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Designing Administrative Organizations for Health Reform

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SUMMARY

Many proposals for expanding health coverage involve the creation of organizations to produce information on comparative effectiveness, make coverage decisions, manage the marketplace for health insurance, or offer a public health insurance plan. These new organizations might take the form of a federal executive branch agency, an independent commission, government corporation, legislative branch agency, or public-private entity. Some proposals would create entities with substantial independence from the usual political processes, such as the Federal Reserve enjoys.

The choice of an appropriate organizational structure to carry out a public function raises several issues: the source and predictability of the entity's funding, its operational flexibilities, its degree of political independence and accountability, and the structure of its management. These matters are not fully determined by an agency's organizational form, however, and targeted solutions are often available and usually preferable. For example, the Congress may provide an agency with a permanent appropriation or exemption from certain legal or regulatory constraints without removing it from an executive department.

Organizations that use governmental powers and funds and make public policy need to be accountable as well as effective. A quasi-governmental or Federal Reserve-like entity might be suitable for producing advisory information on the comparative effectiveness of medical treatments but not for making decisions that directly affect the health coverage of individual Americans.

Any plan for expanding health coverage and containing the growth of health costs will necessarily create additional tasks for government, which may be assigned to existing or new governmental entities. Prompted by concerns over perceived political gridlock, the role of special interests, and inadequate or uncertain funding, several recent proposals would create new health-related entities or agencies with substantial independence from the usual political processes. Sometimes these proposed entities are described as a "Federal Reserve for health."

This paper briefly describes proposals to create new entities or agencies as part of a reformed health coverage system, catalogs the major types of federal executive agencies and non-governmental entities, and considers some of the issues involved in choosing an appropriate organizational design. The appendix to the paper provides more detailed information about some specific proposals in the authors' own words.

PROPOSALS FOR NEW HEALTH-RELATED ORGANIZATIONS

Proposals for new independent, health-related agencies fall into four categories:

- an entity to conduct research on the comparative effectiveness of health care services,
- a commission or other entity to determine which health care items and services public and private insurers should cover,
- an agency to manage the marketplace where health insurance is sold, and
- an agency to offer health insurance services.

Under some proposals, a single entity would combine two or more of these functions. As the Congressional Budget Office has written, "The appropriate organizational form for any new or expanded federal entity, along with the mechanism and level of funding, may depend in large part on what activities it would carry out" (CBO 2007).

Producing Information on Comparative Effectiveness

In health care, comparative effectiveness analysis is a "rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may also weigh both the costs and benefits of those options" (CBO 2007).

Cost-effectiveness analysis is one category of comparative effectiveness analysis. In cost-effectiveness analysis, the resources used in supporting an intervention are measured in monetary terms, but health outcomes or consequences are measured in their natural units, such as number of lives saved, cases diagnosed, cases prevented, or increases in life expectancy or quality-adjusted life years. The strength of cost-effectiveness analysis is that no dollar value is placed on health outcomes or human lives, as in cost-benefit analysis, where both costs and benefits are

expressed in monetary terms. However, in cost-effectiveness analysis only interventions whose outcomes are measured in equivalent terms can be compared.

Comparative effectiveness analysis is increasingly advocated as a way of slowing the growth of health costs without incurring adverse health outcomes. A prominent proponent is Peter R. Orszag, since January 2007 the director of the Congressional Budget Office. "The financial incentives for both providers and patients tend to encourage the adoption of more expensive treatments and procedures, even if evidence of their relative effectiveness is limited," Orszag writes. "The expansion of research on comparative effectiveness could help to correct these problems, especially the addition of analyses that both examine the relative medical benefits and risks of each treatment option (for all patients or some subgroup thereof) and weight the benefits against the costs" (Orszag and Ellis 2007).

The Medicare Payment Advisory Commission (MedPAC) has offered one of the most detailed and carefully analyzed proposals for producing information on comparative effectiveness. In a June 2007 report, MedPAC finds that the private sector cannot be expected to produce systematic, objective comparative-effectiveness information, and there is no comprehensive federal effort to fill the gap. It therefore recommends the creation of an independent entity to examine the comparative effectiveness of alternative ways of diagnosing and treating health conditions, including drugs, medical devices, surgical procedures, and medical services.

The entity proposed by MedPAC would set research priorities, review existing evidence on comparative effectiveness, conduct or sponsor new studies, ensure that its findings are unbiased and not affected by the interests of researchers or funders, operate under a transparent process, obtain input from stakeholders, reexamine the effectiveness of services as new information and treatments become available, and disseminate its findings widely. Its primary mission would be "to sponsor studies that compare the clinical effectiveness of a service with its alternatives," but MedPAC "does not rule out" studies of cost effectiveness as well. MedPAC "envisions that the entity would contract out most of the research to outside groups, including existing governmental agencies, with experience conducting comparative-effectiveness studies," although the entity would need experienced in-house staff to design proposals and monitor contracts. The proposal makes clear that the entity "would have no role in making or recommending either coverage or payment decisions for public or private plans" (MedPAC 2007).

The MedPAC report cites similar previous proposals by AcademyHealth, Joel Kupersmith and colleagues, Uwe Reinhardt, and Gail Wilensky (MedPAC 2007). As part of comprehensive plans to achieve universal health coverage, Ezekiel Emanuel and Victor Fuchs have proposed an Institute for Technology and Outcomes Assessment (Emanuel and Fuchs 2006, 2007), the Committee for Economic Development (CED) has proposed an Institute for Medical Outcomes and Technology Assessment (CED 2007), and Len Nichols has proposed a Comparative Effectiveness Agency (Nichols 2007).

Some of these proposals would give the new entity a high degree of organizational independence. The institute proposed by the CED would, "like the Federal Reserve Board," be "freestanding and semi-autonomous." It would have a "stable budget," independent of the annual appropriation process, "to provide thorough insulation from short-term political

pressures" (CED 2007). Such proposals are prompted in part by unhappy experience with prior efforts at technology assessment by government agencies. The Office of Technology Assessment, a Congressional agency, was abolished in 1995, and the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]) faced a near-death experience in the same year after back surgeons objected to the agency's guidelines for back surgery (Lewis 1995; IOM 2008). Proponents may also have in mind efforts by the Department of Health and Human Services to alter AHRQ's first annual report on racial and ethnic disparities in health care (Pear 2004).

So far, MedPAC has made no recommendation on how to structure or finance the proposed entity that would produce comparative-effectiveness information. Citing Wilensky, the commission suggests that the entity should be able to produce research that is viewed as objective and free of bias and conflict of interest, be independent of stakeholders and political pressures, and have stable financing and staffing. The commission's report considers some of the pros and cons of making the entity a government agency, a public-private partnership (such as a federally funded research and development center), or a private-sector organization (such as a congressionally chartered nonprofit).

The Children's Health and Medicare Protection Act of 2007, passed by the House of Representatives in August 2007, would establish a Center for Comparative Effectiveness Research within the Agency for Healthcare Research and Quality (section 904 of H.R. 3162). It would also establish an independent Comparative Effectiveness Research Commission to oversee, evaluate, and set priorities for the center's work. The commission would be comprised of two designated officials of the executive branch and 15 additional members appointed by the Comptroller General for 4-year terms. The center and the commission would be supported by a permanent appropriation from a Comparative Effectiveness Research Trust Fund, which would be financed by fees on insured and self-insured health plans and transfers from Medicare.

A January 2008 report by the Institute of Medicine (IOM) recommends that the Congress direct the Secretary of Health and Human Services to establish "a single national clinical effectiveness assessment program . . . with the authority and resources to set priorities for and sponsor systematic reviews of clinical effectiveness, and to develop methodologic[al] and reporting standards for conducting systematic reviews and developing clinical guidelines. The IOM panel also recommends that the Secretary "appoint a broadly representative Clinical Effectiveness Advisory Board to oversee the Program." The panel, however, does not address the organizational issues of where to place the program and whether it should be public, private, or a public-private collaboration (IOM 2008).

Making Coverage Decisions

Any government program to require or provide health insurance coverage requires determining the extent and nature of that coverage. While the law creating the program would most likely specify the scope of coverage to some degree (for example, by category of service or actuarial value), the continual development of new medical services, drugs, and devices will always require an administrative agency to determine whether specific procedures or technologies

should be covered. In the Medicare program, for example, coverage decisions are made by the Centers for Medicare & Medicaid Services (CMS) and its contractors, not only for traditional Medicare but also for participating private (Medicare Advantage) plans (Jost 2005).

