

**U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services**

**CMS Regional Office Protocol for
Conducting Full Reviews of
State Medicaid Home and Community-Based
Services Waiver Programs**

Version 1.2

December 20, 2000

(Revised March 11, 2003 to reflect agency name change)

For Mandatory Use Beginning January 1, 2001

Acknowledgments

The *CMS Regional Office Protocol for Conducting Full Reviews of State Medicaid Home and Community-Based Services Waiver Programs (The Protocol)* represents the joint efforts of several organizations and individuals.

The development of *The Protocol* was funded by CMS's Quality Performance Management Group (QPMG) in the Center for Medicaid and State Operations (CSMO), in collaboration with CMS's Disabled and Elderly Health Programs Group (DEHPG). Key CMS staff participating in the development of *The Protocol* include: Thomas Hamilton, Susie Bosstick, Deirdre Duzor, Trish McTaggart, Mary Jean Duckett, Mary Clarkson and Tom Shenk.

The MEDSTAT Group was the contractor, with primary responsibility for coordinating the activities of the project and providing technical expertise. Beth Jackson and Brian Burwell of MEDSTAT's Research and Policy/Chronic Care and Disability Group staffed the project.

Two CMS Regional Office (RO) Work Groups were created for providing input into the development of *The Protocol* and met during 1999 and 2000. The RO Process Work Group was co-chaired by Becky Selig (Chicago RO) and Rick Spector (San Francisco RO); others serving on the Process Work Group included: Sharon Taggart (Kansas City RO), Bob Grauman (Seattle RO), Bill Davis (Philadelphia RO), and Agapito Sanchez (Dallas RO). Terrie Morris (Atlanta RO) and Mary Kissel (Denver RO) co-chaired the RO Content Work Group, and were joined by Joe Reeder (Dallas RO), Sharon Patterson (Kansas City RO), Debra Baumert (San Francisco RO), Nadine Renbarger (Chicago RO), and Steve Blaum (New York RO). In addition, several CMS RO staff have either tested earlier versions of *The Protocol*, or will be field-testing the current version in the near future.

A State-Federal Work Group also provided guidance in the development of *The Protocol*. State representatives serving on this Work Group included: Richard Allen (CO), Roger Auerbach (OR), Peg Dierkers (PA), Annette Hanson (MA), Deb Holtz (MN), and Ernest McKenney (TX). Representatives from the federal government included: Thomas Hamilton (CMS/CMSO), Deirdre Duzor (CMS/CMSO), Becky Selig (CMS Chicago RO), Terrie Morris (CMS Atlanta RO). Representing the advocacy community was Lex Frieden (Institute for Rehabilitation and Research) and John Luehrs (AARP). Three other members served on the Work Group in the capacity of content experts: Penny Feldman (NY VNS), Charlie Lakin (U. of MN) and Shoshanna Sofaer (Baruch College).

This project would not have been possible without the dedication and significant time commitment of all the individuals named above.

Table of Contents

Purpose of <i>The Protocol</i>	1
Overview of <i>The Protocol</i>	2
Preparing for a Full Review	5
When to Conduct Full Reviews.....	5
Contacting the State Prior to the Review.....	5
Who Participates in Reviews.....	6
What Reviews Should Include	6
The Entrance Conference	7
<i>The Protocol</i>	8
I. Design and Implementation of a Quality Assurance System for Assuring Waiver Participant Health and Welfare	9
A. Structural Features of the State’s Quality Assurance System.....	9
B. State Quality Assurance Related to Waiver Participants	11
C. State Quality Assurance Related to Waiver Providers.....	14
D. Other Quality Enhancing Activities Related to the State’s Quality Assurance Program.....	16
II. Design and Implementation of a System for Reviewing Plans of Care	18
A. Plan of Care Development.....	18
B. Plan of Care Approval.....	21
C. Plan of Care Monitoring (Services Delivered in Accordance with Plan of Care).....	23
D. Other Quality Enhancing Activities Related to the State’s Review of Plan of Development, Approval and Monitoring	24
III. Design and Implementation of a System for Assuring Waiver Services are Provided by Qualified Providers	25
A. Provider Qualifications	25
B. Provider Training.....	27
C. Other Quality Enhancing Activities Related to the State’s Review of Provider Qualifications.....	28
IV. Use of Processes/Instruments for Determining Level of Care Need	29
A. Level of Care Determination.....	29
B. Other Quality Enhancing Activities Related to Level of Care Determination	31
V. State Administrative Authority Over the Waiver	32
A. Administering Agency and Operating Agency Responsibilities.....	32
B. Due Process.....	34
VI. State Financial Accountability	35
A. State’s System for Financial Oversight.....	35
Findings, Writing Reports, and Follow-up Activities with the State and CMS’s Central Office	37
The Exit Conference	37
Findings Requiring Immediate Action.....	37
Findings Requiring Additional Reviews.....	37
Draft Report.....	38
Assessing the State’s Response to the Draft Report	39
Final Report	39

Purpose of *The Protocol*

The purpose of *The Protocol* is to provide the CMS Regional Office staff responsible for reviewing 1915(c) waiver programs, i.e., the state Medicaid Home and Community Based Services (HCBS) waiver programs, with *standardized* and *comprehensive* procedures for assessing the quality of care and services provided through these programs. This *Protocol* was developed for reviews of all waivers and all waiver target groups.

While the HCBS waiver programs across the nation are many and diverse, all are required to provide the following assurances, as a condition of waiver approval:

- For the health and welfare of waiver participants;
- For plans of care responsive to waiver participant needs;
- That only qualified providers serve waiver participants;
- That the State conducts level of care need determinations consistent with the need for institutionalization;
- That the State Medicaid Agency retains administrative authority over the waiver Program; and
- That the State provides financial accountability for the waiver.

These assurances constitute the backbone of the quality assurance responsibilities of a State vis-à-vis its 1915(c) waiver program. *The Protocol* is an instrument that leads RO reviewers through a series of activities for assessing the extent to which the State meets its obligations regarding these assurances. *The Protocol* also provides the RO reviewers with a set of parameters in how to prepare for the review, suggested review techniques, guidance in drafting review reports, as well as procedures for conducting follow-up activities with the States and the CMS Central Office.

Because the 1915(c) waiver programs are typically reviewed by CMS every 3-5 years, it is necessary that the reviews be comprehensive when they are conducted. When used as intended, *The Protocol* assures that all waiver programs receive a full, standardized, and thus equitable review.

The format of *The Protocol* was developed with the States in mind, as well. When States review *The Protocol* prior to a review, they will be apprised of the evaluative activities the RO reviewers will be conducting. A portion of *The Protocol* is devoted to operationalizing each of the assurances listed above, and for which the State must demonstrate that it has met its responsibility. Another section of *The Protocol* describes examples of “Quality Enhancing” activities that a State may incorporate into its quality assurance (QA) system, or may wish to develop in the future. These activities are not required, nor should States be penalized for not engaging in such activities. However, RO reviewers are encouraged to take special note of such quality enhancing activities, and to provide technical assistance where appropriate.¹

¹ The National Association of State Medicaid Directors is developing a guide for State waiver programs: *NASMD HCBS QA Guide for States*, which will be a reference source on quality enhancing strategies for the waiver program.

Overview of *The Protocol*

There are at least three different components of program quality:

- Quality System Design
- Quality Assurance
- Quality Improvement

The first component is the *design of the quality system*. It serves as the blueprint for provider requirements, specifies how monitoring activities will be carried out, as well as goals, plans and methods for quality improvement activities. The second and third components, *quality assurance* and *quality improvement* flow from the first, and represent the implementation of the quality system design.

