

GAO

Report to the Chairman, Committee on
Environment and Public Works, U.S.
Senate

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REGULATORY PROGRAMS

Balancing Federal and State Responsibilities for Standard Setting and Implementation



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United States General Accounting Office
Washington, DC 20548

March 20, 2002

The Honorable James M. Jeffords
Chairman, Committee on Environment and Public Works
United States Senate

Dear Mr. Chairman:

In the American system of government there are many policy areas in which both federal and state governments exercise regulatory authority. In enacting new legislation in these shared areas, the Congress faces a key challenge: how to provide federal protections, guarantees, or benefits while preserving an appropriate balance between federal and state regulatory authority and responsibility.

As you noted in your request letter, there is little information available to guide the Congress in selecting or defining an approach to this challenge. Accordingly, you requested that GAO undertake a study of programs in which the federal government shares regulatory functions with the states. Our objectives were to (1) identify major mechanisms and options for achieving national regulatory purposes within the U.S. intergovernmental system and (2) identify advantages, issues, and limitations associated with each mechanism and option and determine how these considerations might guide the choice among them.

Results in Brief

State efforts can be directed toward federal or nationally shared regulatory objectives through a variety of arrangements, each of which reflects (1) a mechanism for defining and issuing regulations or standards and (2) assignment of responsibility for implementing or enforcing the regulations or standards. Regulatory and standard-setting mechanisms with the potential for achieving nationwide coverage include:

- fixed federal standards that preempt all state regulatory action in the subject area covered;
- minimum federal standards that preempt less stringent state laws but permit states to establish standards more stringent than the federal;
- inclusion of federal regulatory provisions in grants or other forms of assistance;
- cooperative programs in which voluntary national standards are formulated by federal and state officials working together; and

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- widespread state adoption of voluntary standards formulated by quasi-official entities.

The first two of these mechanisms involve preemption. The other three represent alternative approaches. Each mechanism represents a different combination of federal and state regulatory authority.

The mechanisms also offer different options with respect to implementation or enforcement. Fixed and minimum federal standards permit three patterns of implementation: (1) direct implementation by a federal agency, (2) implementation by the states with some degree of federal oversight, and (3) state implementation in some states and direct federal implementation in others. The remaining three mechanisms—regulatory provisions in grants or other forms of support, cooperatively set standards, and state adoption of standards set by quasi-official entities—rely primarily on direct implementation by the state under its own authority; they vary in the degree of federal oversight they can accommodate.

Each standard-setting mechanism offers different advantages and limitations, that reflect some of the key considerations of federal-state balance in the context of a given national regulatory objective. Among these considerations are:

- **Uniformity:** Does this mechanism provide uniform standards and nationwide coverage where essential to achieve the objective?
- **Flexibility:** Does the mechanism allow for flexibility—in regulatory content or implementation—where appropriate to the objective?
- **Capacity:** Does the mechanism assign responsibility appropriate to the capacity of each level of government to do the job at hand, taking into account breadth of jurisdiction, enforcement powers, resources, and location?
- **Accountability:** Can accountability to the federal government be incorporated into this mechanism where deemed necessary to achieving the objective?

The mechanisms vary considerably in terms of these factors. For example, fixed federal standards apply to all states and can enlist state capacity for implementation but offer relatively little flexibility. Cooperatively set standards, which generally are not binding on states, offer flexibility but not uniform coverage or accountability to the federal government. (See table 4.)

Shared implementation brings a number of operational challenges. These include finding the appropriate level of federal oversight, allocating costs between the federal government and the states, potentially increasing the vulnerability of federal agencies to sudden increases in responsibilities and costs, handling variation in implementation from state to state, and adjusting to the new federal-state balance.

This report addresses these federal-state balance factors and operational challenges by developing guiding questions that policymakers might use to select a standard-setting mechanism and implementation arrangement appropriate to a given federal regulatory objective and set of conditions. This guidance is summarized in decision flow diagrams, figures 1-3.

Background

The United States Constitution established a union of states that provided for national and state government and gave each its own authority and sphere of power. However, it also allows for these spheres to overlap and thus creates areas of concurrent power in which either level of government or both may regulate. Examples include the power to regulate commerce and the power to tax. Within these areas there may be situations in which laws conflict. To resolve these conflicts, the Constitution's Supremacy Clause provides that federal law is "the Supreme Law of the Land," thereby preempting state law.¹ Preemption occurs when the Congress enacts a statute or a federal agency adopts a regulation in an area in which state legislatures have acted or have the authority to act. The Congress's constitutional power to regulate interstate commerce has proven the source of many preemptive statutes.²

The balance between federal and state government in areas of concurrent powers has been continuously debated and has shifted as political, social, and economic conditions have changed over the years.³ Within the 20th century, for example:

¹U.S. Const., art. VI, cl2.

²Congressional Research Service, *Federalism and the Constitution: Limits on Congressional Power* (September 5, 2000).

³See Congressional Research Service, *American Federalism, 1776 to 2000: Significant Events* (November 30, 2000).

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- The Great Depression of the 1930s led to an expanded federal role in domestic affairs to deal with social and economic problems that states could not respond to effectively on their own.
 - The Great Society programs of the 1960s brought further expansion of the federal role in an effort to achieve socially desirable outcomes and to the use of state and local governments as intermediaries to implement national policies in areas that had previously been the purview of state or local governments or the private sector.
 - The 1980s brought a shift of funds, authority, and responsibility to the states through block grants, such as the Social Services Block Grant, which allowed greater state and local autonomy and flexibility in fashioning local strategies to address federal objectives.
 - The trend toward state flexibility continued in the 1990s, accompanied by concern about “unfunded mandates” (federal regulations that impose new duties on states—duties that require state expenditures).⁴ At the same time, the emergence of the Internet and the increasingly national and international nature of commerce created pressures for federal regulation.

Questions of federal and state responsibility in areas of common regulatory concern continue to spark debate in the twenty-first century, as evidenced by the examination of state-regulated voting procedures following the 2000 presidential election⁵ and of federal and state homeland security responsibilities following the terrorist attacks of 2001.⁶ Such questions are also likely to arise during reauthorization debates on existing programs.

Scope and Methodology

To identify mechanisms for focusing state efforts toward national regulatory objectives, we reviewed the literature on federalism, intergovernmental relations, preemption, and regulatory programs in a broad range of policy areas. We then examined programs and approaches that combined federal with state regulation or implementation. Our review

⁴Unfunded Mandates Reform Act of 1995, P.L. 104-4.

⁵See U.S. General Accounting Office, *Elections: Status and Use of Federal Voting Equipment Standards*, [GAO-02-52](#) (Washington, D.C.: October 15, 2001) and related GAO reports cited therein.

⁶See U.S. General Accounting Office, *Homeland Security: Challenges and Strategies in Addressing Short- and Long-Term National Needs*, [GAO-02-160T](#) (Washington, DC: November 7, 2001) and U.S. General Accounting Office, *Combating Terrorism: Key Aspects of a National Strategy to Enhance State and Local Preparedness*, [GAO-02-473T](#) (Washington, D.C.: March 1, 2002).

included both programs that involved preemption and programs that used other approaches to enlist state effort in support of federal or national regulatory objectives.

Five major mechanisms emerged from our review. We classified programs in terms of these mechanisms and selected two or more programs representing each mechanism for more detailed examination and to serve as examples. We selected examples from a broad range of regulatory agencies with the aim of including major programs as well as a variety of approaches. (The programs we selected are summarized in table 1). For the mechanism concerning grants, we looked at grant programs but did not examine other forms of federal support. Our study focused on the mechanisms and did not review the content or strategic approaches of the regulations and standards involved or the effectiveness of the programs as implemented.

To obtain descriptive material concerning each of these programs we reviewed authorizing statutes, regulations, agency documents, and documents concerning quasi-official standard-setting bodies. We also examined reports from program studies conducted by the Congressional Research Service, GAO, inspectors general, and other sources. We did not conduct new analyses of these programs. Thus, our findings are based on available information.