Studies of coverage determinations typically find that proponents of new technologies are the most active participants in the process. In a recent international comparative study, for example, Timothy Jost concludes that "economic and political pressure in most instances favors adoption of technology coverage, and that coverage determinations institutions are only partially insulated from this pressure" (Jost 2005).

To reduce the influence of health care providers, drug companies, device manufacturers, single-disease organizations, and other interested parties, some analysts have suggested that an independent entity should be created that would not only conduct comparative-effectiveness analyses but also make decisions about which items and services should be covered by public and private health insurance. Leif Haase has proposed the creation of an agency "to review the cost-effectiveness of medical procedures, therapies, and drugs" and to "fix the basis for coverage decisions for different plan benefit levels" (Haase 2005). Jost has proposed creation of a federal commission to determine which items and services insurers would cover. Jost makes explicit that his proposed commission would not only initiate and review assessments of comparative effectiveness but would also engage in policymaking—for example, weighing costs and benefits of medical services and determining which items or services might prove particularly amenable to being used for risk selection. To shield the commission from political pressure, its members would be appointed by "someone reasonably apolitical" and serve for long terms (Jost 2007).

In Len Nichols' plan for universal coverage, a Benefits Board would establish a mandated benefits package, which would be the legally required minimum amount of health insurance coverage. The Benefits Board would also establish a structure of cost-sharing, including cost-sharing subsidies for low-income individuals. The board would be "an independent entity" but "would be expected to work closely with Congress, more or less like the Federal Reserve chairman does" (Nichols 2007). Although Nichols suggests that Comptroller General of the United States appoint the members of the Benefits Board, this arrangement might well be unconstitutional, since the Supreme Court held in *Bowsher v. Synar* (1986) that the Comptroller General may not perform an executive function (in that case, sequestration of spending authority under the Balanced Budget Act) because he is part of the legislative branch and subject to removal by the Congress alone.

Managing the Marketplace for Health Insurance

Many proposals for expanding health coverage include a national system of health insurance exchanges, which would serve as a central marketplace in which much or all health insurance would be bought and sold. Although these plans differ in their details, the proposed exchanges would perform such functions as establishing a basic benefits package (if not determined by a separate benefits board or commission), creating and managing a market for health insurance, assuring that health insurance plans meet standards of financial soundness and customer service, providing educational material to potential applicants, enrolling people in plans individually or

as members of a group, maintaining enrollment information as individual circumstances change, collecting individual premiums and government subsidies (if any), and distributing payments to plans on a risk-adjusted basis. For a more extensive discussion of insurance exchanges, see the background paper prepared for the study panel by Elliot Wicks (Wicks 2007).

Nichols suggests that an insurance purchasing exchange could be managed either by a government agency, like the Federal Employees Health Benefits Program (FEHBP), or by a nonprofit organization, like the Pacific Business Group on Health, which administers health insurance for large employers in California. Exchanges could be organized along state or regional lines (Nichols 2007). Emanuel and Fuchs and the Committee for Economic Development both model their proposed administrative structure—a central board with a network of regional exchanges—on the Federal Reserve System (Emanuel and Fuchs 2007; CED 2007). In the CED proposal, the governors of the "Health Fed" would be appointed for 14-year terms, and the heads of the regional exchanges would be selected by the board of governors. The Health Fed would be funded by fees, such as a levy on health insurance premiums, and not subject to annual appropriations. According to its authors, this model is designed to "convey impartiality, expertise, freedom from narrow political interests, stability, and a long-term perspective" (CED 2007).

Former Senate Majority Leader Tom Daschle has recently become an advocate of a Federal Reserve-like health board. In a book published in February 2008, Daschle argues that the failure to achieve universal coverage and contain health costs "is rooted in the complexity of the health-care issue, the limitations of our political system, and the power of interest groups . . . that have a direct stake in it." Daschle continues:

> I believe that the only way to solve the health-care crisis is to change the way that we approach the challenge. In this book, I propose a Federal Health Board, modeled loosely on the Federal Reserve System, to do so. It would create a public framework for a largely private health-care delivery system. Its main job would be to develop the standards and structure for a health system that ensures accessible, affordable, and high-quality care. . . . Like the Federal Reserve, the Federal Health Board would be composed of highly independent experts, insulated from politics. Congress and the White House would relinquish some of their health policy decisions to it (Daschle 2008).

The notion of a Federal Reserve-like board to manage a health insurance exchange appears to have originated in the early 1990s in the work of the Jackson Hole Group, an informal collection of health policy experts. In its original proposal in 1992, the group proposed a "new National Health Board as an independent agency, like the SEC [Securities and Exchange Commission]." In this way, it wrote, "The NHB will be free from day-to-day interference while still accountable to elected political officials." The group rejected "an autonomous Federal Reserve Board model," which "would have too little public accountability given the scale and public sensitivity of health care reforms" (Ellwood, Enthoven, and Etheredge 1992). Soon thereafter, however, one of the leaders of the group described the proposed board differently: "The board would have a status similar to the Federal Reserve Board, insulated from narrow interest-group pressure" (Enthoven and Singer 1994).

In 1999, Senator John Breaux and Representative Bill Thomas proposed an independent board to manage the Medicare program. Their proposal apparently stemmed from two sources: a desire to remove Congress from many of the details of administering Medicare, and a belief that an inherent conflict exists in having a single agency administer a government-run fee-for-service plan and a system of private insurance plans (King *et al*. 2002). Breaux and Thomas proposed that the role of the Health Care Financing Administration (HCFA, now CMS) be limited to operating Medicare's fee-for-service program and that both the fee-for-service program and private plans be regulated by an independent Medicare Board. They cited the Federal Reserve Board and the Federal Retirement Thrift Investment Board as possible models (National Bipartisan Commission on the Future of Medicare 1999).

Offering a Public Health Insurance Plan

In addition to serving as a clearinghouse for private insurance plans, a new agency might also offer a competing public health insurance plan. In Jacob Hacker's proposal, for example, "every legal resident of the United States who lacks access to Medicare or good workplace coverage would be able to buy into the 'Health Care for America Plan,' a new public insurance pool modeled after Medicare." Like Medicare, this plan would offer participants a choice of a public fee-for-service program and a range of private plans (Hacker 2007).

Hacker's proposal appears to combine the operation of the public insurance plan and supervision of the private plans in one administrative agency, as is now the case with Medicare, but these two functions could potentially be separated, as in the Breaux-Thomas proposal. In the Daschle proposal, the Federal Health Board "would work with Medicare to develop a public insurance option for the [national purchasing] pool, designing it to compete with private insurance plans on the FEHBP menu" (Daschle 2008). Daschle does not specify which agency would administer the public program.

TYPES OF FEDERAL AGENCIES AND PUBLIC-PRIVATE ENTITIES

What types of organizational entities would best be tasked with carrying out the health-related functions just identified? "In organizational design," says Stanton, "the key is to fit the appropriate organizational form to the purposes to be achieved. . . . Once policy makers have identified the intended goals and purposes of an agency, they can look to existing organizations for possible models that they might adapt" (Stanton 2002). We therefore turn to identifying the menu of organizational options and the issues that arise in choosing among them. Table 1 provides a quick summary of the discussion.

For the most part, the federal government carries out its activities through agencies in the executive branch, of which the President of the United States is chief executive. However, the federal government has also created a many public-private and private entities to help achieve public purposes. Governmental and quasi-governmental organizations exist in almost infinite variety, and the following taxonomy lists only the types that are relevant in the present context.