Given the regulatory requirement that States provide a description of the safeguards necessary to protect the health and welfare of its waiver participants and that they implement these safeguards, CMS has determined that a reasonable measure (indicator) of a state's ability to protect health and welfare is the presence of a quality assurance system. Taking into account what is considered standard practice in the field of quality assurance, *The Protocol focuses on both the design and implementation of a state's quality assurance system.* *The Protocol* provides RO reviewers with the tools for assessing the State's design and implementation of the QA system for its 1915(c) waiver program. The core components of *The Protocol* focus on whether a State has the requisite plans and procedures to meet the assurances it has made in its approved waiver, and then whether the State implements these plans and procedures. These components serve as major organizing principles of *The Protocol*.

While quality improvement activities beyond the basic assurances are clearly desirable, they are not required under any current regulatory authority. Acknowledging this constraint but also desiring opportunities to recognize States that employ quality improvement strategies and also to serve as a source of information on such strategies for other States, the developers of *The Protocol* reserved several sections in *The Protocol* for acknowledging quality enhancing activities.²

The Protocol reflects the fact that States have the first-line responsibility for quality assurance in the waiver programs, and that the RO reviewers' responsibility is to evaluate whether and to what extent the States are meeting their responsibilities. The States should be conducting front-line monitoring activities; the RO review should be more of a "look-behind" review.

States provide in their waiver applications information about how they will address the assurances described on page 1 above. The State's compliance with these assurances constitutes the core of a waiver review. Consequently, *The Protocol* is anchored to, and organized around, the assurances.

Each one of the six sections of *The Protocol* corresponds to one of the assurances. Thus, the organization of *The Protocol* assumes the following format:

² CMS is contracting with The MEDSTAT Group to develop performance measures for the HCBS waiver populations, which States will be able to use in their quality improvement programs.

<p>I. Design and Implementation of QA system for Assuring Waiver Participant Health and Welfare</p> <p>A. Structural Features of the State’s Quality Assurance System</p> <p>B. State Quality Assurance Related to Waiver Participants</p> <p>C. State Quality Assurance Related to Waiver Providers</p> <p>D. Other Quality Enhancing Activities Related to the State’s Quality Assurance Program</p> <p>II. Design and Implementation of a System for Reviewing Plans of Care</p> <p>A. Plan of Care Development</p> <p>B. Plan of Care Approval</p> <p>C. Plan of Care Monitoring (Services Delivered in Accordance with Plan of Care)</p> <p>D. Other Quality Enhancing Activities Related to the State’s Review of Plan of Care Development, Approval and Monitoring</p> <p>III. Design and Implementation of System for Assuring All Waiver Services Are Provided By Qualified Providers</p> <p>A. Provider Qualifications</p> <p>B. Provider Training</p> <p>C. Other Quality Enhancing Activities Related to the State’s Review of Provider Qualifications</p> <p>IV. Use of Processes/Instruments for Determining Level of Care Need</p> <p>A. Level of Care Determination</p> <p>B. Other Quality Enhancing Activities Related to Level of Care Determinations</p> <p>V. State Administrative Authority Over the Waiver</p> <p>A. Administering and Operating Agency Responsibilities</p> <p>B. Due Process</p> <p>VI. Design and Implementation of the State’s System for Assuring Financial Accountability</p> <p>A. Financial Oversight and Accountability</p>

Each section, or “review component” (for example I-A), is then divided into several sections:

- ***Required Design Features for States***
QA system design components States are required to have in place.
- ***Required Implementation Features for States***
Evidence/Documentation States must produce to demonstrate they have implemented their QA system.
- ***RO Review Protocols for Verifying/Evaluating Design Features***
Procedures that RO reviewers must use to evaluate whether the State has a QA system that includes the required components.
- ***RO Review Protocols for Verifying/Evaluating Implementation Features***
Procedures that RO reviewers must use to evaluate whether the State has implemented its QA system.
- ***Suggested Review Techniques for Regional Office Reviewers***
Helpful hints for RO reviewers in applying The Protocol.

Sections I through IV of *The Protocol* also include sub-sections devoted to “Quality Enhancing Activities” (See Section I-D, II-D, III-D and IV-B) where quality improvement strategies that States may be employing (or wish to employ) are described. These activities are not required, but are recommended. The Quality Enhancing sections are clearly labeled “Recommended, But Not Mandatory”. States should not be held accountable for these activities, but if RO reviewers find a State using such strategies they should be commended for their quality improvement efforts.

The Protocol also provides RO reviewers with direction in how to prepare for the review and activities prior to the on-site review; guidance in drafting review reports; and procedures for conducting follow-up activities with the States and CMS’s Central Office.

One final note about *The Protocol*: it is designed for review of all waivers, including those with a consumer-directed focus. Consumer-directed models are relatively new in the history of the waiver program, but represent a growing trend. Participant choice and preference have always been cornerstones of the waiver program, so *The Protocol* addresses them in many of its components. CMS encourages States and Regional Offices to continue to work together to assure choice and preference, and to improve our efforts to measure and assure quality.

Preparing for a Full Review

WHEN TO CONDUCT FULL REVIEWS

- Each waiver should receive at least one *full* review during a given waiver cycle:
 1. **Reviews of new waivers (on a 3-year waiver cycle) should be initiated no sooner than 12 months after the effective date of the waiver, and completed at least 12 months prior to the renewal date of the waiver.** Preferably, the review should be conducted earlier, rather than later, in the waiver cycle in order to provide the State with early feedback on the implementation of its approved waiver. A review scheduled to occur after the program has been in operation for at least a year, but well before the waiver is under consideration for renewal, will give the RO review team an opportunity to collaborate with the State on fine-tuning the waiver's quality assurance system as the program establishes itself.
 2. **Reviews of renewed waivers (on a 5-year waiver cycle) should be initiated no sooner than 12 months after the effective date of the renewed waiver, and completed at least 12 months prior to the expiration date of the waiver.** In the event that, based on its findings, the RO review team requires the State to implement a corrective action plan or to submit a new waiver application, the State will have sufficient lead-time to accomplish such requests before the end of the waiver cycle.
- RO reviewers may opt to conduct less than full reviews on model waivers as well as waivers serving less than 200 participants, *provided the RO determines there is a high probability that no significant quality problems exist*, by:
 1. Combining the review of a smaller waiver with a review of a larger waiver in the same State. This is most easily accomplished when the same agency administers both waivers.
 2. Conducting an initial mini-review with the understanding that a more extensive review could follow if problems in quality assurance are detected during the mini-review.

CONTACTING THE STATE PRIOR TO THE REVIEW

- The RO review team should contact the State by letter at least 60 days prior to the date it intends to begin the on-site review. The letter should include:
 1. Suggested dates for the on-site review;
 2. Type of review the RO intends to conduct: *full* review or *mini* review (see above for appropriateness of mini-reviews).
 3. If less than a full review is planned, include in the letter a description of the components of the waiver on which the RO team will focus.

4. RO review staff that will be conducting the review;
5. Request for any information the review team wishes to receive prior to the review (e.g., interagency agreements, QA monitoring policies/plans, program issuances related to the program, etc.) and a date by which the team would wish to receive the material;
6. Request for a suitable working space.
7. Request for a roster of waiver participants for sampling purposes; and
8. A copy of *The Protocol* as an enclosure.

WHO PARTICIPATES IN REVIEWS

- To promote consistency, a core group of RO staff should be dedicated to conducting waiver reviews. It is highly desirable that the RO staff who conduct the waiver reviews be the same individuals who review initial waiver applications, renewals, and amendments.
- It is recommended that the RO review team be *interdisciplinary* and include:
 1. Medicaid program staff familiar with HCBS waiver Federal requirements;
 2. Clinicians;
 3. Persons with experience in working with the target population (for example, QMRPs); and
 4. An individual with financial expertise to evaluate the state's fiscal accountability.

Other possible review team members may include a Medicaid eligibility specialist and/or a health and safety specialist.

