



## EVALUATING DEMONSTRATIONS:

# A TECHNICAL ASSISTANCE GUIDE FOR STATES

Developed by the  
Division of Quality, Evaluation, and Health Outcomes  
Family and Children's Health Programs Group  
Center for Medicaid and State Operations  
Centers for Medicare & Medicaid Services

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## INTRODUCTION

There are enormous demands for information on public programs, especially on innovations that aim to meet the health needs of the Medicaid, SCHIP, and uninsured populations. These demands call for evaluations of new initiatives that seek to produce new knowledge and direction for programs. Learning how successful or challenging these efforts have been, and why, can help inform the debate on how to reshape our programs for the future.

Government agencies at the federal, state, and local levels perform a number of functions in administering public programs for financing health care, including the implementation of demonstrations. Demonstrations, by their very nature, should be formally evaluated in order to document, by providing measurable evidence, the answers to four fundamental questions:

- To what degrees did the demonstration achieve its purposes, aims, goals, objectives, and quantified performance targets?
- What lessons were learned as a result of the demonstration? What would you recommend to other states which may be interested in implementing a similar approach?
- In what ways, and to what extent, were outcomes for enrollees, providers, payers, and employers changed as a result of the demonstration?
- Did the reallocation of resources in the demonstration generate greater “value” for the state’s program expenditures? (See <http://www.hhs.gov/valuedriven/>.)

Many of the above questions cannot be answered until the end of the demonstration period. However, demonstrations proposed by states are often of high and immediate interest to public officials at both the federal and state levels. Consequently, evaluations must also provide information on the short-term progress of the demonstration on an ongoing basis. Information obtained during the evaluation process can help inform the state on next steps, inform federal officials on the progress of the demonstration, and provide valuable information when considering demonstration extensions and renewal options. As a result, evaluations must be designed to not only address the long-term impact of the demonstration, but to provide short-term quantitative data on the progress of the demonstration in order to inform policymakers at both the state and federal levels.

## EVALUATIONS

Evaluation is at the heart of acquiring new information derived from thoughtfully designed demonstrations. Programs developed on sound knowledge are a major need in this time of reform. Well-designed evaluations that provide information on outcomes can lead to knowledge transfers that are enormously helpful to other programs and can inform decisions for these public programs.

The CMS Program Evaluation Plan states:

Information gained from program evaluations plays an important role in planning for the future of [government] programs. In light of the enormous scope of the programs [administered by] CMS ..., there is a critical and ongoing need for information to [assist] operational and policy officials make [future program] decisions ... – [guided by] information that tells them whether, and in what important ways, a program is working well or poorly, and why. Program evaluation information is used to guide and inform both current and future planning. The policies and procedures of CMS programs ... have far-reaching effects on the broader healthcare system. CMS [is required to collect] information about its ongoing programs to support federal management and promote the increased efficiency and effectiveness of these programs. [Evaluation] information is used to identify critical healthcare issues and ... the best available strategies for addressing those issues. [These] program evaluation efforts ... provide information and descriptive statistics on parameters, such as operational workload and production, on populations of health care users and their service and expenditure patterns[,] on providers and health plans, and on CMS expenditures.

[The] plan for systematically evaluating [Medicaid] programs [implies] both performance measurement results (providing more real-time data focused on whether a program is achieving measurable objectives) and more rigorous program evaluation findings that typically examine a broader range of information on [a] program[‘s] performance. Both forms of assessment [yield] valuable information to improve ... program administration. Performance measurement serves as an early warning system to agency management, while ... broader program evaluation efforts typically involve more in-depth examination of program performance and context, an overall assessment of whether the program works, and identification of adjustments that may improve its results. One special aspect of CMS’ program evaluation function is the implementation and evaluation of demonstration projects that test innovative changes to CMS payment methods or benefits under Medicare, Medicaid, or SCHIP.

## POLICY CONTEXT

The Centers for Medicare and Medicaid Services (CMS) has a number of goals for the programs that it administers. These include:

- reducing:
  - the number of uninsured,
  - the rate of uninsurance,
  - disparities in the provision of healthcare services, both geographically and by population groups,
  - reimbursement payment errors, and
  - fraud and abuse; and
  
- improving:
  - the quality of care,
  - patient safety,
  - access to care,
  - program integrity,
  - accountability,
  - cost-effectiveness,
  - efficiency,
  - payment methodologies to reward performance,
  - the “value” of healthcare services paid for,
  - implementation and utilization of health information technologies, and
  - the sharing of experiences, lessons learned, and best practices among States.

States programs often have the same or additional goals. The combination of these goals should be considered when designing, implementing, and evaluating demonstrations.

One of the overriding goals is to improve the quality of care received by beneficiaries of its programs and by enrollees in state demonstrations. The Center for Medicaid and State Operations (CMSO) is responsible for providing technical assistance to States in methodologies for quality improvement and to support States in implementing valid approaches to program evaluation. In evaluating their demonstrations, States should employ valid and reliable performance measures that will enable States to best demonstrate the successes, challenges, and value of their demonstrations.

In their programs and demonstrations, States are accountable for the “value” of the healthcare services provided and reimbursed. Two principal components of the “value” of healthcare services are “quality” and “cost”. The “value” of a state demonstration, for example, would depend upon how the quality and cost of healthcare services change over time relative to each other as a result of the demonstration.

- A state demonstration would increase “value” if it resulted in higher quality and lower costs of healthcare services; if the proportionate increase in quality is greater than the proportionate increase in costs; or even if a significant decrease in costs is accompanied by only a marginal decrease in quality.
- A state demonstration would decrease “value” if it resulted in lower quality and higher costs; if the proportionate decrease in quality exceeded the proportionate decrease in costs; or if a significant increase in costs resulted in only a marginal increase in quality.

The importance of improving the “value” of healthcare services paid for is discussed more fully on the Website of the U.S. Department of Health and Human Services on Secretary Leavitt’s “transparency” initiative on “value-driven health care” for both the public and the private sectors. The URL of this site is <http://www.hhs.gov/transparency>.

Examples of outcome measures demonstrating improved quality would include:

- increased access to, and availability of, appropriate health information or services;
- increased preventive or care-coordination services with correlating decreased acute-care services (improved effectiveness);
- increased timeliness of services or healthcare delivery (improved efficiency);
- improved technology with correlating increased utilization of those services;
- improved health outcomes (e.g., decrease in low birth-weight deliveries); and
- increased patient satisfaction rates.

## **GENERAL GUIDELINES**

The terms and conditions that CMS requires of a state in approving the state’s application for one or more waivers for their Medicaid and / or SCHIP program(s) usually include a requirement that the state conduct or fund an evaluation of the demonstration.

