

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S2-26-12  
Baltimore, Maryland 21244-1850



Disabled and Elderly Health Programs Group

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November 2, 2015

Mary Dalton  
State Medicaid Director  
Department of Public Health and Human Services  
111 North Sanders, PO Box 4210  
Helena, MT 59620

Dear Ms. Dalton:

We are pleased to inform you that the Centers for Medicare & Medicaid (CMS) is approving Montana's request for an initial 1915(b) waiver, CMS control number MT-04, to allow the state to selectively contract with a limited number of providers as necessary to enable the state to implement alternative delivery mechanisms for its Medicaid Expansion program. The section 1915(b) waiver is authorized under section 1915(b)(4) of the Social Security Act (the Act) and provides waivers of the following sections of Title XIX:

- Section 1902(a)(10)(B) Statewidelessness
- Section 1902(a)(23) Freedom of Choice

The state must arrange for an independent evaluation or assessment of their section 1915(b) waiver program and submit the findings when renewing the waiver program. At a minimum, the Independent Assessment (IA) is a requirement of the first two waiver periods. The IA should be submitted with the waiver renewal request ninety (90) days before the expiration of the approved waiver program.

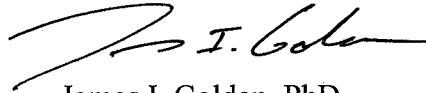
Additionally, our decision is based on the evidence submitted to CMS demonstrating that the state's proposal is consistent with the purposes of the Medicaid program, will meet all statutory and regulatory requirements for assuring beneficiaries' access to and quality of services, and will be a cost-effective means of providing services to those beneficiaries in Montana's Medicaid population.

The waiver is approved for a two-year period effective January 1, 2016 through December 31, 2017 and included, as part of the approval, are the attached Special Terms and Conditions (STCs). The state may request renewal of this authority by providing evidence and documentation of satisfactory performance and oversight. Montana's request that this authority be renewed should be submitted to CMS no later than September 30, 2017. Montana will be responsible for documenting the applicable cost-effectiveness and quality in subsequent renewal requests for this authority.

Ms. Dalton, page 2

We appreciate the cooperation your staff provided during development of these waiver programs. If you have any questions related to this approval letter, please contact Scott Manning, of my staff, at (410) 786-6881 or [Scott.Manning@cms.hhs.gov](mailto:Scott.Manning@cms.hhs.gov). You may also contact Matt Rodriguez, in the Denver Regional Office, at (303) 844-4724 or [Matt.Rodriguez@cms.hhs.gov](mailto:Matt.Rodriguez@cms.hhs.gov).

Sincerely,



James I. Golden, PhD  
Director  
Division of Managed Care Plans

cc: Richard Allen, CMS  
Mary Marchioni, CMS  
Matthew Rodriguez, CMS  
Scott Manning, CMS  
Alexis Gibson, CMS

**Montana Fee-for-Service Third Party Administrator Delivery System  
Special Terms and Conditions**

**1. Table of Contents**

<b>2. Definitions.....</b>	<b>3</b>
<b>3. State Responsibilities .....</b>	<b>4</b>
<b>4. General TPA Contract Requirements .....</b>	<b>9</b>
<b>5. Subcontractual Relationships and Delegation Requirements.....</b>	<b>10</b>
<b>6. Provider-Related TPA Contract Requirements.....</b>	<b>12</b>
<b>7. Enrollee Rights and Beneficiary Protections Requirements.....</b>	<b>13</b>
<b>8. Access to Services and Coordination of Care Requirements.....</b>	<b>14</b>
<b>9. Coverage and Authorization of Services Requirements.....</b>	<b>19</b>
<b>10. Emergency and Poststabilization Services Requirements.....</b>	<b>21</b>
<b>11. Information and Communication Requirements.....</b>	<b>23</b>
<b>12. Provider Directory and Formulary Information Requirements .....</b>	<b>27</b>
<b>13. Health Information Systems and Post-Adjudicated Claims Data Requirements..</b>	<b>28</b>
<b>14. Program Integrity Requirements .....</b>	<b>29</b>

**2. Definitions**

- 2.1. **Prevalent.** Prevalent means a non-English language determined to be spoken by a significant number or percentage of enrollees that are limited English proficient.
- 2.2. **Readily Accessible.** Readily accessible means electronic information and services which comply with modern accessibility standards such as Section 508 guidelines or guidelines that provide greater accessibility to individuals with disabilities.
- 2.3. **Subcontractor.** Subcontractor means any individual or entity with a contract or written arrangement with the TPA that relates directly or indirectly to the performance of the TPA’s obligations under the contract with the State.
- 2.4. **TPA-Medicaid-FFS Enrollees** – For the purposes of these STCs only, TPA-Medicaid-FFS enrollees means Medicaid beneficiaries receiving benefits under the HELP Program TPA Alternative Benefit Plan for services delivered through the TPA.