- ROs should have the discretion to invite State Medicaid agency and other sister agency staff to participate in waiver reviews as observers with the understanding that it is not always appropriate to do so. For example, if the RO team believes the State's presence may negatively impact providers'/waiver participants' willingness to share information freely, or that too many reviewers in small residences would make waiver participants feel uneasy, the RO team can determine not to include State staff as part of the review.
 1. States must clearly understand their observer role in the review process, and that the CMS RO review team has responsibility for conducting this review.
 2. However, regardless of the State's participation in the review, the RO team will consider the recommendations and observations made by relevant State agencies regarding the various aspects of the review and review process.

WHAT REVIEWS SHOULD INCLUDE

- Consistent with the review process specified in this *Protocol*, full waiver reviews should include an assessment of the State's quality assurance system (QA design) and its implementation of that system. Because the State has the first line of responsibility for monitoring the waiver, the RO's review should focus on whether and how the State conducts QA activities, and whether and how they meet the assurances they have made to the Federal Government.
- Full reviews should include interviews with waiver participants, primary direct care staff of waiver providers, and case managers, observation of waiver participants, and observation of the interaction between waiver participant and direct care staff. The primary goal of these contacts is for the RO review team to familiarize itself with how the waiver operates, and to verify that the State has met its obligations regarding the assurances.
- Prior notice of not less than one week should be given to the State concerning which waiver participants that the RO will be visiting. The State should be asked to contact the individuals identified and inquire whether they will consent to a visit from the RO reviewer(s) and inquire about a convenient time for the visit.

THE ENTRANCE CONFERENCE

- Each on-site review should begin with an entrance conference that should be attended by the Regional Office review team.
- The RO review team should introduce each of its members and their role(s) during the review.
- The entrance conference provides an opportunity for RO reviewers to discuss with the State the purpose of the review, to go over the review team's on-site agenda, and to discuss with the State the status of written materials/documents that the reviewers will need in order to complete the review. It is also the opportunity for RO staff to review the post-review process and timeline.

The Protocol

**I.
Design and Implementation of a Quality Assurance System for Assuring
Waiver Participant Health and Welfare**

The State must demonstrate that it has designed and implemented an adequate quality assurance system for assuring the health and welfare of waiver participants.

Authority: 42 CFR 441.302; 42 CFR 441.303; SMM 4442.4; SMM 4442.9

The State must produce evidence of the policies and procedures it uses for assuring the health and welfare of waiver participants. These policies and procedures must contain information on the various components of the State’s quality assurance activities, e.g., role and activities of the Medicaid agency, other State agencies, providers and case management agencies in waiver quality assurance activities, types of reports that are generated, how deficiencies are addressed, etc.

The State must also produce evidence that it *implements* its policies and procedures for assuring the health and welfare of waiver participants. This includes implementing the structural features of its Quality Assurance (QA) System, as well as components of its QA system that focus on waiver participants and providers.

A. Structural Features of the State’s Quality Assurance System	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>State policies and procedures must describe the following:</p> <ul style="list-style-type: none"> • Frequency (e.g., annual, semi-annual, monthly, etc.) and type (waiver-specific, State Medicaid program review, etc.) of quality assurance activities. • Review methodologies, including sampling methodologies (if less than 100% reviews specified). • Persons responsible for conducting the State quality assurance activities and their qualifications. • Provisions for periodically reviewing and revising its quality assurance policies and procedures, when necessary. 	<p>The State must produce:</p> <ul style="list-style-type: none"> • Documentation that the State has implemented its quality assurance policies and procedures. • Evidence that the State periodically reviews its quality assurance policies and procedures, and revises if necessary. • Evidence that the State gathers waiver participant feedback/input (and family/legal guardian feedback/input as appropriate) and uses it for improving system performance and quality of care.

A. Structural Features of the State’s Quality Assurance System, continued	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that the structural features of the State’s QA system include all of the components enumerated above. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Review any State QA reports or findings for evidence that the State has implemented its QA policies and procedures. • Interview State staff and review records to verify that the State has implemented its QA policies and procedures. • Interview State staff to determine whether the QA plan has been (or is being) revised in response to QA activities.

***Suggested Review Techniques
For
Regional Office Reviewers***

Reviewing the Design Features

- Review the approved waiver and CMS Form 372-S (Section D) for information on the State’s specifications related to its quality assurance system; compare what the State specified in its approved waiver with what you find the State’s QA system to be.
- Request copies of all waiver-related QA policies and procedures whether they exist in a single document or in multiple places.
- Following a review of the State’s written QA policies and procedures, if you find that they do not address *all* of the required structural features, interview State staff about how the State addresses the fundamental requirements of a QA plan.
- If a sister State agency is responsible for the operation of the waiver, collect information relevant to the delegated responsibilities of the sister agency, and their QA systems.

Reviewing the Implementation Features

- Look for evidence that the key components of the State’s QA plan are being implemented. The evidence may be found in reports, logs, provider files, case management files, waiver participant records, etc.
- Look for evidence that the frequency with which QA activities are conducted is consistent with the State’s policies and procedures, e.g., reports on QA reviews, letters to providers.
- If the State uses samples of waiver participants in QA activities (i.e., less than the entire waiver population is selected for QA review), interview State staff about how samples are selected (e.g., random? targeted?) and sample sizes. Determine whether sampling is consistent with the State’s policies and procedures.
- Look for evidence that the persons identified in the State’s QA plan as responsible for conducting QA activities are executing these responsibilities.
- How does the State use the QA information it generates?
And/or
Are changes implemented based on results of the State’s review of collected data?

B. State Quality Assurance Related to Waiver Participants	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>The State’s QA policies and procedures must include the following components, focusing on waiver participants:</p> <ul style="list-style-type: none"> • Provisions for waiver participant feedback and input (and family/legal guardian feedback/input when appropriate). • Provisions for identifying, addressing and preventing abuse, neglect and exploitation of waiver participants. • Procedures to identify, address and prevent problems with participant access to waiver services. • Methods to identify, address and prevent discrepancies between the services that the Plan of Care specifies and services the waiver participant receives. 	<p>The State must produce evidence that:</p> <ul style="list-style-type: none"> • The State uses information from its quality assurance activities to improve system performance and/or quality of care pertaining to: preventing/addressing instances of abuse/exploitation/neglect; assuring access to services; assuring Plans of Care meet waiver participant needs; and assuring mechanisms for waiver participant input (as well as family/legal guardian input as appropriate). • The State, on an ongoing basis, identifies and appropriately addresses instances of abuse, neglect and exploitation. • Appropriate actions are taken when the health or welfare of the waiver participant has not been safeguarded. • The State offers all of the services specified in their approved waiver, as appropriate. • When problems with access to waiver services are identified, actions are taken so that waiver participants receive the services that are specified in the Plan of Care, and that their preferences are considered.
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that the State’s QA design addresses each of the required design features related to waiver participants, as enumerated above. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Review State, provider, case manager, waiver participant records (as appropriate) to determine if allegations of abuse, neglect, and exploitation were reported to internal and external (including legal) sources, as necessary and according to the State’s policies and procedures, and whether adequate actions were taken to reasonably prevent reoccurrence.

B. State Quality Assurance Related to Waiver Participants, continued	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
	<ul style="list-style-type: none"> • Interview State staff, providers, waiver participants (and their families/guardians, as appropriate), and advocates to determine whether the State’s mechanism for waiver participant feedback/input is operational. • Review the State’s results of its interviews with waiver participants (and with family/legal guardian as appropriate), as well as any follow-up actions that resulted from these interviews. • Interview waiver participants (and their families/guardians, as appropriate) and/or observe waiver participants, and interview case managers and providers to determine if there are issues concerning abuse, neglect, and exploitation. Determine whether the State is aware of these concerns and whether it has taken appropriate action. • Interview advocates/protective services organizations to determine whether any concerns pertaining to abuse, neglect or exploitation have been identified. Determine whether the State is aware of these concerns and whether it has taken appropriate action. • Interview State staff to determine how complaints are processed and addressed. • Review Plans of Care and claims files to determine whether the State is providing all of the services covered under its approved waiver. • Interview State staff, case managers and providers, and review records, for evidence that the State routinely monitors waiver participants’ service access, i.e., that waiver participants receive the services as specified in their plans of care, and that problems are identified and addressed. • Review waiver participant records, interview waiver participants (and family/legal guardian, as appropriate), case managers, providers and advocates to determine whether waiver participants receive the services that are identified in their plan of care.