While a narrative and anecdotes about what happened during a demonstration provide important information, the principal focus of the evaluation of a demonstration should be on obtaining data on measures of the effects, impacts, and outcomes of the demonstration. Public officials at all levels of government want “hard” evidence on the results of demonstrations.

The evaluation should also be designed to provide on an ongoing basis answers to basic questions, such as the number of enrollees in the demonstration; the most common types of benefits selected by enrollees, when there is a choice; decreases in emergency department visits, if this is a focus of the demonstration; and other questions pertinent to the demonstration objectives.

States have many choices available to them in what to evaluate in their demonstrations and how to evaluate what they choose.

States rarely have the resources available to evaluate everything about a demonstration. Therefore, a state must decide:

- what to evaluate among many possibilities, i.e., what anticipated changes from the demonstration need to be captured for a valid evaluation;
- what the state's priorities are in the evaluation, i.e., what activities are the most important to the state to be evaluated or what does the state most want to learn about the outcomes of the demonstration; and
- how to allocate the finite resources available for the evaluation among all of the things about a demonstration that can be evaluated.

A good place for a state to start is to identify and specify the primary purpose(s), aims, goals, and objectives of the demonstration. The evaluation should be designed to measure the degree to which these purposes, aims, goals, and objectives have been achieved by the demonstration.

A state should translate the purposes, aims, goals, and objectives of its demonstration into quantifiable targets for improvement (e.g., reduce the uninsurance rate 20 percent, decrease the rate of growth in program costs five percent, increase the quality of healthcare services reimbursed 15 percent), so that the performance of the demonstration in achieving these targets can be measured.

In summary, planning the evaluation of a state demonstration might begin as follows:

- (1) State and define the purposes, aims, objectives, and / or goals of the demonstration. These are the "ends" of the demonstration project.
- (2) Translate and convert these purposes, aims, objectives, and / or goals of the demonstration into quantitative performance targets for the demonstration. The evaluation should be designed to measure the degrees to which the demonstration

achieved the purposes, aims, objectives, and goals of the demonstration in terms of the performance targets.

- (3) State and define the interventions / changes to be implemented in the demonstration to achieve the purposes, aims, objectives, goals, and performance targets of the demonstration. These are the “means” of the demonstration. The evaluation should be designed to measure:
- the relative effectiveness of the interventions / changes in achieving the purposes, aims, objectives, goals, and performance targets of the demonstration and
  - the impacts of the interventions / changes in the demonstration on outcomes for enrollees, providers, public and private payers, and employers.

The evaluation design of state demonstrations should follow certain basic principles, standards, and priorities. Some examples are the following:

- Evaluations should focus on what is measurable. The measures used should be statistically “valid” and “reliable”.
- Evaluations should not be limited to measuring only changes in the utilization of healthcare services, but should include the measurement of actual health outcomes and / or the level of functioning in different areas (e.g., physical, mental, activities of daily living) of the enrollees in the demonstration.
- Demonstrations should be designed to improve the cost-effectiveness and quality of the healthcare services provided and reimbursed. Evaluations, in turn, should be designed to capture financial, clinical, and program data that measure the value added under the demonstration relative to the reallocation of financial resources under the demonstration.
- It is usually more important to measure changes in variables over time than it is to measure variables at only one point in time. The evaluation should be designed to measure changes before, during, and after the demonstration. The ideal outcome of an evaluation is to demonstrate sustained improvement over several years on the variables measured.
- The evaluation should be designed based on the expectation that the design and implementation of the demonstration will be changed one or more times during the course of the implementation of the demonstration:
  - due to findings identified through program monitoring and performance measurement activities;
  - due to changes in programmatic, political, economic, and fiscal factors at both the state and the federal levels; and

- in order to improve the performance of the demonstration in meeting its purposes, aims, goals, and objectives.

- Evaluations should be designed so that they will be able to differentiate the impacts on outcomes of the demonstration from the impacts on outcomes of other factors that are independent of the demonstration. To the extent feasible, the effects of the demonstration should be isolated from the effects of other factors on the outcomes being measured in the evaluation. The effects of these other factors should be controlled for in any statistical analyses performed in the evaluation of the effects of the demonstration on the outcomes being measured.

The evaluation should be managed to ensure that the goals and objectives of the demonstration are met within the established timeframes.

- The state should convert key quantitative measures of outcomes to performance targets, e.g., a percentage increase or decrease in the measure that the state aspires to achieve in the demonstration. These performance targets can be used by the state in managing the implementation of the demonstration. If the data collection and monitoring of these key measures of outcomes indicate that the demonstration is falling behind schedule in achieving the specified performance targets, then the state should identify the sources of problems and issues and make appropriate changes in the design, management, operations, and / or implementation of the demonstration. The Special Terms and Conditions outlines when CMS approval is required before a state can implement changes in the demonstration.
- In the continuous performance improvement model, a state should regularly monitor the demonstration on the key outcome measures and performance targets and make changes in the demonstration that will improve achievement of the performance targets (subject to prior CMS approval when required). The process of regularly measuring, monitoring, and making changes should result in continuous performance improvement in the demonstration in terms of achieving its performance targets and intended outcomes.
- In quarterly and annual reports on, and the final report for, the demonstration, the state should describe what changes were made in the implementation of the demonstration during the period of time covered by the report.

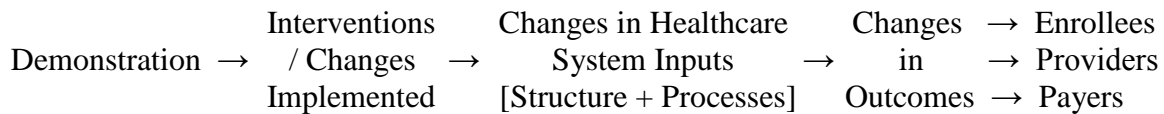
Systems, programs, and demonstrations can be modeled in two dimensions: inputs and outcomes. Inputs, in turn, are made up of two subdimensions: structure and processes.

- “Structure” refers to components (e.g., organizational units, individuals) and their relationships to each other. Evaluating “structure” means determining the degree to which the necessary components and relationships are in place, operational, and of sufficient quality to produce the outcomes desired.

- “Process” refers to what the components do. Evaluating “processes” means measuring the level of performance of the components individually and of the system, program, or demonstration as a whole.
- “Outcomes” refers to the results for, and impacts on, different parties, e.g., enrollees, providers, payers, and employers. Evaluating “outcomes” means measuring the results and impacts for each type of party.