3. State Responsibilities

- 3.1. **Conflict of Interest Safeguards.** The State must have in place conflict of interest 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 TPA contract. These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423) and must ensure compliance with the requirement described in section 1902(a)(4)(C) of the Social Security Act applicable to contracting officers, employees, or independent contractors.
- 3.2. **Making the TPA Contract Available.** The State must post the contract with the TPA on the State's website.
- 3.3. **Location of Contractors.** The State must ensure that the TPA with which the State contracts is not located outside of the United States and that no claims paid by the TPA to a network provider, out-of-network provider, subcontractor or financial institution is located outside of the U.S.
- 3.4. **Network Adequacy.** The State must develop and enforce network adequacy standards for the TPA consistent with this STC.
  - 3.4.1. At a minimum, the State must develop network adequacy standards for the following provider types, if covered under the TPA contract:
    - 3.4.1.1. Primary care.
    - 3.4.1.2. OB/GYN.
    - 3.4.1.3. Behavioral health.
    - 3.4.1.4. Specialists
    - 3.4.1.5. Hospital.
  - 3.4.2. Network standards established under this section must include all geographic areas covered by the TPA. In developing network adequacy standards under this section the State must consider, at a minimum, the following elements:
    - 3.4.2.1. The anticipated Medicaid enrollment.
    - 3.4.2.2. The expected utilization of services.
    - 3.4.2.3. Comparability to traditional Medicaid program.

- 3.4.2.4. Geography and other factors relevant to Montana when establishing such standards.
- 3.4.3. The TPA's network must include:
  - 3.4.3.1. No less than 90% of the hospitals in the state;
  - 3.4.3.2. No less than 80% of the non-hospital licensed health care providers in the state;
  - 3.4.3.3. No less than 80% of the OB/GYNs serving the Non-TPA-Medicaid-FFS-Enrollees;
  - 3.4.3.4. No less than 80% of the behavioral health providers serving the Non-TPA-Medicaid-FFS-Enrollees;
- 3.4.4. If the State grants an exception to the network standards required under this section, it must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report STC 3.6.
- 3.4.5. The State must publish the network adequacy standards developed under this section on its website. Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.
- 3.5. **Readiness Reviews.** The State must assess the readiness of the TPA prior to the State implementing the TPA program.
  - 3.5.1. The State must conduct a readiness review of the TPA as follows:
    - 3.5.1.1. Prior to the effective date of beneficiary enrollment.
    - 3.5.1.2. Completed in sufficient time to ensure adequate time to address barriers to a smooth implementation of contractual requirements.
    - 3.5.1.3. Readiness reviews must include both a desk review of documents and on-site reviews of the TPA. On-site reviews must include interviews with the TPA staff and leadership that manage key operational areas.
  - 3.5.2. The State's readiness review of the TPA must assess the ability and capacity of the TPA to perform satisfactorily for the following areas:
    - 3.5.2.1. Operations/Administration, including:
      - 3.5.2.1.1. Administrative staffing and resources.