Table 1: Programs Reviewed for This Report

Standard setting mechanism	Program reviewed	Federal agency involved in program implementation
Federal fixed standards	Employee Retirement Income Security Act (ERISA) Title I: regulation of fiduciary, reporting, and disclosure practices in privately sponsored employee benefit plans	Department of Labor (DOL), Pension and Welfare Benefits Administration
	Hazardous Materials Transportation: regulations governing transportation of hazardous materials by motor vehicle	Department of Transportation (DOT), Motor Carrier Safety Administration (MCSA)
Federal minimum standards	Clean Air Act: minimum standards for air quality	Environmental Protection Agency (EPA), Office of Air and Radiation
	Motor Carrier Safety: minimum safety standards covering commercial vehicles and drivers	DOT, MCSA
	Health Insurance Portability and Accountability Act (HIPAA): minimum standards concerning portability and renewability of health plan coverage	Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS)
	Meat and Poultry Inspection: food safety standards for plants that process meat and poultry	Department of Agriculture, Food Safety and Inspection Service (FSIS)
	Occupational Safety and Health: minimum standards for workplace safety	DOL, Occupational Safety and Health Administration (OSHA)
	Safe Drinking Water: minimum standards for public drinking water systems	EPA, Office of Water
Conditions of grant program	Synar Amendment to Substance Abuse Prevention and Treatment (SAPT) grant provisions: requires states to have and enforce a law prohibiting the sale or distribution of tobacco products to persons under 18	HHS, Substance Abuse and Mental Health Services Administration (SAMHSA)
	Temporary Assistance to Needy Families (TANF) grant program: sets conditions on state programs that receive federal funds	HHS, Administration for Children and Families (ACF)
	Title I, Education of the Disadvantaged grant program: requires states to set and enforce minimum standards for content and performance in education	Department of Education, Office of Elementary and Secondary Education
Federal/state cooperative standards	Retail Food Protection: guidelines for safe handling of food in retail establishments such as grocery stores and restaurants	Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition
	National Shellfish Sanitation: voluntary standards for safe production and processing of shellfish	FDA, Center for Food Safety and Applied Nutrition, Federal/State Programs
State adoption of externally set standards	National Conference on Uniform State Laws: uniform and model state acts in subjects that benefit from a common approach	None. Members are state-appointed and organization receives funds from states.
	National Association of Insurance Commissioners (NAIC): develops model state-level insurance laws and regulations	Works with CMS and other agencies that deal with insurance.
	Other recognized standard-setting bodies	All agencies are encouraged to contribute to and adopt standards.

Source: Program documents.

It should be noted that each of the mechanisms we describe represents an ideal type—that is, the elements listed for each mechanism are characteristic of that mechanism and define a “pure case” to which specific programs can be compared. In the real world, few, if any,

programs will match the “pure case” completely, and a complex program may incorporate more than one mechanism.

We conducted our work between June 2001 and February 2002 in accordance with generally accepted government accounting standards. Because our work drew only on already available materials, we did not seek agency comments on our findings.

Standard-Setting Mechanisms, Implementation Roles Link States to National Regulatory Objectives

We identified five regulatory or standard-setting mechanisms and four patterns of implementation or enforcement that characterize areas in which the federal government and the states share regulatory objectives and responsibilities. The five mechanisms are:

- fixed federal standards that preempt all state regulatory action in the subject area covered;
- federal minimum standards that preempt less stringent state laws but permit states to establish standards more stringent than the federal;
- inclusion of federal regulatory provisions in grants or other forms of assistance;
- cooperative programs in which voluntary national standards are formulated by federal and state officials working together; and
- widespread state adoption of voluntary standards formulated by quasi-official entities.

The first two mechanisms involve preemption. The other three represent alternative approaches. The mechanisms differ in terms of which level of government sets standards and whether application of the standards within a state is voluntary or mandatory.

The mechanisms also offer different options with respect to implementation or enforcement. Fixed federal standards and minimum federal standards permit three patterns of implementation: (1) direct implementation by the federal agency, (2) implementation by the states, approved by and under some degree of oversight by the federal agency, and (3) a combination of federal agency and federally approved state implementation. Grants follow the second of these patterns. The remaining two mechanisms follow a fourth pattern, direct implementation by the state under its own authority. These three mechanisms vary in the degree of federal oversight they can accommodate.

Standard-setting mechanisms and implementation options in the programs we reviewed form combinations as illustrated in table 2. We will discuss

each mechanism, implementation options associated with that mechanism, and operational issues that have arisen in the programs we reviewed.

Table 2: Standard-Setting Mechanisms and Implementation Patterns

Standard setting mechanism	Origin of standard or regulation	Implementation pattern			
		Direct federal	Assumed by states under federal oversight	Combination of direct federal and state-assumed	State implemented under state authority
Fixed federal standards	Federal (mandatory) ^a	ERISA	HAZMAT motor vehicle		
Federal minimum standards	Federal (mandatory) and state		Clean Air Safe Drinking Water Motor carrier safety	OSHA Meat and Poultry HIPAA	
Grant conditions	Federal (voluntary) ^b and state		TANF Synar		
	State (must set)		Title I Education standards		
Cooperative programs	Federal/state (voluntary)				Retail food Shellfish
State adoption of externally set standards	State and private standard-setting entities (voluntary)				Model laws and regulations

Source: GAO analysis based on program documents.

^a“Mandatory” indicates that the standard applies in every state.

^b“Voluntary” indicates that acceptance of the grant or standard is up to the state.

Fixed Federal Standards Can Involve State Responsibilities

The federal government sometimes assumes sole regulatory authority over a specified subject area, either by prohibiting states from regulating or by issuing federal regulations that states must follow. Both statutes and treaties can preempt in this way. When federal statutes indicate that Congress intended the federal government to assume sole regulatory authority over a specific subject area, states cannot establish either stricter standards or standards that are less strict than the federal. A program under federal regulatory authority may involve (1) no state role, (2) a parallel state regulatory and implementation role, or (3) state implementation of the federal regulatory provisions or standards.

Programs Based on Fixed Standards May Involve No State Role

In some instances, the federal government both regulates and assumes responsibility for enforcement or implementation—states do not perform either function. In addition to establishing uniform standards nationwide,

this approach establishes a single locus of accountability and program direction. The federal agency that administers the program provides the resources and bears the costs.

Regulation of employer-based pension plans, pursuant to the Employee Retirement Income Security Act of 1974 (ERISA), provides an example. Federal standards were viewed as needed in light of the importance of these plans to interstate commerce and the need to protect employees and their beneficiaries from loss of benefits due to unsound or unstable plans. ERISA established, among other requirements, fiduciary, reporting, and disclosure requirements that apply to private employee pension plans in the United States. ERISA supersedes all state laws that relate to ERISA pension plans. The Pension and Welfare Benefits Administration (PWBA) of the Department of Labor is responsible for administering and enforcing these ERISA provisions, and states do not have an enforcement role.

Regulatory Authority May Be Divided between the Federal Government and the States

In other instances, regulatory authority is divided between the federal government and the states. States retain the power to establish and implement regulations for their portion of the sector but are precluded from applying them within the federal portion. Regulation of health coverage under ERISA provides an example. The federal government regulates all employee health plans. If an employer chooses to provide coverage through an insurance policy, that policy is subject to state regulations. Approximately 60 percent of individuals participating in employer sponsored plans are covered by state regulated insurance policies.

This division of authority can lead to potential differences in coverage requirements, uncertainty, and litigation. As a result, individuals in similar plans may have different rights and remedies. Federal legislation in certain health coverage standards in recent years has set federal minimum standards that generally apply to all health plans.⁷

States Can Assume Responsibility for Implementing Federal Provisions

In some program areas, states implement or enforce federal standards that preempt state laws or regulations. The Hazardous Materials Transportation Act, as it applies to motor vehicles, illustrates this approach.⁸ In order to provide adequate nationwide protection against the

⁷Examples include the Mental Health Parity Act of 1996 and the Newborns' and Mothers' Health Protection Act of 1996, both included in P.L. 104-204.

⁸The Hazardous Materials Transportation Act, as amended, is codified at 49 U.S.C. §§5101-5127.

risks to life and property inherent in the transportation of hazardous materials, this act authorizes the Secretary of Transportation to regulate the transportation of such hazardous materials not only in interstate and foreign commerce but also in intrastate commerce. The act and federal regulations prescribed under the act generally preempt state requirements that are not substantively the same as the federal.⁹ However, most of the roadside commercial vehicle inspections applying hazardous material (HAZMAT) regulations are done through state programs. Under the Motor Carrier Safety Assistance Program (MCSAP), states that meet grant requirements can take responsibility for enforcing these regulations for both intrastate and interstate vehicles, and nearly all states have done so.¹⁰ These requirements include adopting state HAZMAT transportation regulations identical to the federal regulations for commercial vehicles and having the legal authority and resources to enforce them. In return, the states receive federal grants to cover a portion of their program costs.

Enlisting the efforts of state agencies greatly expands the resources available for implementation or enforcement. In each of the programs we examined, activities to support federal regulations built upon activities that states already performed. However, this strategy also raises some major operational issues or questions, for example:

- Who will carry out enforcement activities in states that are unwilling or unable to do so?
- What share of state program operation costs, if any, should the federal government cover?
- Which level of government is accountable for ensuring that state performance is adequate, and for taking action if it is not?
- Is uniformity of enforcement important, and if so how can it be achieved?

State implementation was an option under each of the five standard-setting mechanisms we examined. We discuss this option with respect to each mechanism, and include a summary discussion of its advantages and limitations in the final section of the report.

⁹States can apply for a waiver of preemption of a requirement, which the Secretary may grant provided that the state provision provides at least as much protection as the federal and is not an unreasonable burden on commerce.