B. State Quality Assurance Related to Waiver Participants, continued	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
	<ul style="list-style-type: none"> • Interview waiver participants to determine whether they feel that they receive the services that they need, whether their needs are being addressed adequately, whether they are satisfied with how the care is delivered.

***Suggested Review Techniques
For
Regional Office Reviewers***

Reviewing the Design Features

- Review the approved waiver and CMS Form 372-S (Section D) for information on the State’s specifications related to its quality assurance system; compare what the State specified in its approved waiver with what you find the State’s QA system to be.
- Request copies of all waiver-related QA policies and procedures whether they exist in a single document or in multiple places.
- Following a review of the State’s written QA policies and procedures, if you find that they do not address *all* of the “Quality Assurance Features for State HCBS Waiver Programs”, interview State staff about how the State addresses the fundamental requirements of a QA plan.
- If a sister State agency is responsible for the operation of the waiver, collect information relevant to the on-line responsibilities of the sister agency, and their QA systems.

Reviewing the Implementation Features

- What types of data are collected to measure waiver participant outcomes? Review reports generated from these data.
- How does the State monitor, document and follow-up on complaints? For example, is there a documented log of complaints/questions? what protocols are followed when complaints/questions come in?
- Do waiver participants and caregivers (informal and formal), as well as family members and legal guardians, know how to report concerns or incidences of abuse, neglect, and exploitation?
- Questions about access to care to ask waiver participants (and family/legal guardian, as appropriate):
 - Are you getting the help you need?
 - What needs do you have that are not being taken care of?
 - Are you satisfied with the help your case manager gives you?
 - Does your (PCA, respite worker, nurse, etc.) show up on time?
 - Does s/he do a good job?
 - Is s/he courteous and respectful to you?
 - Does s/he take your wishes and preferences into account when working with you?
 - Are you able to make choices about the services you receive and who provides these services?

C. State Quality Assurance Related to Waiver Providers	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>The State’s QA policies and procedures must include the following components, focusing on waiver providers:</p> <ul style="list-style-type: none"> • Provisions for disseminating Medicaid and waiver-specific requirements to all waiver program providers. • Provisions for assuring that the State has a system of contingency plans for emergencies (e.g., severe weather) as well as mechanisms in place to assure back-up care when usual care is unavailable <i>and the lack of immediate care would pose a serious threat to health and welfare.</i> • Methods for verifying that provider quality assurance activities are conducted in accordance with State specified provider agreements, and procedures for addressing non-compliance. 	<p>The State must produce evidence that:</p> <ul style="list-style-type: none"> • It disseminates information about Medicaid and waiver-specific requirements to all waiver program providers. • The State and providers conduct provider quality assurance activities in accordance with provider and/or State specified agreements. • Contingency plan(s) have been established for emergencies and to accommodate backup when usual care is unavailable.
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that the State’s QA design addresses each of the required design features related to waiver providers, as enumerated above. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Interview State staff and providers to determine whether the State disseminates information about Medicaid and waiver-specific requirements to all waiver program providers. • Review State records and interview State staff, providers, and case managers (as appropriate) to verify that the State monitors the QA activities of providers and case managers in accordance with the State’s QA policies and procedures. • Review provider records, to verify that QA activities, when required, were conducted in accordance with provider and/or State requirements. • Verify that providers have explicit procedures for providing care under emergency conditions (e.g., severe weather) and for back-up in the event that usual care is unavailable.

C. State Quality Assurance Related to Waiver Providers, continued	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
	<ul style="list-style-type: none"> • Interview providers, waiver participants (and their families/guardians, as appropriate), case managers and advocates to assess whether providers' emergency and back-up plans have been implemented and work.

***Suggested Review Techniques
For
Regional Office Reviewers***

Reviewing the Design Features

- Review the approved waiver and CMS Form 372-S (Section D) for information on the State’s specifications related to its quality assurance system; compare what the State specified in its approved waiver with what you find the State’s QA system to be.
- Request copies of all waiver-related QA policies and procedures whether they exist in a single document or in multiple places.
- Following a review of the State’s written QA policies and procedures, if you find that they do not address all of the “Quality Assurance Features for State HCBS Waiver Programs”, interview State staff about how the State addresses the fundamental requirements of a QA plan.
- If a sister State agency is responsible for the operation of the waiver, collect information relevant to the on-line responsibilities of the sister agency, and their QA systems.

Reviewing the Implementation Features

- Does the State take action when multiple complaints are received regarding the same provider or the same agency?
- How does the State monitor and follow-up on complaints related to providers?
- Are appropriate actions taken to address providers/agencies that continuously demonstrate non-compliance?

D. Other Quality Enhancing Activities Related to the State’s Quality Assurance Program (Recommended, But Not Mandatory)	
<i>Some Suggested Design Features for States</i>	<i>Some Suggested Implementation Features for States</i>
<ul style="list-style-type: none"> • The State has a comprehensive, written, <i>waiver-specific</i> quality assurance plan. • The State’s quality assurance plan specifies methods for assessing whether (and the extent to which) waiver providers foster waiver participant self-direction and self-determination, and methods for assuring that providers promote waiver participant independence and dignity. • The State’s quality assurance plan includes the use of performance indicators that are measurable. • The State’s quality assurance plan includes clinical standards and/or practice guidelines. • The State has policies/procedures for reducing the use of restraints and seclusion. • The State’s policies/procedures require a formal system for reporting and tracking complaints. 	<ul style="list-style-type: none"> • Collection of performance measures/outcome data that are used to assess, refocus and revise (if necessary) the State’s quality assurance activities. • Use of clinical standards and/or practice guidelines. • Evidence that the State has implemented methods for assessing whether (and the extent to which) waiver providers foster waiver participant self-direction and self-determination, and methods for assuring that providers promote waiver participant independence and dignity. • Implementation of a formal system for reporting and tracking complaints. • Implementation of policies for reducing the use of restraints and seclusion. • Educational initiatives, offered to providers and case managers, focused on reducing the use of restraints and seclusion. • Provision of training to waiver staff to improve waiver participant outcomes, e.g., training to improve specific assessment skills of direct care staff. • Use of waiver participant surveys, focus groups and other methods for obtaining waiver participant (and family/legal guardian, as appropriate) input for measuring quality. • Evidence that the State has used the results of waiver participant surveys and/or performance measure analyses to make changes in the waiver program; i.e. has a quality improvement program. • Implementation of a hotline for participant/caregiver/family/legal guardian complaints/concerns/questions. • Automated reports that highlight discrepancies between POCs and services delivered.

D. Other Quality Enhancing Activities Related to the State’s Quality Assurance Program, continued (Recommended, But Not Mandatory)	
<i>Some Suggested Design Features for States</i>	<i>Some Suggested Implementation Features for States</i>
	<ul style="list-style-type: none"> • Provision of information and training to provider agencies, direct care staff, case managers, waiver participants, caregivers, and family members/legal guardian (as appropriate) on the prevention, identification, and reporting of abuse, neglect and exploitation.
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<ul style="list-style-type: none"> • When reviewing the State’s QA policies and procedures or during interviews with State staff, make note of any of the activities enumerated above. 	<ul style="list-style-type: none"> • When reviewing the State’s QA policies and procedures or during interviews with State staff, make note of any of the activities enumerated above.