Inputs [Structure + Processes] → Outcomes

The central purpose of government interventions into the healthcare system by healthcare financing programs, including demonstrations, is to improve “inputs” in order to produce better “outcomes” for program enrollees, healthcare providers, and / or public programs. Outcomes include both quality and cost factors. Consequently, a basic purpose of the evaluation of a demonstration should be to measure the extent to which the changes made by the demonstration in regard to healthcare system “inputs” change “outcomes” for enrollees, providers, and payers.



A comprehensive evaluation of a demonstration would include structural, process, and outcome measures by:

- measuring the degrees of change in healthcare system “inputs” (e.g., utilization of healthcare services);
- measuring the degrees of change in outcomes for enrollees, providers, and payers; and
- analyzing the degrees to which changes in the measures of healthcare system “inputs” led to (i.e., were associated with) changes in the measures of “outcomes”.

Such an evaluation would be able to document the relative effectiveness of the demonstration in improving outcomes for enrollees, providers, and programs. A more limited evaluation would only document the relative effectiveness of the demonstration in changing healthcare system “inputs” (such as service utilization). This would provide limited knowledge and guidance for future programs and demonstrations and for other states.

If the demonstration, for example, expands the population groups eligible for coverage under Medicaid and / or SCHIP, then the evaluation should document the ways in which, and the degrees to which, the expansion population groups are better off (e.g., they demonstrate

improved health outcomes ) as a result of the demonstration. Similarly, the evaluation should also determine if the costs of health care for the expansion population groups are lower over time than they would have been without the benefits of the demonstration.

If the demonstration reduces or alters the benefit package for some enrollees, then the evaluation should correspondingly determine if the public and private costs of the enrollees with reduced or altered benefits are higher or lower over time than they would have been without the reduction or alteration in benefits. For example, enrollees with reduced benefits may substitute use of hospital emergency rooms for services not covered by the new benefit package.

Public officials and taxpayers, at both the federal and state levels, want to know the value being obtained from the millions of dollars spent by public programs, including demonstrations, for healthcare services. The evaluation of a state demonstration should be designed to tell them that by reporting data on various measures and the findings of analyses. Officials can then make informed decisions with an awareness of the potential risks and benefits.

A state can implement a demonstration with one or more waivers or without any waiver (e.g., under Section 1115(a)(2) of the Social Security Act). Most state demonstrations are usually composed of multiple waivers, components, and interventions. The evaluation of the demonstration should be designed so that it can determine, to the extent feasible, the differential and relative effects or impacts on outcomes of each of these waivers, components, and interventions individually. The extent to which the evaluation can disaggregate the results of the demonstration and the findings of the evaluation according to the separate waivers, components, and interventions, the more useful the evaluation report will be to public officials in the same state and in other states.

The evaluation of a demonstration may be performed internally by the state or through external parties. Often States contract with independent firms to conduct the evaluation in order to lend credibility to the findings. Program directors should consider the following questions when assessing the appropriateness of a proposed evaluation design:

- Does the evaluation design meet the requirements for the evaluation stated in the demonstration’s “Special Terms and Conditions”?
- Do the measures proposed in the evaluation design correspond to the objectives of the demonstration? Will the evaluation analyze the impact of the interventions in the demonstration in relation to the objectives of the demonstration? Will the evaluation be able to measure the degree to which the demonstration met its objectives? Does the evaluation design contain assessments that will enable the state to demonstrate improvement in meeting the objectives of the demonstration?
- Will the evaluation enable the state to determine the degree to which the demonstration meets the goals of the state’s Quality Improvement Strategy?

- Will the evaluation findings address programmatic goals, such as reducing uninsurance, quality improvement, and value-based purchasing / pay-for-performance reimbursement?

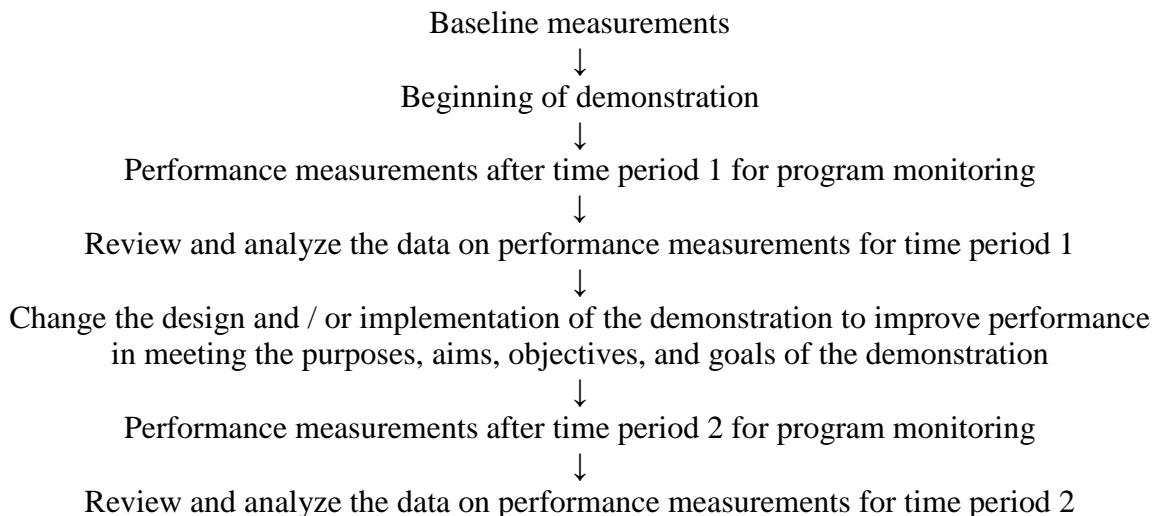
## INTEGRATION OF PROGRAM FUNCTIONS

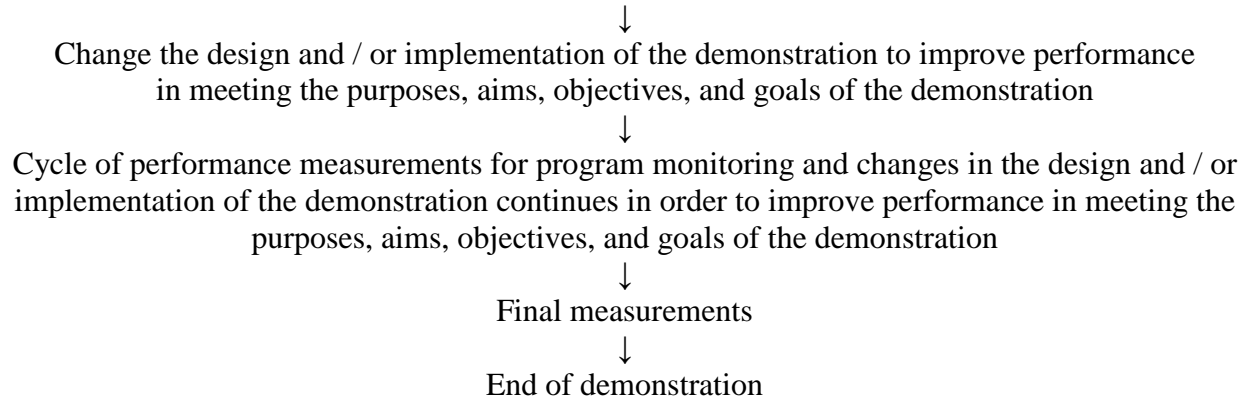
As States begin to determine what they will evaluate in their demonstrations, it is helpful to consider the many other program functions that States are responsible for and how they may be able to benefit from an integrated approach to program design. It is important to determine areas of overlap and duplication among various program functions in order to take advantage of all resources available to a state.