Table 1. Types of Federal Agencies and Public-Private Entities and Their Characteristics

Type of Organization	*Funding Authority*	*Operational Flexibilities*	*Political Independence and Accountability*	*Management Structure*
Executive Departments	Annual appropriations; occasionally, permanent appropriations	Subject to general laws affecting personnel, contracting, disclosure, and due process; flexibility sometimes provided	Subject to presidential direction and control; agency head serves at the pleasure of the President	Headed by cabinet secretary
Independent Regulatory Commissions	Annual appropriations	Subject to general laws affecting personnel, contracting, disclosure, and due process	Regulations not subject to executive review; members appointed for staggered 5- to 7-year terms; some political balance required	Multi-member boards
Government Corporations	Income from business-type transactions; appropriations generally not required	Perform business-like functions; exempt from some or many legal limitations that apply to agencies funded by annual appropriations	May be independent entity with appointed board or part of an executive department	Executive appointed by the board manages operations
Other Independent Executive Agencies	Annual appropriations; occasionally, permanent appropriations	Subject to general laws affecting personnel, contracting, disclosure, and due process	Varies	Varies
Federal Reserve System	Income from U.S. securities acquired through open-market operations; charges for services	Exempt from many federal procedural requirements	Independent central bank; governors appointed for 14-year terms; chair appointed for 4-year term	7-member Board of Governors; 12 regional Federal Reserve Banks
Legislative Branch Agencies	Annual appropriations	Subject to most general laws affecting personnel, contracting, disclosure, and due process	Responsible to the Congress; serve in advisory capacity	Varies; may not carry out executive functions
Federally Funded Research and Development Centers	From the budget of the sponsoring agency and private sources	Generally exempt from federal procedural requirements	Under guidance and oversight of sponsoring federal agency	Managed by non-governmental organizations
Agency-Related Nonprofits	From private sources	Generally exempt from federal procedural requirements	Legal relationship with a federal department or agency	Varies
Congressionally Chartered Organizations	From specific appropriations and private sources	Generally exempt from federal procedural requirements	Non-governmental	Varies

Federal Executive Agencies

The United States Government Manual, the self-described official handbook of the U.S. federal government identifies only two types of executive agencies—(1) departments and (2) independent establishments and government corporations (Federal Register 2007). A more refined taxonomy might distinguish independent regulatory commissions, government corporations, and other types of independent agencies, although the distinctions between these remaining categories are often blurred (Warren 1998).

Executive Departments

The 15 cabinet departments (State, Treasury, Defense, and so on) have been created as administrative agencies to assist the President in implementing laws enacted by the Congress (Warren 1998). Executive agencies are therefore subject to many forms of presidential control (Garcia 1999):

- Each department is headed by a Secretary, who is appointed by the President, confirmed by the Senate, and serves at the pleasure of the President. Non-career appointees below the secretarial level are recruited and screened by the White House Office of Presidential Personnel, and many subcabinet positions require Senate confirmation.
- By statute or Executive Order, each department's budget request, staffing levels, Congressional communications, and data collection activities are subject to review or clearance by the Office of Management and Budget (OMB) in the Executive Office of the President. The Office of Personnel Management determines how many Senior Executive Service positions each agency will have.
- The Department of Justice serves as the central litigating authority for executive departments.
- The Office of Management and Budget reviews and clears newly developed regulations.

For the most part, funding for personnel costs and other day-to-day operating expenses of the cabinet departments depends on annual appropriations by the Congress. Other types of governmental organizations may be exempt from some or all of these types of presidential or Congressional control.

Most federal health agencies are currently part of the Department of Health and Human Services (HHS). These include the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the National Institutes of Health (NIH). Major health programs administered by other departments or independent agencies include military health care (in the Department of Defense), veterans health care (in the Department of Veterans Affairs), the Federal Employee Health Benefits Program (in the Office of Personnel Management), and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) (in the Department of Agriculture).

Independent Regulatory Commissions

A number of commissions have been established outside the executive departments to make rules and orders to regulate specific activities or industries (Warren 1998). These so-called independent regulatory commissions include the Commodity Futures Trading Commission, Consumer Product Safety Commission, Federal Communications Commission, Federal Election Commission, Federal Mine Safety and Health Review Commission, Federal Trade Commission, National Labor Relations Board, National Transportation Safety Board, Nuclear Regulatory Commission, Occupational Safety and Health Review Commission, Postal Rate Commission, Securities and Exchange Commission, and United States International Trade Commission.

Several structural and procedural safeguards are designed to provide a substantial degree of independence for these commissions. They typically consist of three to five members, who are appointed by the President with the consent of the Senate. The members serve staggered five- to seven-year terms and cannot be removed except for cause. No more than a simple majority of a commission may consist of members of the same political party. Regulations issued by independent, multi-headed boards and commissions are not subject to OMB review and clearance (Garcia 1999). However, commissions generally remain subject to budgetary controls imposed by the President and the Congress and to Congressional oversight (Warren 1998).

Government Corporations

Government corporations are agencies that perform a business-like function and that are potentially self-sustaining through revenues generated by the sale of goods or services. For example, Amtrak is in the business of passenger rail transportation, the Federal Deposit Insurance Corporation charges for deposit insurance, the Tennessee Valley Authority sells power, and the U.S. Postal Service sells delivery services (Stanton 2002). Other government corporations that are not part of cabinet departments include the Export-Import Bank, Overseas Private Investment Corporation, and Pension Benefit Guaranty Corporation. These corporations are governed by boards of directors appointed by the President and confirmed by the Senate. An executive appointed by the board typically manages the day-to-day operations of the corporation.

Some government corporations are part of executive departments and fall under the policy supervision and oversight of a cabinet secretary (Rivlin 1995). For example, Federal Prison Industries is overseen by the Bureau of Prisons in the Department of Justice, and the Federal Housing Administration is part of the Department of Housing and Urban Development.

Independent government corporations are generally included in the *Budget of the U.S. Government*, although they typically do not require annual appropriations, except when the government provides a subsidy. To that extent, wholly owned government corporations are exempt from many of the legal limitations that apply to agencies funded by annual appropriations (Stanton 2002). Ultimately, however, a government corporation will has much or as little independence as the Congress allows. Citing a 1995 GAO study, Merlis reports that

different corporations were subject to as few as two and as many as 14 out of 15 laws imposing management requirements on federal agencies (Merlis 2000).

Other Types of Independent Executive Agencies

Several independent agencies—for example, the Environmental Protection Agency (EPA), Federal Retirement Thrift Investment Board, National Aeronautics and Space Administration, Office of Personnel Management, National Science Foundation, Peace Corps, Small Business Administration, and Social Security Administration—do not fit neatly into any of the previous categories. They are subject to most of the same laws and requirements as executive departments but, except for EPA, do not benefit from the prestige and Presidential access that attach to cabinet status. (The administrator of EPA has been accorded cabinet-level rank.) Two of these independent agencies deserve special mention because they are sometimes cited as models for new health-related agencies.

The Social Security Administration (SSA) manages the Social Security retirement, survivors, and disability insurance program and the Supplemental Security Income program for low-income aged and disabled persons and also performs many operational functions for Medicare. It has a staff of about 59,000 and an administrative budget of some $9½ billion (OMB 2007). SSA was made an independent agency by the Social Security Independence and Program Improvements Act of 1994. "Proponents of SSA's independence wanted to insulate it from everyday political, fiscal, and operational policy decisions of the Government" (DeSimone 1995), but that hope was probably unrealistic and has not been fulfilled. The 1994 act requires the Commissioner of Social Security to prepare an annual budget for SSA, which is to be submitted by the President to the Congress without revision along with the President's budget. This requirement is being satisfied only nominally through the inclusion of a paragraph in the budget's *Appendix*, and appropriations for the agency's administrative expenses have been tight. As a practical matter, policymaking for Social Security remains directed from the White House. The Commissioner of Social Security now has a six-year term, although the workability of this arrangement has yet to be tested when the Presidency changes hands from one political party to another.

The Federal Retirement Thrift Investment Board manages the Thrift Savings Plan, a defined-contribution retirement savings program for participating employees of the federal government. The five members of the board are appointed by the President with the advice and consent of the Senate and serve on a part-time basis. The board appoints a full-time executive director, who is responsible for day-to-day operation of the agency (Office of the Federal Register 2007). The board and executive director serve as fiduciaries and manage the investments of the Thrift Savings Fund (now over $230 billion) on behalf of participants. The board employs a staff of 75 and incurs annual administrative expenses of about $90 million. These administrative costs are financed from the Thrift Savings Fund and do not require annual appropriation (OMB 2007).

Federal Reserve System

From 1836, when the charter of the Second Bank of the United States expired, until 1913, when President Wilson signed the law establishing the Federal Reserve System, the United States had

no central bank. During this long interregnum the concept of central banking remained highly controversial, and the Federal Reserve's unique structure reflects the historic circumstances of its birth—what one observer calls "the country's abiding fear of concentrated financial power" (Lowenstein 2008).