¹⁰The MCSAP also provides for states to implement the federal minimum standards for commercial motor carrier safety, discussed in a later section of this report.

Minimum Federal Standards Feature Shared Regulation and Implementation

States Can and Some Do Regulate Beyond the Federal Minimum

Under minimum federal standards, the federal government, through statutory or regulatory means, establishes a minimum national standard that preempts less stringent and conflicting state laws and regulations. Minimum standards are often designed to provide a baseline of consumer protection in areas such as environmental protection, health care, food supply, vehicle safety, and working conditions. This mechanism supports the achievement of a national objective while at the same time permitting states that wish to set higher standards to do so. States typically participate in enforcing the federal regulations, as well as any regulations of their own, and share in the cost.

Although states may not enforce standards less stringent than the federal minimum, they may generally establish standards that are stricter than the federal standards (as long as they do not unduly burden interstate commerce). Some of the minimum standards programs we examined offered states considerable scope in this regard, preserving in part the leadership role that states had performed before the federal government stepped in. For example, under the Occupational Safety and Health Act (OSHA) states may, and many do, set standards for hazards, such as ergonomic injury, for which no federal standard has yet been established.¹¹

For example, states regulate hazards not covered by federal OSHA standards.

- Ten states have state-specific standards on logging practices. Alaska also developed safety codes for highline, tractor, and helicopter logging.
- California adopted the first repetitive-motion injury standard in the nation in 1997. Washington state's ergonomic rule, which differs from California's, followed in 2000.
- Several states adopted needlestick standards to guard against injuries from bloodborne pathogens before there was an OSHA standard. Pursuant to the Needlestick Safety and Prevention Act, an updated OSHA standard for bloodborne pathogen standards was published and made effective in April 2001.¹²

¹¹These examples are taken from *Grassroots Safety & Health in the Workplace*, the 1999-2000 State Plan Activities Report of the Occupational Safety and Health State Plan Association.

¹²66 Fed. Reg. 5318-01, January 18, 2001.

In addition, state requirements exceed OSHA's.

- New Mexico developed a standard for public sector firefighters that state officials describe as “more effective” than OSHA's standard on firefighting.
- Some states require employers to prepare a workplace safety and health plan, which OSHA regulations do not require.

Federal and State Governments
Share Implementation
Responsibilities

Each of the minimum standards programs we examined provide for state implementation or enforcement of federal regulatory provisions, with the federal agency contributing funds and/or oversight to varying degrees. States could assume responsibility for program implementation if they met certain requirements. In every case we examined, states had to show that they had regulations no less stringent than the federal standards and the legal authority necessary for enforcement. Some programs added other requirements, such as having adequate funding and personnel, having enforcement procedures, and participating in certain data systems. OSHA requires a state to demonstrate the adequacy of its enforcement operations for a year before granting final approval for the state to operate the program.

Table 3 illustrates the divisions of implementation responsibility we encountered. As this table illustrates, the federal government, the states, or both may be involved in implementing a particular program in a given state. The state implementation role may encompass the entire regulated sector (as in Motor Carrier Safety), only the intrastate portion (as in Meat/Poultry), or be transferred provision by provision as states are ready to assume responsibility (as in the Clean Air program). Programs also differ in the inducements offered to states to assume responsibility and in provisions for federal oversight.

Table 3: Division of Implementation Responsibility in Minimum Standards Programs

Federal minimum standards program	Federal implementation responsibility	State implementation responsibility	Federal grant as percentage of state cost
Meat and poultry inspection: regulates plants that process meat and poultry	Primary responsibility for all plants in interstate commerce and plants that sell only within a state, where state has not assumed responsibility. Oversees state programs.	States can assume responsibility for implementation in plants that sell only within the state.	Up to 50
Occupational safety and health: regulates workplace hazards	Primary responsibility for the federal program, which covers private employers.	States can assume responsibility for operating the federal program; those that do so must cover state and local government employees as well.	Up to 50
Safe Drinking Water: regulates public drinking water systems	Oversees state implementation; can enforce directly if state performance is deemed inadequate.	Gives primacy in enforcement of federal regulations and standards to states that meet certain requirements.	Up to 75
Clean Air: regulates air quality	Oversees state implementation; can assume responsibilities if state performance is deemed inadequate.	Act recognizes states' primary responsibility for pollution control, gives primacy in enforcement of federal standards to states that submit an acceptable plan .	Up to 60
HIPAA: regulates portability and renewability of health plan coverage	<ul style="list-style-type: none"> • CMS, DOL enforce for health plans under their jurisdiction • CMS enforces for state-regulated plans if state does not do so. 	Primary responsibility enforcing for health insurance plans within state jurisdiction if state standards conform to or exceed the federal standards.	N/A
Motor carrier safety: regulates commercial vehicles and drivers	Complementary to states. Conducts compliance reviews of carriers. Can inspect only vehicles in interstate and foreign commerce.	Required of states that accept the grant. Inspects vehicles in both interstate and intrastate commerce. Can also conduct compliance reviews of carriers.	Up to 80

Source: Program documents.

The minimum standards programs we reviewed induced state participation through (1) statutory language concerning state responsibility for the regulatory area concerned, (2) offering grant funds to states that participate, and (3) providing for direct federal enforcement in states that do not participate. Statutory language may imply that state participation is voluntary or that it is a state responsibility. To illustrate:

- The OSHA statute encourages “states to assume the fullest responsibility for the administration and enforcement of their occupational safety and health laws” and provides for any state that “desires to assume

responsibility” for enforcing federal standards to submit a state plan,¹³ while

- The Clean Air Act specifies, “Each State shall have the primary responsibility for assuring air quality within the entire geographic area comprising such State by submitting an implementation plan for such State which will specify the manner in which national primary and secondary ambient air quality standards will be achieved.”¹⁴

Federal financial incentives to states also vary considerably. As table 3 indicates, all but one of the minimum standards programs we reviewed included federal grants that contributed a portion of state implementation costs, ranging from up to 50 percent of state program costs (OSHA and Meat/Poultry) to up to 80 percent (Motor Carrier Safety). The actual amount of the federal contribution depends on the funds available in a given year and may be less than the percentage shown. The Clean Air Act provides for the state to retain permit fees, and the Safe Drinking Water program includes a revolving loan fund in each state that helps support local infrastructure projects. Funding for two of the programs we studied (safe drinking water and motor carrier safety) was increased substantially in reauthorizations during the 1990s. However, EPA has reduced the funding for Clean Air grants, perhaps in consideration of the availability of permit fees.¹⁵

All programs provided for direct enforcement by the federal agency in states that did not take on implementation responsibility or that did not adequately carry out their responsibilities. This provision is necessary to avoid gaps in the protection afforded by the federal regulations or standards. State officials may view federal enforcement as a threat or as an opportunity, depending on the regulatory function concerned and the importance and cost of keeping the function under state control.

Participation rates varied considerably among these programs. Twenty-one states and 2 territories operate OSHA plans¹⁶ and 27 states operate a meat and poultry inspection program for intrastate processors. These

¹³29 U.S.C. §§651(b)(11), 667(b).

¹⁴42 U.S.C. §7407(a).

¹⁵See U.S. General Accounting Office, *Air Pollution: Status of Implementation and Issues of the Clean Air Act Amendments of 1990*, [GAO/RCED-00-72](#), (Washington, D.C.: April 17, 2000).

¹⁶Three additional states have state OSHA plans that cover only public sector employees.

programs are directly implemented by the federal agency in the remaining states. The other minimum standards programs in this study have enlisted universal or nearly universal state participation.

Once states have accepted responsibility for implementing federal standards, primary accountability for state agency performance rests with state officials and they in turn are accountable to the federal level and subject to various degrees of federal oversight. Oversight tools available to the federal agency include disapproving a state's application for grant funds and withdrawing authorization for the state to implement the program. Some of the programs we examined require performance-oriented annual plans and reports—a relatively new development that reflects the expectations placed on agencies by the Government Performance and Results Act (GPRA).¹⁷ This and other oversight and performance management tools found in these programs are illustrated below.

- *Performance-oriented plans:* States implementing federal OSHA regulations must submit 5-year strategic plans and annual performance plans that are comparable to OSHA's GPRA plans and that adopt OSHA's strategic goal of improving workplace safety and health for all workers.¹⁸ Beyond that, states select their own goals. Under the Motor Carrier Safety Assistance grant program, state plans must include quantifiable performance objectives and measures and strategies and specific activities for achieving the objectives.
- *Overfiling:* EPA can file its own enforcement actions if it concludes that a state's enforcement action under the Clean Air Act was inadequate.
- *Financial incentives:* The Motor Carrier Safety grant program includes incentive funds for states that achieve reductions in fatal accident rates for commercial motor vehicles.
- *Sanctions:* Under the Clean Air Act, EPA can impose sanctions—including the withholding of certain federal highway funds—on states that have not submitted or not implemented adequate plans to attain air quality standards. A "conformity" provision bars federal departments and agencies from approving or supporting transportation

¹⁷Government Performance and Results Act of 1993, P.L. 103-62.

