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State/Territory Name: Arkansas

State Plan Amendments (SPA) #: AR-19-0010

This file contains the following documents in the order listed:

Approval Letter
 State Plan Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-01-16 Baltimore, MD 21244-1850

Children and Adults Health Programs Group



JUL 1 8 2019

Medicaid Director Department of Human Services 112 West 8th Street, Slot S401 Little Rock, AR 72201-4608

Dear Ms. Stehle:

Dawn Stehle

I am pleased to inform you that your title XXI Children's Health Insurance Program (CHIP) state plan amendment (SPA), AR-19-0010, has been approved. AR-19-0010 demonstrates compliance with the CHIP managed care regulations at 42 CFR 457, Subpart L for utilization of a managed care delivery system. This SPA has an effective date of July 1, 2018 for the Healthy Smiles dental managed care program. The effective date for the Provider-Led Arkansas Shared Savings Entity (PASSE) program is March 1, 2019, when the state began to enroll CHIP eligible children into PASSE.

Sections 2101(a), 2103(f)(3), 2107(b), and 2107(e) of the Social Security Act, as implemented through regulations at 42 CFR 457 Subpart L, describe the application of managed care requirements to CHIP. Arkansas has provided the necessary assurances indicating that the state complies with the managed care requirements in the delivery of CHIP services and benefits covered under the state's separate child health plan.

This SPA approval does not substitute for CMS review of any contracts between the state and managed care entities that serve the state's CHIP populations. All managed care contracts for CHIP populations in effect as of the state fiscal year beginning on or after July 1, 2018 must comply with the CHIP managed care regulations and be submitted for CMS review.

Your title XXI project officer is Ms. Jasmine Aplin. She is available to answer questions concerning this amendment and other CHIP-related issues. Her contact information is as follows:

Centers for Medicare & Medicaid Services Center for Medicaid and CHIP Services Mail Stop: S2-01-16 7500 Security Boulevard Baltimore, MD 21244-1850 Telephone: (410) 786-8102 E-mail: Jasmine.Aplin@cms.hhs.gov Page 2 – Ms. Dawn Stehle

Official communications regarding program matters should be sent simultaneously to Ms. Aplin and Mr. Bill Brooks, Director, Division of Medicaid Field Operations South. Mr. Brooks' address is:

Centers for Medicare & Medicaid Services Division of Medicaid Field Operations South 1301 Young St. Suite 714 Dallas, TX 75202

If you have additional questions, please contact Ms. Amy Lutzky, Director, Division of State Coverage Programs at (410) 786-0721. We look forward to continuing to work with you and your staff.

Sincerely,

/signed Anne Marie Costello/

Anne Marie Costello

cc: Mr. Bill Brooks, Director, Division of Medicaid Field Operations South

TEMPLATE FOR CHILD HEALTH PLAN UNDER TITLE XXI OF THE SOCIAL SECURITY ACT CHILDREN'S HEALTH INSURANCE PROGRAM

(Required under 4901 of the Balanced Budget Act of 1997 (New section 2101(b)))

State/Territory: <u>ARKANSAS</u> (Name of State/Territory)

As a condition for receipt of Federal funds under Title XXI of the Social Security Act, (42 CFR, 457.40(b))___Janet Mann, Director, DMS_____(Signature of Governor, or designee, of State/Territory, Date Signed)

submits the following Child Health Plan for the Children's Health Insurance Program and hereby agrees to administer the program in accordance with the provisions of the approved Child Health Plan, the requirements of Title XXI and XIX of the Act (as appropriate) and all applicable Federal regulations and other official issuances of the Department.

The following State officials are responsible for program administration and financial oversight (42 CFR 457.40(c)):

Name: Cindy Gillespie	Position/Title: Director, Department of Human Services (DHS)
Name: Janet Mann	Position/Title: Director, DHS Division of Medical Services (DMS)
Name:	Position/Title:

*Disclosure. In accordance with the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1148 (CMS-10398 #34). The time required to complete this information collection is estimated to average 80 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, write to: CMS, 7500 Security Blvd., Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Introduction: Section 4901 of the Balanced Budget Act of 1997 (BBA), public law 1005-33 amended the Social Security Act (the Act) by adding a new title XXI, the Children's Health Insurance Program (CHIP). In February 2009, the Children's Health Insurance Program Reauthorization Act (CHIPRA) renewed the program. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, further modified the program. The HEALTHY KIDS Act and The Bipartisan Budget Act of 2018 together resulted in an extension of funding for CHIP through federal fiscal year 2027.

This template outlines the information that must be included in the state plans and the State plan amendments (SPAs). It reflects the regulatory requirements at 42 CFR Part 457 as well as the previously approved SPA templates that accompanied guidance issued to States through State Health Official (SHO) letters. Where applicable, we indicate the SHO number and the date it was issued for your reference. The CHIP SPA template includes the following changes:

- Combined the instruction document with the CHIP SPA template to have a single document. Any modifications to previous instructions are for clarification only and do not reflect new policy guidance.
- Incorporated the previously issued guidance and templates (see the Key following the template for information on the newly added templates), including:
 - Prenatal care and associated health care services (SHO #02-004, issued November 12, 2002)
 - Coverage of pregnant women (CHIPRA #2, SHO # 09-006, issued May 11, 2009)
 - Tribal consultation requirements (ARRA #2, CHIPRA #3, issued May 28, 2009)
 - Dental and supplemental dental benefits (CHIPRA # 7, SHO # #09-012, issued October 7, 2009)
 - Premium assistance (CHIPRA # 13, SHO # 10-002, issued February 2, 2010)
 - Express lane eligibility (CHIPRA # 14, SHO # 10-003, issued February 4, 2010)
 - Lawfully Residing requirements (CHIPRA # 17, SHO # 10-006, issued July 1, 2010)
- Moved sections 2.2 and 2.3 into section 5 to eliminate redundancies between sections 2 and 5.
- Removed crowd-out language that had been added by the August 17 letter that later was repealed.
- Added new provisions related to delivery methods, including managed care, to section 3 (81 FR 27498, issued May 6, 2016)

States are not required to resubmit existing State plans using this current updated template. However, States must use this updated template when submitting a new State Plan Amendment.

Federal Requirements for Submission and Review of a Proposed SPA. (42 CFR Part 457 Subpart A) In order to be eligible for payment under this statute, each State must submit a Title XXI plan for approval by the Secretary that details how the State intends to use the funds and fulfill other requirements under the law and regulations at 42 CFR Part 457. A SPA is approved in 90 days unless the Secretary notifies the State in writing that the plan is disapproved or that specified additional information is needed. Unlike Medicaid SPAs, there is only one 90-day review period, or clock for CHIP SPAs, that may be stopped by a request for additional information and restarted after a complete response is received. More information on the SPA review process is found at 42 CFR 457 Subpart A.

When submitting a State plan amendment, states should redline the changes that are being made to the existing State plan and provide a "clean" copy including changes that are being made to the existing state plan.

The template includes the following sections:

- 1. General Description and Purpose of the Children's Health Insurance Plans and the Requirements- This section should describe how the State has designed their program. It also is the place in the template that a State updates to insert a short description and the proposed effective date of the SPA, and the proposed implementation date(s) if different from the effective date. (Section 2101); (42 CFR, 457.70)
- 2. General Background and Description of State Approach to Child Health Coverage and Coordination- This section should provide general information related to the special characteristics of each state's program. The information should include the extent and manner to which children in the State currently have creditable health coverage, current State efforts to provide or obtain creditable health coverage for uninsured children and how the plan is designed to be coordinated with current health insurance, public health efforts, or other enrollment initiatives. This information provides a health insurance baseline in terms of the status of the children in a given State and the State programs currently in place. (Section 2103); (42 CFR 457.410(A))
- 3. **Methods of Delivery and Utilization Controls** This section requires the State to specify its proposed method of delivery. If the State proposes to use managed care, the State must describe and attest to certain requirements of a managed care delivery system, including contracting standards; enrollee enrollment processes; enrollee notification and grievance processes; and plans for enrolling providers, among others. (Section 2103); (42 CFR Part 457. Subpart L)
- 4. Eligibility Standards and Methodology- The plan must include a description of the standards used to determine the eligibility of targeted low-income children for child health assistance under the plan. This section includes a list of potential eligibility standards the State can check off and provide a short description of how those standards will be applied. All eligibility standards must be consistent with the provisions of Title XXI and may not discriminate on the basis of diagnosis. In addition, if the standards vary within the state, the State should describe how they will be applied and under what circumstances they will be applied. In addition, this section provides information on income eligibility for Medicaid expansion programs (which are exempt from Section 4 of the State plan template) if applicable. (Section 2102(b)); (42 CFR 457.305 and 457.320)
- 5. **Outreach-** This section is designed for the State to fully explain its outreach activities. Outreach is defined in law as outreach to families of children likely to be eligible for child health assistance under the plan or under other public or private health coverage programs. The purpose is to inform these families of the availability of, and to assist them in enrolling their children in, such a program. (Section 2102(c)(1)); (42 CFR 457.90)
- 6. **Coverage Requirements for Children's Health Insurance** Regarding the required scope of health insurance coverage in a State plan, the child health assistance provided must consist of any of the four types of coverage outlined in Section 2103(a) (specifically, benchmark coverage; benchmark-equivalent coverage; existing comprehensive state-based coverage; and/or Secretary-approved coverage). In this section States identify the scope of coverage and benefits offered under the plan including the categories under which that coverage is offered. The amount, scope, and duration of each offered service should be fully explained, as well as any corresponding

limitations or exclusions. (Section 2103); (42 CFR 457.410(A))

- 7. **Quality and Appropriateness of Care** This section includes a description of the methods (including monitoring) to be used to assure the quality and appropriateness of care and to assure access to covered services. A variety of methods are available for State's use in monitoring and evaluating the quality and appropriateness of care in its child health assistance program. The section lists some of the methods which states may consider using. In addition to methods, there are a variety of tools available for State adaptation and use with this program. The section lists some of these tools. States also have the option to choose who will conduct these activities. As an alternative to using staff of the State agency administering the program, states have the option to contract out with other organizations for this quality of care function. (Section 2107); (42 CFR 457.495)
- 8. **Cost Sharing and Payment-** This section addresses the requirement of a State child health plan to include a description of its proposed cost sharing for enrollees. Cost sharing is the amount (if any) of premiums, deductibles, coinsurance and other cost sharing imposed. The cost-sharing requirements provide protection for lower income children, ban cost sharing for preventive services, address the limitations on premiums and cost-sharing and address the treatment of pre-existing medical conditions. (Section 2103(e)); (42 CFR 457, Subpart E)
- 9. Strategic Objectives and Performance Goals and Plan Administration- The section addresses the strategic objectives, the performance goals, and the performance measures the State has established for providing child health assistance to targeted low income children under the plan for maximizing health benefits coverage for other low income children and children generally in the state. (Section 2107); (42 CFR 457.710)
- 10. Annual Reports and Evaluations- Section 2108(a) requires the State to assess the operation of the Children's Health Insurance Program plan and submit to the Secretary an annual report which includes the progress made in reducing the number of uninsured low income children. The report is due by January 1, following the end of the Federal fiscal year and should cover that Federal Fiscal Year. In this section, states are asked to assure that they will comply with these requirements, indicated by checking the box. (Section 2108); (42 CFR 457.750)
- 11. **Program Integrity** In this section, the State assures that services are provided in an effective and efficient manner through free and open competition or through basing rates on other public and private rates that are actuarially sound. (Sections 2101(a) and 2107(e); (42 CFR 457, subpart I)
- 12. **Applicant and Enrollee Protections** This section addresses the review process for eligibility and enrollment matters, health services matters (i.e., grievances), and for states that use premium assistance a description of how it will assure that applicants and enrollees are given the opportunity at initial enrollment and at each redetermination of eligibility to obtain health benefits coverage other than through that group health plan. (Section 2101(a)); (42 CFR 457.1120)

Program Options. As mentioned above, the law allows States to expand coverage for children through a separate child health insurance program, through a Medicaid expansion program, or through a combination of these programs. These options are described further below:

- **Option to Create a Separate Program-** States may elect to establish a separate child health program that are in compliance with title XXI and applicable rules. These states must establish enrollment systems that are coordinated with Medicaid and other sources of health coverage for children and also must screen children during the application process to determine if they are eligible for Medicaid and, if they are, enroll these children promptly in Medicaid.
- **Option to Expand Medicaid-** States may elect to expand coverage through Medicaid. This option for states would be available for children who do not qualify for Medicaid under State rules in effect as of March 31, 1997. Under this option, current Medicaid rules would apply.

Medicaid Expansion- CHIP SPA Requirements

In order to expedite the SPA process, states choosing to expand coverage only through an expansion of Medicaid eligibility would be required to complete sections:

- 1 (General Description)
- 2 (General Background)

They will also be required to complete the appropriate program sections, including:

- 4 (Eligibility Standards and Methodology)
- 5 (Outreach)
- 9 (Strategic Objectives and Performance Goals and Plan Administration including the budget)
- 10 (Annual Reports and Evaluations).