The Federal Reserve System comprises a Board of Governors and 12 regional Federal Reserve Banks. The seven members of the Board of Governors are appointed by the President and confirmed by the Senate for 14-year terms. The chairman and vice chairman of the board are named by the President from among the members and confirmed by the Senate for a term of four years. Each of the Federal Reserve Banks is supervised by a board of nine directors. Six directors are elected by member banks in the district, and three are appointed by the Board of Governors. The directors appoint the Reserve Bank presidents (the chief executive officers) to five-year terms, subject to approval by the Board of Governors.

As the U.S. central bank, the Federal Reserve is responsible for conducting the nation's monetary policy in pursuit of stable prices and maximum employment. It is considered to be an independent central bank because its decisions do not need to be ratified by the President or anyone else in the executive branch. The Federal Open Market Committee (FOMC) oversees open market operations, the principal tool of monetary policy. The FOMC comprises the seven members of the Board of Governors, the president of the Federal Reserve Bank of New York, and presidents of four other Reserve Banks, who serve as voting members on a rotating basis. One contemporary observer describes the FOMC as "an unwieldy and archaic body in the best of times" (Lowenstein 2008). The Federal Reserve also plays a major role in supervising and regulating the banking system and operating the payment system, including the distribution of cash and the clearance of checks and electronic payments (Board of Governors 2005).

The income of the Federal Reserve System derives primarily from interest on the U.S. government securities that it acquires through open market operations. The Federal Reserve also receives revenue from priced services, primarily check clearing. The system's income is available to pay its operating expenses (an estimated $3.3 billion in 2007) without Congressional appropriation or review by the Office of Management and Budget (Board of Governors 2007). The rest of the system's income ($32 billion in 2007) is returned to the U.S. Treasury.

Legislative Branch Agencies

Several agencies, boards, and commissions—for example, the Government Accountability Office (GAO, formerly the Government Accounting Office), the Congressional Budget Office (CBO), and the Medicare Payment Advisory Commission—are located in the legislative branch of the federal government. These organizations assist the Congress in undertaking its legislative functions and serve the Congress in a staff role or an advisory capacity. Any attempt to assign executive functions to a Congressional agency would most likely "violate the Constitution's command that Congress play no direct role in the execution of the laws" (*Bowsher v. Synar*).

The Medicare Payment Advisory Commission, for example, is a 17-member commission that advises the Congress on issues affecting the Medicare program, including payment rates, access

to care, quality of care, and the interaction of Medicare policies with health care delivery generally. Commissioners are appointed to three-year terms by the Comptroller General (who heads GAO) and serve part-time. The members include health care providers, payers, employers, consumers, biomedical and health services researchers, and health economists, but providers may not constitute a majority (see section 1805 of the Social Security Act).

Public-Private Entities

Sometimes the federal government carries out public purposes through non-governmental organizations. Such entities are variously called public-private entities, quasi-governmental organizations, or private instrumentalities of government. Three types of public-private entities have been suggested as possible producers of information on comparative effectiveness: federally funded research and development centers, agency-related nonprofit organizations, and Congressionally chartered nonprofit organizations. These entities have some legal connection to the federal government and may receive most or all of their funding from the federal government, but they are not federal government agencies. We do not consider government-sponsored enterprises (GSEs), which are government chartered and privately owned institutions created by the Congress to help make credit more available to certain sectors of the economy (Kosar 2007).

Federally Funded Research and Development Centers

Federally funded research and development centers (FFRDCs) are nonprofit, private organizations that federal agencies sponsor to meet technical or research needs. FFRDCs are managed by non-governmental organizations, including industrial firms, universities and colleges, and other nonprofit institutions, under the overall guidance and oversight of the sponsoring agency. Federal funding comes from the budget of the organization within the sponsoring agency that requests the work. An FFRDC may receive up to 30 percent of its funding from private sources (IOM 2007).

Currently, nine departments or agencies sponsor 38 FFRDCs. The Department of Energy sponsors 16, and the Department of Defense sponsors 10 (NSF 2007). For example, the National Cancer Institute at Frederick, operated by four firms for the National Institutes of Health, provides scientific and technical support services for programs of the National Cancer Institute. The Homeland Security Institute, administered by Analytic Services, Inc., evaluates systems and technologies and conducts risk analyses for the Department of Homeland Security (IOM 2007). Fermi National Accelerator Laboratory (Fermilab), administered by a consortium of universities for the Department of Energy, conducts basic research in high-energy physics and related disciplines. If an FFRDC were established to conduct comparative effectiveness analyses, it might be affiliated with the Agency for Healthcare Research and Quality (IOM 2007).

Establishment of an FFRDC does not absolve the sponsoring agency of responsibility if a problem arises. In 2003, for example, the Department of Energy put the management of Los Alamos National Laboratory up for competitive bidding after a series of security, safety, and financial lapses by its then operator, the University of California (Broad 2005). Nor do FFRDCs

escape the uncertainties of the Congressional appropriation process. Unanticipated reductions in spending for high-energy physics in the fiscal year 2008 appropriation required Fermilab to lay off staff and furlough the rest for two days a month (Chang 2007).

Agency-Related Nonprofit Organizations

The term "agency-related nonprofit organization" covers several disparate types (and an indeterminate number) of organizations that have a legal relationship with a department or agency of the federal government. Sometimes agencies have found it useful to create such organizations to accept and administer gifts of money and property. The most prominent example is the National Park Foundation, established in 1967, which accepts and administers gifts given to the National Park Service. The Secretary of the Interior chairs the board and appoints its members. The foundation is viewed as an adjunct activity of the Department of the Interior and is controlled by the department, although the foundation is off-budget, and its employees are not federal employees (Kosar 2007).

Another such organization is the Foundation for the National Institutes of Health (FNIH). The Congress established the foundation as a non-profit corporation in 1996 to support the research priorities of the National Institutes of Health by raising private sector funds to stimulate and facilitate the formation of public-private partnerships (FNIH 2007a). The foundation is involved in nearly 50 public-private partnerships and has raised approximately $350 million since its inception, including $200 million from the Bill & Melinda Gates Foundation for the Grand Challenges in Global Health initiative (FNIH 2007b). Members of the foundation's board are appointed under the bylaws of the Foundation, and the directors of the National Institutes of Health and the Food and Drug Administration are *ex officio* members (as clarified by Public Law 109-482, section 107).

Congressionally Chartered Organizations

Congressionally chartered nonprofit organizations represent still another category of quasi-governmental organizations. Under subtitle II of title 36 of the U.S. Code, the Congress has chartered 92 "patriotic and national organizations." The federal chartering process is largely honorific, and in recent years the Congressional committees of jurisdiction have attempted to place a moratorium on new charters (Kosar 2007).

Congressionally chartered organizations do not receive direct federal appropriations (Kosar 2007). The charters of the National Academy of Public Administration and the National Academy of Sciences, however, provide that the federal government may request the academies to prepare reports in their areas of expertise, and that the reports shall be paid by the government from appropriations for that purpose (36 U.S.C. 1501, 1503). Although the academies also receive funding from private sources, the bulk of their funding comes from the federal government.

ISSUES IN CHOOSING AN APPROPRIATE ORGANIZATIONAL STRUCTURE

The choice of an appropriate organizational structure to carry out a particular public function raises several issues or questions. These range from relatively mundane questions of funding sources and managerial flexibility to the highest one—should the organization be located in the public or private sector (Merlis 2000; Stanton 2002).

Funding Authority

The degree of control by the President and the Congress over a government agency's funding—and the predictability of that funding—may vary, but it is not fully determined by an agency's organizational form. Most federal executive agencies, as previously noted, are subject to the executive budget process and rely on annual Congressional appropriations to fund their personnel costs and other operating expenses. Even when the administrative expenses are paid out of dedicated taxes or premiums (as for the Medicare program) or user fees (as with the review of drugs and medical devices by the Food and Drug Administration), annual appropriations action is usually required.

A permanent appropriation—authority to spend money without annual Congressional action—can provide a substantial degree of stability in funding for an executive branch agency. For example, the Office of the Comptroller of the Currency and the Office of Thrift Supervision, which regulate national banks and savings associations, respectively, are authorized to finance their administrative expenses through mandatory assessments on the institutions which they regulate (OMB 2007). Despite this degree of financial independence, the two agencies remain responsible to the President (both are part of the Department of the Treasury) and the Congress (through their authorizing statute and periodic oversight).