II. Design and Implementation of a System for Reviewing Plans of Care

The State must demonstrate that it has designed and implemented an adequate system for reviewing the adequacy of plans of care for waiver participants.

Authority: 42 CFR 441.301; 42 CFR 441.302; 42 CFR 441.303; SMM 4442.6; SMM 4442.7; Section 1915© Waiver Format, Item Number 13

The State must produce evidence of the policies and procedures it uses for reviewing the adequacy of waiver participants' Plans of Care (POC). These policies and procedures must contain information on the various components of the State's POC review activities, including how reviews of the following components will be conducted: POC development; POC approval; as well as review of mechanisms for assuring that services are delivered in accordance with POCs.

The State must produce evidence that it *implements* its policies and procedures for reviewing the adequacy of waiver participants' Plans of Care (POC). That is, the State must show that, *in accordance with its policies and procedures*, it monitors the development and approval of POCs, as well as the extent to which mechanisms for assuring that services are delivered in accordance with POCs are implemented.

A. Plan of Care Development	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>Policies and procedures for POC development must include:</p> <ul style="list-style-type: none"> • A description of the POC development process; • A description of the persons responsible for developing POCs; • Method(s) for assessing whether the waiver participant and informal caregivers (as appropriate) have input into the POC, and whether the participant's preferences are considered. • Method(s) for assessing whether waiver applicants/participants are afforded the freedom to choose between waiver services and institutional care, and between/among waiver services and providers. 	<p>The State must produce evidence that it:</p> <ul style="list-style-type: none"> • Monitors POC development in accordance with its policies and procedures; • Takes appropriate action when it identifies inadequacies in the development of POCs; • Assesses whether the waiver participant and informal caregivers (as appropriate) have input into the POC, and whether the participant's preferences are considered. (Waiver participants have the right to refuse specific service(s). However, when a waiver participant refuses a service, the State must have a process for assuring that the risks associated with refusing a service(s) are addressed, to the extent possible.)

A. Plan of Care Development, continued	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
	<ul style="list-style-type: none"> • Affords all waiver applicants/participants the freedom to choose between waiver services and institutional care, and between/among needed waiver services and providers.
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that policies and procedures exist for: <ul style="list-style-type: none"> - The development of POCs, and that these policies and procedures address all the features enumerated above. - How the State will monitor the POC development process to assure that POCs are developed appropriately. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Review documented results or other indicators which demonstrate that the State monitors the POC development process. • Review POCs to determine whether they appear to address all needs of waiver participants, including general health and welfare issues. Verify that services recommended by an attending physician or other professional involved in the assessment process were appropriately addressed in the POC. • Verify that the waiver participant's goals are addressed and preferences considered when the POC is developed. • When reviewing POCs determine whether, to the extent possible, the waiver participant and/or a legal representative participated in the development of the POC. • When reviewing POCs where waiver participants refused a waiver service(s), determine whether the risks associated with refusing the service(s) was addressed appropriately. • Interview waiver participant (and family/guardian, as appropriate) and review Plan of Care documentation for evidence that waiver participants were afforded choice: 1) between waiver services and institutional care; and 2) between/among needed waiver services and providers.

A. Plan of Care Development, continued	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
	<ul style="list-style-type: none"> • Review POCs to determine if plans address specific needs and whether the waiver participant’s goals are considered in addressing needs (i.e., individuals vs. “cookie cutter” plans). • Verify that POCs are updated/revised when warranted by changes in the waiver participant’s condition and goals. • Interview State staff and individuals responsible for developing and monitoring POCs to verify that plans are developed in a timely fashion and in accordance with the approved waiver. • Interview waiver participants (and their families/guardians, as appropriate) and/or observe waiver participants, and interview providers, and State staff as necessary to evaluate whether there are discrepancies between identified needs/goals (as indicated by an assessment) and services delineated in the POC. If discrepancies exist, determine how they are being addressed.

<i>Suggested Review Techniques For Regional Office Reviewers</i>
Reviewing the Design Features
<ul style="list-style-type: none"> • Review the approved waiver. • Interview appropriate State staff to determine if the procedures specified in the approved waiver are the procedures currently followed by the State.
Reviewing the Implementation Features
<ul style="list-style-type: none"> • If POCs will be reviewed in the RO home office, request State to send copies of POCs in advance. • If needs outside the scope of waiver services are identified in POCs, determine whether providers/case managers have knowledge and access to community resources, and made referrals as appropriate.

B. Plan of Care Approval	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>The State’s policies and procedures for its POC approval processes must contain the following information:</p> <ul style="list-style-type: none"> • A description of the POC approval process, consistent with the State’s approved waiver; • Frequency of the State’s approval of POC activities; • Sampling methodologies used in the approval process, if less than 100% review conducted; • Persons responsible for conducting the POC approval activities and their qualifications; • Method(s) the State uses to document its POC approval activities; and • Method(s) for assessing whether the POCs identify all of the waiver participant’s (assessed) needs, not merely needs that can be addressed with waiver services. 	<p>The State must produce evidence that it:</p> <ul style="list-style-type: none"> • Has implemented its methodologies for reviewing the adequacy of POCs, and that it exercises its oversight by assuring that POCs reflect changes in waiver participant needs and goals, and that POCs are developed not only at pre-set time intervals (e.g., quarterly, annual assessment time).
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that policies and procedures for reviewing POCs exist and are consistent with the approved waiver. • Verify that the State’s plan for the frequency of POC review activities is consistent with what is stipulated in the approved waiver. • Verify that the State’s plan for personnel conducting the POC review activities is consistent with what is stipulated in the approved waiver. • Verify that the State’s methodology for determining POC adequacy is based on waiver participant need (via assessment). 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that the POCs are approved by the State Medicaid Agency as specified in the approved waiver. • Interview State staff and individuals responsible for developing and monitoring POCs to verify that plans are reviewed/approved in accordance with the approved waiver.

B. Plan of Care Approval, continued	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<ul style="list-style-type: none"> • Verify that the State’s methodology for assessing POC adequacy addresses whether the POC meets all waiver participant needs. • Verify that if sampling is used by the State in reviewing POCs that the sampling methodologies are specified. 	

<i>Suggested Review Techniques For Regional Office Reviewers</i>
Reviewing the Design Features
<ul style="list-style-type: none">• Review the approved waiver.• Interview appropriate State staff to determine if the procedures specified in the approved waiver are the procedures currently followed by the State.
Reviewing the Implementation Features
<ul style="list-style-type: none">• Approvals may take the form of prior approvals or post approvals that use sampling methodologies.

C. Plan of Care Monitoring (Services Delivered in Accordance with Plan of Care)	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>The State’s policies and procedures must provide information on:</p> <ul style="list-style-type: none"> • Method(s) for determining whether all needs and goals identified in POCs are addressed, either by waiver services or through other means. • Method(s) for assessing whether POCs are revised when waiver participant needs change. 	<p>The State must produce evidence that it:</p> <ul style="list-style-type: none"> • Has implemented its methodology for assuring that services are delivered in accordance with POC; and • Takes appropriate action when it determines that services are not being provided in accordance with POCs.
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Interview appropriate State staff to determine if the State has procedures to monitor the provision of services in accordance with POCs. • Verify that the State has a methodology for assessing whether POCs are revised when waiver participant needs change. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Review documentation that demonstrates the State monitors to assure that waiver participants receive the services specified in the POC. • Review waiver participant records, and verify that services in the POC have been received. • If the POC specifies goals and objectives, verify that these goals are being monitored and updated as necessary. • Interview waiver participants (and their families/guardians, as appropriate), providers, and State staff to determine if reasonable efforts are made to verify that services are provided in accordance with POCs. • Observe/assess community and residential settings as necessary to determine whether care is coordinated across various settings and to evaluate discrepancies from the POC.