Medicaid Expansion- Medicaid SPA Requirements

States expanding through Medicaid-only will also be required to submit a Medicaid State plan amendment to modify their Title XIX State plans. These states may complete the first check-off and indicate that the description of the requirements for these sections are incorporated by reference through their State Medicaid plans for sections:

- 3 (Methods of Delivery and Utilization Controls)
- 4 (Eligibility Standards and Methodology)
- 6 (Coverage Requirements for Children's Health Insurance)
- 7 (Quality and Appropriateness of Care)
- 8 (Cost Sharing and Payment)
- 11 (Program Integrity)
- 12 (Applicant and Enrollee Protections)
- **Combination of Options-** CHIP allows states to elect to use a combination of the Medicaid program and a separate child health program to increase health coverage for children. For example, a State may cover optional targeted-low income children in families with incomes of up to 133 percent of poverty through Medicaid and a targeted group of children above that level through a separate child health program. For the children the State chooses to cover under an expansion of Medicaid, the description provided under "Option to Expand Medicaid" would apply. Similarly, for children the

State chooses to cover under a separate program, the provisions outlined above in "Option to Create a Separate Program" would apply. States wishing to use a combination of approaches will be required to complete the Title XXI State plan and the necessary State plan amendment under Title XIX.

Where the state's assurance is requested in this document for compliance with a requirement of 42 CFR 457 et seq., the state shall place a check mark to affirm that it will comply no later than the applicable compliance date.

Proposed State plan amendments should be submitted electronically and one signed hard copy to the Centers for Medicare & Medicaid Services at the following address:

Name of Project Officer Centers for Medicare & Medicaid Services 7500 Security Blvd Baltimore, Maryland 21244 Attn: Children and Adults Health Programs Group Center for Medicaid and CHIP Services Mail Stop - S2-01-16

Section 1. <u>General Description and Purpose of the Children's Health Insurance Plans and the</u> <u>Requirements</u>

1.1.3. \square A combination of both of the above. (Section 2101(a)(2))

A. Background

Arkansas aggressively pursued health care for children by covering optional benefits and categories that benefit children. For example, Arkansas elected to provide the full range of EPSDT services to children without requiring the EPSDT screen. Also Arkansas was one of the first states in the nation to cover the TEFRA-134 children authorized by the Tax Equity and Fiscal Responsibility Act of 1982.

Effective 1-1-03, the State began covering TEFRA children in a TEFRA-like 1115(a) demonstration waiver in which the parents pay a premium based on a sliding scale; some parents are not required to pay a premium. The TEFRA-like demonstration waiver provides for the care of a child in his/her home, if he/she qualifies for Medicaid as a resident in a Title XIX institution, e.g., a nursing facility or an Intermediate Care Facility for the Mentally Retarded, etc. Parental income and resources are not counted in the child's eligibility determination. Before eligibility determination for the TEFRA-like demonstration waiver, the child must first be determined if he/she would meet Title XIX Medicaid eligibility. Parental income is counted in the premium amount calculation. The eligibility income limit for this demonstration waiver is three times the SSI limit. The TEFRA-like demonstration waiver makes Medicaid available to a large segment of the state's chronically ill children.

In its quest to provide health care for children, the State also opted to cover uninsured children through a Medicaid 1115(a) demonstration waiver, AR Kids First. This demonstration is discussed in item B, below.

CHIP Phase I, a Medicaid expansion, was approved August 6, 1998 and implemented October 1, 1998. This was a small CHIP Medicaid expansion in which the last of the eligible children aged-out of the program September 30, 2002. CHIP Phase II is a separate CHIP program that was approved February 16, 2001 but not implemented. Phase III superseded Phase II. Phase III covered some of the children in the State's 1115(a) demonstration waiver, ARKids-B, as an CHIP Medicaid expansion and the Unborn Child program as a separate child health program.

In 2013, on recommendation from CMS, the State made the decision to transition the ARKids-B program from an 1115(a)-demonstration waiver CHIP Medicaid expansion program to a separate child health program through the CHIP state plan. The Unborn

Child program has been in the CHIP state plan since 1-1-04 as a separate child health program, and the State continues to serve this population.

B. ARKids First Background and Development

In 1997, Arkansas' Governor, the Arkansas State legislature, the President and Congress were all addressing the issue of health care for vast numbers of uninsured children. Governor Mike Huckabee supported enabling state legislation and an appropriations bill in the 1997 legislative session that created and funded ARKids First, an 1115(a)-demonstration waiver. The Arkansas Legislature passed both bills and Governor Mike Huckabee signed both bills into law on March 10, 1997 Effective August 4, 2000, the 1115(a)-demonstration waiver was renamed ARKids-B.

Ray Hanley, then Director, Division of Medical Services (DMS), formed and chaired an ARKids First work group, composed of individuals from the Governor's Office (the Department of Human Services liaison), Arkansas Children's Hospital, Arkansas Department of Health, Catholic Social Services, Arkansas Advocates for Children and Families, Easter Seals, Communities in School of Arkansas, Arkansas Chapter for American Academy of Pediatrics, Electronic Data Systems (Arkansas Medicaid's then fiscal agent), and various individuals in the Department of Human Services (DHS), including Tom Dalton, then Department Director. The first meeting was held February 7, 1997, one day after President Clinton announced his FFY '98 budget package that included a proposal to expand health insurance access for poor children in families that earn too much for Medicaid but not enough to afford private health insurance. Additional ARKids First meetings were held as needed. Most of the discussion and concerns involved eligibility factors and the benefit package.

The Arkansas legislation, though not as detailed, mirrors the CHIP legislation in its purpose, i.e., to provide health insurance coverage for uninsured children under age 19 whose family income is at or below 200% of the poverty level. The ARKids First program was designed as a CHIP program, but used the 1115(a) demonstration waiver process for implementation, since the CHIP legislation had not been passed at the time Arkansas' program was under development. The ARKids First 1115(a) demonstration waiver was approved by CMS on August 19, 1997 and implemented on September 1, 1997; only days after the CHIP legislation was signed by the President.

Arkansas developed the ARKids First Program with the thought that it would be able to roll the ARKids First 1115 demonstration waiver into a CHIP program. However, the State recognized that as the ARKids First demonstration waiver and the CHIP legislation were developing, they didn't make completely parallel steps. Therefore, ARKids First enrollees, who did not meet the definition of a CHIP targeted low-income child, would continue to receive their health care services through Title XIX federal funding. Children in ARKids First who met the definition of a CHIP targeted low-income child would be able to receive their services through either Title XIX or Title XXI federal funding, at the discretion of the State. All of the ARKids First children would remain in the 1115(a) demonstration waiver regardless of the funding source. The children who did not meet the definition of a CHIP targeted low-income child were the children of state employees and the children who met the eligibility requirements for regular Title XIX Medicaid. In 2002, CMS instructed the State that parents or guardians of children who met eligibility for Title XIX Medicaid did not have the choice to have their children receive services through either Title XIX Medicaid or the Title XXI CHIP ARKids First 1115(a) demonstration waiver. Children found eligible for Title XIX Medicaid must receive services through the Title XIX Medicaid program. Effective August 4, 2000, the ARKids First program was separated into ARKids-A (regular children's Title XIX Medicaid program) and ARKids-B (1115(a) demonstration waiver Title XXI CHIP program), and ARKids First became an umbrella for these two programs.

The application form and the promotional materials for ARKids-A and ARKids-B identify the two programs as ARKids First. Applications may be made at the local DHS County Office, by mail, or through the internet, and a toll free number is available to clients. Applications in English or Spanish may be printed from the ARKids First website at www.arkidsfirst.com. Applications in other languages are available upon request.

C. ARKids-B Title XXI CHIP Separate Child Health Program

In November 2013, CMS recommended the State transition the ARKids-B 1115(a) demonstration waiver Title XXI CHIP Medicaid expansion program to a Title XXI CHIP separate child health program through the CHIP state plan and advised that if this was done, orthodontia services would have to be added to the ARKids-B program's benefit package of services. As the current ARKids-B 1115(a) demonstration waiver's renewal was due to end December 31, 2013, the State requested and CMS approved an extension of the ARKids-B demonstration waiver to allow the State time to prepare, submit, and have approved an amendment to the CHIP state plan.

Effective 1/1/14 ARKids-B beneficiaries ages 6 through 18 in families with incomes from 100% FPL up to 142% FPL were moved to Title XIX Medicaid ARKids-A (MAGI CHIP SPA Group 2/CS2 PDF page) but continue to be funded through title XXI CHIP.

Children ages 0 through age 18 in families with a household income above 142% FPL up to and including 211% FPL are eligible for ARKids-B. There is no asset test. The State maintains qualifying criteria for ARKids-B that includes income criteria based on modified adjusted gross income methodologies as defined at 42 CFR §435.603. As allowed under

42 CFR §457.805, all ARKids-B enrollees must not have had employer-sponsored or group health insurance within 90 days prior to program enrollment. The State maintains, at minimum, the required exemptions to the period of uninsurance as specified at 42 CFR §457.805. There is no presumptive eligibility. Retroactive eligibility may be determined up to three months prior to the date of application. ARKids-B offers a less comprehensive benefit package than the State's traditional Title XIX Medicaid program (ARKids-A) and requires co-payments.

The State elected a copayment as the only cost sharing requirement, because it is the most equitable form of cost sharing. The State did not want to assess an enrollment fee nor monthly premiums because it wanted the family's cost sharing responsibility to be related solely to usage. Cost sharing is required for services that are not categorized as well-health. The State will keep the current copayment structure in place for ARKids-B enrollees.

The benefit package includes inpatient and outpatient hospital services, physician surgical and medical services, laboratory and x-ray services, well-baby care, including age-appropriate immunizations. Enrollees in the ARKids-B are not eligible for the full range of Medicaid State Plan services. The ARKids-B schedule of benefits is outlined in the table in section 6.2. ARKids-B Program).

ARKids-B utilizes the same provider system as ARKids-A (regular children's Title XIX Medicaid) and operates under a primary care case management model. ARKids-B beneficiaries select or align with a primary care physician responsible for furnishing primary and preventive services and making medically necessary referrals. Enrollees are entitled to change their primary care physician selection at any time, without limitation. As part of the enrollment materials, enrollees are provided with information concerning their disenrollment rights.

The Division of Medical Services (DMS) and the Division of County Operations (DCO) are divisions of the Department of Human Services. DMS is responsible for the administration of the Medicaid and CHIP programs except for eligibility, which is the responsibility of DCO.

D. Overview of Unborn Child Title XXI CHIP Separate Child Health Program

The Arkansas Department of Human Services administers the CHIP Unborn Child program.

The essential elements of the program are:

- Medical verification of the pregnancy is required.
- Applicant must have no other insurance that covers the pregnancy.
- Statewide income standard is from zero up to 209% FPL
- There is no resource test for the Unborn Child program.
- The benefits (with the exception of sterilization or any other family planning services) will be the same as the SIXTH OMNIBUS BUDGET RECONCILIATION ACT (SOBRA) pregnant women category under Title XIX Medicaid and include only obstetrical services and treatment for conditions that may complicate or endanger the pregnancy. Benefits include:
 - Prenatal services
 - Delivery
 - Postpartum services (Postpartum coverage is through the end of the month in which the 60th day from the date of delivery falls. When one or more physicians in a group see the Unborn Child program beneficiary and at least two months of antepartum care were provided culminating in delivery or the beneficiary was continuously CHIP eligible for two or more months before delivery and on the delivery date, the global method of billing CHIP for postpartum services provided is used. When less than two months of antepartum care was provided to the Unborn Child program beneficiary or the beneficiary was not CHIP eligible for at least the last two months of the pregnancy, the antepartum/obstetrical care without delivery and the delivery and postpartum care can be billed to CHIP using the itemized billing method.)
- Services that are determined by the physician as medically necessary as, if not provided, could complicate or endanger the eligible Unborn Child program's beneficiary's pregnancy.

E. Healthy Smiles Dental Managed Care Program

The Arkansas Department of Human Services transitioned the Medicaid dental program to a prepaid ambulatory health plan (PAHP) on January 1, 2018. Two vendors were selected to provide state-wide dental benefits:

- a. Delta Dental
- b. Managed Care of North America (MCNA)

In early December 2017, all Arkansas Medicaid and CHIP beneficiaries who are eligible for dental benefits were randomly and evenly assigned to one of the two dental managed care plans. Each plan sent a welcome packet to each member and the members were able to access plan providers starting January 1, 2018, for covered dental services. Both dental vendors will provide the same dental services that were covered under the Medicaid and CHIP

fee-for-service program.

F. Provider Led Arkansas Shared Savings Entity (PASSE)-MCO Model of care for client with high behavioral health or developmental disabilities service needs.

Effective February 1, 2018, Arkansas included the ARKids-B Title XXI CHIP program beneficiaries as part of its overall 1915(b) waiver implementing a Provider-Led Arkansas Shared Savings Entity (PASSE) Program. As of May 6, 2019, approximately 2,598 children who participate in ARKids-B were also enrolled in a PASSE. More ARKids-B eligible children will be mandatorily enrolled in a PASSE if they are determined to be a Tier 2 or Tier 3 on the Arkansas Independent Assessment (ARIA) for behavioral health or developmental disabilities services.

The PASSE program is an innovative approach to organizing and managing the delivery of services for Medicaid beneficiaries with high behavioral health and developmental disability service needs. It was created by Act 775 of the 2017 Arkansas Regular Session, which was signed into law by Arkansas Governor, Asa Hutchinson, on March 31, 2017. Under this unique model of organized care, Arkansas provider-led and owned organizations, known Provider-Led Arkansas Shared Savings Entities (PASSEs), are responsible for integrating the physical health services, behavioral health services, and specialized developmental disability services for approximately 30,000 individuals who have intensive levels of treatment or care needs due to mental illness, substance abuse, or intellectual and developmental disability. These vulnerable Arkansans will benefit from the provision and continuity of all medically necessary services in a well-organized system of coordinated care.