¹⁸As stated in the OSHA State Plan Policies and Procedures Manual, the goal is to "improve workplace safety and health for all workers, as evidenced by fewer hazards, reduced exposures, and fewer injuries, illnesses and fatalities."

improvements in geographic areas that have not attained air quality standards, unless the improvements conform with the State Implementation Plan.¹⁹

Grants or Other Forms of Support May Require States to Undertake Regulatory Activities

Grant programs or other forms of support can also be used to direct state efforts toward federal regulatory purposes. Under this mechanism, the grant or other instrument requires recipients to perform federally specified regulatory or enforcement activities as a condition of eligibility to receive support. These requirements apply only in states that voluntarily accept the support. However, if the grant in question is a significant source of funds for a state, then nonparticipation may not be a practical alternative.

Historically, conditions of the type described above have been incorporated in federal grants to states that focused on a particular purpose and population—termed categorical grants. Such grants also included administrative and reporting requirements to help ensure both financial and programmatic accountability. Categorical grants can be contrasted to block grants, which are aimed at achieving a broad national purpose, afford states considerable flexibility, and have limited administrative and reporting requirements.

In practice, the line between “categorical” and “block” grants has become blurred, and many programs include features of both.²⁰ We examined several recent examples that illustrate how regulatory components aimed at directing states’ efforts toward specific national objectives have been incorporated into grants that otherwise give states the broad flexibility of a block grant. The Synar Amendment to the Public Health Service Act (Synar Amendment) illustrates the use of grant conditions to induce states to have and enforce laws consistent with a federal regulatory purpose—restricting access to tobacco by underage youth. In another example, the Temporary Assistance for Needy Families (TANF) block grant illustrates the use of performance-oriented federal regulatory provisions in a program that otherwise gives states new flexibility in welfare program operation. Finally, the Elementary and Secondary Education Act (ESEA)

¹⁹For a discussion of these sanctions and their use, see Congressional Research Service, *Highway Fund Sanctions and Conformity Under the Clean Air Act*, CRS, Updated October 15, 1999.

²⁰See U.S. General Accounting Office, *Grant Programs: Design Features Shape Flexibility, Accountability, and Performance Information*, [GAO/GGD-98-137](#) (Washington, D.C.: June 22, 1998).

The Synar Amendment Ties
Grant Eligibility to State
Legislation

amendments of 1994, Public Law 107-110, exemplify an effort to achieve comparably challenging standards nationwide by requiring each state that accepts a Title I ESEA grant to set and enforce its own standards.

The Synar Amendment, passed in 1992, added regulatory conditions to the Substance Abuse Prevention and Treatment (SAPT) block grant with the national objective of reducing underage youths' access to tobacco products. In order to receive a SAPT block grant, a state must have and enforce a law prohibiting the sale or distribution of tobacco products to any individual under the age of 18. The state is required to report annually on enforcement activities and on the extent to which the availability of tobacco products to underage youth has been reduced. A state's grant funds can be reduced if the state fails to meet a target compliance rate negotiated with the Department of Health and Human Services (HHS).

The use of the grant mechanism to regulate underage access to tobacco reflects the status of tobacco regulation at the time the Synar Amendment was passed. HHS had authority, through the SAPT block grant, to fund activities aimed at preventing abuse of alcohol and other drugs. Adding the Synar Amendment requirements to the grant enabled the Congress to make use of existing state authority to ensure that states' substance abuse prevention activities were directed toward achieving a particular national public health objective.

TANF Block Grant Combines
Federal Conditions with
Increased State Flexibility

In 1996, welfare reform legislation, known as the Personal Responsibility and Work Opportunity Reconciliation Act, Public Law 104-193, replaced previous assistance programs with a single block grant called Temporary Assistance for Needy Families (TANF). TANF was expressly intended to increase states' flexibility in welfare program operation. TANF gives states broad flexibility to determine eligibility, methods of assistance, and benefit levels as long as funds are directed to achieving the purposes of the legislation.²¹ Unlike the classic block grant, however, TANF couples this flexibility with federal regulatory provisions that states must apply, such as a 60-month limit on a parent's receipt of assistance. TANF also includes

²¹These purposes include assisting needy families so that children can be cared for in their own homes; reducing needy parents' dependence on government benefits by promoting job preparation, work, and the formation and maintenance of two-parent families; and reducing the incidence of out-of-wedlock pregnancies. For more information see U.S. General Accounting Office, *Welfare Reform: Challenges in Maintaining a Federal-State Fiscal Partnership*, GAO-01-828 (Washington, D.C.: August 10, 2001).

accountability requirements that link state performance to the purposes expressed in the legislation, among them

- detailed, results-oriented state reporting requirements;
- financial penalties for failure to submit timely reports, meet certain financial requirements, or achieve minimum work participation rates; and
- bonuses for performance.

These requirements, like those in the Synar Amendment, are similar to those that states must meet under preemptive regulatory programs. However, there is an important difference between federal fixed and minimum standards and those mechanisms based solely on assistance. Federal fixed and minimum standards apply to and must be implemented in every state, with the federal agency implementing the program directly if the state does not do so. Regulatory conditions imposed by means of acceptance of grants or other forms of assistance apply only to states that accept the assistance. If a state elects not to participate in the grant program, the federal standards contained in the grant do not apply in that state and the federal agency that administers the grant program does not step in to implement them. Thus, the condition-of-assistance mechanism may lead to gaps in coverage. Federal interest in avoiding such gaps gives states some leverage to negotiate for acceptable conditions or for limiting the existence and application of federal sanctions.

Education Grant Requires States to Set Standards

Amendments to Title I of the Elementary and Secondary Education Act (ESEA) of 1994 illustrate the use of grant conditions to induce states to establish their own standards in the interest of achieving a national objective. That objective is to ensure that students served through the grant (which is targeted to the disadvantaged) are offered the same challenging content as students in the state generally and are held to the same performance standards.²² Under the 1994 law, states that received grant funds were required to develop and implement challenging content standards that apply to all students; develop assessments aligned to those standards; and, based on these assessments, develop procedures for

²²Standards were to be developed in at least two subjects, mathematics and reading or language arts.

identifying and assisting schools that fail to make adequate progress toward helping students meet these standards.²³

The notable feature here is that while the requirement to develop and implement standards was federal and induced states to adopt a federally designated approach to school reform, the standards themselves were to be set by each state. There was no expectation of national uniformity and no federal minimum—only the criterion that every state’s standards should, in its own judgment, be “challenging.” Similarly, the legislation included federal accountability requirements, reflecting concern that federal funds spent on education had not sufficiently narrowed the gap between disadvantaged students and others in the past. However, it provided for each state to set its own definition of what constitutes “adequate yearly progress” (AYP), which is key to identifying low performing schools and districts that are targeted for improvement.

Experience to date with these grant provisions illustrates the dilemmas—from the federal perspective—of relying on state-developed standards. While nearly all states had established content standards by January 2001,²⁴ outside groups that reviewed these standards observed that they varied considerably in clarity and specificity and that some could not be considered rigorous.²⁵ In addition, states differed in how they defined and measured “low performing schools.” This led to substantial differences in the numbers and percentage of schools identified as needing improvement, such that schools with comparable levels of student performance could be targeted for improvement in one state but not in another. These variations directly reflect the kinds of flexibility that were

²³Content standards describe what students should know and be able to do. Performance standards define partially proficient, proficient, or advanced levels of mastery of the material in the content standards.

²⁴Two states—Iowa and Nebraska—found it difficult to set statewide standards and attempted to develop hybrid systems that rely on state guidelines for locally selected standards.

²⁵The Council for Basic Education, the American Federal Teachers, and the Fordham Foundation conducted separate reviews of the standards.

built into the Title I legislation. However, the variations—and states’ slowness in devising adequate assessments—generated concerns.²⁶

The ESEA reauthorization in the winter of 2002 incorporated new or expanded requirements for the Title I program, many of them aimed at strengthening accountability for results.²⁷ In addition to requiring states that accept grant funds to conduct annual assessments in mathematics and reading or language arts in grades 3 through 8 by the 2005-2006 school year, the law specifies how states must define AYP, details the steps that states and local education agencies must take with respect to schools that fail to make adequate progress, and lists the options they must offer to students in such schools. The law also requires states to develop a plan to ensure that, by the end of the 2005-2006 school year, all teachers teaching core academic subjects within the state are highly qualified. Although it significantly expanded the federal role in education, the 2001 legislation also acknowledges the state role. It prohibits federal mandates, direction, or control over a state, local education agency, or school’s instructional content, academic achievement standards and assessments, curriculum, or program of instruction, and it gives states and school districts greater flexibility in how they use federal funds. In addition, the law establishes a negotiated rulemaking process, directing the Secretary of Education to obtain advice and recommendations from state and local administrators, board members, education professionals, parents, and others involved in implementation before issuing proposed federal regulations for the program.