3.5.2.1.2. Delegation and oversight of the TPA responsibilities.

3.5.2.1.3. Enrollee and provider communications.

3.5.2.1.4. Customer service and notification of grievance and appeals rights

3.5.2.1.5. Member services and outreach.

3.5.2.1.6. Provider Network Management.

3.5.2.1.7. Program Integrity/Compliance.

3.5.2.2. Service delivery, including:

3.5.2.2.1. Care coordination;

3.5.2.2.2. Service planning;

3.5.2.2.3. Quality improvement, and

3.5.2.2.4. Utilization review.

3.5.2.3. Financial management, including:

3.5.2.3.1. Reporting and monitoring.

3.5.2.4. Systems management, including:

3.5.2.4.1. Claims management; and

3.5.2.4.2. Post-adjudicated claims data and enrollment information management.

**3.6. TPA Monitoring System.** The State must have in effect a monitoring system for the TPA.

3.6.1. The State's system must address all aspects of the TPA, including at least the following areas:

3.6.1.1. Administration and management.

3.6.1.2. Customer service systems, notification of appeals rights, and appeal requirements under STC 9.5.

3.6.1.3. Claims management.

3.6.1.4. Enrollee materials and customer services.

- 3.6.1.5. Information systems, including post-adjudicated claims data reporting.
  - 3.6.1.6. Medical management, including utilization management.
  - 3.6.1.7. Program integrity, including a system to verify and document that any responsibilities delegated to the TPA related to STC 3.8 are conducted in compliance with the State's written instructions.
  - 3.6.1.8. Provider network management.
  - 3.6.1.9. Availability and accessibility of services.
  - 3.6.1.10. Quality improvement efforts.
  - 3.6.1.11. All other provisions of the contract, as appropriate.
- 3.6.2. The State must use data collected from its monitoring activities to improve the performance of the TPA. The State must collect the following monitoring information at a minimum:
- 3.6.2.1. Member grievance and appeal logs.
  - 3.6.2.2. Provider complaint and appeal logs.
  - 3.6.2.3. Results from any enrollee satisfaction survey conducted by the State or TPA.
  - 3.6.2.4. Performance on any required quality measures.
  - 3.6.2.5. An annual performance report card for the TPA.
  - 3.6.2.6. Audited financial and post-adjudicated claims data submitted by the TPA.
  - 3.6.2.7. Customer service performance data submitted by the TPA.
- 3.7. **Monitoring Report to CMS.** The State must submit to CMS no later than 150 days after each contract year, a report on the demonstration and TPA operations that support the demonstration.
- 3.7.1. The annual report authorized under this demonstration will be deemed to satisfy the requirement of this STC provided that the report provides information on, and an assessment of, the TPA's operations to support the demonstration and include, at a minimum, the following:

- 3.7.1.1. Performance of the TPA financial and accounting system, including the ability to reconcile the accounting system to all post-adjudicated claims.
  - 3.7.1.2. Post-adjudicated claims data reporting by the TPA.
  - 3.7.1.3. Enrollment of the TPA.
  - 3.7.1.4. Modifications to, and implementation of, TPA benefits covered under the contract with the State.
  - 3.7.1.5. Customer service, grievance and appeals rights.
  - 3.7.1.6. Availability and accessibility of covered services within the TPA contracts.
  - 3.7.1.7. Evaluation of the TPA performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance.
  - 3.7.1.8. Results of any sanctions or corrective action plans imposed by the State or other formal or informal intervention with the TPA to improve performance.
- 3.7.2. The program report required in this section must be:
- 3.7.2.1. Posted on the State's website.
- 3.8. Screening and Enrolling Providers.** The State must ensure that all TPA network providers are screened and enrolled, and periodically revalidated, in accordance with the requirements of 42 CFR 455, subparts B and E. This STC does not require the TPA's network provider to render services to Medicaid beneficiaries other than TPA-Medicaid-FFS enrollees.
- 3.8.1. The State must review the ownership and control disclosures submitted by the TPA and any subcontractors in accordance with 42 CFR 455 subpart B.
  - 3.8.2. Consistent with the requirements at 42 CFR 455.436, the State must confirm the identity and determine the exclusion status of the TPA, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the TPA through routine checks of Federal databases. The Federal databases include the Social Security Administration's Death Master File, the List of Excluded Individuals/Entities (LEIE), the System for Award Management (SAM), and any other databases as the State or Secretary may prescribe.