The PASSE program was implemented in two phases. The first phase was a Primary Care Case Management (PCCM) model approved by CMS under 1915(b) authority. In Phase I, which began on February 1, 2018, the PASSEs provided care coordination to each member attributed to the PASSE, but medical services were still provided on a fee for service basis. The purpose of this phase was to allow the PASSEs time to build their infrastructure and become more familiar with the population they would be serving and their unique needs. During Phase I, members were "attributed" to a PASSE based on their previous provider relationships. In Phase I, there were four PASSEs licensed and providing care coordination.

For Phase II, which began on March 1, 2019, the began providing all services to members under a "full-risk" Medicaid Managed Care (MCO) model. In this phase, the PASSEs continue to provide care coordination to enrolled beneficiaries. Additionally, PASSEs are now responsible for development of each member's person-centered service plan (PCSP), as well as for the delivery of services. Only three PASSE's signed the Provider Agreement and moved into Phase II. Under Phase II, members are no longer attributed to a PASSE but are auto-assigned through a "round-robin" approach that assures equal distribution among the three PASSEs. Each PASSE signs a PASSE Provider Agreement (PA) that is renewed annually and will be held accountable for the requirements laid out in the PA during that year. Medicaid pays the PASSE an actuarially sound per member per month (PMPM) that must be used to cover all needed services for each of its members.

DHS has created a new Office of Innovation and Delivery System Reform (IDSR) which will provide monitoring and oversight of the services provided to PASSE members. The IDSR includes Beneficiary Support, which will provide guidance to beneficiaries on the PASSE system.

The State will be using the following system to deliver services:

MCO: Risk-comprehensive contracts are fully-capitated and require that the contractor be an MCO or HIO. Comprehensive means that the contractor is at risk for inpatient hospital services and any other mandatory State plan service in section 1905(a), or any three or more mandatory services in that section. References to MCOs generally apply to these risk-comprehensive entities.

1.1-DS 1.4.

Provide the effective (date costs begin to be incurred) and implementation (date services begin to be provided) dates for this SPA (42 CFR 457.65). A SPA may only have one effective date, but provisions within the SPA may have different implementation dates that must be after the effective date.

Original Plan

Effective Date: Medicaid Expansion (ARKids First Program) – Phase I: 10-1-98

Implementation Date: Medicaid Expansion (ARKids First Program) – Phase I: 10-1-98

<u>SPA #1, Purpose of SPA:</u> Separate State CHIP – Phase II_____ Proposed effective date: Not Implemented

Proposed implementation date: Not Implemented

SPA # 2, Purpose of SPA: Medicaid Expansion (ARKids-B Program) – Phase III

Effective Date: 1-1-01

Implementation Date: Implemented retroactively to 1-1-01

SPA # 3, Purpose of SPA: Separate State CHIP (Unborn Child Program) – Phase III

Effective Date: 7-1-04

Implementation Date: 7-1-04

SPA # 4, Purpose of SPA: To make technical changes to align Arkansas' CHIP state plan with current practice in the State---To delete the references to the ARKids-B opt-out provision & to clarify that Primary Care Case Management (PCCM) is now included in the HIFA ARHealthNetworks 1115(a) demonstration waiver.

Effective Date: 5-5-11

Implementation Date: 5-1-11

SPA # 5, Purpose of SPA: Add Poison Control & Drug Information Center Health Services

Initiative

Effective Date: 7-1-11

Implementation Date: 7-1-11 Superseding Pages of MAGI CHIP State Plan Material

Transmittal Number & Effective/Implementation Date	SPA Group	PDF Number	Description	Superseded Plan Section(s)
AR-13-0039 Effective/Implementation Date: 10/1/13	Eligibility Processing	CS24	Single, streamlined application, screening & enrollment process, renewals	Supersedes the current sections 4.3 & 4.4
AR-14-0015 Effective/Implementation Date: 8/1/15	MAGI Eligibility & Methods	CS13	Deemed newborn	Section 4.3
		CS7	Coverage of targeted low-income children	Sections 4.1.1; 4.1.2 & 4.1.3
		CS10	Coverage for children who have access to public employee coverage	Section 4.1.7
AR-13-0021 Effective/Implementation Date: 1/1/14	XXI Medicaid Expansion	CS3	Eligibility for Medicaid expansion program	Section 4.0
AR-13-0040 Effective/Implementation Date: 1/1/14	Establish 2101(f) groups	CS14	Children ineligible for Medicaid as a result of the elimination of income disregards	Incorporate within a separate subsection under section 4.1
AR-14-0042 Effective/Implementation Date: 1/1/14	Non- Financial Eligibility	CS17	Residency	Section 4.1.5

Superseding Pages of MAGI CHIP State Plan Material

	Transmittal Number & Effective/Implementation Date	SPA Group	PDF Number	Description	Superseded Plan Section(s)
ŀ	AR-14-0016	Non-Financial	CS18	Citizenship	Sections 4.1.0;

Effective/Implementation Date: 8/1/15	Eligibility			4.1-LR & 4.1.1- LR
		CS19	Social security number	Section 4.1.9.1
		CS20	Substitution of coverage	Section 4.4.4
		CS27	Continuous eligibility	Sections 4.1.8 & 4.1.9.2
AR-13-0022 Effective/Implementation Date: 1/1/14	MAGI Eligibility & Methods	CS9	Conception to Birth	Sections 4.1.1; 4.1.2 & 4.1.3
		CS15	MAGI-based income methodology	Incorporated within a separate subsection under Section 4.3
AR-17-0006 Effective/Implementation Date: 1/1/18	Non-Financial Eligibility	CS18	Citizenship	Supersedes previously approved CS18
AR-18-0003 Effective/Implementation Date: 1/1/18	Eligibility Processing	CS24	Change Arkansas to an Assessment State	Supersedes previously approved CS24

SPA # 6, Purpose of SPA: Separate State CHIP (ARKids-B Program)

Effective Date: 8-1-15

Implementation Date: 8-1-15

SPA # 7. Purpose of SPA: Add Intensive Home & Community-Based Family & Child/Youth Support Health Services Initiative

Effective Date: 11-1-16

Implementation Date: 11-1-16

SPA # 8, Purpose of SPA: Add Health & Well-Being Program for Maltreated Children Health

Services Initiative

Effective Date: 1-1-17

Implementation: 1-1-17

SPA #10, Purpose of SPA:

Provide information regarding the implementation of two new organized care models. The first is "Healthy Smiles," the Arkansas Dental Managed Care program authorized under 1915(b). The second is called the Provider-Led Arkansas Shared Savings Entities (PASSE) program. PASSE is authorized under a concurrent 1915(b)/1915(c) Waiver and 1915(i) State Plan Amendment. This amendment changes the service delivery system for dental services and for the beneficiaries going into the PASSE from fee-for-service to managed care.

Effective Date, Healthy Smiles: 7-1-18

Implementation, Health Smiles: 7-1-18

Effective Date, PASSE: -37-1-19

Implementation, PASSE: -73-1-19

Section 3. <u>Methods of Delivery and Utilization Controls</u>

- Check here if the State elects to use funds provided under Title XXI only to provide expanded eligibility under the State's Medicaid plan, and continue on to Section 4 (Eligibility Standards and Methodology).
- Guidance:In Section 3.1, describe all delivery methods the State will use to provide services to
enrollees, including: (1) contracts with managed care organizations (MCO), prepaid
inpatient health plans (PIHP), prepaid ambulatory health plans (PAHP), primary care
case management entities (PCCM entities), and primary care case managers (PCCM); (2)
contracts with indemnity health insurance plans; (3) fee-for-service (FFS) paid by the
State to health care providers; and (4) any other arrangements for health care delivery.
The State should describe any variations based upon geography and by population
(including the conception to birth population). States must submit the managed care
contract(s) to CMS' Regional Office for review.
- **3.1.** Delivery Systems (Section 2102(a)(4)) (42 CFR 457.490; Part 457, Subpart L)

3.1.1 Choice of Delivery System

- **3.1.1.1** Does the State use a managed care delivery system for its CHIP populations? Managed care entities include MCOs, PIHPs, PAHPs, PCCM entities and PCCMs as defined in 42 CFR 457.10. Please check the box and answer the questions below that apply to your State.
 - No, the State does not use a managed care delivery system for any CHIP populations.
 - Yes, the State uses a managed care delivery system for all CHIP populations.

All children enrolled in CHIP will be enrolled in Healthy Smiles.

Yes, the State uses a managed care delivery system; however, only some of the CHIP population is included in the managed care delivery system and some of the CHIP population is included in a fee-for-service system.

If the State uses a managed care delivery system for only some of its CHIP populations and a fee-for-service system for some of its CHIP populations, please describe which populations are, and which are not, included in the State's managed care delivery system for CHIP. States will be asked to specify which managed care entities are used by the State in its managed

care delivery system below in Section 3.1.2.

Children in the ARKids-B Title XXI CHIP Separate Child Health Program will receive all medically necessary services, except for those listed in 3.1.1.2, through a PASSE if they have been identified through the independent assessment as in need of behavioral health services or services for individuals with developmental or intellectual disabilities at a Tier II or Tier III level of need.

For individuals served by the Division of Behavioral Health:

- Tier II: Rehabilitative Level Services—At this level of need, services are provided in a counseling services setting, but the level of need requires a broader array of services to address functional deficits.
- Tier III: Intensive Level Services—Eligibility for this level of need will be identified by additional criteria, which could lead to placement in residential settings for more intensive delivery of services.

For individuals served by the Division of Developmental Disabilities Services:

- Tier II: Institutional Level of Care—The individual scored high enough in certain areas to be eligible for paid services and supports.
- <u>Tier III: Institutional Level of Care</u>—The individual scored high enough in certain areas to be eligible for the most intensive level of services, including 24 hours a day/7 days a week paid services and supports.
- Guidance:Utilization control systems are those administrative mechanisms that are
designed to ensure that enrollees receiving health care services under the
State plan receive only appropriate and medically necessary health care
consistent with the benefit package.

Examples of utilization control systems include, but are not limited to: requirements for referrals to specialty care; requirements that clinicians use clinical practice guidelines; or demand management systems (e.g., use of an 800 number for after-hours and urgent care). In addition, the State should describe its plans for review, coordination, and implementation of utilization controls, addressing both procedures and State developed standards for review, in order to assure that necessary care is delivered in a cost-effective and efficient manner. (42 CFR 457.490(b))

If the State <u>does not</u> use a managed care delivery system for any or some of its CHIP populations, describe the methods of delivery of the child health assistance using Title XXI funds to targeted low-income children. Include a description of:

- The methods for assuring delivery of the insurance products and delivery of health care services covered by such products to the enrollees, including any variations. (Section 2102(a)(4); 42 CFR 457.490(a))
- The utilization control systems designed to ensure that enrollees receiving health care services under the State plan receive only appropriate and medically necessary health care consistent with the benefit package described in the approved State plan. (Section 2102(a)(4); 42 CFR 457.490(b))
- Guidance:Only States that use a managed care delivery system for all or some CHIP
populations need to answer the remaining questions under Section 3
(starting with 3.1.1.2). If the State uses a managed care delivery system for
only some of its CHIP population, the State's responses to the following
questions will only apply to those populations.
- **3.1.1.2** Do any of your CHIP populations that receive services through a managed care delivery system receive any services outside of a managed care delivery system?

	No
N	

Yes

If yes, please describe which services are carved out of your managed care delivery system and how the State provides these services to an enrollee, such as through fee-for-service. Examples of carved out services may include transportation and dental, among others.

For children who are **not** enrolled in the PASSE, they will only receive dental services through the Healthy Smiles Dental Managed Care program. All other services will still be provided in the fee-for-service system.

For children who are enrolled in the PASSE, the following services are carved-out of the model:

- Nonemergency Medical Transportation
- Dental Benefits
- School-based services provided by school employees
- Services provided to residents of a human development center, a skilled nursing facility, or an assisted living facility
- <u>They are enrolled in ARChoices, Independent Choices, the 1915(c)</u> Autism Waiver, or any successor to these programs.

3.1.2 Use of a Managed Care Delivery System for All or Some of the State's CHIP Populations

- **3.1.2.1** Check each of the types of entities below that the State will contract with under its managed care delivery system, and select and/or explain the method(s) of payment that the State will use:
 - Managed care organization (MCO) (42 CFR 457.10)
 - Capitation payment Describe population served:

Those individuals who receive behavioral health and developmental disabilities services who are determined to meet the Tier II or Tier III level of need, unless they are residing in a Human Development Center, a skilled nursing facility, or an assisted living facility or they are enrolled in ARChoices, Independent Choices, the 1915(c) Autism Waiver, or a successor to one of these programs.

- Prepaid inpatient health plan (PIHP) (42 CFR 457.10)
 - Capitation payment
 - Other (please explain)
 - Describe population served:
- Guidance:If the State uses prepaid ambulatory health plan(s) (PAHP) to exclusively
provide non-emergency medical transportation (a NEMT PAHP), the State
should not check the following box for that plan. Instead, complete section
3.1.3 for the NEMT PAHP.