In contrast, entities that earn money from voluntary, business-type transactions with the public (such as the sale of power or postage) are subject more to market discipline than to the Congressional power of the purse, yet even in those cases political and regulatory oversight is never entirely lacking. For example, the Postal Service (a government corporation) is regulated by the Postal Rate Commission (an independent regulatory commission), and the Congress continues to name post offices, subsidize certain types of mail, and set the terms under which the Postal Service operates. No new agency can expect to obtain the financial independence of the Federal Reserve System, which can literally issue legal tender.

Operational Flexibilities

Government agencies are subject to various general laws affecting their operations, such as civil service and other personnel rules, contracting and other procurement requirements, and freedom of information or government-in-the-sunshine rules. These requirements were originally adopted to assure organizational accountability, to prevent use of public positions and funds for political patronage or personal profit, and for other laudable purposes, but they are now sometimes seen as "barriers to efficient or responsive operations" (Merlis 2000).

In recent years, various steps have been taken to provide additional flexibilities for government agencies. The Clinton Administration established a new organizational type, the performance-based organization (PBO), which provides flexibilities in personnel, contracting, and other areas in exchange for a commitment to achieving performance goals. Only two PBOs have been established—the Office of Federal Student Aid in the Department of Education and the Patent and Trademark Office in the Department of Commerce. "The PBO concept," writes Stanton, "is premised on the assumption that policy issues, which remain with the larger department, can be separated from operations, which are the province of the PBO" (Stanton 2002).

Stanton observes, however, that the achievement of operational flexibilities does not necessarily require large-scale organizational redesign, and that targeted solutions are often available and usually preferable (Stanton 2002). For example, the Office of Federal Housing Enterprise Oversight (OFHEO), an agency within the Department of Housing and Urban Development that regulates Fannie Mae and Freddie Mac (both government-sponsored enterprises), is exempt from many standard civil service personnel rules including those for compensation. This exemption allows OFHEO to compete for financial analysts and other skilled personnel. (In 2008, the Federal Housing Finance Agency replaced OFHEO.) Similarly, the National Institutes of Health and other agencies are provided special flexibilities for the hiring of physicians. Upon its creation in 2002, the Department of Homeland Security was exempted from many civil service requirements (Lee 2005). And in the 2004 National Defense Authorization Act, Congress authorized the Department of Defense to design and implement a new personnel system for its civilian employees (Ballenstedt 2008).

Conversely, public-private organizations can also be made subject to some of the same procedural requirements as government agencies. In 1997, for example, the Congress added certain requirements relating to the National Academy of Sciences and the National Academy of Public Administration to the Federal Advisory Committee Act (5 U.S.C. App. §15).

Political Independence and Accountability

A public or public-private entity must steer a course between maintaining political accountability and avoiding undue political interference. There is no clear line, however, that separates accountability from interference, and two different observers may not view a given situation in the same way.

The typical agency is subject to Presidential direction, Congressional oversight, and other outside influences, and the results are sometimes open to question. We have already recounted the story of the Agency for Health Care Policy and Research, which was almost abolished when back surgeons attacked the agency's finding that most back surgery was unnecessary (Lewis 1995). AHRQ, the successor to AHCPR, continues to conduct comparative-effectiveness reviews, although this is not the agency's main mission (MedPAC 2007). In a study of selective Medicare coverage determinations, Jost found that the proponents of new technologies—such as providers, manufacturers, and single-disease advocates—were the only external participants in the decision-making process (Jost 2005). Pharmaceutical companies continually attempt to speed up the FDA's approval of new drugs.

How the form and locus of an organization affects its accountability and independence is not at all clear. If an agency is part of an executive department, the cabinet secretary can potentially assist the agency in the competition for resources and can defend the agency against outside pressures and narrow interests (Stanton 2002). As the examples of the three HHS agencies in the previous paragraph show, however, this is not necessarily the result. Nor does making an agency independent necessarily solve the problem—as the Social Security Administration illustrates. And even (or especially) an independent agency is subject to what is called "regulatory capture"—domination by representatives of the industry that it oversees.

"The usual argument for removing a function from the political process ," writes Merlis, "is that it is technical and better managed by experts. However, if an entity is freed from politics, if it does not answer to the President, just whom does it answer to? This is not just a question of accountability, but rather of the entity's own sense of its constituency and hence of its mission." In the case of a Medicare (or other health insurance) board, Merlis asks, who would be its constituency—beneficiaries, taxpayers, insurers, providers (Merlis 2000)?

Some contend that giving an agency more political independence will facilitate decisions that have long-term benefits but impose short-term costs. In the case of the Federal Reserve and other central banks, maintaining price stability or low inflation may require raising interest rates, which is likely to cause higher unemployment and lower plant utilization. An agency that conducts comparative-effectiveness analysis may issue findings that could cause economic losses for some providers (such as back surgeons) or producers (such as manufacturers of drugs or medical devices). An agency that makes coverage decisions will affect the livelihood of providers and manufacturers, the access of people to possibly life-saving treatments, and the cost of health insurance to those who pay the taxes or premiums. Others would respond, however, that balancing such conflicting objectives is an inherently political responsibility that should not be assigned to an entity that is far removed from the normal political processes.

Management Structure

"As a general rule," writes Stanton, "a single administrator rather than multi-member board best governs a federal agency." Among the limitations of the board structure are the following:

- Members of a government board are likely to have divergent views on some major issues and little incentive to act in a collaborative fashion.
- The board structure can impede accountability, since no one person if fully responsible for decisions.
- *Ex officio* members of a board may be too busy to attend board meetings, and their alternates may not have the authority to act on their own.
- Boards are less capable of timely decision-making.

Conversely, Stanton notes, "there are some times when a board structure is appropriate or even necessary for a government agency":

- For regulatory agencies (but not operating agencies), a divergence of viewpoints may help assure that a fair decision is reached.
- Multi-member boards also help insulate agencies from possible political interference. In the case of both the Postal Service and the Federal Retirement Thrift Investment Board, the insertion of a board between the chief executive of the agency and the political process helps "insulate the agency's operations from the kind of untoward political intervention that characterized the Post Office Department" (Stanton 2002).

An advisory board can provide some of the advantages of a governing board without all the disadvantages. Federal agencies are advised by a vast number of boards and committees, whose operations are generally covered by the Federal Advisory Committee Act (FACA). Advisory boards provide an opportunity to involve a wide variety of stakeholders and points of view in a deliberative process. Their recommendations, even if only advisory, also provide some degree of political protection for an agency administrator. However, an agency that does not accept an advisory board's recommendation may invite political criticism.

The Commonwealth Health Insurance Connector Authority, which administers many elements of the health reforms in Massachusetts, is "an independent public entity" governed by a 10-member board. The Connector is assigned considerable discretion in important areas, for example, in establishing affordability standards and defining minimum creditable coverage for purposes of the individual mandate. Although described as independent, the Connector is closely tied to the political process. Four members of the board are state officials who serve *ex officio*, three are appointed by the governor, and three are appointed by the attorney general (who, like the governor, is directly elected). The appointed members are chosen from specified categories (actuaries, health economists, small business, consumer organizations, organized labor, and employee benefit specialists) and serve for three-year terms. The chair of the board, who is the governor's Secretary of Administration and Finance, selects the executive director of the Connector (Massachusetts 2007). In carrying out its functions, the Connector works closely with many other state agencies, including MassHealth (the state Medicaid agency), the Department of Revenue, the Division of Health Care Finance and Policy, the Division of Insurance, and the Division of Unemployment Assistance.

Public or Private

The ultimate issue in designing an organization to carry out a public purpose is whether it should be governmental or private. As a general principle, activities that are "inherently governmental" must be performed by a government agency and government personnel (OMB 2003). However, the scope of "inherently governmental" activities is contested and changeable. As part of its effort to put out more activities to private competition, the George W. Bush Administration has narrowed the definition of "inherently governmental," although not without controversy. Some states and countries (notably, New Zealand) use private contractors to perform activities similar to those carried out by U.S. government personnel.

According to the current version of the Office of Management and Budget's *Circular A-76*:

> An inherently governmental activity is an activity that is so intimately related to the public interest as to mandate performance by government personnel. These activities require the exercise of substantial discretion in applying government authority and/or in making decisions for the government. Inherently governmental activities normally fall into two categories: the exercise of sovereign government authority or the establishment of procedures and processes related to the oversight of monetary transactions or entitlements (OMB 2003).

