 to be an unconstitutional intrusion into an area traditionally regulated by the states. The Court provided a strict reading of the Commerce Clause and noted that the regulation of handguns within school zones

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[56] *See generally* GREVE, *supra* note 53.

[57] *See* FURROW ET AL., *supra* note 19, § 12-1, at 585-86.

[58] *See* American Enterprise Institute, Federalism & Separation of Powers Practice Group, Federalist Society, *Federalism: A Tenth Amendment and Enumerated Powers Revival?* [hereinafter AEI Federalism Project] (visited May 17, 2001) <http://www.federalismproject.org/news/fedsoc.html> (presenting a panel discussion of the issues surrounding federalism and the meaning of the Tenth Amendment).

[59] *See id.*

[60] 505 U.S. 144 (1992).

[61] New York v. United States, 505 U.S. 144, 188 (1992).

[62] *See* Stephen Ganter, Comment, *Did United States v. Lopez Turn Back the Clock on the Commerce Clause?*, 21 T. MARSHALL L. REV. 343 (1996).

[63] 514 U.S. 549 (1995).

could not be construed as a form of interstate commerce regulation.[64] Justice Kennedy in a concurring opinion presented a very strong endorsement of state sovereignty, characterizing it as an essential safeguard of individual liberty.[65] Kennedy argued that the Court needs to intervene to preserve the necessary balance between states and the federal government, and that deference should be provided to the states in areas, like education, where they have traditionally taken the lead in regulation.[66]

If the recent Tenth Amendment cases are read in conjunction with the Commerce Clause decisions, it seems apparent that the Court has taken a different tact in the area of states rights, and that any suggestions of altering the intergovernmental balance in health policy will hit a wall of constitutional challenges. No doubt federalism has been reinvigorated, but the recent cases decisions must be viewed against a broader legal backdrop which is one that has endorsed a broad concept of federal power. The dissenting opinion in *Lopez* by Justice Breyer harkens back to a more familiar legal tradition in which the power of the Congress to regulate under the Commerce Clause is very broad and all encompassing.[67] Breyer points out in *Lopez* that the Court in past cases found no Commerce Clause violations in situations in which the link between regulation and commerce was far weaker than in *Lopez*.[68] The Court in *Lopez* was also careful not to overrule prior Commerce Clause cases and disavow a long tradition in this area. In looking at the recent cases involving federalism, a noted analyst in the area pointed out that the recent Supreme Court opinions have a distinct status bent, with the dominant focus being on state sovereignty, as opposed to citizen choice or state competition.[69] Federalism has been asserted in areas where states have strong traditions of regulation, such as health care and the concept of dramatic failure in state regulatory efforts, justifying intervention by the Congress, is not one the courts have considered in balancing intergovernmental power. These recent federalism decisions, however, do nothing to alter the Congress' abilities to use the power of the purse to circumvent the states,

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[64] *See Lopez*, U.S. 514 at 564-68.
[65] *See id.* at 568 (Kennedy, J., concurring)
[66] *See id.* at 579-83 (Kennedy, J., concurring).
[67] *See id.* at 615-31 (Breyer, J., dissenting).
[68] *See id.* at 625-27 (Breyer, J., dissenting).
[69] *See* GREVE, *supra* note 53.

and if an arm of the federal government is limited by the Court, it is the federal courts and not the Congress which is most directly affected.

While the legal concepts surrounding issues of federalism must be given due deference, the overriding reality in this sector is one which concerns politics and related issues of economics.[70] (It seems unlikely that any serious student of American government would argue that the states do not have a significant role in governance and the federal government needs to respect that role, but the daily workings of government force the practical reality on us, that the United States cannot function without a large centralized government.) The debates which have surrounded the development of presidential positions on federalism are telling, infrequently told saga, of how the issues of intergovernmental relationships are first and foremost matters dealt with in the political arena. In 1987, President Ronald Reagan issued Executive Order 12,612 which articulated the Reagan position on the relationship of Washington with the states, and reflected the President's conservative views that the size and scope of the federal government should be limited.[71] President Clinton took it on himself to articulate a different vision of government, and actually issued three major executive orders dealing with federalism. Clinton's second Executive Order 13,083 was explicitly designed to replace the prior Reagan order, and expressed a more expansive view of federal power by removing restrictions on regulations that had federalism implications or imposed direct costs.[72] Executive Order 13,083 was harshly criticized by state officials, to the point that it was rescinded and replaced with Executive Order 13,132 which adopted more of a conciliatory, collaborative tone to federalism issues.[73] The Bush administration has indicated that it will move further to collaborate with states, and will develop an executive order on federalism which stresses regulatory consolidation, streamlining

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[70] AEI Federalism Project, *supra* note 58.

[71] Exec. Order No. 12,612, 52 Fed. Reg. 41,685 (1987); *see also* Jennie Holman Blake, Note & Comment, *Presidential Power Grab or Pure State Might? A Modern Debate Over Executive Interpretations on Federalism*, 2000 BYU L. REV. 293 *passim* (2000) (discussing executive orders and their implications concerning federalism issues).

[72] Exec. Order No. 13,083, 63 Fed. Reg. 27,651 (1998).