	Prepaid ambulatory health plan (PAHP) (42 CFR 457.10) Capitation payment Other (please explain) Describe population served: —<u>All children who are enrolled in CHIP will be mandatorily enrolled in the Healthy Smiles PAHP.</u>
	Primary care case manager (PCCM) (individual practitioners) (42 CFR 457.10) Case management fee Other (please explain)
	 Primary care case management entity (PCCM Entity) (42 CFR 457.10) Case management fee Shared savings, incentive payments, and/or other financial rewards for improved quality outcomes (see 42 CFR 457.1240(f)) Other (please explain)
fund	CCM entity is selected, please indicate which of the following ction(s) the entity will provide (as described in 42 CFR 457.10), in ition to PCCM services: Provision of intensive telephonic case management Provision of face-to-face case management Operation of a nurse triage advice line Development of enrollee care plans Execution of contracts with fee-for-service (FFS) providers in the FFS program Oversight responsibilities for the activities of FFS providers in the FFS program Provision of payments to FFS providers on behalf of the State Provision of enrollee outreach and education activities Operation of a customer service call center Review of provider claims, utilization and/or practice patterns to conduct provider profiling and/or practice improvement Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers Other (please describe)

3.1.2.2 The State assures that if its contract with an MCO, PAHP, or PIHP allows the entity to use a physician incentive plan, the contract stipulates that the entity must comply with the requirements set forth in 42 CFR 422.208 and 422.210. (42 CFR 457.1201(h), cross-referencing to 42 CFR 438.3(i))

3.1.3 Nonemergency Medical Transportation PAHPs

Guidance:Only complete Section 3.1.3 if the State uses a PAHP to exclusively provide non-
emergency medical transportation (a NEMT PAHP). If a NEMT PAHP is the
only managed care entity for CHIP in the State, please continue to Section 4 after
checking the assurance below. If the State uses a PAHP that does not exclusively
provide NEMT and/or uses other managed care entities beyond a NEMT PAHP,
the State will need to complete the remaining sections within Section 3.

The State assures that it complies with all requirements applicable to NEMT PAHPs, and through its contracts with such entities, requires NEMT PAHPs to comply with all applicable requirements, including the following (from 42 CFR 457.1206(b)):

- All contract provisions in 42 CFR 457.1201 except those set forth in 42 CFR 457.1201(h) (related to physician incentive plans) and 42 CFR 457.1201(l) (related to mental health parity).
- The information requirements in 42 CFR 457.1207 (see Section 3.5 below for more details).
- The provision against provider discrimination in 42 CFR 457.1208.
- The State responsibility provisions in 42 CFR 457.1212 (about disenrollment), 42 CFR 457.1214 (about conflict of interest safeguards), and 42 CFR 438.62(a), as cross-referenced in 42 CFR 457.1216 (about continued services to enrollees).
- The provisions on enrollee rights and protections in 42 CFR 457.1220, 457.1222, 457.1224, and 457.1226.
- The PAHP standards in 42 CFR 438.206(b)(1), as cross-referenced by 42 CFR 457.1230(a) (about availability of services), 42 CFR 457.1230(d) (about coverage and authorization of services), and 42 CFR 457.1233(a), (b) and (d) (about structure and operation standards).
- An enrollee's right to a State review under subpart K of 42 CFR 457.
- Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in 42 CFR 438.610, as cross referenced by 42 CFR 457.1285.
- Requirements relating to contracts involving Indians, Indian Health Care Providers, and Indian managed care entities in 42 CFR 457.1209.

3.2. General Managed Care Contract Provisions

- **3.2.1** The State assures that it provides for free and open competition, to the maximum extent practical, in the bidding of all procurement contracts for coverage or other services, including external quality review organizations, in accordance with the procurement requirements of 45 CFR part 75, as applicable. (42 CFR 457.940(b); 42 CFR 457.1250(a), cross referencing to 42 CFR 438.356(e))
- **3.2.2** The State assures that it will include provisions in all managed care contracts that define a sound and complete procurement contract, as required by 45 CFR part 75, as applicable. (42 CFR 457.940(c))
- 3.2.3 The State assures that each MCO, PIHP, PAHP, PCCM, and PCCM entity complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its employees and contract providers observe and protect those rights (42 CFR 457.1220, cross-referencing to 42 CFR 438.100). These Federal and State laws include: Title VI of the Civil Rights Act of 1964 (45 CFR part 80), Age Discrimination Act of 1975 (45 CFR part 91), Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, Titles II and III of the Americans with Disabilities Act, and section 1557 of the Patient Protection and Affordable Care Act.
- **3.2.4** The State assures that it operates a Web site that provides the MCO, PIHP, PAHP, and PCCM entity contracts. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(3))

3.3 Rate Development Standards and Medical Loss Ratio

3.3.1

- The State assures that its payment rates are:
 - Based on public or private payment rates for comparable services for comparable populations; and
 - Consistent with actuarially sound principles as defined in 42 CFR 457.10. (42 CFR 457.1203(a))

Guidance:States that checked both boxes under 3.3.1 above do not need to make the next
assurance. If the state is unable to check both boxes under 3.1.1 above, the state
must check the next assurance.

☐ If the State is unable to meet the requirements under 42 CFR 457.1203(a), the State attests that it must establish higher rates because such rates are necessary to ensure sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services. (42 CFR 457.1203(b))

3.3.2 🔀	The State assures that its rates are designed to reasonably achieve a medical loss ratio standard equal to at least 85 percent for the rate year and provide for reasonable administrative costs. (42 CFR 457.1203(c))
3.3.3 🔀	The State assures that it will provide to CMS, if requested by CMS, a description of the manner in which rates were developed in accordance with the requirements of 42 CFR 457.1203(a) through (c). (42 CFR 457.1203(d))
3.3.4 🔀	The State assures that it annually submits to CMS a summary description of the reports pertaining to the medical loss ratio received from the MCOs, PIHPs, and PAHPs. (42 CFR 457.1203(e), cross referencing to 42 CFR 438.74(a))
3.3.5	 Does the State require an MCO, PIHP, or PAHP to pay remittances through the contract for not meeting the minimum MLR required by the State? (42 CFR 457.1203(e), cross referencing to 42 CFR 438.74(b)(1)) No, the State does not require any MCO, PIHP, or PAHP to pay remittances. Yes, the State requires all MCOs, PIHPs, and PAHPs to pay remittances. Yes, the State requires some, but not all, MCOs, PIHPs, and PAHPs to pay remittances.

If the State requests some, but not all, MCOs, PIHPs, and PAHPs to pay remittances through the contract for not meeting the minimum MLR required by the State, please describe which types of managed care entities are and are not required to pay remittances. For example, if a state requires a medical MCO to pay a remittances but not a dental PAHP, please include this information.

If the answer to the assurance above is yes for any or all managed care entities, please answer the next assurance:

The State assures that it if a remittance is owed by an MCO, PIHP, or PAHP to the State, the State:

- Reimburses CMS for an amount equal to the Federal share of the remittance, taking into account applicable differences in the Federal matching rate; and
- Submits a separate report describing the methodology used to determine the State and Federal share of the remittance with the annual report provided to CMS that summarizes the reports received from the MCOs, PIHPs, and PAHPs. (42 CFR 457.1203(e), cross referencing to 42 CFR 438.74(b))

3.3.6 The State assures that each MCO, PIHP, and PAHP calculates and reports the medical loss ratio in accordance with 42 CFR 438.8. (42 CFR 457.1203(f))

3.4 Enrollment

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The State assures that its contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities provide that the MCO, PIHP, PAHP, PCCM or PCCM entity:

- Accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), up to the limits set under the contract (42 CFR 457.1201(d), cross-referencing to 42 CFR 438.3(d)(1));
- Will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll (42 CFR 457.1201(d), cross-referencing to 42 CFR 438.3(d)(3)); and
- Will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, national origin, sex, sexual orientation, gender identity or disability. (42 CFR 457.1201(d), cross-referencing to 438.3(d)(4))

3.4.1 Enrollment Process

- **3.4.1.1** The State assures that it provides informational notices to potential enrollees in an MCO, PIHP, PAHP, PCCM, or PCCM entity that includes the available managed care entities, explains how to select an entity, explains the implications of making or not making an active choice of an entity, explains the length of the enrollment period as well as the disenrollment policies, and complies with the information requirements in 42 CFR 457.1207 and accessibility standards established under 42 CFR 457.340. (42 CFR 457.1210(c))
- **3.4.1.2** The State assures that its enrollment system gives beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM, or PCCM entity does not have the capacity to accept all those seeking enrollment under the program. (42 CFR 457.1210(b))

If the State uses a default enrollment process, please make the following assurances:

The State assigns beneficiaries only to qualified MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities that are not subject to the intermediate sanction of having suspension of all new enrollment

(including default enrollment) under 42 CFR 438.702 and have capacity to enroll beneficiaries. (42 CFR 457.1210(a)(1)(i))

The State maximizes continuation of existing provider-beneficiary relationships under 42 CFR 457.1210(a)(1)(ii) or if that is not possible, distributes the beneficiaries equitably and does not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered. (42 CFR 457.1210(a)(1)(ii), 42 CFR 457.1210(a)(1)(iii))

3.4.2 Disenrollment

- **3.4.2.1** The State assures that the State will notify enrollees of their right to disenroll consistent with the requirements of 42 CFR 438.56 at least annually. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(f)(2))
- **3.4.2.2** The State assures that the effective date of an approved disenrollment, regardless of the procedure followed to request the disenrollment, will be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the request to the State. (42 CFR 457.1212, cross-referencing to 438.56(e)(1))
- **3.4.2.3** If a beneficiary disenrolls from an MCO, PIHP, PAHP, PCCM, or PCCM entity, the State assures that the beneficiary is provided the option to enroll in another plan or receive benefits from an alternative delivery system. (Section 2103(f)(3) of the Social Security Act, incorporating section 1932(a)(4); 42 CFR 457.1212, cross referencing to 42 CFR 438.56; State Health Official Letter #09-008)

3.4.2.4 MCO, PIHP, PAHP, PCCM and PCCM Entity Requests for Disenrollment.

- The State assures that contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities describe the reasons for which an MCO, PIHP, PAHP, PCCM and PCCM entity may request disenrollment of an enrollee, if any. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(b))
- Guidance:Reasons for disenrollment by the MCO, PIHP, PAHP, PCCM, and
PCCM entity must be specified in the contract with the State. Reasons
for disenrollment may not include an adverse change in the enrollee's
health status, or because of the enrollee's utilization of medical services,
diminished mental capacity, or uncooperative or disruptive behavior

resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees). (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(b)(2))

3.4.2.5 Enrollee Requests for Disenrollment.

Guidance:The State may also choose to limit disenrollment from the MCO, PIHP,
PAHP, PCCM, or PCCM entity, except for either: 1) for cause, at any
time; or 2) without cause during the latter of the 90 days after the
beneficiary's initial enrollment or the State sends the beneficiary notice of
that enrollment, at least once every 12 months, upon reenrollment if the
temporary loss of CHIP eligibility caused the beneficiary to miss the
annual disenrollment opportunity, or when the State imposes the
intermediate sanction specified in 42 CFR 438.702(a)(4). (42 CFR
457.1212, cross-referencing to 42 CFR 438.56(c))

Does the State limit disenrollment from an MCO, PIHP, PAHP, PCCM and PCCM entity by an enrollee? (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c))

- Yes
- No

If the State limits disenrollment by the enrollee from an MCO, PIHP, PAHP, PCCM and PCCM entity, please make the following assurances (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c)):

- The State assures that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(f)(1))
- The State assures that beneficiary requests to disenroll for cause will be permitted at any time by the MCO, PIHP, PAHP, PCCM or PCCM entity. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c)(1) and (d)(2))
- The State assures that beneficiary requests for disenrollment without cause will be permitted by the MCO, PIHP, PAHP, PCCM or PCCM entity at the following times:
 - During the 90 days following the date of the beneficiary's initial enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity, or during the 90 days following the date the State sends the beneficiary notice of that enrollment, whichever is later;
 - At least once every 12 months thereafter;

- If the State plan provides for automatic reenrollment for an individual who loses CHIP eligibility for a period of 2 months or less and the temporary loss of CHIP eligibility has caused the beneficiary to miss the annual disenrollment opportunity; and
- When the State imposes the intermediate sanction on the MCO, PIHP, PAHP, PCCM or PCCM entity specified in 42 CFR 438.702(a)(4). (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c)(2))
- **3.4.2.6** The State assures that the State ensures timely access to a State review for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(f)(2))

3.5 Information Requirements for Enrollees and Potential Enrollees

- **3.5.1** The State assures that it provides, or ensures its contracted MCOs, PAHPs, PIHPs, PCCMs and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of 42 CFR 457.1207, cross-referencing to 42 CFR 438.10.
- **3.5.2** \boxtimes The State assures that all required information provided to enrollees and potential enrollees are in a manner and format that may be easily understood and is readily accessible by such enrollees and potential enrollees. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(1))
- **3.5.3** The State assures that it operates a Web site that provides the content specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(g)-(i) either directly or by linking to individual MCO, PIHP, PAHP and PCCM entity Web sites.
- **3.5.4** \boxtimes The State assures that it has developed and requires each MCO, PIHP, PAHP and PCCM entity to use:
 - Definitions for the terms specified under 42 CFR 438.10(c)(4)(i), and
 - Model enrollee handbooks, and model enrollee notices. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(4))
- **3.5.5** If the State, MCOs, PIHPs, PAHPs, PCCMs or PCCM entities provide the information required under 42 CFR 457.1207 electronically, check this box to confirm that the State assures that it meets the requirements under 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(6) for providing the material in an accessible manner. Including that:
 - The format is readily accessible;
 - The information is placed in a location on the State, MCO's, PIHP's, PAHP's,

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or PCCM's, or PCCM entity's Web site that is prominent and readily accessible;

- The information is provided in an electronic form which can be electronically retained and printed;
- The information is consistent with the content and language requirements in 42 CFR 438.10; and
- The enrollee is informed that the information is available in paper form without charge upon request and is provided the information upon request within 5 business days.