- 4.1.1. Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80;
  - 4.1.2. Title IX of the Education Amendments of 1972 (regarding education programs and activities);
  - 4.1.3. The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91;
  - 4.1.4. The Rehabilitation Act of 1973;
  - 4.1.5. The Americans with Disabilities Act of 1990 as amended; and
  - 4.1.6. Section 1557 of the Patient Protection and Affordable Care Act.
- 4.2. **Privacy Requirements.** The State must ensure, through its contract with the TPA, that (consistent 42 C. F.R. 431, subpart F), for medical records and any other health and enrollment information that identifies a particular enrollee, the TPA uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.
- 4.3. **Inspection and Audit.** All contracts associated with this waiver, including with the TPA, must provide that the State, CMS, and the Office of the Inspector General may, at any time, inspect and audit any records or documents of the TPA or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted.
5. Subcontractual Relationships and Delegation Requirements
- 5.1. **General Requirements for Subcontractual Relationships.** The requirements of this section apply to the contract or written arrangement that the TPA has with any individual or entity that relates directly or indirectly to the performance of the TPA's obligations under its contract with the State. The State must ensure, through its contracts with the TPA, that:
- 5.1.1. Notwithstanding any relationship(s) that the TPA may have with any other individual or entity, the TPA maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the State; and
  - 5.1.2. All contracts or written arrangements between the TPA and any individual or entity that relates directly or indirectly to the performance of the TPA's activities or obligations under its contract with the State must meet the requirements of this section of the STCs.

**5.2. Specific Requirements for Subcontractual Relationships.** Each contract or written arrangement described in paragraph (b) of this section must specify that:

- 5.2.1. If any of the TPA's activities or obligations under its contract with the State are delegated to another individual or entity :
  - 5.2.1.1. The delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement.
  - 5.2.1.2. The individual or entity agrees to perform the delegated activities and reporting responsibilities specified in compliance with the TPA's contract obligations.
  - 5.2.1.3. 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 TPA determines that the individual or entity has not performed satisfactorily.
  - 5.2.1.4. The individual or entity agrees to comply with all applicable Medicaid laws, regulations, subregulatory guidance, and contract provisions.
- 5.2.2. The subcontracting individual or entity agrees that:
  - 5.2.2.1. The State, CMS, the HHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems of the individual or entity, or of the individual's or entity's contractor or subcontractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the contract with the State, if the reasonable possibility of fraud is determined to exist by any of these entities.
  - 5.2.2.2. The individual or entity will make available, for purposes of an audit, evaluation, or inspection described this section, its premises, physical facilities, equipment, and records relating to its Medicaid enrollees.
  - 5.2.2.3. The right to audit under this section will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.
  - 5.2.2.4. If the State, CMS, or the HHS Inspector General determines that there is a reasonable possibility of fraud or similar risk, the State, CMS, or the HHS Inspector General may inspect, evaluate, and audit the individual or entity at any time.

## 6. Provider-Related TPA Contract Requirements

- 6.1. **Excluded Providers.** The TPA may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.
- 6.2. **Provider Selection.** The State must ensure, through its contracts with the TPA, that the state reviews and approves the TPA's written credentialing and recredentialing policies and procedures for selection and retention of providers. The state must determine that the policies and procedures:
  - 6.2.1. Assure access to quality, efficient and economic provisions of covered services; and
  - 6.2.2. Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services.
- 6.3. **Provider Preventable Conditions.** The contract between the State and the TPA must comply with the requirements mandating provider identification of provider preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in 42 CFR 447.26. The TPA must report to the State all identified provider-preventable conditions in a form and frequency as specified by the State no less frequently than quarterly.
- 6.4. **Physician Incentive Plan Requirements.** The State must require the TPA, to the extent applicable, to comply with the physician incentive plan requirements set forth in 42 CFR 422.208 and 422.210. In applying the provisions of 42 C.F.R. 422.208 and 422.210, references to "MA organization," "CMS," and "Medicare beneficiaries" must be read as references to "TPA," "State," and "Medicaid beneficiaries," respectively.
- 6.5. **No Provider Discrimination.** The State through its contract with the TPA shall ensure that the TPA does not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If the TPA declines to include individual or groups of providers in its provider network, it must give the affected providers written notice of the reason for its decision. Nothing in this paragraph shall be construed to:
  - 6.5.1. Require the TPA to contract with providers beyond the number that the state has determined to be necessary to meet the needs of its enrollees,
  - 6.5.2. Preclude the TPA from establishing measures that the state authorizes it to implement to maintain quality of services and control costs, that are consistent with enrollee access to quality health care services.

## 7. Enrollee Rights and Beneficiary Protections Requirements

7.1. **Enrollee Rights: General Principle.** An enrollee of the TPA has the right to be furnished health care services in accordance with STCs 8.2, 8.7, 8.9, and 9.1.