States are responsible for many of the following functions:

- Ensuring, validating, and monitoring compliance with the requirements of statutes, regulations, and contractual terms and conditions (e.g., for approving waivers and demonstrations). This is done through such means as reporting requirements, reviews, and inspections, both by the agency itself and by independent public or private organizations.
- Continuous performance improvement, which is the process of:
  - monitoring the performance of program implementation, management, operations, processes, and the delivery of services through the use of performance measures and
  - taking actions when deficiencies are identified in order to correct the deficiencies and to improve performance.

The stages of this cycle in a demonstration can be illustrated as follows:





- Developing and implementing a prospective performance-improvement plan to improve the future performance of organizational units and the program or demonstration.
- Quality assurance, which is the organizational structure and process for retrospectively and concurrently reviewing and assessing the appropriateness, sufficiency, and quality of healthcare services provided.
- Quality improvement, which is the development and implementation of a prospective strategy for improving and strengthening the quality of health care provided.
- Evaluations, which are conducted:
  - to document and disseminate information on what happened, successes, opportunities for improvement, the lessons learned, and best practices and
  - to measure:
    - the results, outcomes, and impacts of the program or demonstration and
    - the degrees to which the purposes, aims, objectives, goals, and quantified performance targets of the program or demonstration were met.
- Periodic reporting: The Special Terms and Conditions of most demonstrations require that the state submit to its CMS project officer quarterly and annual reports on the demonstration during the period of time for which CMS has approved the demonstration. At the end of this period of time, or at the time that a state submits to CMS an application for renewal or extension of the demonstration, the state should submit both a final report on the demonstration and a report on the evaluation of the demonstration. The final report and the evaluation report can either be submitted as separate documents or they can be combined into one document, at the state's discretion.

These program functions are closely related to each other and frequently overlap. Consequently, they should be designed and implemented jointly. For example, data collection activities should be geared and integrated to meet the needs of compliance, performance measurement and improvement, quality assurance and improvement, and program evaluation.

## **RELATIONSHIPS AMONG STATE DEMONSTRATIONS, EVALUATIONS, AND THE MEDICAID / SCHIP QUALITY STRATEGY**

In the Special Terms and Conditions for approving state demonstrations, CMS now requires States to conduct or fund an evaluation of each demonstration as a condition for its approval of the demonstration. In 2005, the Center for Medicaid and State Operations (CMSO) created the Division of Quality, Evaluation, and Health Outcomes (DQEHO), in part, to work collaboratively with CMSO project officers in providing technical assistance to States in designing and conducting program evaluations of these demonstrations.

In addition, the DQEHO is working with States to implement the new Medicaid / SCHIP Quality Strategy (<http://www.cms.hhs.gov/MedicaidSCHIPQualPrac/>) as part of the new CMS Quality Improvement Roadmap. States which utilize Managed Care Organizations, Prepaid Inpatient Health Plans, and / or Health Insurance Organizations in their Medicaid Managed Care program are now required to develop and implement a Quality Improvement Strategy.

At the state's discretion, the evaluation of the quality of care received by enrollees in a demonstration can be one component of the program evaluation of the demonstration. The scope of the program evaluation of a state demonstration is broader than evaluation of the quality of care alone. The evaluation of a state demonstration should evaluate one or more other aspects or dimensions of the demonstration in addition to quality.

The scope of the implementation of a state's Quality Improvement Strategy should include any and all demonstrations that the state has implemented. Annual reporting by External Quality Review Organizations (EQROs) should include state demonstration initiatives that include managed-care enrollees. The program evaluation of each demonstration that CMS requires States to conduct or fund is independent of, and in addition to, evaluation of the state's Quality Improvement Strategy or the evaluation conducted by the state's EQRO. However, the findings of these separate evaluations on quality of care should be integrated in assessing state opportunities and enhancements for each activity, including efficiencies in cross-agency interventions and concurrent reporting.

### **AREAS STATES CAN EVALUATE IN THEIR DEMONSTRATIONS**

#### **EFFECTIVENESS**

The evaluation of a state's demonstration should measure the extent to which the demonstration met its purposes, aims, objectives, goals, and quantified performance targets. To what degree did the demonstration accomplish what it set out to do?

What were the impacts of the demonstration on enrollees, providers, payers, and employers?

Who benefited from the demonstration and who did not?

How effective was the demonstration relative to other initiatives in the state or to similar efforts in other states?

How did the demonstration inform the debate on improving services and the quality of care or provide evidence of improved services or quality of care?

What are the prospects for sustainability in the state and for replication in other parts of the state and in other states?

## **SUCSESSES**

What were the successes and positive outcomes of the demonstration? If measurable, are the successes and positive outcomes statistically significant?

What did the demonstration achieve?

What are the implications of the successful elements of the demonstration for other population groups and for public policy?

## **OPPORTUNITIES FOR IMPROVEMENT**

The transfer of knowledge regarding “opportunities” for future or revised demonstrations is just as significant as identifying current successful strategies. It is with that understanding that CMS acknowledges that States will not meet all program objectives and this should be recognized by all demonstration stakeholders. Therefore, States should not hesitate to establish performance targets as a means to strengthen their evaluation methodology and use of quality-improvement methodologies.

Examples of questions that can be answered as part of the findings of the evaluation of a demonstration include the following:

- Why did the demonstration not fully achieve its intended purposes, aims, objectives, and goals? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?
- What was the impact of the demonstration not covering certain kinds of healthcare services? Which additional services or benefits, if covered, would result in the most significant improvements in health outcomes?

- Why did some eligible individuals, employers, and / or healthcare providers not participate in the demonstration? What interventions or changes would encourage more eligible individuals, employers, and / or healthcare providers to participate in the future?
- What problems did the demonstration cause and why? What are the possible solutions or other changes that are needed? What improvements should be made?
- What problems were attributable to the design of the demonstration? Were the changes and interventions in the demonstration appropriate for meeting the purposes, aims, goals, and objectives of the demonstration? In what ways should the design be strengthened or improved?
- What problems were attributable to how the demonstration was implemented, in terms of delays, marketing / outreach, the enrollment process, and administration? What can be done in the future to improve future implementations like this demonstration?