3.5.6

The State assures that it meets the language and format requirements set forth in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(d), including but not limited to:

- Establishing a methodology that identifies the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area;
- Making oral interpretation available in all languages and written translation available in each prevalent non-English language;
- Requiring each MCO, PIHP, PAHP, and PCCM entity to make its written materials that are critical to obtaining services available in the prevalent non-English languages in its particular service area;
- Making interpretation services available to each potential enrollee and requiring each MCO, PIHP, PAHP, and PCCM entity to make those services available free of charge to each enrollee; and
- Notifying potential enrollees, and requiring each MCO, PIHP, PAHP, and PCCM entity to notify its enrollees:
 - That oral interpretation is available for any language and written translation is available in prevalent languages;
 - That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and
 - How to access the services in 42 CFR 457.1207, cross-referencing 42 CFR 438.10(d)(5)(i) and (ii).
- **3.5.7** The State assures that the State or its contracted representative provides the information specified in 42 CFR 457.1207, cross-referencing to 438.10(e)(2), and includes the information either in paper or electronic format, to all potential enrollees at the time the potential enrollee becomes eligible to enroll in a voluntary managed care program or is first required to enroll in a mandatory managed care program and within a timeframe that enables the potential enrollee to use the information to choose among the available MCOs, PIHPs, PAHPs, PCCMs and PCCM entities:
 - Information about the potential enrollee's right to disenroll consistent with the

requirements of 42 CFR 438.56 and which explains clearly the process for exercising this disenrollment right, as well as the alternatives available to the potential enrollee based on their specific circumstance;

- The basic features of managed care;
- Which populations are excluded from enrollment in managed care, subject to mandatory enrollment, or free to enroll voluntarily in the program;
- The service area covered by each MCO, PIHP, PAHP, PCCM, or PCCM entity;
- Covered benefits including:
 - Which benefits are provided by the MCO, PIHP, or PAHP; and which, if any, benefits are provided directly by the State; and
 - For a counseling or referral service that the MCO, PIHP, or PAHP does not cover because of moral or religious objections, where and how to obtain the service;
- The provider directory and formulary information required in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(h) and (i);
- Any cost-sharing for the enrollee that will be imposed by the MCO, PIHP, PAHP, PCCM, or PCCM entity consistent with those set forth in the State plan;
- The requirements for each MCO, PIHP or PAHP to provide adequate access to covered services, including the network adequacy standards established in 42 CFR 457.1218, cross-referencing 42 CFR 438.68;
- The MCO, PIHP, PAHP, PCCM and PCCM entity's responsibilities for coordination of enrollee care; and
- To the extent available, quality and performance indicators for each MCO, PIHP, PAHP and PCCM entity, including enrollee satisfaction.
- 3.5.8 🖂

The State assures that it will provide the information specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(f) to all enrollees of MCOs, PIHPs, PAHPs and PCCM entities, including that the State must notify all enrollees of their right to disenroll consistent with the requirements of 42 CFR 438.56 at least annually.

3.5.9 🔀

The State assures that each MCO, PIHP, PAHP and PCCM entity will provide the information specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(f) to all enrollees of MCOs, PIHPs, PAHPs and PCCM entities, including that:

- The MCO, PIHP, PAHP and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider within the timeframe specified in 42 CFR 438.10(f), and
- The MCO, PIHP, PAHP and, when appropriate, the PCCM entity must make available, upon request, any physician incentive plans in place as set forth in 42 CFR 438.3(i).

3.5.10

The State assures that each MCO, PIHP, PAHP and PCCM entity will provide enrollees of that MCO, PIHP, PAHP or PCCM entity an enrollee handbook that meets the requirements as applicable to the MCO, PIHP, PAHP and PCCM entity, specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(g)(1)-(2), within a reasonable time after receiving notice of the beneficiary's enrollment, by a method consistent with 42 CFR 438.10(g)(3), and including the following items:

- Information that enables the enrollee to understand how to effectively use the managed care program, which, at a minimum, must include:
 - Benefits provided by the MCO, PIHP, PAHP or PCCM entity;
 - How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided; and
 - In the case of a counseling or referral service that the MCO, PIHP, PAHP, or PCCM entity does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM entity must inform enrollees that the service is not covered by the MCO, PIHP, PAHP, or PCCM entity and how they can obtain information from the State about how to access these services;
- The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled;
- Procedures for obtaining benefits, including any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider;
- The extent to which, and how, after-hours and emergency coverage are provided, including:
 - What constitutes an emergency medical condition and emergency services;
 - The fact that prior authorization is not required for emergency services; and
 - The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care;
- Any restrictions on the enrollee's freedom of choice among network providers;
- The extent to which, and how, enrollees may obtain benefits, including family planning services and supplies from out-of-network providers;
- Cost sharing, if any is imposed under the State plan;
- Enrollee rights and responsibilities, including the elements specified in 42 CFR §438.100;
- The process of selecting and changing the enrollee's primary care provider;

- Grievance, appeal, and review procedures and timeframes, consistent with 42 CFR 457.1260, in a State-developed or State-approved description, including:
 - The right to file grievances and appeals;
 - The requirements and timeframes for filing a grievance or appeal;
 - The availability of assistance in the filing process; and
 - The right to request a State review after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee;
- How to access auxiliary aids and services, including additional information in alternative formats or languages;
- The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees; and
- Information on how to report suspected fraud or abuse.
- **3.5.11** The State assures that each MCO, PIHP, PAHP and PCCM entity will give each enrollee notice of any change that the State defines as significant in the information specified in the enrollee handbook at least 30 days before the intended effective date of the change. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(g)(4))
- **3.5.12** The State assures that each MCO, PIHP, PAHP and when appropriate, PCCM entity, will make available a provider directory for the MCO's, PIHP's, PAHP's or PCCM entity's network providers, including for physicians (including specialists), hospitals, pharmacies, and behavioral health providers, that includes information as specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(h)(1)-(2) and (4).
- **3.5.13** The State assures that each MCO, PIHP, PAHP and when appropriate, PCCM entity, will update any information included in a paper provider directory at least monthly and in an electronic provider directories as specified in 42 CFR 438.10(h)(3). (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(h)(3))
- **3.5.14** The State assures that each MCO, PIHP, PAHP and when appropriate, PCCM entity, will make available the MCO's, PIHP's, PAHP's, or PCCM entity's formulary that meets the requirements specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(i), including:
 - Which medications are covered (both generic and name brand); and
 - What tier each medication is on.

	3.5.15 🔀	The State assures that each MCO, PIHP, PAHP, PCCM and PCCM entity follows the requirements for marketing activities under 42 CFR 457.1224, cross-referencing to 42 CFR 438.104 (except 42 CFR 438.104(c)).
	Guidance:	Requirements for marketing activities include, but are not limited to, that the MCO, PIHP, PAHP, PCCM, or PCCM entity does not distribute any marketing materials without first obtaining State approval; distributes the materials to its entire service areas as indicated in the contract; does not seek to influence enrollment in conjunction with the sale or offering of any private insurance; and does not, directly or indirectly, engage in door-to-door, telephone, email, texting, or other cold-call marketing activities. (42 CFR 104(b))
	Guidance:	Only States with MCOs, PIHPs, or PAHPs need to answer the remaining assurances in Section 3.5 (3.5.16 through 3.5.18).
	3.5.16 🔀	The State assures that each MCO, PIHP and PAHP protects communications between providers and enrollees under 42 CFR 457.1222, cross-referencing to 42 CFR 438.102.
	3.5.17 🔀	The State assures that MCOs, PIHPs, and PAHPs have arrangements and procedures that prohibit the MCO, PIHP, and PAHP from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of the MCO, PAHP, or PIHP for the purpose of influencing the individual to enroll with the entity. (42 CFR 457.1280(b)(2))
	Guidance:	States should also complete Section 3.9, which includes additional provisions about the notice procedures for grievances and appeals.
	3.5.18 🔀	The State assures that each contracted MCO, PIHP, and PAHP comply with the notice requirements specified for grievances and appeals in accordance with the terms of 42 CFR 438, Subpart F, except that the terms of 42 CFR 438.420 do not apply and that references to reviews should be read to refer to reviews as described in 42 CFR 457, Subpart K. (42 CFR 457.1260)
3.6	Benef	its and Services
<u>Guidan</u>	ice: The St	tate should also complete Section 3.10 (Program Integrity).
	3.6.1 🔀	The State assures that MCO, PIHP, PAHP, PCCM entity, and PCCM contracts

involving Indians, Indian health care providers, and Indian managed care entities comply with the requirements of 42 CFR 438.14. (42 CFR 457.1209)

3.6.2 The State assures that all services covered under the State plan are available and accessible to enrollees. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206)

3.6.3 The State assure

The State assures that it:

- Publishes the State's network adequacy standards developed in accordance with 42 CFR 457.1218, cross-referencing 42 CFR 438.68(b)(1) on the Web site required by 42 CFR 438.10;
- Makes available, upon request, the State's network adequacy standards at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services. (42 CFR 457.1218, cross-referencing 42 CFR 438.68(e))
- <u>Guidance:</u> Only States with MCOs, PIHPs, or PAHPs need to complete the remaining assurances in Section 3.6 (3.6.4 through 3.6.20.
- **3.6.4** The State assures that each MCO, PAHP and PIHP meet the State's network adequacy standards. (42 CFR 457.1218, cross-referencing 42 CFR 438.68; 42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206)
- **3.6.5** The State assures that each MCO, PIHP, and PAHP includes within its network of credentialed providers:
 - A sufficient number of providers to provide adequate access to all services covered under the contract for all enrollees, including those with limited English proficiency or physical or mental disabilities;
 - Women's health specialists to provide direct access to covered care necessary to provide women's routine and preventative health care services for female enrollees; and
 - Family planning providers to ensure timely access to covered services. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206(b)
- **3.6.6** The State assures that each contract under 42 CFR 457.1201 permits an enrollee to choose his or her network provider. (42 CFR 457.1201(j), cross-referencing 42 CFR 438.3(l))
- **3.6.7** The State assures that each MCO, PIHP, and PAHP provides for a second opinion from a network provider, or arranges for the enrollee to obtain one outside the network, at no cost. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206(b)(3))
- **3.6.8** The State assures that each MCO, PIHP, and PAHP ensures that providers, in furnishing services to enrollees, provide timely access to care and services, including by:

- Requiring the contract to adequately and timely cover out-of-network services if the provider network is unable to provide necessary services covered under the contract to a particular enrollee and at a cost to the enrollee that is no greater than if the services were furnished within the network;
- Requiring the MCO, PIHP and PAHP meet and its network providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services;
- Ensuring that the hours of operation for a network provider are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid or CHIP Fee-For-Service, if the provider serves only Medicaid or CHIP enrollees;
- Ensuring that the MCO, PIHP and PAHP makes available services include in the contract on a 24 hours a day, 7 days a week basis when medically necessary;
- Establishing mechanisms to ensure compliance by network providers;
- Monitoring network providers regularly to determine compliance;
- Taking corrective action if there is a failure to comply by a network provider. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206(b)(4) and (5) and (c))
- **3.6.9** The State assures that each MCO, PIHP, and PAHP has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care. (42 CFR 457.1230(b), cross-referencing to 42 CFR 438.207)
- **3.6.10** The State assures that each MCO, PIHP, and PAHP will be required to submit documentation to the State, at the time of entering into a contract with the State, on an annual basis, and at any time there has been a significant change to the MCO, PIHP, or PAHP's operations that would affect the adequacy of capacity and services, to demonstrate that each MCO, PIHP, and PAHP for the anticipated number of enrollees for the service area:
 - Offers an appropriate range of preventative, primary care and specialty services; and
 - Maintains a provider network that is sufficient in number, mix, and geographic distribution. (42 CFR 457.1230, cross-referencing to 42 CFR 438.207(b))
- **3.6.11** Except that 42 CFR 438.210(a)(5) does not apply to CHIP, the State assures that its contracts with each MCO, PIHP, or PAHP comply with the coverage of services requirements under 42 CFR 438.210, including:
 - Identifying, defining, and specifying the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer; and

• Permitting an MCO, PIHP, or PAHP to place appropriate limits on a service. (42 CFR 457.1230(d), cross referencing to 42 CFR 438.210(a) except that 438.210(a)(5) does not apply to CHIP contracts)

3.6.12 Except that 438.210(b)(2)(iii) does not apply to CHIP, the State assures that its contracts with each MCO, PIHP, or PAHP comply with the authorization of services requirements under 42 CFR 438.210, including that:

- The MCO, PIHP, or PAHP and its subcontractors have in place and follow written policies and procedures;
- The MCO, PIHP, or PAHP have in place mechanisms to ensure consistent application of review criteria and consult with the requesting provider when appropriate; and
- Any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested be made by an individual with appropriate expertise in addressing the enrollee's medical, or behavioral health needs. (42 CFR 457.1230(d), cross referencing to 42 CFR 438.210(b), except that 438.210(b)(2)(iii) does not apply to CHIP contracts)
- **3.6.13** The State assures that its contracts with each MCO, PIHP, or PAHP require each MCO, PIHP, or PAHP to notify the requesting provider and given written notice to the enrollee of any adverse benefit determination to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. (42 CFR 457.1230(d), cross-referencing to 42 CFR 438.210(c))
- **3.6.14** The State assures that its contracts with each MCO, PIHP, or PAHP provide that compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee. (42 CFR 457.1230(d), cross-referencing to 42 CFR 438.210(e))
- **3.6.15** The State assures that it has a transition of care policy that meets the requirements of 438.62(b)(1) and requires that each contracted MCO, PIHP, and PAHP implements the policy. (42 CFR 457.1216, cross-referencing to 42 CFR 438.62)
- **3.6.16** The State assures that each MCO, PIHP, and PAHP has implemented procedures to deliver care to and coordinate services for all enrollees in accordance with 42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208, including:
 - Ensure that each enrollee has an ongoing source of care appropriate to his or her needs;
 - Ensure that each enrollee has a person or entity formally designated as primarily responsible for coordinating the services accessed by the

enrollee;