<i>Suggested Review Techniques For Regional Office Reviewers</i>
Reviewing the Design Features
<ul style="list-style-type: none">• Review the approved waiver.• Interview appropriate State staff to determine if the procedures specified in the approved waiver are the procedures currently followed by the State.
Reviewing the Implementation Features
<ul style="list-style-type: none">• If POCs will be reviewed in the RO home office, request State to send copies of POCs in advance.• If discrepancies are identified following review of POCs and services received, request a payment history file to compare POCs with services billed.

D. Other Quality Enhancing Activities Related to the State's Review of Plan of Development, Approval and Monitoring

(Recommended, But Not Mandatory)

Some Suggested Implementation Features for States

- An automated decision-support system that assists the case manager in developing a care plan based on automated assessment data.
- Automated reports that describe discrepancies between POCs and services authorized/received.
- Waiver participant/caregiver surveys that include a focus on unmet need and/or whether the waiver participant received all the services specified in his/her POC.

III. Design and Implementation of a System for Assuring Waiver Services are Provided by Qualified Providers

The State must demonstrate that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers.

Authority: 42 CFR 441.302; SMM 4442.4

The State must produce evidence of policies and procedures that specify its approach for verifying and assuring that waiver provider agencies and individual service providers meet provider requirements.

The State must produce evidence that it *implements* its policies and procedures for verifying and assuring that provider agencies and individual service providers meet waiver provider requirements.

A. Provider Qualifications	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>The State must provide evidence of policies and procedures that demonstrate how it verifies that provider agencies, individual service providers, and board and care facilities that serve the waiver population meet provider requirements.</p> <p>These policies and procedures must include:</p> <ul style="list-style-type: none"> • Licensing, certification, and other standards for each provider type; • A process for enrolling as waiver providers those providers who are not licensed/certified (i.e., State does not require licensing and/or certification); • A process for ongoing monitoring of providers not licensed/certified by the State in order to assure adherence to waiver requirements; • A description of activities that the State will perform to assure waiver providers meet provider standards, and persons responsible for such monitoring activities; • Frequency of verification/monitoring activities related to provider qualifications; 	<p>The State must produce evidence that it:</p> <ul style="list-style-type: none"> • Verifies provider licensing, certification and adherence to other State standards on a periodic basis to assure waiver providers meet standards; • Implements its process for enrolling as waiver providers those providers for whom the State does not require licensing and/or certification; • Monitors non-licensed/non-certified providers periodically to assure adherence to waiver requirements; and • Identifies and rectifies situations where providers are determined not to meet requirements, and that there are persons who are responsible for taking appropriate action.

A. Provider Qualifications, continued	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<ul style="list-style-type: none"> • A description of how verification of provider requirements are documented; and • Protocols for identifying and addressing situations where providers are determined to not meet requirements and a description of persons responsible for taking appropriate action when unqualified providers are identified. 	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that the State has policies and procedures that assure providers meet requirements, and that the policies and procedures address: <ul style="list-style-type: none"> - The State’s methodology for verifying that provider requirements for each provider type are met and are current; - The State’s plan for the frequency of verifying provider requirements; - The personnel conducting provider requirement verification activities; - Documentation of verification activities; and - Protocols for addressing unqualified providers. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that agreements are in place for providers rendering waiver services. • Review State and provider files to verify requirements are being met. • Determine that the State monitors providers to assure that qualifications specified in the approved waiver are met prior to the provider rendering services to waiver participants. • Review State provider files documenting corrective actions taken with providers when they do not meet requirements as stipulated in the State’s approved waiver.

<p><i>Suggested Review Techniques For Regional Office Reviewers</i></p>
<p>Reviewing the Design Features</p>
<ul style="list-style-type: none"> • While it is incumbent upon the State Medicaid agency to have a policy/procedure for verifying, on a periodic basis, that the board and care facilities to which waiver participants are admitted or in which they reside meet State standards, reviewers should note that most State Medicaid waiver programs do not have regulatory authority over, nor QA monitoring responsibilities for, board and care facilities. Typically this regulatory authority is delegated to the State’s health facility survey and certification unit. Therefore, the State’s policies and procedures should reflect this limitation by specifying what actions it will take if it uncovers a board and care facility out of compliance with State standards, i.e., notification of the agency that has regulatory authority over board and care facilities, removal of waiver participants from facilities if their health or welfare is in immediate jeopardy, etc.
<p>Reviewing the Implementation Features</p>
<ul style="list-style-type: none"> • Does the State monitor providers to ensure an understanding and adherence to waiver requirements? How often are providers reviewed? How does the State assure that provider-specific requirements or limitations (such as supervisory reviews) are met? • If the waiver utilizes an organized health care delivery system (OHCDs) among its providers, make sure there is a Medicaid provider agreement between the Medicaid State Agency and the OHCDs, and that the agreement/contract specifies roles and responsibilities of all parties, including subcontractors. • Reviewers should note that since the State Medicaid agencies do not typically have regulatory authority over board and care facilities, it is expected that the Medicaid agency would verify with the appropriate State agency that facilities providing services to waiver participants are certified as meeting State requirements. • Similarly, the Medicaid agency typically would not have regulatory authority for taking actions against board and care facilities determined out of compliance with State standards. However, Reviewers should expect that if the Medicaid Agency (or its contracted providers) suspects a facility to be out of compliance with State standards, that at a minimum it would notify the agency with regulatory authority. If a waiver participant’s health or welfare was determined to be at immediate risk, Reviewers should expect the Medicaid agency to take action to protect the resident, up to and including removal from the facility.

B. Provider Training	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>The State must provide evidence of its policies and procedures for verifying that provider training requirements, as specified in its approved waiver, are met. These must include:</p> <ul style="list-style-type: none"> • Methods for verifying that provider training is conducted in accordance with State requirements and the approved waiver. 	<p>The State must produce evidence that it:</p> <ul style="list-style-type: none"> • Implements its policies and procedures for verifying that training, as specified in its approved waiver, is provided and that it is provided in accordance with State requirements.
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Review approved waiver for details on provider training. • Review State documents and interview State staff to verify that policies and procedures exist that address training requirements of waiver providers. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Review State and provider documentation, and interview State staff and providers to determine if provider training was provided according to State requirements.

*Suggested Review Techniques
For
Regional Office Reviewers*

Reviewing the Implementation Features

- Is training on going, such that new providers receive training before they begin working with the waiver population, or shortly thereafter?
- How does the State distribute information on the waiver program to providers?
- Are providers aware of community resources that may be beneficial to the waiver population that they serve? Do they have access to these community resources?

C. Other Quality Enhancing Activities Related to the State’s Review of Provider Qualifications (Recommended, But Not Mandatory)	
<i>Some Suggested Design Features for States</i>	<i>Some Suggested Implementation Features for States</i>
<ul style="list-style-type: none"> • Review of State-generated reports on provider requirement verification. • Development of training requirements that are appropriate and specific to the population that the waiver targets. • Methods for receiving and analyzing the results of State Licensure Agency surveys of providers/facilities to identify non-compliant providers. 	<ul style="list-style-type: none"> • The State has a system for routinely receiving and analyzing the results of State Licensure Agency surveys of waiver providers. • The State implements its policies and procedures for verifying that providers receive training appropriate to the waiver population that they serve.

**IV.
Use of Processes/Instruments for Determining Level of Care Need**

The State must demonstrate that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care need (consistent with care provided in a hospital, NF, or ICF-MR).