[73] Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (1999).

of regulatory controls, and providing a liberal grants of waivers.[74]

On the legislative side Congress has seen its share of attempts to create laws which ensure that states will not be overrun by federal regulations. The most noteworthy of the legislative efforts is the Unfunded Mandate Act of 1995[75] which gives state and locally elected officials the chance to seek a roll call vote in the Congress concerning any proposed unfunded mandate. In addition, a somewhat obscure law, the Congressional Review Act of 1995, provides Congress with the ability to review, and rescind federal agency regulations which have an economic impact of at least $100 million.[76] There have been other proposed bills which are designed to respect the rights of states such as the Federalism Accountability Act. Congressional involvement in the federalism issue is pure politics at work, and it is not surprising that the state governors through the National Governors Association have taken up the political gauntlet of federalism on the state side.[77] Unlike the Congress which is using federalism as a way to court favor with local constituencies, the governors are more conflicted. States may rail against the evils of Washington regulators, but their need for money often turns their invocations of federalism into a plea for funds with no strings attached.

CONCLUSION

This essay is centered around a very simple notion, namely that American health policy is desperately in need of a workable vision, and that vision must inevitably originate with, or be adopted by, government. The current regulatory landscape in its attempts to control managed care, and safeguard the public from abuses, presents a dramatic illustration of the breakdown of government policy in this major domestic sector. In very broad terms, the positions which government leaders have taken to-

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[74] *See* NGA Actions, *Federalism, Preemption, and Regulatory Reform* (last modified Mar. 6, 2001) <http://www.nga.org/nga/lobbyIssues/1,1169,D_1189, 00.html> (discussing current views on federalism).

[75] *See* The Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, §205, 109 Stat. 66 (1995) (codified at 2 U.S.C. § 1535).

[76] Federalism Accountability Act, H.R. 2245, S. 1214, 106th Cong., § 2 (1999) (promoting federalism and imposing accountability for federal preemption of state and local laws).

[77] *See id.*

ward managed care are fundamentally schizophrenic, promoting the concept as a type of cost effective, market based salvation for health care, but simultaneously, in reaction to politics, government leaders are railing against the very vehicles of care and coverage they are promoting. At the core of the current health care regulatory dysfunction is a system of federalism in which the respective levels of government are acting in a competitive, duplicative, and ultimately financially irresponsible manner. Perhaps this current period of imbalance in intergovernmental relations could be tolerated in the past, but it is a central feature in a health system which the Institute of Medicine has recently classified as being in crisis.[78]

This essay posits six recommendations, none of which are original to this author. The six recommendations, creating a minimum benefit package, eliminating regional variations in reimbursement policies and available services, developing national medical practice standards, federalizing patient rights, recognizing the primacy of state regulation in delivery systems, and recreating a state based health planning process, would collectively have a profound impact on health care federalism, but would each individually also alter intergovernmental relations in this sector. No doubt there are numerous other approaches which would be equally, or more, helpful in restoring a rational balance to health care federalism. The fact is that whatever solutions are posited, they will be meet with strong legal and political objections, as the interests in maintaining the status quo run very deep in the area of federalism. The legal objections to a realtered federalism have been buttressed by recent Supreme Court decisions which appear to have revitalized this dormant area. Analysis of recent changes in the Court's position on federalism demonstrates, however, that while state sovereignty may have gotten a boost, Congressional power has not been so much reduced, as it has been mandated by courts to

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[78] *See, e.g.*, COMMITTEE ON THE CHANGING MARKET, MANAGED CARE, AND THE FUTURE VIABILITY OF SAFETY NET PROVIDERS, INSTITUTE OF MEDICINE, AMERICA'S HEALTH CARE SAFETY NET: INTACT BUT ENDANGERED 10, 205-07 (Marion Ein Lewin & Stuart Altman, eds., 2000) (describing American "safety-net" healthcare system, including managed care components, as verging on crisis); National Governor's Ass'n, *Policy Position: HR-37. Private Sector Health Care Reform Policy* (visited May 14, 2001) <http//www.nga.org/legislativeUpdate/1,1169, C_POLICY_POSITION^D_555,00.html> (describing NGA's positions on key federal-state health policy issues emphasizing greater need for federal-state coordination and cooperation in state-focused regulation).

be exercised in less overt ways. Intergovernmental relations in all sectors, not just health, are first and foremost matters of politics, and it is in this area where the most serious barriers to the six recommendations made in this essay will be faced. Politics, however, is even more malleable than law and even here, sooner or later pressures for change do create movements.

Perhaps it is inappropriate to be flippant when beginning a proverbial assault on one of the peaks of American health policy, federalism, but legal and political realities must not prevent us from scaling into the thin air of reform. Managed care regulation, as it now stands, lacks vision and purpose, and is not effective in the face of mounting cost, quality and access problems. As major changes in health care are being recommended across the board to deal with managed care problems, commensurate changes must occur in the ways in which this sector is regulated, and changes in federalism should lie at the heart of any reform agenda. A new century demands new solutions to the problems inherited from the past and while progress should be guided by a sense of basic legal principles underpinning the structure of government, such principles should never be viewed as absolute, but only as tools to be refitted to the needs of the times.