The circular takes an additional 1-½ pages to elaborate upon this basic definition and to distinguish "inherently governmental" from "commercial activities," which may (but need not) be performed by the private sector.

An important difference between governmental and private entities is the extent of procedural and due process rights they must accord to individuals or businesses affected by their decisions (Merlis 2000; Stanton 2002). Medicare, for example, has formal appeal mechanisms both for health plans and for beneficiaries enrolled in both traditional Medicare and private Medicare Advantage plans. In contrast, most enrollees in employer-sponsored health insurance plans have "only a limited ability to contest plan benefit or coverage decisions" (Merlis 2000). The appropriate scope of appeal rights for those affected by cost-effectiveness studies, coverage decisions, health insurance exchanges, or a new public health insurance plan would doubtless be hotly debated. Although a governmental entity, the Federal Reserve System, like other central banks, provides for no public input and no appeal by those affected by its decisions to raise or lower interest rates.

Stanton observes that governmental and private entities also perform differently because they have different incentives (Stanton 2002). Moreover, non-profit private organizations differ from for-profit ones. None of the health reform proposals discussed here, however, involves creating a for-profit entity to carry out a public purpose.

CONCLUSION

The Standing Panel on Executive Organization Management of the National Academy of Public Administration has identified several principles to guide the structure and organization of the federal government. One principle is that "organizational design should be tailored to reflect the distinct requirements of different types of government programs so as to facilitate effective performance and maintain accountability." In elaboration, the panel observes, "One size does not fit all types of governmental programs. . . . The distinction between agencies responsible [for] formulating basic policies and those responsible for operations is especially important." The panel expresses particular concern that mislabeling of governmental organizations as quasi- or non-governmental entities "raise[s] serious constitutional questions" when they "use government powers and funds without being fully accountable either to the President or the Congress" (NAPA 1997).

This principle leads to the conclusion that a quasi-governmental organization might be suitable for producing advisory information on the comparative effectiveness of medical treatments and procedures but not for making coverage decisions or managing the marketplace for health insurance—activities that clearly involve policy formulation. Proposals for a "Health Fed" to manage the health insurance marketplace also raise serious issues of accountability. One of the nation's foremost experts on administrative law and health policy, Jerry L. Mashaw of Yale Law School, observes:

> [A "Health Fed"] would quite clearly be the most powerful administrative agency ever created in the U.S. [The proposal] imagines that all the politically fraught decisions that this agency would be called upon to make (coverage, cost, payment rates, plan regulation, etc., etc.) could be taken out of politics.
>
> This seems to me to be "pie in the sky" thinking. There is a good reason that there is one and only one agency like the Fed—long painful experience in every industrialized country has demonstrated that you must have an independent central bank if you want any semblance of monetary stability. And the Fed does only one thing--regulate the money supply (sort of)—a thing that coerces no one and that affects ordinary Americans only indirectly and opaquely. Hence, the Fed's independence is acceptable—but only reluctantly.
>
> Maybe a similar case could be made for a health insurance czar, but I suspect that it could be only if one were thinking about a limited technical function—like setting risk adjustment formulae. The reason that no one has fleshed out the idea of a "Health Fed" that would administer a national health insurance system may be that it is simply too implausible to spend much time on (Mashaw 2007).

In the end, as Stanton observes, "Many problems do not have solutions that involve organizational design. Elements such as leadership, quality of personnel and systems, level of funding, and freedom from unwise legal and regulatory constraints may be as important as organizational structure in the search for solutions to many problems that confront government agencies and programs" (Stanton 2002).

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APPENDIX—DETAILED PROPOSALS

Breaux-Thomas Proposal

Medicare Board—Overview

There is a critical need for an administrative body that would perform a number of functions to ensure that a premium support system in successful. This administrative body—probably in the form of a Medicare Board—would look like other federal boards, for example, the Federal Reserve Board or the Thrift Savings Plan Board. The Medicare Board would:

1. Be established outside of the Health Care Financing Administration (HCFA) for the purpose of administering the Medicare program.

2. Be an active purchaser of health care for beneficiaries, negotiating benefits and premiums with private plans wishing to participate in the Medicare market.

3. Have full negotiating authority, similar to that of the board that administers the California Public Employees' Retirement System (CalPERS). The CalPERS board controls health insurance plans' access to the Medicare market in that state. Plans failing to meet the Board's criteria for price, quality, efficiency, and other factors would not be able to offer coverage to the Medicare population.

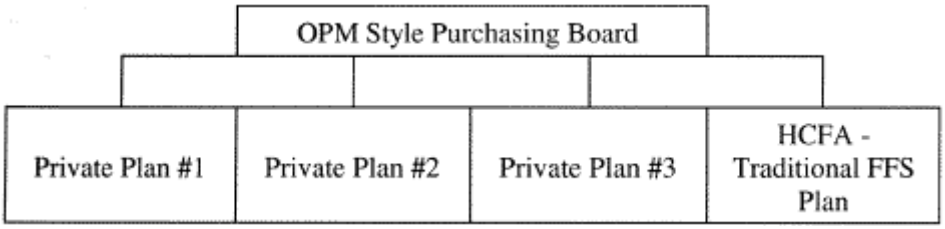
4. Have the authority to make all determinations regarding covered benefits. The Board would provide clear explanations of exactly what plans, including HCFA, are being asked to bid during each contract period. Plans would have the opportunity to offer their own ideas of how benefits might be structured, such as cost-sharing differences in and out-of-network, but the Board would have final authority.

5. As part of its annual negotiations with plans, would ensure that benefits offered by plans would not lead to an unintended government contribution expansion. If plans wished to offer additional benefits the Board believed would lead to an expanded government contribution--"benefit creep"--they could do so under certain conditions. Those benefits might be offered as a separate "rider," fully funded by the beneficiaries and not included in any computation of the government contribution.

6. Operate an annual open enrollment process similar to the one operated by the Federal Employees Health Benefits Program (FEHBP). The process would offer beneficiaries a wide choice of plans and stimulate active competition among plans for the beneficiaries' business. Beneficiaries would have been exposed to this type of process through their Medicare+Choice open-enrollment experiences.

7. HCFA would continue to offer the traditional fee-for-service (FFS) plan and compete for beneficiaries like all other plans. There would be an updated benefit package with

combined deductibles. The FFS plan would be available in all markets. HCFA could use third party administrators in some areas or for some services.



Board Responsibilities

The Medicare Board would be established outside of HCFA, which would run the FFS program and deal with the Board as any private plan. The Board would have the same authority and responsibility regarding FFS as it has for private plans. The traditional Medicare fee-for-service (FFS) program would be one of the plans under premium support and be available nationwide to all beneficiaries.

The Board's management processes would be similar to those used by the CalPERS Board with its health insurance program and by the Office of Personnel Management (OPM) with FEHBP.

The Board would be responsible for determining beneficiary eligibility. Coordinating and contracting with the Social Security Administration, currently done by HCFA, would fall to the Board.

The Board would issue an annual request for proposals from health plans to furnish benefits to Medicare beneficiaries. The request would specify all the requirements a plan must meet to have its bid considered acceptable including core benefits, adequacy of access to care through the plan's provider network, financial solvency, quality assurance, and beneficiary appeals. The request would highlight any changes in requirements enacted by Congress and the President as well as any new requirements administratively adopted by the Board.[1]

The Board would review submitted bids to assure that all statutory requirements have been met. Benefit packages offered in the bids would be reviewed with an eye toward assuring that each package adequately meets core benefit requirements and is not designed to attract a non-representative subpopulation of beneficiaries and thus lead to either favorable or adverse selection. The Board would also review benefit packages to prevent benefit creep resulting in increased costs to both beneficiaries and taxpayers. If benefits are not acceptable, the Board would negotiate with the plan a package that is acceptable or not permit the plan to solicit enrollees. The Board would assess the premiums each plan intends to charge to assure that premiums are neither too high nor too low for the benefit package agreed upon.

After approving benefits packages and premium rates, the Board would inform beneficiaries of the plans available to them, including Medicare FFS, in preparation for the annual open enrollment period when beneficiaries can choose to change plans. The Board manages the open

enrollment and notifies plans of any beneficiary enrollment changes. Based on beneficiary selections and the statutory formula for establishing the beneficiary and government contributions toward the premium, the Board will compute a beneficiary premium for each plan.[2] The Board cannot change the statutory formula, but will merely apply it.