Authority: 42 CFR 441.301; 42 CFR 441.302; 42 CFR 441.303; SMM 4442.5

A. Level of Care Determination
<i>Required Implementation Features for States</i>
<p>The State must demonstrate that:</p> <ul style="list-style-type: none"> • It provides an individual evaluation for the required level of care for each eligible <i>applicant</i> for whom there is reasonable indication that such services may be needed in the near future but for the provision of home and community-based services; • It uses the processes and instrument(s) described in its approved waiver for determining level of care; • It provides an individual reevaluation at least annually for the required level of care for persons enrolled in the waiver, but more frequently if specified in its approved waiver. The State must demonstrate that it is using the processes and instrument(s) described in its approved waiver; • Persons performing the evaluations/reevaluations and making the level of care determinations are the types of individuals specified in the approved waiver, with documentation provided in the applicant/waiver participant file; • It monitors level of care decisions to assure that waiver participants do in fact require an institutional level of care, • It takes action to address inappropriate level of care decisions (e.g., training or other staff interventions) when it finds inappropriate determinations have been made. • It maintains documentation pertaining to all evaluations/reevaluations as specified in it approved waiver.

A. Level of Care Determination, continued***RO Review Protocols for Verifying/Evaluating Implementation Features***

RO Reviewers must conduct the following verification/evaluation activities:

- Review applicant files to verify that an initial evaluation of level of care need has been conducted. Applicants found to be eligible as well as those denied eligibility should be included in this review. Verify that the instrument described in its approved waiver is the instrument used in all level of care need determinations.
- Review waiver participant files to verify reevaluations of level of care need. Verify that the instrument described in its approved waiver is the instrument used in all level of care need redeterminations.
- Review of applicant and waiver participant files to verify that the person conducting the evaluation/reevaluation is identified (via signature or some other means), and that their qualifications/title/position are also identified in the level of care determination.
- Review waiver participant charts to verify that evaluations/reevaluations are completed in accordance with procedures specified in the approved waiver (including timeliness, qualifications of responsible individuals and assessment instrument).
- Review waiver participant charts to determine whether the State monitors evaluations/reevaluations to assure that waiver participants do, in fact require an institutional level of care and that the level of care they are assigned is appropriate to their level of need.
- Review waiver participant charts to verify that reevaluations are conducted when warranted by changes in the waiver participant's condition, regardless of the periodicity schedule.
- Verify that when the state finds inappropriate level of care determinations being made that it takes actions to address the situation.

**B. Other Quality Enhancing Activities Related to Level of Care Determination
(Recommended, But Not Mandatory)**

Some Suggested Design Features for States

- Evidence of an automated tickler system that reminds persons responsible for conducting level of care determinations when a waiver participant is due for a redetermination.
- An automated system which tracks reevaluation dates, and produces reports documenting whether reevaluations are conducted on time, and if not conducted on time, what the lag time is between date of actual reevaluation and target reevaluation date. Use of such reports for improving the performance of the reevaluation system.
- An automated system that tracks applicant/waiver participant level of care evaluations/reevaluations and that generates reports that include evaluator's name and qualifications/title/position.
- A second-opinion review of LOC determinations by clinicians/ supervisors, employing sampling techniques.

V.
State Administrative Authority Over the Waiver

The State must demonstrate that it retains administrative authority of the waiver program and that its administration of the waiver program is consistent with its approved waiver application.

Authority: 42 CFR 441.303; 42 CFR 431; SMM 4442.6; SMM 4442.7

A. Administering Agency and Operating Agency Responsibilities
<i>Required Implementation Features for States</i>
<p>The State must demonstrate that:</p> <ul style="list-style-type: none">• If an agency other than the State Medicaid agency has operational responsibility for the waiver program:<ul style="list-style-type: none">- There is an interagency agreement or memorandum of understanding between the State Medicaid agency and the operating agency that delineates the roles and responsibilities of each party;- The State Medicaid agency assumes responsibility for all policy decisions regarding the waiver, as well as monitoring their implementation by the operating agency;- Both the administering and operating agencies provide the information and data needed to carry out the interagency agreement or memorandum of understanding. For example, the State Medicaid agency may need to provide to the operating agency information pertaining to the Medicaid program, Federal requirements for waiver programs (e.g., Health and Welfare Assurances and other Basic Assurances, Level of Care Eligibility Determination, Freedom of Choice, Plan of Care requirements). Likewise, the operating agency may be required to provide reports or data to the State Medicaid agency.- The State Medicaid agency monitors the interagency agreement or the memorandum of understanding to assure that the provisions specified are executed.
<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none">• Review any interagency agreements or memorandum of agreements between the State Medicaid agency and the agency operating the waiver to verify that they clearly delineate the roles and responsibilities of each agency.• Interview staff in the administering and operating agencies to determine whether they understand their respective roles and implement them accordingly.

A. Administering Agency and Operating Agency Responsibilities, continued

RO Review Protocols for Verifying/Evaluating Implementation Features

RO Reviewers must conduct the following verification/evaluation activities:

- Interview staff in the administering and operating agencies to determine whether policies related to the waiver program are promulgated solely by the administering agencies.
- Interview staff in the operating agency to determine whether they understand relevant Federal Medicaid regulations and other State- or waiver-specific requirements.
- Interview staff in the administering agency to determine how they monitor any interagency agreement or memorandum of understanding.

***Suggested Review Techniques
For
Regional Office Reviewers***

- In interviewing case managers in the operating agency ask them to describe what steps they go through when enrolling waiver participants, developing the Plan of Care, and in other waiver processes.

B. Due Process***Required Implementation Features for States***

The State must demonstrate that it:

- Provides due process in handling requests for waiver services, i.e., informing applicants, at the time of application, of their right to request a fair hearing if their request for waiver services is denied.
- Observes due process in the operation of the waiver, i.e., it provides written notice to waiver participants when a decision is made to reduce, suspend or terminate services under the waiver, and that the written notice includes: (1) a description of the action the agency intends to take, (2) the reasons for the intended action, (3) information about the participants' rights to request a hearing, and (4) an explanation of the circumstances under which Medicaid services will continue if a hearing is requested.

RO Review Protocols for Verifying/Evaluating Implementation Features

RO Reviewers must conduct the following verification/evaluation activities:

- Review approved and disapproved applications and beneficiary correspondence to verify that the waiver applicant was provided written notice about the right to request a hearing if waiver services are denied.
- Review the forms and documentation used to provide written notice to waiver participants of the State's actions (regarding changes, reductions or termination of wavier services) and verify that they describe: (1) the action the State intends to take, (2) the reasons for the intended action, (3) information about the participants rights to request a hearing, and (4) an explanation of the circumstances under which Medicaid services will continue if a hearing is requested.
- Verify that requests for hearings are addressed, that decisions are made in a timely manner, and that the State complies with the decisions of the hearing officer(s).

***Suggested Review Techniques
For
Regional Office Reviewers***

- Interview appropriate State staff and/or review appeals logs for evidence about the State's compliance with fair hearings requests.

VI. State Financial Accountability

The State must demonstrate that it has designed and implemented an adequate system for assuring financial accountability of the waiver program.

Authority: 42 CFR 441.302; 42 CFR 441.303; 42 CFR 441.308; 45 CFR 74; SMM 2500; SMM 4442.8; SMM 4442.10

A. State's System for Financial Oversight	
<i>Required Design Features for States</i>	<i>Required Implementation Features for States</i>
<p>The State must produce evidence of its policies and procedures for financial oversight of the waiver. These policies and procedures must contain information on:</p> <ul style="list-style-type: none"> • How financial records are maintained by the state and by providers. • The nature and frequency of reviews/audits it conducts. • Actions the State takes if problems are identified. • The nature and frequency of reviews/audits of operating agencies when other than the State Medicaid agency. • Staff who conduct the reviews/audit. • Procedures for assuring appropriate financial oversight if the review of claims (to insure they are coded and paid for in accordance with the reimbursement methodology specified in the approved waiver) is delegated to the operating agency. 	<p>The State must produce:</p> <ul style="list-style-type: none"> • Evidence that it conducts financial reviews according to its policies and procedures, and consistent with any relevant specifications in its approved waiver.