7.2. **Enrollee Freedom to Exercise their Rights.** The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the TPA and its network providers or the State agency treat the enrollee.

7.2.1. The contract between the State and the TPA must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

7.3. **Requirement for Written Policies and Procedures.** The State must ensure that that the TPA has written policies regarding the enrollee rights specified in this section, and that the TPA complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its employees and contracted providers observe and protect those rights.

7.4. **Guaranteed Enrollee Rights.** The State must ensure that each TPA enrollee is guaranteed the following rights:

7.4.1. Receive information in accordance with these STCs.

7.4.2. Be treated with respect and with due consideration for his or her dignity and privacy.

7.4.3. Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand.

7.4.4. Participate in decisions regarding his or her health care, including the right to refuse treatment.

7.4.5. Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

7.4.6. If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR 164.524 and 164.526.

7.5. **Prohibition on Restricting Health Care Professionals.** The TPA may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

- 7.5.1. The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.
- 7.5.2. Any information the enrollee needs to decide among all relevant treatment options.
- 7.5.3. The risks, benefits, and consequences of treatment or nontreatment.
- 7.5.4. The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

7.6. **Sanctions for Violating Enrollee Rights.** The State shall ensure through its contract with the TPA, that the TPA shall be subject to sanctions if it violates the prohibition in STC 7.5

8. Access to Services and Coordination of Care Requirements

- 8.1. **Access to Services: General Requirements.** The State must ensure that all services covered under the HELP Program TPA Alternative Benefit Plan that are offered through the TPA are available and accessible to enrollees of the TPA in a timely manner. The State must also ensure that TPA provider network for services covered under the contract meet the standards developed by the State in accordance with STC 3.4
- 8.2. The State must ensure, through its contract with the TPA, that the TPA, consistent with the scope of its contracted services, meets the following requirements:
  - 8.2.1. The TPA shall maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient 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.
  - 8.2.2. The TPA shall provide female enrollees with direct access to a women's health specialist within the provider network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.
  - 8.2.3. If the provider network is unable to provide necessary services, covered under the contract, to a particular enrollee, the TPA must adequately and timely cover these services out of network for the enrollee, for as long as the TPA's provider network is unable to provide them.

8.2.3.1. The State may require that the out-of-network provider is enrolled in Montana Medicaid or for a provider that is not enrolled in Montana Medicaid, that the TPA negotiate a rate that is no greater than the rate the provider would receive if enrolled in Montana Medicaid. These requirements cannot be used as basis for the TPA or State not providing an enrollee services included in the HELP Program TPA Alternative Benefit Plan.

8.2.4. The TPA shall require out-of-network providers to coordinate with the TPA for payment and ensure the cost to the enrollee is no greater than it would be if the services were furnished within the network.

**8.3. Enrollee Access to Choice of Providers.** Montana Medicaid beneficiaries receiving services through the TPA will have a choice of primary care providers and specialty providers. To the extent beneficiary access to such providers is limited in the future, the State through its contract with the TPA must permit the beneficiary:

8.3.1. To choose from at least two primary care providers.

8.3.2. To obtain services from any other provider under any of the following circumstances:

8.3.2.1. The service or type of provider (in terms of training, experience, and specialization) is not available within the TPA network.

8.3.2.2. The provider is not part of the TPA network, but is the main source of a service to the beneficiary, provided that:

8.3.2.3. The provider is given the opportunity to become a participating provider under the same requirements for participation in the TPA network as other network providers of that type.

8.3.2.4. If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 calendar days (after being given an opportunity to select a provider who participates).

8.3.2.5. The only plan or provider available to the beneficiary does not, because of moral or religious objections, provide the service the enrollee seeks.

8.3.2.6. The beneficiary's primary care provider or other provider determines that the beneficiary needs related services that would subject the beneficiary to unnecessary risk if received separately (for example, a

cesarean section and a tubal ligation) and not all of the related services are available within the network.