Cooperative Programs Set Standards Jointly, Limit Agency Oversight Role

We found examples within the Food and Drug Administration (FDA) of programs in which national standards for food safety are developed by agency and state officials acting together. The general mechanism is a cooperative body that develops proposed standards. Those that are approved are incorporated as guidance to states in carrying out inspection and enforcement procedures. Such nonbinding guidance does not preempt state law or have the binding force of federal law or regulation. States

²⁶Technical difficulties in the assessment process are a contributing factor. Devising assessments that are of adequate technical quality, aligned to standards, and appropriate for students with disabilities or limited English proficiency is a challenge that only a few states were able to meet by June of 2001, and states’ systems for identifying schools in need of improvement were still in transition.

²⁷The reauthorization is known as the No Child Left Behind Act of 2001, P.L. 107-110.

conduct enforcement activities under their own authority, and FDA provides training, program evaluation or audits, and technical assistance to state agencies.

Within this general design, there are variations. For example:

- In the Retail Food Protection Program, guided by FDA's Food Code, the standards development body is the Conference for Food Protection, a nonprofit organization that brings together federal, state, and local regulators, academics, and representatives of industry and consumer groups.²⁸ The conference submits recommendations on Food Code issues to the FDA; the FDA then reviews the recommendations and either accepts or turns back for further discussion. States are encouraged (but not required) to adopt the Food Code as the basis for their own regulation of retail food establishments such as grocery stores, restaurants, cafeterias, and vending machines. Adoption by a significant number of jurisdictions generally has taken 3 to 5 years.
- The National Shellfish Sanitation Program (NSSP) reflects policies developed by the Interstate Shellfish Sanitation Conference (ISSC), whose members represent states, the industry, and several federal agencies (FDA, EPA, and the National Marine Fisheries Service). All representatives participate in developing standards, but only the states vote in the general assembly, and FDA must sometimes compromise to get an issue approved or accept defeat of its proposals. FDA must concur with ISSC's proposed policy changes before they are incorporated into the program's catalogue of safety procedures, referred to as the model ordinance. States agree to enforce the requirements of the model ordinance through their participation in the NSSP and ISSC.²⁹ The FDA conducts program audits to ensure compliance with NSSP policy and applicable federal regulations, but its oversight activities are subject to resource, data, and other limitations.³⁰

²⁸The FDA also works with the Codex Alimentarius Commission, an international food standard-setting organization of the Food and Agriculture Organization and the World Health Organization.

²⁹Four foreign countries also have signed memorandums of understanding with the FDA to abide by NSSP's shellfish safety policies.

³⁰U.S. General Accounting Office, *Food Safety: Federal Oversight of Shellfish Safety Needs Improvement*, [GAO-01-702](#) (Washington, D.C.: July 9, 2001).

The cooperative programs are unlike others within FDA in that they reflect FDA's statutory authority under the Public Health Service Act, which directs FDA to assist states in the prevention of communicable diseases and advise them on the improvement of public health.

Under the cooperative program mechanism, as under the grant mechanism, states have the primary responsibility and authority for implementing federally approved standards—and a key role in framing them as well. Adoption of the standards is voluntary unless states have bound themselves to adopt, as in the shellfish program. There are two major drawbacks to this mechanism from a federal perspective. First, voluntary adoption does not necessarily provide nationwide application of a common standard, as some states may choose not to adopt. Second, the federal agency's limited role gives it little leverage over states that do not adequately protect their citizens. There is the added challenge of how to apply crosscutting food safety regulations such as the Hazard Analysis and Critical Control Points (HACCP) process control system, which the Department of Agriculture now requires for meat and poultry processing. FDA has mandated HACCP for all seafood production, including molluscan shellfish.³¹ Although seafood retailers are exempt from the HACCP regulations, the 1997 edition of the Food Code encourages them to apply HACCP-based food safety principles.

We found federal-state cooperation in framing highway design standards as well. Through the National Cooperative Highway Research Program (NCHRP), DOT's Federal Highway Administration (FHWA) cooperates with the American Association of State Highway and Transportation Officials (AASHTO)—an organization of state officials in which DOT is a nonvoting member—to support highway research.³² Drawing on these results and on task force efforts, AASHTO produces manuals, guidance, and specifications regarding highway design, safety, maintenance, and materials. FHWA supports the cooperatively produced materials. In contrast to the FDA, FHWA does not itself issue the guidance documents—they are published by AASHTO and incorporated into federal

³¹FDA is responsible for ensuring the safety of seafood under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. § 376.

³²The NCHRP is state-sponsored. Support is voluntary and funds are drawn from states' federal-aid highway funds. The Transportation Research Board of the National Research Council, a unit within the National Academies of Science, administers the research program.

regulations by reference. Thus, the highway design example falls on the border between a cooperative program and our next category, reliance on standards produced by nonfederal entities.

Standards Set by Other Entities Can Become National in Effect

Our discussion thus far has focused on regulatory standards that are developed by the federal government itself or in cooperation with states. However, a variety of other entities also develop standards and model ordinances covering subject areas within federal and state regulatory authority. Some of these entities focus on producing model state laws or regulations. When adopted by a sufficient number of states, these standards may provide a uniform approach and virtually national coverage without federal regulation. In addition, numerous private organizations such as Underwriters Laboratories and the National Fire Protection Association set national or international standards for a given material, product, service, or practice. These standards are available for voluntary adoption by industry, states, or federal agencies. When incorporated into a U.S.-ratified treaty or adopted by a federal agency such as OSHA, these externally developed standards have the status of federal law.

Uniform State Laws Can Provide National Coverage

State officials long ago recognized that certain areas within their jurisdiction would benefit from a uniform approach. The National Conference of Commissioners on Uniform State Laws (Uniform Law Commissioners, or ULC), a nonprofit unincorporated association consisting of commissioners appointed by the states and supported by state appropriations, has worked for uniform laws since 1892.³³ The ULC drafts uniform or model state acts in subject areas in which uniformity will produce significant benefits (such as facilitating commerce across state lines through the Uniform Commercial Code) or will avoid the disadvantages that arise from diversity of state laws (such as the Act on Reciprocal Enforcement of [child] Support). While the ULC generally avoids taking up areas in which no legislative experience is available or that are controversial among the states, it does address emergent needs. For example, ULC proposed model laws on electronic signatures and health care privacy before there was federal legislation on these subjects.

Once a uniform or model law is drafted, commissioners take it back to their states for consideration. Some (including the model electronic

³³Although some commissioners serve as state legislators, most are practitioners, judges, and law professors. They serve for specific terms and receive no pay for their services.

signatures law) have been adopted by most states. Others (such as the model health information law) have been adopted by relatively few. Implementation is left to each state. There is no federal role unless the Congress determines that federal legislation on the subject is needed. The same is true when states adopt standards developed through private standards development organizations.

Uniform state laws or regulations are also developed by entities that address a particular regulatory area, such as insurance. The National Association of Insurance Commissioners (NAIC), an organization of insurance regulators from the states, is such an entity. It was founded to address the need to coordinate regulation of insurers that operate in a number of states. The NAIC develops model laws, regulations, and guidelines and reviews the activities of state insurance departments as part of its accreditation program.³⁴ Model laws have addressed issues such as capital and surplus requirements and risk limitation. The NAIC's model regulation that sets minimum standards for Medicare supplemental insurance policies (known as "medigap" policies) has been incorporated by reference into federal Medicare legislation and regulations. The Gramm-Leach-Bliley Act of 1999 (P.L. 106-102) involves NAIC in a different way. That act, which deals with the financial services industry, encourages states to adopt uniform laws and regulations governing licensure of individuals and entities authorized to sell insurance within the state and providing for cross-state reciprocity in licensure. The act directs NAIC to determine whether at least a majority of the states have achieved uniformity within 3 years of the legislation's enactment. This target was met—by January 2002 the model act adopted by NAIC had been adopted by 39 states. If the target had not been met, the Act specified that a new nonprofit corporation, subject to NAIC supervision, be established to provide for state adoption of uniform insurance licensing laws.

Federal Regulations May Incorporate Private-Sector or International Standards

In the United States, private sector standards are the product of a decentralized, largely self-regulated network of more than 620 private, independent standards-development organizations and testing laboratories. A private nonprofit organization, the American National Standards Institute, establishes rules for developing standards on the basis of the consensus of the parties represented in the technical committees.

³⁴For a review of this program, see U.S. General Accounting Office, *Insurance Regulation: The NAIC Accreditation Program Can Be Improved*, [GAO-01-948](#) (Washington, D.C.: August 30, 2001).