- Provide the enrollee with information on how to contract their designated person or entity responsible for the enrollee's coordination of services;
- Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee between settings of care; with services from any other MCO, PIHP, or PAHP; with fee-for-service services; and with the services the enrollee receives from community and social support providers;
- Make a best effort to conduct an initial screening of each enrollees needs within 90 days of the effective date of enrollment for all new enrollees;
- Share with the State or other MCOs, PIHPs, or PAHPs serving the enrollee the results of any identification and assessment of the enrollee's needs;
- Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards; and
- Ensure that each enrollee's privacy is protected in the process of coordinating care is protected with the requirements of 45 CFR parts 160 and 164 subparts A and E. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(b))
- Guidance:For assurances 3.6.17 through 3.6.20, applicability to PIHPs and PAHPs is based
a determination by the State in relation to the scope of the entity's services and on
the way the State has organized its delivery of managed care services, whether a
particular PIHP or PAHP is required to implement the mechanisms for
identifying, assessing, and producing a treatment plan for an individual with
special health care needs. (42 CFR 457.1230(c), cross-referencing to 42 CFR
438.208(a)(2))
- **3.6.17** The State assures that it has implemented mechanisms for identifying to MCOs, PIHPs, and PAHPs enrollees with special health care needs who are eligible for assessment and treatment services under 42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c) and included the mechanism in the State's quality strategy.
- **3.6.18** The State assures that each applicable MCO, PIHP, and PAHP implements the mechanisms to comprehensively assess each enrollee identified by the state as having special health care needs. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c)(2))

- **3.6.19** The State assures that each MCO, PIHP, and PAHP will produce a treatment or service plan that meets the following requirements for enrollees identified with special health care needs:
 - Is in accordance with applicable State quality assurance and utilization review standards;
 - Reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c)(3))
- **3.6.20** The State assures that each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist as appropriate for the enrollee's condition and identified needs for enrollees identified with special health care needs who need a course of treatment or regular care monitoring. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c)(4))

3.7 Operations

- **3.7.1** The State assures that it has established a uniform credentialing and recredentialing policy that addresses acute, primary, behavioral, and substance use disorders providers and requires each MCO, PIHP and PAHP to follow those policies. (42 CFR 457.1233(a), cross-referencing 42 CFR 438.214(b)(1))
- <u>Guidance:</u> Only States with MCOs, PIHPs, or PAHPs need to answer the remaining assurances in Section 3.7 (3.7.2 through 3.7.9).
- **3.7.2** The State assures each contracted MCO, PIHP and PAHP will comply with the provider selection requirements in 42 CFR 457.1208 and 457.1233(a), cross-referencing 42 CFR 438.12 and 438.214, including that:
 - Each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of network providers (42 CFR 457.1233(a), cross-referencing 42 CFR 438.214(a));
 - MCO, PIHP, and PAHP network provider selection policies and procedures do not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment (42 CFR 457.1233(a), cross-referencing 42 CFR 438.214(c));
 - MCOs, PIHPs, and PAHPs do not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification, solely on the basis of that license or certification (42 CFR 457.1208, cross referencing 42 CFR 438.12(a));
 - If an MCO, PIHP, or PAHP declines to include individual or groups of providers in the MCO, PIHP, or PAHP's provider network, the MCO, PIHP,

and PAHP gives the affected providers written notice of the reason for the decision (42 CFR 457.1208, cross referencing 42 CFR 438.12(a)); and

- MCOs, PIHPs, and PAHPs do not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act. (42 CFR 457.1233(a), crossreferencing 42 CFR 438.214(d)).
- **3.7.3** The State assures that each contracted MCO, PIHP, and PAHP complies with the subcontractual relationships and delegation requirements in 42 CFR 457.1233(b), cross-referencing 42 CFR 438.230, including that:
 - The MCO, PIHP, or PAHP maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the State;
 - All contracts or written arrangements between the MCO, PIHP, or PAHP and any subcontractor specify that all delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement, the subcontractor agrees to perform the delegated activities and reporting responsibilities specified in compliance with the MCO's, PIHP's, or PAHP's contract obligations, and the contract or written arrangement must either provide for revocation of the delegation of activities or obligations, or specify other remedies in instances where the State or the MCO, PIHP, or PAHP determine that the subcontractor has not performed satisfactorily;
 - All contracts or written arrangements between the MCO, PIHP, or PAHP and any subcontractor must specify that the subcontractor agrees to comply with all applicable CHIP laws, regulations, including applicable subregulatory guidance and contract provisions; and
 - The subcontractor agrees to the audit provisions in 438.230(c)(3).
- **3.7.4** The State assures that each contracted MCO and, when applicable, each PIHP and PAHP, adopts and disseminates practice guidelines that are based on valid and reliable clinical evidence or a consensus of providers in the particular field; consider the needs of the MCO's, PIHP's, or PAHP's enrollees; are adopted in consultation with network providers; and are reviewed and updated periodically as appropriate. (42 CFR 457.1233(c), cross referencing 42 CFR 438.236(b) and (c))
- **3.7.5** The State assures that each contracted MCO and, when applicable, each PIHP and PAHP makes decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the practice guidelines. (42 CFR 457.1233(c), cross referencing 42 CFR 438.236(d))

	3.7.6 🔀	The State assures that each contracted MCO, PIHP, and PAHP maintains a health information system that collects, analyzes, integrates, and reports data consistent with 42 CFR 438.242. The systems must provide information on areas including, but not limited to, utilization, claims, grievances and appeals, and disenrollments for other than loss of CHIP eligibility. (42 CFR 457.1233(d), cross referencing 42 CFR 438.242)
	3.7.7 🔀	The State assures that it reviews and validates the encounter data collected, maintained, and submitted to the State by the MCO, PIHP, or PAHP to ensure it is a complete and accurate representation of the services provided to the enrollees under the contract between the State and the MCO, PIHP, or PAHP and meets the requirements 42 CFR 438.242 of this section. (42 CFR 457.1233(d), cross referencing 42 CFR 438.242)
	3.7.8 🖂	The State assures that it will submit to CMS all encounter data collected, maintained, submitted to the State by the MCO, PIHP, and PAHP once the State has reviewed and validated the data based on the requirements of 42 CFR 438.242. (CMS State Medicaid Director Letter #13-004)
	3.7.9 🔀	The State assures that each contracted MCO, PIHP and PAHP complies with the privacy protections under 42 CFR 457.1110. (42 CFR 457.1233(e))
• •		
3.8	Benef	ficiary Protections
3.8	Benef 3.8.1 🔀	The State assures that each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the enrollee rights specified in 42 CFR 438.100. (42 CFR 457.1220, cross-referencing to 42 CFR 438.100(a)(1))
3.8		The State assures that each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the enrollee rights specified in 42 CFR 438.100. (42

arrangement that are in excess of the amount the enrollee would owe if the MCO, PIHP or PAHP covered the services directly. (42 CFR 457.1226, cross-referencing to 42 CFR 438.106(c))

3.9	Griev	vances and Appeals
	Guidance:	Only States with MCOs, PIHPs, or PAHPs need to complete Section 3.9. States with PCCMs and/or PCCM entities should be adhering to the State's review process for benefits.
	3.9.1	The State assures that each MCO, PIHP, and PAHP has a grievance and appeal system in place that allows enrollees to file a grievance and request an appeal. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c))
	3.9.2 🔀	The State assures that each MCO, PIHP, and PAHP has only one level of appeal for enrollees. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(b))
	3.9.3 🔀	The State assures that an enrollee may request a State review after receiving notice that the adverse benefit determination is upheld, or after an MCO, PIHP, or PAHP fails to adhere to the notice and timing requirements in 42 CFR 438.408. (42 CFR 457.1260, cross-referencing to 438.402(c))
	3.9.4.	Does the state offer and arrange for an external medical review? Yes No
	Guidance:	Only states that answered yes to assurance 3.9.4 need to complete the next assurance (3.9.5).
	3.9.5	 The State assures that the external medical review is: At the enrollee's option and not required before or used as a deterrent to proceeding to the State review; Independent of both the State and MCO, PIHP, or PAHP; Offered without any cost to the enrollee; and Not extending any of the timeframes specified in 42 CFR 438.408. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c)(1)(i))
	3.9.6 🔀	The State assures that an enrollee may file a grievance with the MCO, PIHP, or PAHP at any time. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and $438.402(c)(2)(i)$)
	3.9.7 🔀	The State assures that an enrollee has 60 calendar days from the date on an adverse benefit determination notice to file a request for an appeal to the MCO,

PIHP, or PAHP. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c)(2)(ii))

- **3.9.8** \square The State assures that an enrollee may file a grievance and request an appeal either orally or in writing. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c)(3)(i))
- **3.9.9** The State assures that each MCO, PIHP, and PAHP gives enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below in Section 3.9.10 and in 42 CFR 438.10.

3.9.10

- The State assures that the notice of an adverse benefit determination explains:
 - The adverse benefit determination.
 - The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.
 - The enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal and the right to request a State review.
 - The procedures for exercising the rights specified above under this assurance.
 - The circumstances under which an appeal process can be expedited and how to request it. (42 CFR 457.1260, cross-referencing to 42 CFR 438.404(b))
- **3.9.11** The State assures that the notice of an adverse benefit determination is provided in a timely manner in accordance with 42 CFR 457.1260. (42 CFR 457.1260, cross-referencing to 42 CFR 438.404(c))
- **3.9.12** The State assures that MCOs, PIHPs, and PAHPs give enrollees reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability. (42 CFR 457.1260, cross-referencing to 42 CFR 438.406(a))
- **3.9.13** The state makes the following assurances related to MCO, PIHP, and PAHP processes for handling enrollee grievances and appeals:
 - Individuals who make decisions on grievances and appeals were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

- Individuals who make decisions on grievances and appeals, if deciding any of the following, are individuals who have the appropriate clinical expertise in treating the enrollee's condition or disease:
 - An appeal of a denial that is based on lack of medical necessity.
 - A grievance regarding denial of expedited resolution of an appeal.
 - A grievance or appeal that involves clinical issues.
- All comments, documents, records, and other information submitted by the enrollee or their representative will be taken into account, without regard to whether such information was submitted or considered in the initial adverse benefit determination.
- Enrollees have a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments.
- Enrollees are provided the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the MCO, PIHP or PAHP (or at the direction of the MCO, PIHP or PAHP) in connection with the appeal of the adverse benefit determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals.
- The enrollee and his or her representative or the legal representative of a deceased enrollee's estate are included as parties to the appeal. (42 CFR 457.1260, cross-referencing to 42 CFR 438.406(b))
- **3.9.14** The State assures that standard grievances are resolved (including notice to the affected parties) within 90 calendar days from the day the MCO, PIHP, or PAHP receives the grievance. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(b))
- **3.9.15** The State assures that standard appeals are resolved (including notice to the affected parties) within 30 calendar days from the day the MCO, PIHP, or PAHP receives the appeal. The MCO, PIHP, or PAHP may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or the MCO, PIHP, or PAHP shows that there is need for additional information and that the delay is in the enrollee's interest. (42 CFR 457.1260, cross-referencing to 42 CFR 42 CFR 438.408(b) and (c))
- **3.9.16** The State assures that each MCO, PIHP, and PAHP establishes and maintains an expedited review process for appeals that is no longer than 72 hours after the MCO, PIHP, or PAHP receives the appeal. The expedited review process applies when the MCO, PIHP, or PAHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution

could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(b) and (c), and 42 CFR 438.410(a))

- **3.9.17** The State assures that if an MCO, PIHP, or PAHP denies a request for expedited resolution of an appeal, it transfers the appeal within the timeframe for standard resolution in accordance with 42 CFR 438.408(b)(2). (42 CFR 457.1260, cross-referencing to 42 CFR 438.410(c)(1))
- **3.9.18** The State assures that if the MCO, PIHP, or PAHP extends the timeframes for an appeal not at the request of the enrollee or it denies a request for an expedited resolution of an appeal, it completes all of the following:
 - Make reasonable efforts to give the enrollee prompt oral notice of the delay.
 - Within 2 calendar days give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision.
 - Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(c) and 42 CFR 438.410(c))
- **3.9.19** The State assures that if an MCO, PIHP, or PAHP fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process and the enrollee may initiate a State review. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(c)(3))
- **3.9.20** The State assures that has established a method that an MCO, PIHP, and PAHP will use to notify an enrollee of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at 42 CFR 438.10. (42 CFR 457.1260, cross referencing to 42 CFR 457.408(d)(1))
- **3.9.21** For all appeals, the State assures that each contracted MCO, PIHP, and PAHP provides written notice of resolution in a format and language that, at a minimum, meet the standards described at 42 CFR 438.10. The notice of resolution includes at least the following items:
 - The results of the resolution process and the date it was completed; and
 - For appeals not resolved wholly in favor of the enrollees:
 - The right to request a State review, and how to do so.
 - The right to request and receive benefits while the hearing is pending, and how to make the request.
 - That the enrollee may, consistent with State policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination. (42 CFR 457.1260, cross referencing to 42 CFR 457.408(d)(2)(i) and (e))