8.3.2.7. The State determines that other circumstances warrant out-of-network treatment, including:

8.3.2.7.1. If a beneficiary has exceptional health care needs including medical, behavioral health or developmental conditions;

8.3.2.7.2. If a beneficiary lives in a region where the TPA is unable to contract with sufficient providers;

8.3.2.7.3. Required continuity of care for a beneficiary is not available or is not cost effective to be effectively delivered through the TPA; or

8.3.2.7.4. The beneficiary is otherwise exempt under Federal law.

**8.4. Enrollee Changing Primary Care Providers.** Montana Medicaid beneficiaries receiving services through the TPA will not have any limitations with respect to changing primary care providers. To the extent an enrollee of the TPA has limited access to primary care providers in the future, any limitation the State or the TPA imposes on his or her freedom to change between primary care providers must still allow the beneficiary to change primary care providers for the following:

8.4.1. For cause, at any time;

8.4.2. Without cause, at the following times:

8.4.2.1. During the 90 days following the date of the beneficiary's initial enrollment into the TPA, or the date the State sends the beneficiary notice of the enrollment, whichever is later.

8.4.2.2. At least once every 12 months thereafter.

8.4.2.3. Upon automatic reenrollment, if the temporary loss of Medicaid eligibility has caused the beneficiary to miss the annual disenrollment opportunity.

**8.5. Requirements for TPA Oversight of Network Providers.** The State must ensure that the contract with the TPA requires the TPA to do the following:

8.5.1. Meet, and require its network providers to meet, the State's standards for timely access to care and services, taking into account the urgency of the need for services.



- 8.5.2. Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid beneficiaries that are not TPA-Medicaid-FFS enrollees.
  - 8.5.3. Establish mechanisms to ensure compliance by network providers.
  - 8.5.4. Monitor network providers regularly to determine compliance.
  - 8.5.5. Take corrective action if there is a failure to comply by a network provider.
- 8.6. TPA Participation in Culturally Competent Care Efforts.** The State must ensure that the contract with the TPA requires the TPA to participate in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity.
- 8.7. Requirements for Accessibility.** The State must ensure that the contract with the TPA requires that the TPA must ensure that its network providers provide physical access, accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.
- 8.8. TPA Assurances of Capacity to the State.** The State must ensure, through its contract with the TPA, that the TPA gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under STC 8.8.
- 8.8.1. The State must ensure, through its contract with the TPA, that the TPA must submit documentation to the State, in a format specified by the State to demonstrate that it complies with the following requirements:
    - 8.8.1.1. Offers an appropriate range of preventive, primary care, and specialty services that are adequate for the anticipated number of enrollees for the service area.
    - 8.8.1.2. Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.
  - 8.8.2. The State must ensure, through its contract with the TPA, that the TPA must submit the documentation described in paragraph (g) of this section as specified by the State, but no less frequently than the following:
    - 8.8.2.1. At the time it enters into a contract with the State.

8.8.2.2. On an annual basis.

8.8.2.3. At any time there has been a significant change (as defined by the State) in the TPA's operations that would affect the adequacy of capacity and services, including, but not limited to changes in the TPA's services, benefits, geographic service area, composition of or payments to its provider network.

**8.9. Care Coordination Requirements.** The State must ensure, through its contract with the TPA, that the TPA must implement procedures to deliver care to and coordinate services for all TPA enrollees. These procedures must meet State requirements and must do the following:

8.9.1. Ensure that each enrollee has an ongoing source of care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee.

8.9.2. Coordinate the services the TPA furnishes to the enrollee:

8.9.2.1. Between settings of care including appropriate discharge planning for short term and long-term hospital and institutional stays;

8.9.2.2. With the services the enrollee receives from any other delivery system; and

8.9.2.3. With the services the enrollee receives in FFS Medicaid.

8.9.3. The State must ensure, through its contract with the TPA, that the TPA, within 90 days of the effective date of enrollment for all new enrollees, makes a best effort to conduct an initial assessment of each enrollee's needs, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful. The TPA shall be required to share with the State the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities.

8.9.4. The State must ensure, through its contract with the TPA, that the TPA shall ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

**8.10. Enrollee Health Record Requirements.** The State must ensure, through its contract with the TPA, that the TPA shall ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards.

9. Coverage and Authorization of Services Requirements

9.1. The contract between the State and the TPA must do the following:

- 9.1.1. Identify, define, and specify the amount, duration, and scope of each service that the TPA is required to offer. Amount, duration, and scope cannot be less than what is in the approved HELP Program TPA Alternative Benefit Plan.
- 9.1.2. Require that the TPA must ensure that the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished.
- 9.1.3. Require that the TPA may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary.
- 9.1.4. Permit the TPA to place appropriate limits on a service only on the basis of criteria applied under the State plan, such as medical necessity.
- 9.1.5. Require that Family planning services are provided in a manner that protects and enables the enrollee's freedom to choose the method of family planning to be used consistent with 42 C.F.R §441.20.