The federal government directs agencies to use standards developed through this system except where inconsistent with law or otherwise impractical, and it encourages them to participate where appropriate in standards-setting organizations.³⁵ The Occupational Safety and Health Act contains similar direction, and the OSHA Administration and other federal regulatory agencies have incorporated privately developed standards into their own agency regulations.

Hazards addressed through federal-state regulation in the United States may also be of international concern and become the subject of international agreements. For example, criteria for classifying dangerous chemicals in transportation have been internationally harmonized through the United Nations' Recommendations on the Transport of Dangerous Goods. DOT uses these criteria in developing U.S. HAZMAT regulations, which in turn are translated into state regulations for HAZMAT transportation as discussed previously in this report. Similarly, the FDA works with the Codex Alimentarius Commission, an international food standard-setting organization, thus helping ensure consistency of the Food Code (which states can adopt) with international standards. Thus, regulation through the mechanisms discussed above serves to align state as well as federal standards to those set internationally.

Experience with These Mechanisms Suggests Considerations for Future Programs

Our review indicates that regulations or standards consistent with federal objectives can be formulated through a variety of mechanisms and implemented through various combinations of state and federal efforts. Each standard-setting mechanism offers different advantages and limitations, as do the various patterns of implementation. We discuss these advantages and limitations in terms of federal-state balance and in terms of operational challenges. Drawing on this discussion, we suggest how findings from our review could guide decisions regarding future programs.

³⁵These directions are found in Office of Management and Budget Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*, and in the National Technology Transfer and Advancement Act of 1995, P.L. 104-113.

Differences among Mechanisms Reflect Key Factors for Considering Federal-State Balance

The standard-setting mechanisms we reviewed can be compared in terms of factors that the U.S. Advisory Commission on Intergovernmental Relations and other students of federalism have considered to be key in examining issues of federal-state balance.³⁶ As the body of literature from these authors suggests, the factors apply on a case-by-case basis, taking into consideration the particular national objective concerned and circumstances relevant to its achievement. Key factors include:

- **Uniformity:** Does this mechanism provide uniform standards and nationwide coverage if essential to the national objective?
- **Flexibility:** Does it allow for flexibility where appropriate to that objective?
- **Capacity:** Does the mechanism assign responsibility appropriate to each level of government's capacity to do the job at hand, taking into account breadth of jurisdiction, enforcement powers, resources, and location?
- **Accountability:** Can accountability to the federal government be incorporated into this mechanism if essential to achieving the national objective?

Table 4 compares the five mechanisms in terms of these factors. This presentation reveals more clearly how the mechanisms differ in terms of the factors that a policymaker may consider critical to a particular objective. The table also highlights program design choices that can be made within each mechanism. For example, while flexibility is inherently limited under federal fixed standards, grant conditions can be written to give as much or as little flexibility as is appropriate to the federal objective concerned.

³⁶A congressionally chartered organization, the commission examined federalism issues from 1959 to 1996.

Table 4: Standard-Setting Mechanisms and Federal-State Balance Factors

Factor	Federal fixed standards	Federal minimum standards	Grant conditions	Cooperative standards	External standards
Uniformity	Establishes uniform standards Ensures coverage in all states	Establishes uniform minimum standards; beyond that, standards may vary across states Ensures coverage in all states	Can provide for uniform, uniform minimum, or state-specific standards Coverage limited to participating states	Provides uniform model standards; states can adopt in entirety or in part Coverage limited to states that adopt the standards	Provides uniform model standards; states can adopt in entirety or in part Unless incorporated into federal regulation, coverage limited to states that adopt
Flexibility	None, unless there is provision for waiver	States can establish standards more stringent than the federal	Varies: as specified in each grant	Unless otherwise bound by their participation, states are free to adopt these standards or use others of their own choosing	Except where incorporated into federal regulation, states are free to adopt these standards or use others of their own choosing
Capacity	Can tap federal resources, enlist state resources in implementation Division of costs an issue	Can tap federal resources, enlist state resources in implementation Division of costs an issue	Can tap federal resources, enlist state resources in implementation Division of costs an issue	Relies primarily on state capacity but can be augmented through federal grants Division of costs an issue	Unless incorporated into federal regulation, relies primarily on state capacity
Accountability	Federal agency unless states implement; can incorporate provisions holding states accountable	Federal agency unless states implement; can incorporate provisions holding states accountable	Can incorporate provisions holding states accountable	Rests with state agencies, accountable to state officials	Unless incorporated into federal regulation, rests with state agencies accountable to state officials

Source: GAO analysis.

Implementation Brings Operational Challenges

Although direct implementation by a federal agency can be advantageous in certain situations, this approach presents its own set of challenges and limitations. In this study, we focused on the operational challenges that arise in shared federal-state implementation. First, shared implementation raises delicate issues of federal-state agency relations, oversight, and accountability. Legislators and agencies may have difficulty finding a level of oversight that is sufficient to protect against the harm that could come from inadequate state action while providing states the authority and flexibility needed to do the job effectively. Oversight tools such as the performance incentives and sanctions illustrated in our discussion of

federal minimum standards programs can be designed with this purpose in mind. Another approach is the use of performance partnerships.³⁷

Second, while overall resource adequacy may be an issue under any pattern of implementation, reliance on states to implement federal standards also raises questions about allocating costs between the federal government and the states. If federal funds are provided, the issue of fiscal substitution (use of federal funds to replace state funds) may also arise. Options for addressing these issues include the following:

- The state's share can be preserved through the use of fiscal provisions such as maintenance of effort or matching requirements.³⁸
- The federal share may be provided through grants to participating states or by permitting states to retain payments generated through program operation and enforcement. Grant payments may be "up to" a specified percentage of state program cost, but actual payments depend on funds available and have sometimes been substantially less.

If both levels of government participate in administering federal regulations, both levels contribute toward the cost. However, if the state does not participate, the federal agency administers the program at no cost to the state, which leads to a third challenge.

The third challenge is that implementation arrangements that give the federal agency a back-up role can leave it vulnerable to sudden increases in responsibility and costs. This can happen when states drop their participation, as has happened in the OSHA and Meat and Poultry programs. It can also happen when states are judged by the agency to have failed to meet their responsibilities. The federal government may also bear the cost of enforcement temporarily when new provisions need enforcement before states are ready to assume this responsibility. We saw examples of each of these circumstances in the programs we reviewed.

Fourth, shared implementation tends to produce variation in program implementation because states' approaches may differ from each other

³⁷See, for example, U.S. General Accounting Office, *Environmental Protection: Collaborative EPA-State Effort Needed to Improve New Performance Partnership System*, [GAO/RCED-99-17](#) (Washington, D.C.: June 21, 1999).

³⁸U.S. General Accounting Office, *Federal Grants: Design Improvements Could Help Federal Resources Go Further*, [GAO/AIMD-97-7](#) (Washington, D.C.: December 18, 1996.)

and from the federal agency's. For example, states may prefer to emphasize assistance while the federal agency relies more on enforcement actions to induce compliance.³⁹ The variation may be appropriate and reflect a need for flexibility in light of differing conditions and to target limited resources to the problems that pose the greatest risk. If variation is not deemed appropriate—for example, if the national objective requires that enforcement actions as well as standards be uniform—federal requirements and oversight can be strengthened to provide uniformity.

Finally, change can be cumbersome under federal-state implementation. Every time a federal statute or regulation changes, each state must make a corresponding change to its own statute or regulation before it can implement the new provision. This can lead to substantial delays, and states have observed that frequent change can become a burden. For example, the Association of Food and Drug Officials have noted the difficulty of amending regulations to keep up with changes in the Food Code every two years.

Questions Derived from These Observations Can Guide Future Program Decisions

Our review led us to conclude that setting up a regulatory program involves three stages of decision making and to develop questions to guide those decisions based on the observations summarized above. The three stages are

- identifying the national regulatory objective and reviewing pertinent background information,
- selecting a standard-setting mechanism appropriate to that objective, and
- designing appropriate federal and state roles in implementation.

The last two stages are intertwined. For example, cooperative standard setting or reliance on states' adoption of externally set standards usually means little or no federal role in implementation. However, other mechanisms leave considerable choice with respect to implementation arrangements. We illustrate this overall decision process, as guided by questions reflecting key factors, below.

³⁹Such differences in philosophy may also exist between regional offices of the federal agency. See U.S. General Accounting Office, *Environmental Protection: More Consistency Needed Among EPA Regions in Approach to Enforcement*, GAO/RCED-00-10 (Washington, D.C.: June 2, 2000).

The National Objective Shapes the Choice of Standard-Setting Mechanism

The national objective provides the starting point for selecting the mechanism for enlisting state efforts toward that objective. Assuming that the objective itself is consistent with the Constitution, factors to be considered include

- the nature of the hazard or practice to be regulated, for example,
 - how widely it is distributed geographically and whether it is cross-state in nature,
 - the risks it poses, and
 - whether protection against these risks is needed immediately or within a period of years;
- existing federal statutory authority and capacity that could form the basis for setting and implementing standards;
- the extent to which state or other standards and enforcement are already in place and the resources and capacities available to support them; and
- the resources and capacities that are likely to be needed to formulate and implement or enforce new standards in this area.