## **TYPES OF MEASURES**

There are at least three types of measures that States can use in their evaluations of their demonstrations: financial measures, measures of inputs, and measures of outcomes.

### **Financial Measures**

Financial measures refer to types of costs incurred. Costs are incurred both in the public sector and in the private sector. Costs incurred in the public sector include costs incurred by the Medicaid and SCHIP programs. For example, what was the impact of the demonstration in regard to its budget neutrality requirements? Costs incurred in the private sector include costs incurred by third parties, such as employers and private health insurers; by program beneficiaries or enrollees who utilize healthcare services; and by healthcare providers who provide services to these beneficiaries or enrollees. Healthcare providers include healthcare practitioners, such as physicians; healthcare facilities, such as clinics, hospitals, and nursing homes; and home-health agencies. Costs incurred by private parties should be further broken down by costs which are compensated (i.e., reimbursed) and costs which are not compensated (i.e., not reimbursed).

In evaluating the costs of a demonstration, it is important to look at how costs, particularly program costs, change over time. For example, the changes made by a demonstration may initially lower program costs for a short period of time compared to what they would have been without the demonstration. However, over a longer period of time, program costs may end up being higher than they would have been without the demonstration. For example, if increased participant cost sharing leads to decreased utilization of primary care services, then program costs for hospitalization and emergency-room use may increase later on. The reverse can occur as well: if a demonstration facilitates the use of primary care services, then program costs may initially be higher than they would have been in the absence of the demonstration, but may be

lower in the long run as a result of the demonstration because of lower program costs for hospitalization and emergency-room use.

If the evaluation finds, for example, that program costs are lower as a result of providing primary and / or secondary preventive care services under the demonstration, then projected savings can be estimated if coverage of such services was to be expanded beyond the demonstration.

Similarly, in evaluating the costs of implementing a demonstration, it is also important to look at how the incidence of costs changes over time in terms of how costs incurred shift among various parties in the healthcare system as a whole. This means that an evaluation of financial measures should look at how the costs for different parties change during the time of the demonstration. The evaluation should also seek to determine the extent to which costs changed and shifted as a result of the demonstration and the extent to which they changed and shifted as a result of other factors.

### Measures of Inputs

There are many types of healthcare inputs and they can be measured in different ways.

#### *Access to Healthcare Services by Population Groups / Participation by Healthcare Providers*

One type of healthcare input is the scope (breadth) and the scale (depth) (1) of access to healthcare services by program recipients or, alternatively, (2) of participation in the demonstration program by noninstitutional and institutional healthcare providers. Demonstrations are generally designed to increase access to healthcare services and to increase the participation of healthcare providers in Medicaid and / or SCHIP.

#### *Types of Services*

Healthcare inputs can also be measured in terms of the types of services provided. Services can be categorized in many ways, e.g., healthcare versus social / assistive / personal care / transport services; acute versus long-term care services; preventive versus case management versus treatment services.

#### *Utilization of Services*

The numbers and rates of service utilization are considered to be measures of healthcare inputs. Increases in these inputs do not necessarily indicate better health outcomes in patients. Up to a certain level, the health outcomes of patients generally improve as a result of higher service

utilization, but after a certain point the health outcomes of patients can worsen if the amount of services provided increases further.

### *Quality*

There are many types of measures of quality (which includes patient safety):

- One major group of quality measures consists of clinical measures of quality. This group is one of the underpinnings of pay-for-performance systems. A possible source of clinical measures of quality that may be utilized by an evaluation of a demonstration is the data collected in the state on Health Plan Employer Data and Information Set (HEDIS) measures.
- A second group of quality measures consists of professional and industry standards and credentials.
- A third category consists of programmatic measures of quality in terms of the quality of program design, program management, the program implementation process, program operations, program efficiency, and program integrity.
- A fourth category measures quality in regard to the quality of the patient's life and of the patient's environment.

### Measures of Outcomes

Similarly, there are many types of outcomes and they can be measured in many ways:

### *Health*

The health outcomes of individuals can be measured in terms of mortality, morbidity, and disease stabilization or improvement. Measures of health outcomes can include measures of behavioral health as well as measures of physical health. Health outcomes can be assessed by the individuals themselves, by their families, and by healthcare professionals.

### *Levels of Functioning*

The functional outcomes of individuals can be measured in terms of mental functioning, physical functioning, social functioning, activities of daily living, and compliance with treatment regimens. Similarly, functional outcomes can be assessed by the individuals themselves, by their families, and by healthcare professionals.

### *Satisfaction*

The satisfaction of individuals and their families participating in the demonstration is one type of measure of outcomes. Their satisfaction can be measured both in terms of their satisfaction with the demonstration program itself and in terms of their satisfaction with the health care available to them and that they receive. Their satisfaction with the health care available to them and with the health care received by them can be measured in terms of sufficiency, availability, and accessibility and in terms of its quality as they perceive it.

The satisfaction of those providing healthcare services in the demonstration is another type of outcome measure. Providers include individual practitioners, such as physicians, nurses, and therapists; facilities; and organizations.

### *Program Performance*

Another category of measures of the outcomes of a demonstration consists of various measures of program performance, such as the number of additional people covered or receiving services; total costs; cost per person served; a decrease in unmet healthcare problems; declines in the rates of emergency room utilization and institutionalization; improved timeliness in access to, or in the delivery of, care; improved health information technology (e.g., implementation of an immunization registry that improves the capture of administrative data); etc..

## **TYPES OF TARGETS**

An evaluation of a demonstration can evaluate many different types of targets:

### *Payers*

The evaluation of a demonstration can assess the impact of the demonstration on payers in both the public and the private sectors. Payers in the public sector include programs, such as direct payers, such as Medicaid and SCHIP, and indirect payers, such as TANF and unemployment insurance. Payers in the private sector include individuals and organizations, which can be both nonprofit and commercial, such as employers and insurers.

### *Population Groups*

An evaluation of a demonstration can evaluate the impact of the demonstration on different population groups, in order to perform comparative cross-sectional analyses across groups, e.g., those who are in the demonstration population and those who are not. Because of disparities in the provision of healthcare services to different ethnic and racial population groups, it is important in evaluating a state demonstration to measure and analyze the ways and degrees to

which healthcare system inputs (e.g., service utilization) and outcomes (e.g., health status) varied and changed by different ethnic and racial population groups as a result of the demonstration.