9.2. **Medically Necessary Services.** The contract between the State and the TPA must specify what constitutes "medically necessary services" in a manner that:

- 9.2.1. Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and
- 9.2.2. Meets the requirements for providing early and periodic screening and diagnosis of beneficiaries under age 21 to ascertain physical and mental defects, and treatment to correct or ameliorate defects and chronic conditions found (EPSDT).

9.3. **Processing Authorization of Services.** For the processing of requests for initial and continuing authorizations of services, the contract with the TPA must require:

- 9.3.1. That the TPA and its subcontractors have in place, and follow, written policies and procedures. the contract with the TPA must require that the TPA:
  - 9.3.1.1. Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions.

- 9.3.1.2. Consult with the requesting provider for medical services when appropriate.
  - 9.3.2. That 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 a health care professional who has appropriate expertise in addressing the enrollee's medical or behavioral health needs.
  - 9.3.3. That the TPA is to notify the requesting provider, and give the enrollee written notice of any decision by the TPA to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. The notice must meet the requirements of §438.404 of 80 FR 31097.
- 9.4. **Decisions and Notification of Authorization of Services.** The contract with the TPA must provide for the following decisions and notices:
- 9.4.1. For standard authorization decisions, provide notice as expeditiously as the enrollee's condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if:
    - 9.4.1.1. The enrollee, or the provider, requests extension; or
    - 9.4.1.2. The TPA justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.
  - 9.4.2. For cases in which a provider indicates, or the TPA determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the TPA must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.
  - 9.4.3. The TPA may extend the 72 hour time period by up to 14 calendar days if the enrollee requests an extension, or if the TPA justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.
- 9.5. **State Review of TPA Decisions to Deny, Limit, or Delay Services.** The State and the TPA shall develop, in writing, a mechanism to exchange: 1) Enrollees' requests for appeals on decisions to deny, limit, or delay services; and 2) Outcomes and/or decisions from enrollees' appeals.

- 9.5.1. The exchange of information shall be as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date of a request, outcome, or decision.
- 9.5.2. If a State fair hearing officer, or other State official, reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the TPA 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.

**9.6. Compensation for Individuals and Entities that Conduct Utilization Management.**

The contract between a State and the TPA must provide that, consistent with STC 6.4 and 42 C. F.R. §422.208, 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.

**10. Emergency and Poststabilization Services Requirements**

**10.1. Definitions** as used in this section:

- 10.1.1. **Emergency medical condition.** Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:
  - 10.1.1.1. Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.
  - 10.1.1.2. Serious impairment to bodily functions.
  - 10.1.1.3. Serious dysfunction of any bodily organ or part.
- 10.1.2. **Emergency services.** Emergency services means covered inpatient and outpatient services that are as follows:
  - 10.1.2.1. Furnished by a provider that is qualified to furnish these services under this title.
  - 10.1.2.2. Needed to evaluate or stabilize an emergency medical condition.
- 10.1.3. **Poststabilization care services.** Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized to maintain the stabilized condition, or, under the

circumstances described in STC 10.2, to improve or resolve the enrollee's condition.

**10.2. Coverage and Payment of Emergency Services and Poststabilization Care Services.**

The TPA is responsible for coverage and payment of emergency services and poststabilization care services. The TPA or the State:

10.2.1. Must cover and pay for emergency services

10.2.1.1. The State may require that the Emergency services provider is enrolled in Montana Medicaid or alternatively for a provider that is not enrolled in Montana Medicaid, that the TPA negotiates a rate with a non-enrolled provider that is no greater than the rate the provider would receive if enrolled in Montana Medicaid. These requirements cannot be used as basis for the TPA or State not providing an enrollee emergency services .

10.2.2. May not deny payment for treatment obtained under either of the following circumstances:

10.2.2.1. An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in the definition of emergency medical condition in this section.