A. State’s System for Financial Oversight, continued	
<i>RO Review Protocols for Verifying/Evaluating Design Features</i>	<i>RO Review Protocols for Verifying/Evaluating Implementation Features</i>
<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Verify that policies and procedures for financial oversight of the waiver are in place, that they contain the information enumerated above. 	<p>RO Reviewers must conduct the following verification/evaluation activities:</p> <ul style="list-style-type: none"> • Review the State’s financial documentation to verify it is maintaining appropriate financial records as specified in its approved waiver. • Verify that financial reviews/audits have been conducted in accordance with the State’s financial accountability plan/procedures by reviewing reports from the reviews/audits. • Interview State staff and providers, as appropriate, to verify that any identified financial irregularities were addressed. • Conduct site visits with providers to verify that they maintain financial records according to provider agreements/contracts. • Review waiver participant claims to verify that they are coded and paid in accordance with the waiver reimbursement methodology.

***Suggested Review Techniques
For
Regional Office Reviewers***

Reviewing the Design Features

- Review the approved waiver for any specifications related to financial oversight/accountability.
- Review interagency agreements or memorandum of understanding for specifications on financial accountability, maintenance of financial records, reporting requirements, etc.
- Review provider agreements/contracts for specification on maintenance of financial records.

Reviewing the Implementation Features

- Verify the State maintains supporting documentation such as:
 - Contracts/provider agreements
 - Date of payment
 - Date of service
 - Medicaid ID#
 - Name of Medicaid recipient
 - Services provided
 - Units of service
 - Amount of payment
 - Location where service was provided

The above information must be maintained by the State in accordance with Section 2500.2 of the State Medicaid Manual. This section also precludes states from using sampling, projections or other estimating techniques for claiming federal funds. It is important to note, 45 CFR 74.53 requires states to maintain financial records and supporting documentation for a period of three years.

- Verify the state has conducted reviews or audits as specified in the waiver agreement. Reviewers should also verify the State Auditor has conducted an audit for the period under review under OMB Circular A-133.
- Verify that any known financial errors/adjustments were corrected by the State and/or providers. This could also include a follow-up of adjustments or expenditures reported on the CMS-64 report if determined material.
- Review the waiver agreement, provider agreements and/or contracts. This should include verification that providers maintain records in accordance with their agreements or contracts. Reviewers should verify providers maintain documentation which includes: date of service, name of client, services provided, units of service, amount of payment, and location where services were provided. This requirement is found in Section 2500 of the State Medicaid Manual. (The same three year retention requirement applies to providers).

***Suggested Review Techniques
For
Regional Office Reviewers
Continued***

Reviewing the Implementation Features

- Select paid claims for each type of service provided through the waiver and verify the following:
 - Accuracy of codes
 - Amounts paid
 - Beneficiary's name
 - Service provided
 - Date of service
 - Client Medicaid eligibility
 - Application of approved/authorized payment rates for the period involved.

Findings, Writing Reports, and Follow-up Activities with the State and CMS's Central Office

THE EXIT CONFERENCE

- Unless there are findings that require immediate action (see next section), the exit conference should be as brief as possible, and focused on outcomes and actions.
- Review outstanding materials that you require in order to complete the review, and arrange for them to be sent to the RO.
- Highlight significant findings from your review – this includes positive as well as negative findings.
- Give the State a time frame for when you will issue the Draft Report and the State's response.

FINDINGS REQUIRING IMMEDIATE ACTION

- If RO reviewers find that waiver participants' health or welfare is determined to be in immediate jeopardy, the RO review team **MUST** alert the State Medicaid agency immediately while still on-site. This should be confirmed either with a conference call to the State or through a letter. When these situations arise the review team's RO manager should be informed. These transmittals (verbal and written) to the State should specify time frame, taking into account the urgency of the situation, within which the State must convey to the RO how it handled the situation; specifically, the State must convey the following information:
 1. Its findings;
 2. Follow-up actions that were taken; and
 3. Future actions will be taken to address the problem and prevent re-occurrences.

FINDINGS REQUIRING ADDITIONAL REVIEWS

- When identified problems concern the adequacy of waiver participant health and/or welfare, the RO must determine if additional reviews are necessary before an assessment about the pervasiveness of the identified problem can be ascertained. In this instance, the preferred approach is for the RO review team to direct the State to conduct focused reviews to identify the pervasiveness of a particular problem. The RO review team may choose to conduct its own focused review, depending upon the nature of the problem.

- Examples of findings warranting additional reviews generally fall into two categories:
 1. Demonstration of one or more egregious situations indicative of gross malfeasance which place one or more waiver participants at risk of physical and/or mental harm such as preventable deaths; substantiated or unsubstantiated sexual or physical abuse; gross violations of waiver participant rights, etc.
 2. Demonstration of a pattern of unacceptable performance that indicates that a significant percentage of the waiver participant population appears to be at risk or is being adversely impacted, such as failing to monitor for inappropriate waiver participant treatment; failing to investigate waiver participant complaints; failing to assure the resolution of waiver participant care problems, etc.

DRAFT REPORT

- Review findings should be issued as a draft report within 60 days of completion of all review activities (fieldwork activities and any work needed to complete the review steps) and at least 6 months prior to the scheduled waiver renewal date.
- Regardless of whether the RO has directed the State to conduct additional reviews, the RO should proceed with drafting its report. The Draft Report should identify the situations that necessitate additional reviews, if appropriate.
- All waiver review reports should address both positive and negative findings.
- Waiver programs that have implemented any of the features identified in *The Protocol* as “Quality Enhancing” (i.e., QA activities above and beyond what the assurances require) or what would otherwise be considered a “Best Practice”, should be commended for their accomplishments.
- The cover letter to the State that accompanies the Draft Report should specify that the State is expected to respond within 30 days of its receipt. If there are findings that require a corrective action plan, the State should be instructed that their response must include a corrective action plan that adequately addresses all of the findings identified. Also included in this letter should be instructions to the State that if they wish an extension for their response to the Draft Report, they should provide justification as to why an extension is necessary, as well as a timeframe for providing a response, and critical tasks/milestones (and associated projected dates) to be completed before a response can be made.
- In the draft report’s cover letter the RO should convey its interest in assisting State staff with whatever technical support they may need in their response to the findings of the review.

ASSESSING THE STATE'S RESPONSE TO THE DRAFT REPORT

- Upon receipt of the State's response to the Draft Report, the RO should thoroughly analyze the State's comments and corrective action plan and determine if they can be implemented in conjunction with the waiver's renewal.
- If the RO is satisfied with the State's approach as documented in their response to the Draft Report, the RO should convey their acceptance of the State's response.
- Based on the State's response to the Draft Report, the RO should make the necessary changes to its findings and/or recommendations (in the Final Report) to adequately reflect the waiver's operations for the period in which it was reviewed.
- If the RO is not satisfied with the State's response to the Draft Report and/or the corrective action plan (if required), the RO should determine if the outstanding issues are serious enough to prevent the waiver from being renewed. If the RO determines that a waiver is in jeopardy of not being renewed it should alert CMS CO HCBS waiver staff by phone call and in writing to the Center for Medicaid and State Operations' Director.
- If the State was directed to conduct additional/focused reviews, the results of these reviews should also be taken into consideration when determining if the necessary safeguards are in place to assure waiver participants' health and welfare, and thus whether the waiver should be renewed.
- RO review teams also have the prerogative of conducting targeted reviews to assess a State's progress in implementing corrective action plans. The scope of a targeted review should be more focused than a full review. If the RO review team decides it is appropriate they might consider accompanying State reviewers during their regular monitoring visits or on additional monitoring activities required by the RO review team.

FINAL REPORT

- The RO should issue a Final Report within 30 days of receiving the State's comments on the Draft Report.
- Final Reports should be sent CMS's Central Office (CMSO), and if appropriate, shared with CMS Regional Offices.