### *Providers*

An evaluation of a demonstration can evaluate the impact of the demonstration on different types of providers, which include individual and group practitioners (both generalists and specialists), facilities, institutions, and organizations in both the public and the private sectors.

### *Employers*

An evaluation of a demonstration can evaluate the impact of the demonstration on employers, in terms of their participation, the health insurance coverage they offer their employees, their satisfaction with the demonstration, its impact on their employees, and its impact on their business.

## **TYPES OF COMPARISONS**

The evaluation of a demonstration can make different types of comparisons:

### *Within State*

An evaluation can compare the differential impacts of the demonstration among different areas within the state, e.g., among different regions of the state or among urban, suburban, and rural areas of the state. Comparisons can also be made if the demonstration is implemented in different ways in different parts of the state. The relative impacts of the demonstration on other state programs and initiatives can be evaluated as well.

### *With Other States*

An evaluation can compare the outcomes of the demonstration with the outcomes using the same measures in the same period of time in other states with the same interventions, in other states with different interventions, and in other states with no interventions.

### *Across Time*

An evaluation of a state demonstration can look at evaluation measures at different points in time to determine how they have changed over time as a result of the demonstration. These can include such points in time as the following:

- The evaluation of a state demonstration can look at available data on measures of interest several years before the start of the demonstration in order to identify baseline trends that were occurring before implementation of the demonstration.
- The evaluation of a state demonstration should capture data on the measures of interest at the start of the demonstration to serve as baseline measures for determining changes that occur as a result of the demonstration.
- The evaluation of a state demonstration can capture data on the measures of interest at different points in time during the period of implementation and operation of the demonstration to determine the relative impacts of the demonstration and the degree to which the purposes of the demonstration are being achieved. Data on these measures can provide feedback to state officials to determine if changes or adjustments in the demonstration are needed in order to better achieve the purposes of the demonstration.
- The evaluation of a state demonstration should capture data on the measures of interest at the time of renewal and at the end of the demonstration, in order to determine the changes that occurred during the demonstration and to determine the extent to which the stated purposes of the demonstration were achieved.
- The evaluation of a state demonstration could capture data on the measures of interest several months or years after the end of the demonstration in order to determine the effects of the demonstration after it is completed or terminated.

## **RECOMMENDED COMPONENTS OF STATE EVALUATION PLANS AND REPORTS FOR DEMONSTRATIONS**

The evaluation of a demonstration will require at least two types of documents: a proposed evaluation plan and evaluation reports. States have great flexibility in the structures they choose for their evaluation plan and reports. The following are recommended components that a state should consider in order to ensure that its evaluation plan and reports are comprehensive in answering stakeholder questions about the demonstration.

### **COMPONENTS OF A PROPOSED EVALUATION PLAN**

#### **Information About the Demonstration**

A proposed plan for evaluating a demonstration should include the following basic information about the demonstration:

- the name, start date, and end date of the demonstration;

- the purposes, aims, objectives, goals, and quantified performance targets of the demonstration;
- the key interventions, waivers, changes, and differences in the demonstration;
- the population groups to be impacted by the demonstration;
- the state's hypotheses about the outcomes of the demonstration;
- a summary of the requirements for the evaluation in the special terms and conditions of CMS' approval of the demonstration; and
- a brief history of the implementation of the demonstration, if the proposed evaluation plan is for a change in, or for an extension, renewal, or expansion of, the demonstration.

### **Evaluation Design**

A proposed plan for evaluating a demonstration should include information on:

- the management / coordination of the evaluation, including:
  - information about the organization conducting the evaluation and
  - timelines for implementation of the evaluation and for deliverables such as reports;
- the specific metrics and methodologies that will be used and the rationales for the selected approach, including information on:
  - the targets that data will be collected on, such as enrollees, payers, providers, and employers;
  - the data to be collected by the evaluation in terms of the statistically reliable and valid measures to be used for each target;
  - the methods by which the data will be collected, including data sources and sampling techniques, if any;
  - when data on each measure will be collected; and
  - the population groups of enrollees for which data will be analyzed;
- the plan for analysis of the findings, including information on:
  - the methods by which the data collected will be analyzed, including the statistical methodologies to be used;

- how the information will be analyzed in regard to programmatic goals, such as reducing uninsurance, quality improvement, cost-effectiveness, program efficiency, and value-based purchasing / pay-for-performance reimbursement; and
- the plan to address outcomes, limitations / challenges / opportunities, successes / best practices, interpretations, revisions to strategy or goals, and recommendations and implications of the findings at both the state and national levels; and
- integration of the state Quality Improvement Strategy, including reporting of external quality reviews, when applicable.

The proposed evaluation plan should describe the data to be collected. One example of how the data plan may be displayed is the following:

TARGETS AND MEASURES	RELEVANT DEMONSTRATION		TYPE OF MEASURE (Financial, Input, Outcome)	SOURCE OF DATA	WHEN MEASURED
	PURPOSE, OBJECTIVE, GOAL	PERFORMANCE TARGET			
PAYERS (PA)					
PA Measure 1					
...					
PA Measure m					
POPULATION GROUPS (PO)					
PO Measure 1					
...					
PO Measure n					
PROVIDERS (PR)					
PR Measure 1					
...					
PR Measure o					
EMPLOYERS (EM)					
EM Measure 1					
...					
EM Measure p					

## **COMPONENTS OF EVALUATION REPORTS**

Ideally, for sharing information with multiple audiences, a report on the evaluation of a demonstration would be formatted to include components such as the following:

### Executive Summary

- A one-page summary of what the demonstration did and the principal findings, conclusions, and recommendations of the evaluation to date.

### Information About the Demonstration

- Present basic information about the demonstration (see above).

### Evaluation Design

- Describe in detail:
  - the evaluation design that was actually implemented and
  - the specific ways in which the evaluation design that was implemented changed from the original plan.
- Discuss the reasons why the evaluation design was changed.

### Data, Findings, and Statistical Analyses

#### *Data*

- On each measure in the evaluation:
  - discuss the quality of the data collected;
  - present descriptive statistics on the data collected; and
  - describe how the data collected changed over time.

#### *Effectiveness*

- Present quantitative measures of the degrees to which:

- the purposes, aims, objectives, goals, and quantified performance targets of the demonstration were met and
- the demonstration achieved programmatic goals in the state, such as reducing the number of uninsured and the rate of uninsurance, improving the quality of care, and increasing the use of value-based purchasing / pay-for-performance reimbursement.
- To the extent possible, describe measurements of the relative effectiveness of the major interventions / changes in the demonstration individually in achieving the purposes, aims, objectives, goals, and performance targets of the demonstration.