3.9.22 For notice of an expedited resolution, the State assures that each contracted MCO, PIHP, or PAHP makes reasonable efforts to provide oral notice, in addition to the written notice of resolution. (42 CFR 457.1260, cross referencing to 42 CFR 457.408(d)(2)(ii))

The State assures that if it offers an external medical review:

3.9.23

- The review is at the enrollee's option and is not required before or used as a deterrent to proceeding to the State review;
- The review is independent of both the State and MCO, PIHP, or PAHP; and
- The review is offered without any cost to the enrollee. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(f))
- **3.9.24** The State assures that MCOs, PIHPs, and PAHPs do not take punitive action against providers who request an expedited resolution or support an enrollee's appeal. (42 CFR 457.1260, cross-referencing to 42 CFR 438.410(b))
- **3.9.25** \boxtimes The State assures that MCOs, PIHPs, or PAHPs must provide information specified in 42 CFR 438.10(g)(2)(xi) about the grievance and appeal system to all providers and subcontractors at the time they enter into a contract. This includes:
 - The right to file grievances and appeals;
 - The requirements and timeframes for filing a grievance or appeal;
 - The availability of assistance in the filing process;
 - The right to request a State review after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee; and
 - The fact that, when requested by the enrollee, benefits that the MCO, PIHP, or PAHP seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State review within the timeframes specified for filing, and that the enrollee may, consistent with State policy, be required to pay the cost of services furnished while the appeal or State review is pending if the final decision is adverse to the enrollee. (42 CFR 457.1260, cross-referencing to 42 CFR 438.414)
- **3.9.26** The State assures that it requires MCOs, PIHPs, and PAHPs to maintain records of grievances and appeals and reviews the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy. The record must be accurately maintained in a manner accessible to the state and available upon request to CMS. (42 CFR 457.1260, cross-referencing to 42 CFR 438.416)
- **3.9.27** The State assures that if the MCO, PIHP, or PAHP, or the State review officer reverses a decision to deny, limit, or delay services that were not furnished while

the appeal was pending, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. (42 CFR 457.1260, cross-referencing to 42 CFR 438.424(a))

3.10 Program Integrity

- Guidance: The State should complete Section 11 (Program Integrity) in addition to Section 3.10.
- <u>Guidance:</u> Only States with MCOs, PIHPs, or PAHPs need to answer the first seven assurances (3.10.1 through 3.10.7).
 - **3.10.1** The State assures that any entity seeking to contract as an MCO, PIHP, or PAHP under a separate child health program has administrative and management arrangements or procedures designed to safeguard against fraud and abuse, including:
 - Enforcing MCO, PIHP, and PAHP compliance with all applicable Federal and State statutes, regulations, and standards;
 - Prohibiting MCOs, PIHPs, or PAHPs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of the MCO, PAHP, or PIHP for the purpose of influencing the individual to enroll with the entity; and
 - Including a mechanism for MCOs, PIHPs, and PAHPs to report to the State, to CMS, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors, providers, or enrollees of an MCO, PIHP, or PAHP and other individuals. (42 CFR 457.1280)
 - **3.10.2** The State assures that it has in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or enrollment processes described in 42 CFR 457.1210(a). (42 CFR 457.1214, cross referencing 42 CFR 438.58)
 - **3.10.3** The State assures that it periodically, but no less frequently than once every 3 years, conducts, or contracts for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP or PAHP. (42 CFR 457.1285, cross referencing 42 CFR 438.602(e))
 - **3.10.4** The State assures that it requires MCOs, PIHPs, PAHP, and or subcontractors (only to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims) implement and

maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:

- A compliance program that include all of the elements described in 42 CFR 438.608(a)(1);
- Provision for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State;
- Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility;
- Provision for notification to the State when it receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the MCO, PIHP or PAHP;
- Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis;
- In the case of MCOs, PIHPs, or PAHPs that make or receive annual payments under the contract of at least \$5,000,000, provision for written policies for all employees of the entity, and of any contractor or agent, that provide detailed information about the False Claims Act and other Federal and State laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers;
- Provision for the prompt referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid/CHIP program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit; and
- Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the State determines there is a credible allegation of fraud in accordance with 42 CFR 455.23. (42 CFR 457.1285, cross referencing 42 CFR 438.608(a))
- **3.10.5** The State assures that each MCO, PIHP, or PAHP requires and has a mechanism for a network provider to report to the MCO, PIHP or PAHP when it has received an overpayment, to return the overpayment to the MCO, PIHP or PAHP within 60 calendar days after the date on which the overpayment was identified, and to notify the MCO, PIHP or PAHP in writing of the reason for the overpayment. (42 CFR 457.1285, cross referencing 42 CFR 438.608(d)(2))

- **3.10.6** The State assures that each MCO, PIHP, or PAHP reports annually to the State on their recoveries of overpayments. (42 CFR 457.1285, cross referencing 42 CFR 438.608(d)(3))
- **3.10.7** The State assures that it screens and enrolls, and periodically revalidates, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E. This requirement also extends to PCCMs and PCCM entities to the extent that the primary care case manager is not otherwise enrolled with the State to provide services to fee-for-service beneficiaries. (42 CFR 457.1285, cross referencing 42 CFR 438.602(b)(1) and 438.608(b))
- **3.10.8** The State assures that it reviews the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM or PCCM entity, and any subcontractors. (42 CFR 457.1285, cross referencing 42 CFR 438.602(c))
- **3.10.9** The State assures that it confirms the identity and determines the exclusion status of the MCO, PIHP, PAHP, PCCM or PCCM entity, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the MCO, PIHP, PAHP, PCCM or PCCM entity through routine checks of Federal databases. If the State finds a party that is excluded, the State promptly notifies the MCO, PIHP, PAHP, PCCM, or PCCM entity and takes action consistent with 42 CFR 438.610(c). (42 CFR 457.1285, cross referencing 42 CFR 438.602(d))
- **3.10.10** The State assures that it receives and investigates information from whistleblowers relating to the integrity of the MCO, PIHP, PAHP, PCCM, or PCCM entity, subcontractors, or network providers receiving Federal funds under this part. (42 CFR 457.1285, cross referencing 42 CFR 438.602(f))
- 3.10.11 The State assures that MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities with which the State contracts are not located outside of the United States and that no claims paid by an MCO, PIHP, or PAHP to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates. (42 CFR 457.1285, cross referencing to 42 CFR 438.602(i); Section 1902(a) (80) of the Social Security Act)
- **3.10.12**The State assures that MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities submit
to the State the following data, documentation, and information:
Encounter data in the form and manner described in 42 CFR 438.818.

- Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in 42 CFR 438.8.
- Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under 42 CFR 438.116.
- Documentation described in 42 CFR 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in 42 CFR 438.206.
- Information on ownership and control described in 42 CFR 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by 42 CFR 438.230.
- The annual report of overpayment recoveries as required in 42 CFR 438.608(d)(3). (42 CFR 457.1285, cross referencing 42 CFR 438.604(a))
- **3.10.13** The State assures that:
 - It requires that the data, documentation, or information submitted in accordance with 42 CFR 457.1285, cross referencing 42 CFR 438.604(a), is certified in a manner that the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's Chief Executive Officer or Chief Financial Officer is ultimately responsible for the certification. (42 CFR 457.1285, cross referencing 42 CFR 438.606(a))
 - It requires that the certification includes an attestation that, based on best information, knowledge, and belief, the data, documentation, and information specified in 42 CFR 438.604 are accurate, complete, and truthful. (42 CFR 457.1285, cross referencing 42 CFR 438.606(b)); and
 - It requires the MCO, PIHP, PAHP, PCCM, or PCCM entity to submit the certification concurrently with the submission of the data, documentation, or information required in 42 CFR 438.604(a) and (b). (42 CFR 457.1285, cross referencing 42 CFR 438.604(c))
- **3.10.14** The State assures that each MCO, PIHP, PAHP, PCCM, PCCM entity, and any subcontractors provides: written disclosure of any prohibited affiliation under 42 CFR 438.610, written disclosure of and information on ownership and control required under 42 CFR 455.104, and reports to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the contract. (42 CFR 457.1285, cross referencing 42 CFR 438.608(c))
- **3.10.15** \boxtimes The State assures that services are provided in an effective and efficient manner. (Section 2101(a))

3.10.16 The State assures that it operates a Web site that provides:

- The documentation on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services;
- Information on ownership and control of MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors; and
- The results of any audits conducted under 42 CFR 438.602(e). (42 CFR 457.1285, cross-referencing to 42 CFR 438.602(g)).

3.11 Sanctions

Guidance: Only States with MCOs need to answer the next three assurances (3.11.1 through 3.11.3).

Intermediate sanctions are defined at 42 CFR 438.702(a)(4) as: (1) Civil money penalties; (2) Appointment of temporary management (for an MCO); (3) Granting enrollees the right to terminate enrollment without cause; (4) Suspension of all new enrollment; and (5) Suspension of payment for beneficiaries.

- **3.11.1** The State assures that it has established intermediate sanctions that it may impose if it makes the determination that an MCO has acted or failed to act in a manner specified in 438.700(b)-(d). (42 CFR 457.1270, cross referencing 42 CFR 438.700)
- **3.11.2** The State assures that it will impose temporary management if it finds that an MCO has repeatedly failed to meet substantive requirements of part 457 subpart L. (42 CFR 457.1270, cross referencing 42 CFR 438.706(b))
- **3.11.3** The State assures that if it imposes temporary management on an MCO, the State allows enrollees the right to terminate enrollment without cause and notifies the affected enrollees of their right to terminate enrollment. (42 CFR 457.1270, cross referencing 42 CFR 438.706(b))
- <u>Guidance:</u> Only states with PCCMs, or PCCM entities need to answer the next assurance (3.11.4).
- <u>Guidance:</u> Only states with MCOs and states that answered yes to assurance 3.11.4 need to complete the next three assurances (3.11.5 through 3.11.7).

- **3.11.5** The State assures that before it imposes intermediate sanctions, it gives the affected entity timely written notice. (42 CFR 457.1270, cross referencing 42 CFR 438.710(a))
- **3.11.6** The State assures that if it intends to terminate an MCO, PCCM, or PCCM entity, it provides a pre-termination hearing and written notice of the decision as specified in 42 CFR 438.710(b). If the decision to terminate is affirmed, the State assures that it gives enrollees of the MCO, PCCM or PCCM entity notice of the termination and information, consistent with 42 CFR 438.10, on their options for receiving CHIP services following the effective date of termination. (42 CFR 457.1270, cross referencing 42 CFR 438.710(b))
- **3.11.7** X The State assures that it will give CMS written notice that complies with 42 CFR 438.724 whenever it imposes or lifts a sanction for one of the violations listed in 42 CFR 438.700. (42 CFR 457.1270, cross referencing 42 CFR 438.724)

3.12 Quality Measurement and Improvement; External Quality Review

- Guidance:The State should complete Sections 7 (Quality and Appropriateness of Care) and 9(Strategic Objectives and Performance Goals and Plan Administration) in addition to
Section 3.12.
- Guidance:States with MCO(s), PIHP(s), PAHP(s), or certain PCCM entity/ies (PCCM entities
whose contract with the State provides for shared savings, incentive payments or other
financial reward for improved quality outcomes see 42 CFR 457.1240(f)) should
complete the applicable sub-sections for each entity type in this section, regarding 42
CFR 457.1240 and 1250.

3.12.1 Quality Strategy

- <u>Guidance:</u> All states with MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities need to complete section 3.12.1.
- **3.12.1.1** The State assures that it will draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished CHIP enrollees as described in 42 CFR 438.340(a). The quality strategy must include the following items:
 - The State-defined network adequacy and availability of services standards for MCOs, PIHPs, and PAHPs required by 42 CFR 438.68 and 438.206 and examples of Evidence-based clinical practice guidelines the State requires in accordance with 42 CFR 438.236;
 - A description of:
 - The quality metrics and performance targets to be used in

measuring the performance and improvement of each MCO, PIHP, and PAHP with which the State contracts, including but not limited to, the performance measures reported in accordance with 42 CFR 438.330(c); and

- The performance improvement projects to be implemented in accordance with 42 CFR 438.330(d), including a description of any interventions the State proposes to improve access, quality, or timeliness of care for beneficiaries enrolled in an MCO, PIHP, or PAHP;
- Arrangements for annual, external independent reviews, in accordance with 42 CFR 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each contract;
- A description of the State's transition of care policy required under 42 CFR 438.62(b)(3);
- The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, and primary language;
- For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of 42 CFR Part 438;
- A description of how the State will assess the performance and quality outcomes achieved by each PCCM entity;
- The mechanisms implemented by the State to comply with 42 CFR 438.208(c)(1) (relating to the identification of persons with special health care needs);
- Identification of the external quality review (EQR)-related activities for which the State has exercised the option under 42 CFR 438.360 (relating to nonduplication of EQR-related activities), and explain the rationale for the State's determination that the private accreditation activity is comparable to such EQR-related activities;
- Identification of which quality measures and performance outcomes the State will publish at least annually on the Web site required under 42 CFR 438.10(c)(3); and
- The State's definition of a "significant change" for the purposes of updating the quality strategy under 42 CFR 438.340(c)(3)(ii). (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(b))
- **3.12.1.2** The State assures that the goals and objectives for continuous quality improvement in the quality strategy are measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, and PAHP. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(b)(2))

- **3.12.1.3** The State assures that for purposes of the quality strategy, the State provides the demographic information for each CHIP enrollee to the MCO, PIHP or PAHP at the time of enrollment. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(b)(6))
- **3.12.1.4** The State assures that it will review and update the quality strategy as needed, but no less than once every 3 years. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(2))
- **3.12.1.5** The State assures that its review and updates to the quality strategy will include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years and the recommendations provided pursuant to 42 CFR 438.364(a)(4). (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(2)(i) and (iii).
- **3.12.1.6** \boxtimes The State assures that it will submit to CMS:
 - A copy of the initial quality strategy for CMS comment and feedback prior to adopting it in final; and
 - A copy of the revised strategy whenever significant changes are made to the document, or whenever significant changes occur within the State's CHIP program, including after the review and update required every 3 years. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(3))
- **3.12.1.7** Before submitting the strategy to CMS for review, the State assures that when it drafts or revises the State's quality strategy it will:
 - Make the strategy available for public comment; and
 - If the State enrolls Indians in the MCO, PIHP, or PAHP, consult with Tribes in accordance with the State's Tribal consultation policy. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(1))
- **3.12.1.8** The State assures that it makes the results of the review of the quality strategy (including the effectiveness evaluation) and the final quality strategy available on the Web site required under 42 CFR 438.10(c)(3). (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(2)(ii) and (d))

3.12.2 Quality Assessment and Performance Improvement Program

3.12.2.1 Quality Assessment and Performance Improvement Program: Measures and Projects

<u>Guidance:</u> Only states with MCOs, PIHPs, or PAHPs need to complete the next two assurances (3.12.2.1.1 and 3.12.2.1.2).