The Board would be responsible for monitoring health plan performance throughout the year, arranging for quality monitoring through organizations like the current Peer Review Organizations (PROs). Quality indicators of plan performance based on enrollee rating results would be sent to every enrollee annually. Plans would be rated according to their performance regarding coverage, access to care, emergency care, choice of doctors, and other factors. Accreditations, such as the National Committee for Quality Assurance (NCQA) and the Joint Commission on the Accreditation of Health Organizations (JCAHO), would be encouraged and reported to enrollees.

The Board would set up a mechanism to provide an outside-of-plan process for beneficiary grievances and denials of services appeals. Ombudsman services and other services to facilitate the relationship between beneficiaries and plans would be established.

Members would be appointed by the President and confirmed by the Senate. Terms would overlap and be long enough length so no one President would be able to appoint the majority of the Board, and a significant percentage of the Board would not turn over at the same time.

Members would be chosen to reflect the interests of beneficiaries, working taxpayers and providers. "Providers" include health plans and health care providers--such as hospitals and physicians. The Board would have a staff of full time civil servants, as well as contracting authority for outside assistance, such as consulting actuaries.

Characteristics of HCFA under Premium Support

The FFS program would be subject to the Medicare Board. HCFA would have the same relationship with the Board as would private plans. For example, the FFS bid would be submitted to the Board and subject to the same requirements/review as private plans.

The Congress and the President would retain authority over benefit modifications to the FFS program through an appropriate legislative approval/disapproval process. The process would be expeditious to enable FFS to make any necessary changes in time to compete for enrollees.

The current FFS administrative structure should meet FFS' needs in a premium support system. Continued use of intermediaries and carriers to process claims, PROs to review quality and necessity of care, and other contractors for various functions would be appropriate. Additional flexibility to select and compensate contractors is desirable so better efficiency and effectiveness incentives could be realized.

Source: National Bipartisan Commission on the Future of Medicare. 1999. “Medicare Board.” http://thomas.loc.gov/medicare/3fmedbrd.htm.

Committee for Economic Development

To move from the current health-care system to sustainable, affordable, quality care for all, CED recommends the following . . . :

- To create an appropriate administrative structure: modernize and adapt the FEHBP to make it the framework for a national system of health insurance exchanges. Put the FEHBP under the supervision of a new agency patterned on the Federal Reserve Board. Here we will refer to it as the "Health Fed."
- To ease market entry across the country, to make health care more competitive and less costly, and to eliminate conflicts between state and federal regulation of health insurance: modernize and simplify health insurance regulation by creating an alternative federal regulatory system that multi-state health plans can choose. Designate the Health Fed as the regulatory agency.
- To provide reliable, objective and authoritative scientific information about the value and costs of clinical interventions: create a national institute for medical outcomes and technology assessment, or build it onto the National Institutes of Health (NIH) Translational Medicine Program which determines the effectiveness of new technology and procedures in the delivery system. . . .

The Health Fed would oversee a network of regional exchanges and direct their operation, and become the regulator of health insurance for insurers choosing the national regulatory option. . . . Like the Federal Reserve, the Health Fed Board would make judgments about complex issues such as the specific details of coverage contracts and acceptable business practices. Also like the Federal Reserve, the Health Fed would be fee-funded and thus not subject to annual appropriations. One potential funding source is a small percentage of all health insurance premiums; for example, in 2006, a one percent assessment on premiums would have yielded over $6 billion.

The Health Fed would be semi-independent. Its governors would be appointed for fourteen-year terms. They would not be drawn as ex-officio, but rather would be the best candidates with knowledge of the complexities of health care, without personal conflicts of interest. They would be supported by an expert staff that could be drawn from the existing agencies of Congress and the executive, such as the Medicare Payment Advisory Commission, the Agency for Health Research and Quality, and perhaps the Centers for Medicare and Medicaid Services, as well as from state governments. The board and its staff could build on the work of the National Association of Insurance Commissioners (NAIC), which has been successful in moving to national financial standards. It could seek input broadly to establish the regulatory framework for those insurers who choose national accreditation.

If a network of independent regional exchanges was chosen to manage the regional markets, the Board would establish their locations and responsibilities. Regional exchange presidents or chairs could be selected by the national Health Fed Governors, while the remaining officers could be elected from among the appropriate stakeholders. The Health Fed would establish

standards to be used by all regional exchanges. The standards would ensure that the exchanges operated fairly, transparently and uniformly, that the plans' offerings were easily understood, and that the plans met financial, quality and service standards. Regional exchanges could have both regulatory and research staffs to understand and evaluate innovative programs. Risk equalization methods would be set forth by the Health Fed, informed by the experience and insights of the regional exchanges. . . .

This Health Fed is a fitting model for the agency that would modernize and simplify health-insurance regulation, and also provide an alternative federal regulatory system. It is based on a trusted semi-independent governmental agency: the Federal Reserve Board of Governors. The Federal Reserve model would convey impartiality, expertise, freedom from narrow political interests, stability, and a long-term perspective with a board of governors serving long terms. . . .

The health-care system urgently needs a new entity, which might be called the Institute for Medical Outcomes and Technology Assessment (IMOTA), to assess the effectiveness, cost and overall value of health interventions and practices – including drugs, devices, diagnostic tests, and medical practices and procedures. IMOTA could make recommendations for how to integrate new drugs or devices into the delivery system to realize savings – that is, process redesign. For example, it might consider how a new product enables improved processes.

IMOTA would need a stable budget, large enough for its complex mission, to provide thorough insulation from short-term political pressures. It must be rigorously protected from conflicts of interest, and accountable to the public. One potential model would be to make IMOTA, like the health-insurance exchange system, a part of the Health Fed. Like the Federal Reserve Board, IMOTA should be freestanding and semi-autonomous. Its board should resemble the Federal Reserve in selection of members, numbers and terms. The board should set priorities, approve research, oversee staff and operations, coordinate with outside health groups, and ensure integrity and independence. The director should brief Congress periodically. Like the funding of the Health Fed, funding for IMOTA should come from the health-care financing system without annual appropriations.

IMOTA would provide analyses, evaluations and findings. It would not itself make decisions about coverage. Rather, such decisions would remain with the same agencies and private insurers now responsible for them. . . .

The Health Fed should integrate data from the exchange system and other national agencies. Like the Federal Reserve, it should issue periodic "Beige Books" to describe available plans and their affordability, and the performance of the plans and providers. This would facilitate public discussion of the affordability of health plans, what services should be covered, and targets and strategy for performance, efficiency, and quality improvement with universal coverage. If health expenditures continue to grow unsustainably, the Health Fed should analyze the causes, and report to the Congress with recommendations.

Source: Committee for Economic Development. 2007. *Quality, Affordable Health Care for All: Moving Beyond the Employer-Based Health Insurance System*. Washington.

Emanuel-Fuchs Proposal

Independent Oversight

To reduce political interference and allow tough administrative choices to be made, a National Health Board and twelve regional health boards would be established, modeled on the Federal Reserve System. Members of the National Health Board and the chairs of each regional health board would be nominated by the president and confirmed by the Senate for a long fixed term (say, ten years), which could be renewed only once. The terms of the National Health Board members would be staggered, with the term of only one member expiring in any given year. This board would appoint the members of the regional health boards to similarly staggered terms of the same length.

The administrative budgets of the National Health Board and the regional health boards would be funded from the dedicated VAT, not by an annual appropriation by Congress. The National Health Board would have responsibility to

- define and regularly adjust the standard health benefits to reflect changes in standards of care, advances in technology, and fiscal realities;
- conduct research to determine the risk adjustments necessary for the premiums paid to health plans;
- determine payment differences based on geography;
- sponsor research on quality, outcomes, and performance of the health care system;
- oversee and coordinate the regional health boards; and
- report regularly to Congress and the American public on the health care system.

Within their geographic regions, the twelve regional health boards would have responsibility to

- oversee the insurance exchanges;
- certify and oversee the participating health plans and insurance companies and ensure that they have sufficient financial reserves and medical resources to provide the health services offered in the standard benefits package;
- manage the enrollment of individuals and families in health plans and insurance companies and assign to a health plan those who do not enroll on their own;
- pay the health plans and insurance companies the risk-adjusted premiums on their enrollees' behalf; and
- collect, analyze, and disseminate information on the quality of health care delivered by the individual health plans and insurance companies.