### *Impacts*

- Describe the impact of the demonstration:
  - on enrollees, in terms of their utilization of healthcare services; their physical and mental health; their levels of physical, mental, and social functioning;
  - on the costs of different programs, the amount and distribution of costs in the healthcare system as a whole, and the shifting of the incidence of costs between and within the private and public sectors, in terms of who bore those costs and uncompensated care; and
  - not covering certain kinds of healthcare services.
- Describe the relative, differential impacts of the major interventions / changes in the demonstration on outcomes for enrollees, providers, public and private payers, and employers.

### *Comparisons*

- Compare:
  - how the demonstration impacted different population groups, payers, providers, and employers in different parts of the state participating in the demonstration and
  - the outcomes of the demonstration to outcomes in other:
    - parts of the state not participating in the demonstration and
    - states with and without similar interventions.

### *Multivariate Statistical Analyses*

- Present the results of any multivariate statistical analyses performed.

### Discussion

#### *Successes*

- Describe the successes, achievements, and positive outcomes of the demonstration.

#### *Opportunities for Improvement*

- Describe the problems, barriers, limitations, undesired outcomes, remaining challenges, and opportunities for improvement in the demonstration.
- Describe any problems caused by the demonstration.

#### *Reasons*

- Discuss:
  - the reasons for what happened in the demonstration, both in terms of its successes and achievements and in terms of its limitations and shortcomings;
  - the reasons why:
    - the demonstration did not fully achieve its intended purposes, aims, objectives, goals, and quantified performance targets;
    - some eligible individuals, healthcare providers, and employers did not participate in the demonstration; and
    - problems occurred in the implementation of both the demonstration and the evaluation;
  - the extent to which the problems which occurred in the demonstration were attributable to the design of the demonstration; and
  - the extent to which the problems which occurred in the demonstration were attributable to how the demonstration was implemented, in terms of delays and deficiencies in marketing / outreach, the enrollment process, and administration.

## *Other*

- Discuss:
  - the value of the demonstration for different parties, in terms of the benefits of the demonstration relative to the costs of the demonstration for enrollees, payers, providers, and employers;
  - the lessons learned, both in the demonstration and in the evaluation;
  - the implications of the outcomes of the demonstration for other population groups and for public policy;
  - the “business case” for continuing, expanding, or replicating the demonstration in the same state or in other states; and
  - the prospects for sustainability of the demonstration in the state and for replication of the demonstration in other parts of the state and in other states.

## Recommendations

### *In the Demonstration State*

- Describe the ways in which:
  - the purposes, aims, objectives, goals, and quantified performance targets of the demonstration can be more fully achieved;
  - the design of the demonstration could be strengthened or improved;
  - the implementation of a program like the demonstration could be improved, in regard to reducing delays and improving marketing / outreach, enrollment, and administration; and
  - the participation of eligible individuals, healthcare providers, and employers could be increased in a program like the demonstration.
- Describe the additional benefits or services not covered in the demonstration that would result in the most significant improvements in the health outcomes of enrollees, if these benefits or services had been, or were to be, covered.
- Discuss possible solutions or other changes that are needed to remedy any problems caused by the demonstration. Describe any improvements that should be made.

*For Other States*

- Discuss recommendations for other states which may be interested in implementing a program or demonstration similar to that in the demonstration state.

Conclusions

- Discuss your principal conclusions concerning:
  - the findings of the evaluation and
  - the policy and program issues involved in the demonstration.

**ADDITIONAL TECHNICAL ASSISTANCE**

A state desiring technical assistance in designing or conducting an evaluation of a demonstration should contact their CMSO project officer or the DQEHO at 410.786.9012 or [Barbara.Dailey@cms.hhs.gov](mailto:Barbara.Dailey@cms.hhs.gov).

**TABLE A**

**RECOMMENDED COMPONENTS OF A STATE EVALUATION PLAN  
FOR SECTION 1115 DEMONSTRATIONS**

<b>EVALUATION SECTION</b>	<b>CONTENT ADDRESSES:</b>
<b>Information about the Demonstration</b>	<ul style="list-style-type: none"> <li>• Name, start date, and end date of the demonstration.</li> <li>• Brief description and history of the demonstration.</li> <li>• Population groups impacted by the demonstration.</li> <li>• Purposes, aims, objectives, and goals of the demonstration, including:               <ul style="list-style-type: none"> <li>○ overarching strategy, principles, goals, and objectives;</li> <li>○ state’s hypotheses on outcomes of the demonstration; and</li> <li>○ key interventions planned.</li> </ul> </li> <li>• Summary of the requirements for the evaluation in the special terms and conditions.</li> </ul>
<b>Evaluation Design</b>	<ul style="list-style-type: none"> <li>• Management / coordination of evaluation, including:               <ul style="list-style-type: none"> <li>○ information about the organization conducting the evaluation and</li> <li>○ timelines for implementation of the evaluation and delivering reports.</li> </ul> </li> <li>• Performance measures, including:               <ul style="list-style-type: none"> <li>○ specific performance measures and the rationale for selection, including statistical reliability and validity;</li> <li>○ measurement methodology and specifications, including eligible / target populations and time period of study for each measure used; and</li> <li>○ data sources, method for data collection, rationale for the approach, and sampling methodology.</li> </ul> </li> <li>• Integration of State Quality Improvement Strategy, including external quality review reporting, when applicable.</li> <li>• Plan for analysis, including:               <ul style="list-style-type: none"> <li>○ Evaluation of performance</li> <li>○ Outcomes</li> <li>○ Limitations / Challenges / Opportunities</li> <li>○ Successes / Best Practices</li> <li>○ Interpretations / Conclusions</li> <li>○ Revisions to strategy or goals</li> <li>○ Recommendations and implications at the state and national levels.</li> </ul> </li> </ul>
<b>Evaluation Reports to be Provided</b>	<ul style="list-style-type: none"> <li>• Ongoing quarterly reports designed to provide answers to significant questions regarding the progress of the demonstration.</li> <li>• Annual reports</li> <li>• Final report</li> </ul>

**TABLE B**

**REPORTS ON STATE EVALUATIONS OF SECTION 1115 DEMONSTRATIONS**

**TYPES OF REPORTS**

- PROGRESS REPORTS
  - QUARTERLY REPORTS
    - First Quarter
    - Second Quarter
    - Third Quarter
  - ANNUAL REPORT
- FINAL REPORT