This background information can be expressed in the form of questions that will help in assessing the extent to which federal action is or is not needed and what form it might take (see figure 1). For example, the information may indicate that states are already handling the problem. The review of existing statutory authority will help policymakers determine whether new authority would be needed to establish federal standards. Finally, background information will provide a foundation for examining the objective in terms of federal-state balance factors and for proceeding to consider the choice of standard-setting mechanism. The discussion and figures that follow assume that policymakers have concluded that federal action is warranted and are contemplating designing a new program or rethinking an existing program.

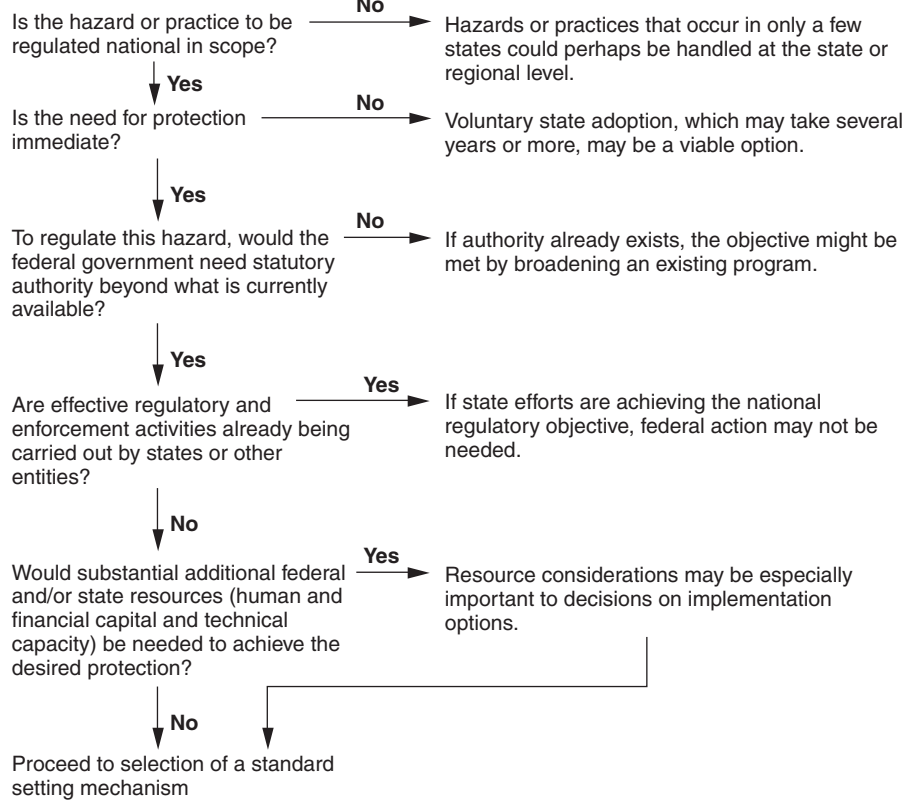
Figure 1: Defining the National Objective and Examining Background Questions

Starting point for decision

Define the national regulatory objective

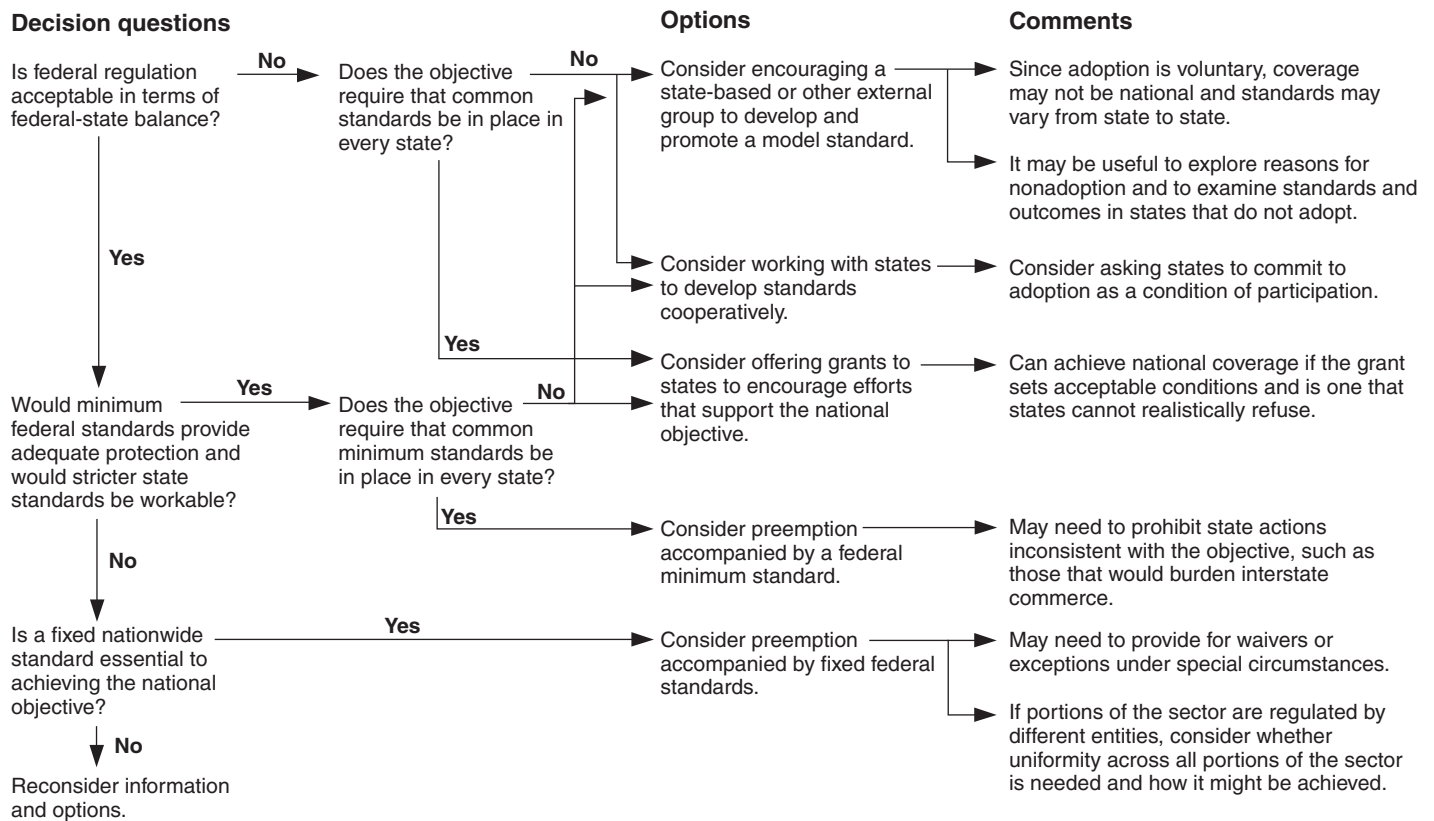
Background questions

Considerations



For the next stage of decision making, selection of a mechanism for pursuing the national objective, we depict the decision process as a series of questions or gates in order to make explicit what are often implicit considerations in decision making (see figure 2). We start with the question of whether—pursuant to the national objective in question—federal fixed or minimum standards would be acceptable in terms of federal-state balance. Our presentation does not imply that federal standards are the best choice but only that if they raise difficult issues consideration must move immediately to other options.

Figure 2: Selecting a Standard-Setting Mechanism



If federal standards would likely be unacceptable, the next question (to the right on figure 2) is whether uniform regulations and nationwide coverage are essential to attaining the national objective. If not, policymakers may explore what could be achieved through state adoption of externally developed standards or by cooperating with states to set voluntary standards. This exploration should bear in mind that these mechanisms rely wholly on states for implementation and may not provide for central monitoring and uniform reporting. It is important to review the potential need for these practices and how they could be provided in the absence of direct federal oversight. If uniformity and nationwide coverage are essential, incorporating a federal standard into grant conditions could enlist the efforts of nearly all states.

The next step is to consider whether federal minimum standards—which provide a baseline of protection but also allow variation from state to state above the minimum—or fixed federal standards would best achieve the national objective in question. For purposes of illustration (one could start with either option) our diagram first asks whether minimum standards would be appropriate. If so, and if that objective does not demand full national coverage, each of the alternative mechanisms would again be an option. However, if national coverage were essential, federal minimum standards would be the mechanism of choice.