- **3.12.2.1.1** The State assures that it requires that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees as provided in 42 CFR 438.330, except that the terms of 42 CFR 438.330(d)(4) (related to dual eligibles) do not apply. The elements of the assessment and program include at least:
 - Standard performance measures specified by the State;
 - Any measures and programs required by CMS (42 CFR 438.330(a)(2);
 - Performance improvement projects that focus on clinical and non-clinical areas, as specified in 42 CFR 438.330(d);
 - Collection and submission of performance measurement data in accordance with 42 CFR 438.330(c);
 - Mechanisms to detect both underutilization and overutilization of services; and
 - Mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the State in the quality strategy under 42 CFR 457.1240(e) and Section 3.12.1 of this template). (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(b) and (c)(1))
- Guidance:A State may request an exemption from including the
performance measures or performance improvement programs
established by CMS under 42 CFR 438.330(a)(2), by submitting a
written request to CMS explaining the basis for such request.
- **3.12.2.1.2** The State assures that each MCO, PIHP, and PAHP's performance improvement projects are designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction. The performance improvement projects include at least the following elements:
 - Measurement of performance using objective quality indicators;
 - Implementation of interventions to achieve improvement in the access to and quality of care;
 - Evaluation of the effectiveness of the interventions based on the performance measures specified in 42 CFR 438.330(d)(2)(i); and

- Planning and initiation of activities for increasing or sustaining improvement. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(d)(2))
- Guidance:Only states with a PCCM entity whose contract with the Stateprovides for shared savings, incentive payments or other financialreward for improved quality outcomes need to, complete the nextassurance (3.12.2.1.3).
- **3.12.2.1.3** The State assures that it requires that each PCCM entity establishes and implements an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees as provided in 42 CFR 438.330, except that the terms of 42 CFR 438.330(d)(4) (related to dual eligibles) do not apply. The assessment and program must include:
 - Standard performance measures specified by the State;
 - Mechanisms to detect both underutilization and overutilization of services; and
 - Collection and submission of performance measurement data in accordance with 42 CFR 438.330(c). (42 CFR 457.1240(a) and (b), cross referencing to 42 CFR 438.330(b)(3) and (c))

3.12.2.2 Quality Assessment and Performance Improvement Program: Reporting and Effectiveness

- Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete Section 3.12.2.2.
- **3.12.2.2.1** The State assures that each MCO, PIHP, and PAHP reports on the status and results of each performance improvement project conducted by the MCO, PIHP, and PAHP to the State as required by the State, but not less than once per year. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(d)(3))
- **3.12.2.2.2** The State assures that it annually requires each MCO, PIHP, and PAHP to:

1) Measure and report to the State on its performance using the standard measures required by the State;

2) Submit to the State data specified by the State to calculate the MCO's, PIHP's, or PAHP's performance using the standard measures identified by the State; or

3) Perform a combination of options (1) and (2) of this assurance. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(c)(2))

- **3.12.2.3** The State assures that the State reviews, at least annually, the impact and effectiveness of the quality assessment and performance improvement program of each MCO, PIHP, PAHP and PCCM entity. The State's review must include:
 - The MCO's, PIHP's, PAHP's, and PCCM entity's performance on the measures on which it is required to report; and
 - The outcomes and trended results of each MCO's, PIHP's, and PAHP's performance improvement projects. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(e)(1))

3.12.3 Accreditation

- Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete Section 3.12.3.
- 3.12.3.1 The State assures that it requires each MCO, PIHP, and PAHP to inform the state whether it has been accredited by a private independent accrediting entity, and, if the MCO, PIHP, or PAHP has received accreditation by a private independent accrediting agency, that the MCO, PIHP, and PAHP authorizes the private independent accrediting entity to provide the State a copy of its recent accreditation review that includes the MCO, PIHP, and PAHP's accreditation status, survey type, and level (as applicable); accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings; and expiration date of the accreditation. (42 CFR 457.1240(c), cross referencing to 42 CFR 438.332(a) and (b)).
- **3.12.3.2** The State assures that it will make the accreditation status for each contracted MCO, PIHP, and PAHP available on the Web site required under 42 CFR 438.10(c)(3), including whether each MCO, PIHP, and PAHP has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level; and update this information at least annually. (42 CFR 457.1240(c), cross referencing to 42 CFR 438.332(c))

3.12.4 Quality Rating

Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete Section 3.12.4.

The State assures that it will implement and operate a quality rating system that issues an annual quality rating for each MCO, PIHP, and PAHP, which the State will prominently display on the Web site required under 42 CFR 438.10(c)(3), in accordance with the requirements set forth in 42 CFR 438.334. (42 CFR 457.1240(d))

Guidance:States will be required to comply with this assurance within 3 years after CMS, in
consultation with States and other Stakeholders and after providing public notice
and opportunity for comment, has identified performance measures and a
methodology for a Medicaid and CHIP managed care quality rating system in the
Federal Register.

3.12.5 Quality Review

<u>Guidance:</u> All states with MCOs, PIHPs, PAHPs, PCCMs or PCCM entities need to complete Sections 3.12.5 and 3.12.5.1.

The State assures that each contract with a MCO, PIHP, PAHP, or PCCM entity requires that a qualified EQRO performs an annual external quality review (EQR) for each contracting MCO, PIHP, PAHP or PCCM entity, except as provided in 42 CFR 438.362. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.350(a))

3.12.5.1 External Quality Review Organization

- **3.12.5.1.1** The State assures that it contracts with at least one external quality review organization (EQRO) to conduct either EQR alone or EQR and other EQR-related activities. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.356(a))
- **3.12.5.1.2** The State assures that any EQRO used by the State to comply with 42 CFR 457.1250 must meet the competence and independence requirements of 42 CFR 438.354 and, if the EQRO uses subcontractors, that the EQRO is accountable for and oversees all subcontractor functions. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.354 and 42 CFR 438.356(b) through (d))

3.12.5.2 External Quality Review-Related Activities

Guidance:Only states with MCOs, PIHPs, or PAHPs need to complete the next three
assurances (3.12.5.2.1 through 3.12.5.2.3). Under 42 CFR 457.1250(a),
the State, or its agent or EQRO, must conduct the EQR-related activity
under 42 CFR 438.358(b)(1)(iv) regarding validation of the MCO, PIHP,
or PAHP's network adequacy during the preceding 12 months; however,
the State may permit its contracted MCO, PIHP, and PAHPs to use
information from a private accreditation review in lieu of any or all the
EQR-related activities under 42 CFR 438.358(b)(1)(i) through (iii)
(relating to the validation of performance improvement projects,
validation of performance measures, and compliance review).

- 3.12.5.2.1 The State assures that the mandatory EQR-related activities described in 42 CFR 438.358(b)(1)(i) through (iv) (relating to the validation of performance improvement projects, validation of performance measures, compliance review, and validation of network adequacy) will be conducted on all MCOs, PIHPs, or PAHPs. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.358(b)(1))
- 3.12.5.2.2 The State assures that if it elects to use nonduplication for any or all of the three mandatory EQR-related activities described at 42 CFR 438.358(b)(1)(i) – (iii), the State will document the use of nonduplication in the State's quality strategy. (42 CFR 457.1250(a), cross referencing 438.360, 438.358(b)(1)(i) through (b)(1)(iii), and 438.340)
- 3.12.5.2.3 The State assures that if the State elects to use nonduplication for any or all of the three mandatory EQR-related activities described at 42 CFR 438.358(b)(1)(i) – (iii), the State will ensure that all information from a Medicare or private accreditation review for an MCO, PIHP, or PAHP will be furnished to the EQRO for analysis and inclusion in the EQR technical report described in 42 CFR 438.364. ((42 CFR 457.1250(a), cross referencing to 42 CFR 438.360(b))
- Guidance: Only states with PCCM entities need to complete the next assurance (3.12.5.2.4).
- **3.12.5.2.4** The State assures that the mandatory EQR-related activities described in 42 CFR 438.358(b)(2) (cross-referencing 42 CFR 438.358(b)(1)(ii) and (b)(1)(iii)) will be conducted on all PCCM entities, which include:
 - Validation of PCCM entity performance measures required in accordance with 42 CFR 438.330(b)(2) or PCCM entity performance measures calculated by the State during the preceding 12 months; and
 - A review, conducted within the previous 3-year period, to determine the PCCM entity's compliance with the standards set forth in subpart D of 42 CFR part 438 and the quality assessment and performance improvement requirements described in 42 CFR 438.330. (42 CFR 457.1250(a), cross referencing to 438.358(b)(2))

3.12.5.3 External Quality Review Report

- Guidance:All states with MCOs, PIHPs, PAHPs, PCCMs or PCCM entitiesneed to complete Sections 3.12.5.3.
- 3.12.5.3.1 The State assures that data obtained from the mandatory and optional, if applicable, EQR-related activities in 42 CFR 438.358 is used for the annual EQR to comply with 42 CFR 438.350 and must include, at a minimum, the elements in §438.364(a)(2)(i) through (iv). (42 CFR 457.1250(a), cross referencing to 42 CFR 438.358(a)(2))
- **3.12.5.3.2** The State assures that only a qualified EQRO will produce the EQR technical report (42 CFR 438.364(c)(1)).
- **3.12.5.3.3** The State assures that in order for the qualified EQRO to perform an annual EQR for each contracting MCO, PIHP, PAHP or PCCM entity under 42 CFR 438.350(a) that the following conditions are met:
 - The EQRO has sufficient information to use in performing the review;
 - The information used to carry out the review must be obtained from the EQR-related activities described in 42 CFR 438.358 and, if applicable, from a private accreditation review as described in 42 CFR 438.360;
 - For each EQR-related activity (mandatory or optional), the information gathered for use in the EQR must include the elements described in 42 CFR 438.364(a)(2)(i) through (iv); and
 - The information provided to the EQRO in accordance with 42 CFR 438.350(b) is obtained through methods consistent with the protocols established by the Secretary in accordance with 42 CFR 438.352. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.350(b) through (e))
- **3.12.5.3.4** The State assures that the results of the reviews performed by a qualified EQRO of each contracting MCO, PIHP, PAHP, and PCCM entity are made available as specified in 42 CFR 438.364 in an annual detailed technical report that summarizes findings on access and quality of care. The report includes at least the following items:
 - A description of the manner in which the data from all activities conducted in accordance with 42 CFR 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the

MCO, PIHP, PAHP, or PCCM entity (described in 42 CFR 438.310(c)(2));

- For each EQR-related activity (mandatory or optional) conducted in accordance with 42 CFR 438.358:
 - o Objectives;
 - o Technical methods of data collection and analysis;
 - Description of data obtained, including validated performance measurement data for each activity conducted in accordance with 42 CFR 438.358(b)(1)(i) and (ii); and
 - Conclusions drawn from the data;
- An assessment of each MCO's, PIHP's, PAHP's, or PCCM entity's strengths and weaknesses for the quality, timeliness, and access to health care services furnished to CHIP beneficiaries;
- Recommendations for improving the quality of health care services furnished by each MCO, PIHP, PAHP, or PCCM entity, including how the State can target goals and objectives in the quality strategy, under 42 CFR 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to CHIP beneficiaries;
- Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities, consistent with guidance included in the EQR protocols issued in accordance with 42 CFR 438.352(e); and
- An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.350(f) and 438.364(a))
- 3.12.5.3.5 The State assures that it does not substantively revise the content of the final EQR technical report without evidence of error or omission. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(b))
- **3.12.5.3.6** The State assures that it finalizes the annual EQR technical report by April 30th of each year. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(1))
- **3.12.5.3.7** The State assures that it posts the most recent copy of the annual EQR technical report on the Web site required under 42 CFR 438.10(c)(3) by April 30th of each year. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(2)(i))

- 3.12.5.3.8 The State assures that it provides printed or electronic copies of the information specified in 42 CFR 438.364(a) for the annual EQR technical report, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, PAHP, or PCCM, beneficiary advocacy groups, and members of the general public. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(2)(ii))
- 3.12.5.3.9 The State assures that it makes the information specified in 42 CFR 438.364(a) for the annual EQR technical report available in alternative formats for persons with disabilities, when requested. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(3))
- 3.12.5.3.10 ☐ The State assures that information released under 42 CFR 438.364 for the annual EQR technical report does not disclose the identity or other protected health information of any patient. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(d))