**RECOMMENDED COMPONENTS OF REPORTS**

<b>EVALUATION SECTION</b>	<b>CONTENT ADDRESSES:</b>
<b>Executive Summary</b>	<ul style="list-style-type: none"><li>• Brief summary of principal findings, conclusions, and recommendations of the evaluation to date.</li></ul>
<b>Information about the Demonstration</b>	<ul style="list-style-type: none"><li>• Name, start date, and end date of the demonstration.</li><li>• Brief history.</li><li>• Population groups impacted.</li><li>• Summary of the requirements for the evaluation in the Special Terms and Conditions.</li><li>• Purposes, aims, objectives, and goals of the demonstration, including:<ul style="list-style-type: none"><li>○ overarching strategy, principles, goals and objectives;</li><li>○ state’s hypotheses on outcomes of the demonstration; and</li><li>○ key interventions planned.</li></ul></li></ul>
<b>Evaluation Design</b>	<ul style="list-style-type: none"><li>• Management / coordination of evaluation, including:<ul style="list-style-type: none"><li>○ information about the organization conducting the evaluation and</li><li>○ timelines for implementation of the evaluation and delivering reports.</li></ul></li><li>• Performance metrics, including:<ul style="list-style-type: none"><li>○ specific performance metrics and the rationale for selection, including statistical reliability and validity;</li><li>○ measurement methodology and specifications, including eligible / target populations and time period of study for each measure used; and</li></ul></li></ul>

EVALUATION SECTION	CONTENT ADDRESSES:
	<ul style="list-style-type: none"> <li>○ data sources, method for data collection, and rationale for the approach and sampling methodology.</li> <li>● Integration of State Quality Improvement Strategy, including external quality review reporting, when applicable.</li> </ul>
<b>Analysis</b>	<p><u>Data, Findings, and Statistical Analysis</u></p> <p><i>Data</i></p> <ul style="list-style-type: none"> <li>● On each measure in the evaluation: <ul style="list-style-type: none"> <li>○ discuss the quality of the data collected;</li> <li>○ present descriptive statistics on the data collected; and</li> <li>○ describe changes in data collection over time.</li> </ul> </li> </ul> <p><i>Effectiveness</i></p> <ul style="list-style-type: none"> <li>● Present quantitative measures of the degrees to which: <ul style="list-style-type: none"> <li>○ the purposes, aims, objectives, goals, and quantified performance targets were met and</li> <li>○ the demonstration achieved programmatic goals in the state.</li> </ul> </li> </ul> <p><i>Impacts</i></p> <ul style="list-style-type: none"> <li>● Describe the impact of the demonstration: <ul style="list-style-type: none"> <li>○ on enrollees, in terms of their utilization of healthcare services; their physical and mental health; their levels of physical, mental, and social functioning; and employment indicators; and</li> <li>○ on the costs of different programs, the amount and distribution of costs in the healthcare system as a whole, and the shifting of the incidence of costs between and within the private and public sectors, in terms of who bore those costs and uncompensated care.</li> </ul> </li> </ul> <p><i>Comparisons</i></p> <ul style="list-style-type: none"> <li>● Compare any variations in impacts on different population groups, payers, providers, and employers in different parts of the state.</li> </ul> <p><i>Multivariate Statistical Analyses</i></p> <ul style="list-style-type: none"> <li>● Present the results of any multivariate statistical analyses performed.</li> </ul> <p><u>Discussion</u></p> <p><i>Successes</i></p> <ul style="list-style-type: none"> <li>● Successes, achievements, and positive outcomes of the demonstration.</li> </ul> <p><i>Opportunities for Improvement</i></p> <ul style="list-style-type: none"> <li>● Problems, barriers, limitations, undesired outcomes, remaining challenges, and opportunities for improvement in the demonstration.</li> </ul> <p><i>Reasons</i></p> <ul style="list-style-type: none"> <li>● Discuss: <ul style="list-style-type: none"> <li>○ the reasons for what happened in the demonstration, both in terms of its successes and shortcomings;</li> <li>○ the reasons why: <ul style="list-style-type: none"> <li>- the demonstration did not fully achieve its intended</li> </ul> </li> </ul> </li> </ul>

EVALUATION SECTION	CONTENT ADDRESSES:
<p><b>Analysis - continued</b></p>	<p>purposes, aims, objectives, goals, and quantified performance targets;</p> <ul style="list-style-type: none"> <li>- some eligible individuals, healthcare providers, and employers did not participate in the demonstration; and</li> <li>- problems occurred in the implementation of both the demonstration and the evaluation;</li> </ul> <ul style="list-style-type: none"> <li>○ the extent to which the problems were attributable to the design of the demonstration; and</li> <li>○ the extent to which the problems were attributable to how the demonstration was implemented, in terms of delays and deficiencies in marketing / outreach, the enrollment process, and administration.</li> </ul> <p><i>Other</i></p> <ul style="list-style-type: none"> <li>• Discuss: <ul style="list-style-type: none"> <li>○ the value of the demonstration for different parties, in terms of the benefits of the demonstration relative to the costs of the demonstration for enrollees, payers, providers, and employers;</li> <li>○ the lessons learned, both in the demonstration and in the evaluation;</li> <li>○ the implications of the outcomes of the demonstration for other population groups and for public policy;</li> <li>○ the “business case” for continuing, expanding, or replicating the demonstration in the same state or in other states; and</li> <li>○ the prospects for sustainability of the demonstration in the state and for replication of the demonstration in other parts of the state and in other states.</li> </ul> </li> </ul>
<p><b>Recommendations</b></p>	<p><i>In the Demonstration State</i></p> <ul style="list-style-type: none"> <li>• Describe the ways in which: <ul style="list-style-type: none"> <li>○ the purposes, aims, objectives, goals, and quantified performance targets of the demonstration can be more fully achieved;</li> <li>○ the design of the demonstration could be strengthened or improved;</li> <li>○ the implementation of a program like the demonstration could be improved, in regard to reducing delays and improving marketing / outreach, enrollment, and administration; and</li> <li>○ the participation of eligible individuals, healthcare providers, and employers could be increased in a program like the demonstration.</li> </ul> </li> <li>• Describe the additional benefits or services that would result in the most significant improvements in the health outcomes of enrollees, if these benefits or services had been, or were to be, covered.</li> <li>• Discuss possible solutions or other changes that are needed to remedy any problems caused by the demonstration. Describe any</li> </ul>

<b>EVALUATION SECTION</b>	<b>CONTENT ADDRESSES:</b>
	<p>improvements that should be made.</p> <p><i>For Other States</i></p> <ul style="list-style-type: none"> <li>• Discuss recommendations for other states which may be interested in implementing a program or demonstration similar to that in the demonstration state.</li> </ul>
<b>Conclusions (For Final Report)</b>	<ul style="list-style-type: none"> <li>• Discuss your principal conclusions concerning: <ul style="list-style-type: none"> <li>○ the findings of the evaluation and</li> <li>○ the policy and program issues involved in the demonstration.</li> </ul> </li> </ul>
<b>Appendices</b>	<ul style="list-style-type: none"> <li>• Appendices, as needed</li> </ul>