Cost and Quality Control Mechanisms

An Institute for Technology and Outcomes Assessment would be created to judge the value of new drugs, medical devices, tests, and other interventions and to assess patient outcomes under the system. This Institute would be responsible for

- systematic review of research studies and other data on the effectiveness of different drugs, devices, new technologies, and other interventions;
- comparison of the effectiveness and costs of drugs, devices, diagnostic tests, and other interventions;
- commissioning of research studies to compare drugs, devices, diagnostic tests, and other interventions;
- collecting data from health plans and insurance companies on patient outcomes and on the drugs, medical technologies, and interventions used; and
- disseminating data on technology and outcomes assessments to health plans, physicians, patients, drug and technology manufacturers, and the general public, while respecting patient confidentiality.

To ensure the independence and objectivity of the Institute's work, funding would come from a fixed share (estimated at 0.5 percent) of the total revenues of the dedicated VAT. In addition, its operations would be overseen by an independent board appointed by the National Health Board.

Source: Ezekiel J. Emanuel and Victor R. Fuchs. 2007. *A Comprehensive Cure: Universal Health Vouchers.* Washington: Brookings Institution. Hamilton Project Discussion Paper 2007-11.

Jost Proposal

A federal commission should be created to determine which items and services insurers should cover. In part this task would be technical–the entity would commission and review technology assessments to determine which items and services were sufficiently effective and cost-effective to justify coverage. The commission would also engage in policy-making, however, determining which items and services might prove particularly amenable to being used for risk selection, and thus for unfair competition among insurers. The entity should, insofar as possible, be shielded from political pressure. [See Timothy S. Jost (ed.), *Health Care Coverage Determinations: An International Comparative Study* (Open University Press 2005).] Its members should be appointed by someone reasonably apolitical . . . and serve for long terms. This commission would review coverage of existing as well as new items and services, but it could not possibly review all possible candidates. Its agenda should rather be driven by requests from insurers, concerned about the cost implications of covering questionable technologies, or from patients or providers seeking services not generally covered by insurers.

The Commission should sort items and services into four categories. The first of these would be those that must be covered by all insurers, such as vaccinations for common diseases or emergency treatment for trauma victims. These would in all likelihood be relatively uncontroversial in most instances, and indeed the list could be quite short since most of these services will not come to the attention of the commission. Second, there would be items and services that should not be covered by insurance policies subsidized by tax credits or other public funds because there is no credible evidence that they are effective or because they are even dangerous, like laetrile therapy for cancer. Third, there would be items or services that insurers could cover or not cover at their option, like Lasik surgery for correcting refractive error. Finally, there should be a list of services that would be recommended for coverage but not required. Insurers would not have to cover these services, but would have to prominently disclose in their marketing literature that these items or services were recommended by the federal commission, but were not covered by the particular policy. This would allow insurers to compete on the basis of coverage and cost, but in an environment where consumers knew what they were giving up for the price they were paying.

Source: Timothy Stoltzfus Jost. 2007. “Fresh Thinking—Legal and Regulatory Issues Presented by Health Care Reform.” Unpublished.

Medicare Payment Advisory Commission Proposal

Recommendation: The Congress should charge an independent entity to sponsor credible research on comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers.

Congress should establish an independent entity whose sole mission is to produce and provide information about the comparative effectiveness of health care services. Since the information can benefit all users and is a public good, a federal role is necessary to produce the information and make it publicly available.

Such an entity would:

- be independent and have a secure and sufficient source of funding;
- produce objective information and operate under a transparent process;
- seek input on agenda items from patients, providers, and payers;
- re-examine comparative effectiveness of interventions over time;
- disseminate information to providers, patients, and public and private payers; and
- have no role in making or recommending coverage or payment decisions for payers.

There are different ways to carry out a federal role. The Commission prefers a public–private option, to reflect that all payers and patients will gain from comparative-effectiveness information. Funding could come from some public and some private sources or from all public sources. An independent board of experts should oversee the development of a research agenda and ensure that the research is objective and methodologically rigorous.

The entity's primary mission is to sponsor studies that compare the clinical effectiveness of a service with its alternatives. While cost effectiveness is not a primary mission, the Commission does not rule it out. In the simplest case, cost may be an important factor to consider for two services that are equally effective in a given population. But even when clinical effectiveness differs, it may be important for end users to be aware of costs. We emphasize that the entity would not have a role in how public and private payers apply this information—that is, coverage or payment decisions. Instead, it would produce and disseminate comparative-effectiveness information to purchasers, providers, and patients who would then decide how to use it.

The Commission envisions that the entity would contract out most of the research to outside groups, including existing governmental agencies, with experience conducting comparative-effectiveness studies. Thus, a federal role need not result in a large expansion of the government. To ensure that its research is credible, the entity would collaborate with other researchers to help establish high standards for the methods used to conduct comparative effectiveness studies.

Widespread use of the information will depend on the credibility of the entity conducting the studies. Operating under a transparent process and providing a public forum for stakeholders to critique ongoing work will enhance the credibility of the research. Because comparative

effectiveness is a public good, the entity's agenda should reflect priorities of public and private groups and encompass all patient groups.

Disseminating the research findings to a wide audience will be an important function of the entity; it should not be treated as a minor activity to be undertaken after studies are completed. The entity should communicate its findings to reach audiences with different levels of sophistication.

Source: Medicare Payment Advisory Commission. 2007. *Promoting Greater Efficiency in Medicare*. Washington.

New America Foundation Proposal

A New Insurance Marketplace

The bedrock of our proposal is an insurance market that preserves and improves upon the advantages of employer group purchasing and marketing, with its inbuilt administrative economies of scale and broad risk pooling. Ensuring that the new insurance marketplace is efficient, fair, and transparent can best be accomplished by establishing an Insurance Purchasing Exchange, designed to govern the health insurance marketplace. The exchange could be managed by a public entity, as is the Federal Employees Health Benefits Program, which is run by the Office of Personnel Management. Or it could be managed by a nonprofit entity like the Pacific Business Group on Health, which administers coverage for large employers in California. It might also make sense initially to have multiple exchanges operating throughout the country. These exchanges could also be organized along state lines, or on a regional basis, with smaller states joining forces to form a single marketplace. Large states like California and New York might consider establishing several separate exchanges to serve their local health markets more efficiently.

Benefits Board

The Basic Plan and its mandated benefits package would be determined and modified periodically by a Benefits Board, whose members would be appointed by the U.S. comptroller general. This board would be charged with balancing the natural tension between expanding coverage of clinically valuable services and minimizing the increase in taxpayer-financed subsidies. It would also evaluate medical research to identify effective treatments and procedures. This knowledge would inform decisions about which services to cover as well as how to set cost-sharing with respect to services covered in the Basic Plan. This will enable cost-sharing, or demand-side incentives, to be used to guide patients toward effective treatments and away from treatments that have not been proven effective. A similar approach, pioneered at the University of Michigan and used as an employee-benefit negotiation tool, has been successful in getting diverse citizens to see the need to balance benefit package limits with concerns about access to appropriate care. The Benefits Board would also be responsible for developing the complementary cost-sharing subsidy package that low-income individuals will receive along with the Basic Plan at no cost or at reduced cost. . . .

The Benefits Board would be an independent entity, but since Congress would fund the board, the Insurance Purchasing Exchange, and subsidies, it would be expected to work closely with Congress, more or less like the Federal Reserve chairman does.

Comparative Effectiveness Agency

To further the cause of efficiency, we should create a Comparative Effectiveness Agency (CEA), a public organization that would fund and direct a series of efficiency studies on new medical devices and surgical procedures. The research itself would be conducted by universities and

private research entities using rigorous scientific methods. The CEA would not have the power to force the Benefits Board to follow its recommendations, but it would have the power and capacity to disseminate its findings to the health care providers, health plans and to the media, so that with proper pay for performance incentives in place, the use of inferior products or techniques would become far more rare and persist for a shorter time than is the case today. The CEA could be constituted as quasi-public agency, because although it would need federal funding it could and should be governed by a combination of political appointees and the leadership of the major learned medical societies and of academic medicine. By this means, we would obtain a "buy in" from research leaders to improve the efficiency of health care delivery services. This is the best way to make a 21st-century health system continue to function well for all Americans.

Source: Len M. Nichols. 2007. *A Sustainable Health System for All Americans*. Washington: New America Foundation.