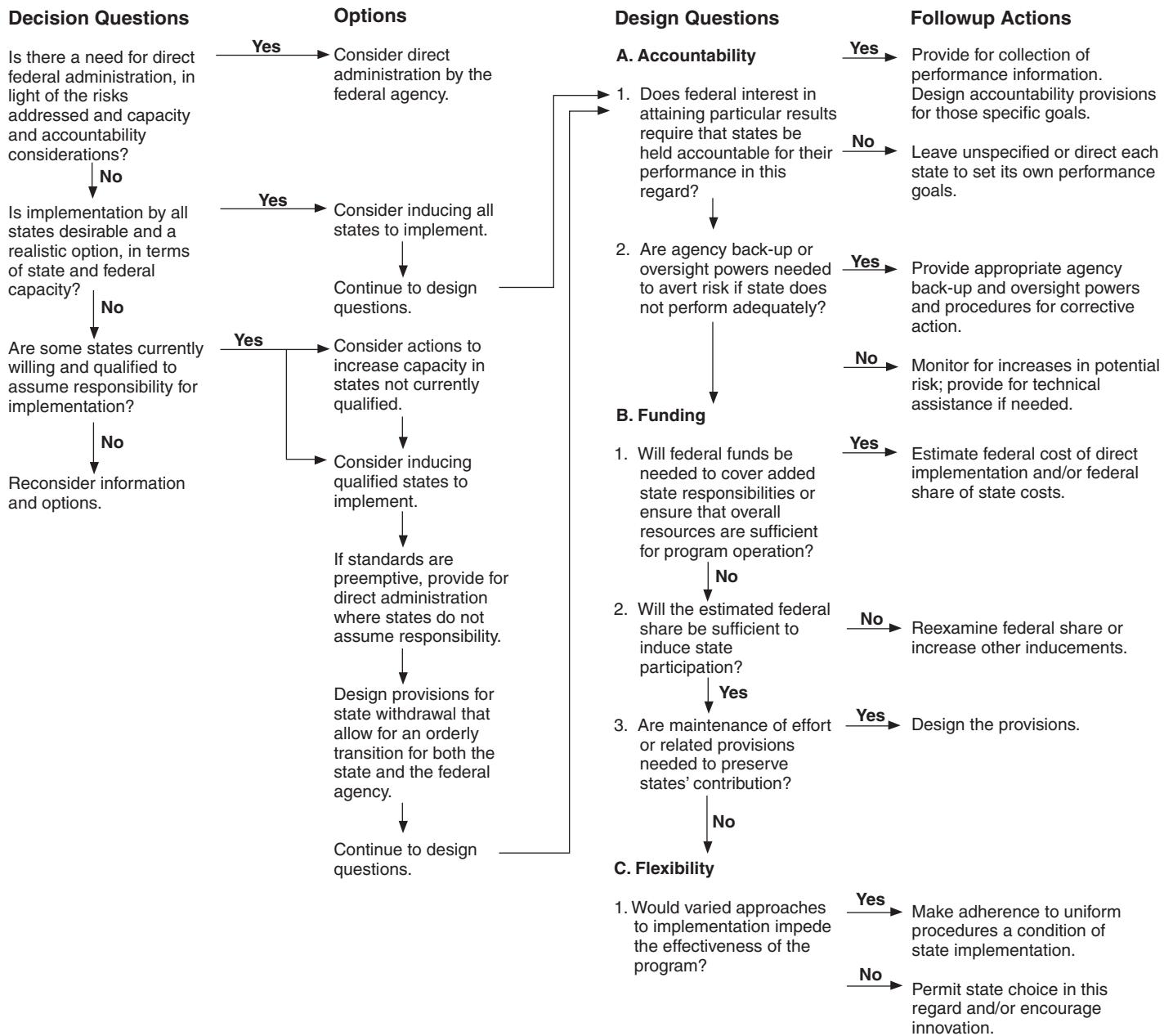
If federal standards are allowable and minimum standards are not appropriate—or if a common, unvarying nationwide standard is essential to attainment of the objective—fixed federal standards and the possible need to allow waivers should be considered. In considering the coverage needed for the standards to be effective, it is useful to think in terms of sector coverage as well as geographic scope. As the ERISA health plan example illustrates, uniformity will not be attained if standards cover only the federally regulated portion of a divided sector.

It may happen that when all mechanisms have been considered, none seems truly appropriate. Such an outcome suggests that something has been missed along the way and that it would be useful to gather additional information and to revisit earlier steps in the decision process. The final step is to ensure that the mechanism chosen and the purpose are consistent with Congress’s authority to regulate under the Constitution.

Some Mechanisms Offer Options for Implementation

Fixed federal standards and minimum federal standards offer a choice between (1) direct federal implementation, (2) assumption of implementation responsibility by all states, and (3) assumption by some states, with direct federal administration in others. Whenever implementation by states is selected (under federal standards or through grants) there are choices to be made regarding the design of accountability, funding, and flexibility provisions. We now discuss factors to be considered in selecting and designing implementation options, as illustrated in figure 3.

Figure 3: Examining Implementation Options



In this figure, we begin the decision process by asking whether the national objective and related considerations suggest a need for direct federal administration. Direct federal administration might be appropriate when

- centralized accountability and central direction are critical given the nature of the hazards that the standards address;
- states do not currently have, and the federal government has or can develop, the capacity needed to operate the program;
- uniformity of implementation will enhance or variance will undermine the effectiveness of the regulatory approach; and
- state and local involvement is not critical to achieving the objective.

While we did not study in depth the option of direct federal administration in the regulatory area for this report, experience certainly suggests that this option has its own set of challenges and limitations. For example, the federal government may not have the personnel in place to carry out a program of national concern while state and local governments may have sufficient staff with the right kind of expertise to provide the needed services. Another challenge with this approach is overcoming any reluctance of state and local governments to accept the dictates of the federal government in a given policy area. It is also important to note that direct implementation and enforcement by a federal agency is not a self-executing decision and that there could be design and implementation challenges that might prove sufficiently problematic as to require rethinking the decision to use the direct federal administration option.

If direct federal administration is not essential, the next question for a federal regulatory program is whether assumption of implementation responsibility by all states is desirable and is feasible in terms of their capacity. This question arises both under federal standards programs and under grants or other forms of support. The background information mentioned in figure 1 will likely be of assistance here, but additional inquiry may be needed to ascertain states' capacity to implement the standards and their likely willingness to do so. If assignment to all states appears feasible, the next step is to consider more detailed questions of design in areas such as federal-state accountability arrangements, funding, and flexibility that arise under this option, and to take follow up action as needed. Note that while our figure shows only actions for clear "yes" or "no" answers, in reality both the answer and the appropriate follow up may fall in between or be a mix of the actions shown.

If many states, but not all, are prepared to accept responsibility for implementation of federal standards, the first step might be to consider actions to increase capacity in states not currently qualified, so as to be able to enlist participation by all states in implementation at some future point. The other option would be to consider inducing currently willing and qualified states to assume responsibility, as in the OSHA program or the meat and poultry inspection program. To ensure national coverage, the program design will need to provide for direct administration by the federal agency in the remaining states. We suggest that the design provide for an orderly transition in case of state withdrawal from participation. Again, the next step will be to consider the various design questions. The funding question is of particular importance for any approach that relies largely on financial inducements for state participation.

Design Questions Can Be Adapted to Purely State Programs

The remaining two regulatory mechanisms—cooperative programs and state adoption of externally set standards—rely solely on states to implement standards under their own authority. States are not accountable to the federal government and the federal agency does not oversee their activities, although it may perform monitoring functions such as collecting and reporting performance data. Because the federal role is so limited, the design questions we have listed for shared-implementation approaches are not directly applicable. However, the accountability and flexibility questions can be adapted to this context. For example, some purely state regulatory programs include provision for monitoring and oversight by a central body, such as the NAIC. The accountability questions could be applied to its functions.

Concluding Observations

This study of a broad range of existing programs illustrates the rich variety of ways in which the federal government and the states can work toward achieving shared regulatory objectives. Each variation reflects circumstances and sensitive issues specific to the program concerned, and each program is unique in some way. But comparative analysis reveals both underlying features of program design and trade-offs between the various options available. Explicitly considering these features and trade-offs could help guide decisions about how to structure future federal-state regulatory programs.

The decision framework we have developed displays the range of options available, identifies the major choice points in the decision process, and alerts policymakers to trade-offs and key follow-up actions associated with each choice. The framework is a neutral tool and does not favor any particular program design option or division of federal and state

responsibilities. Rather, it is intended to help policymakers select a program design in keeping with the regulatory objective they seek to attain.

As agreed with your office, we are sending copies of this report to appropriate congressional committees and other interested parties. We will also make copies available to others upon request.

If you or your staff have any questions about this report, please contact me on (202) 512-9573 or Thomas James on (202) 512-2996. Individuals making key contributions to this report included Gail MacColl, Andrea Levine, Thomas Phan, and Mary Reintsma.

Sincerely,

A handwritten signature in black ink that reads "Paul L. Posner". The signature is written in a cursive, flowing style.

Paul L. Posner
Managing Director, Federal Budget and Intergovernmental Relations
Strategic Issues

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