10.2.2.2. A representative of the TPA instructs the enrollee to seek emergency services.

10.2.3. The TPA or the State may not:

10.2.3.1. Limit what constitutes an emergency medical condition on the basis of lists of diagnoses or symptoms.

10.2.3.2. Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, the TPA, or applicable State entity of the enrollee's screening and treatment within 365 calendar days of presentation for emergency services.

10.2.3.3. Hold an enrollee who has an emergency medical condition liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

10.2.4. The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently

stabilized for transfer or discharge, and that determination is binding on the TPA and the State as responsible for coverage and payment.

- 10.2.5. Poststabilization care services are covered and paid for in accordance with provisions set forth at 42 CFR 422.113(c). In applying those provisions, reference to “MA organization” and “financially responsible” must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section, and payment rules governed by Title XIX of the Act and the States.

## 11. Information and Communication Requirements

**11.1. Enrollee Assistance: General Requirements.** The State through its contract with the TPA must:

- 11.1.1. Have in place a mechanism to help enrollees and potential enrollees understand the requirements of the TPA for accessing services, benefits, and appeal rights.
- 11.1.2. Provide all required information in these STCs to enrollees and potential enrollees in a manner and format that may be easily understood and readily accessible by enrollees.

**11.2. Requirements to Provide Information Electronically.** Enrollee information required in this STC may not be provided electronically by either the State or the TPA, unless all of the following are met:

- 11.2.1. The format is readily accessible.
- 11.2.2. The information is placed in a location on the State or TPA website that is prominent and readily accessible.
- 11.2.3. The information is provided in an electronic form which can be electronically retained and printed.
- 11.2.4. The information is consistent with the content and language requirements of this STC.
- 11.2.5. The State or the TPA informs the enrollee that the information is available in paper form without charge upon request and provides it upon request within 5 calendar days.

**11.3. Enrollee Handbook.** The State through its contract with the TPA must provide each enrollee an enrollee handbook, either in paper or electronic form, at the time the enrollee first required to enroll in the TPA. The content of the member handbook must

include information that enables the enrollee to understand how to effectively use the TPA. This information must include at a minimum:

- 11.3.1. Benefits provided by the TPA.
- 11.3.2. How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided.
  - 11.3.2.1. In the case of a counseling or referral service that the TPA does not cover because of moral or religious objections, the TPA must inform enrollees that the service is not covered.
  - 11.3.2.2. The TPA must inform enrollees how they can to obtain information from the State about how to access those services.
- 11.3.3. 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.
- 11.3.4. Procedures for obtaining benefits, including any requirements, if any, for service authorizations or referrals.
- 11.3.5. The extent to which, and how, after-hours and emergency coverage are provided, including:
  - 11.3.5.1. What constitutes an emergency medical condition and emergency services.
  - 11.3.5.2. The fact that prior authorization is not required for emergency services.
  - 11.3.5.3. 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.
- 11.3.6. Any restrictions on the enrollee's freedom of choice among network providers.
- 11.3.7. The extent to which, and how, enrollees may obtain benefits, including family planning services and supplies, from out-of-network providers.
- 11.3.8. Cost sharing, if any is imposed under this waiver.
- 11.3.9. Enrollee rights and responsibilities, including the elements specified in STC 7.2 and 7.3.
- 11.3.10. The process of selecting and changing the enrollee's primary care provider.



- 11.3.11. Grievance, appeal, and fair hearing procedures and timeframes, consistent with subpart F of 42 CFR 438, in a State-developed or State-approved description. Such information must include:
  - 11.3.11.1. The right to file grievances and appeals.
  - 11.3.11.2. The requirements and timeframes for filing a grievance or appeal.
  - 11.3.11.3. The availability of assistance in the filing process.
  - 11.3.11.4. The right to request a State fair hearing after the TPA has made a determination on an enrollee's appeal which is adverse to the enrollee.
  - 11.3.11.5. The fact that, when requested by the enrollee benefits that the TPA seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing, the enrollee may, consistent with state policy, be required to pay the cost of services furnished while the appeal or State Fair Hearing is pending if the final decision is adverse to the enrollee.
- 11.3.12. How to access auxiliary aids and services, including additional information in alternative formats or languages.
- 11.3.13. The toll-free telephone number for member services medical management and any other unit providing services directly to enrollees.
- 11.3.14. Information on how to report suspected fraud or abuse.
- 11.3.15. Any other content required by the State.
- 11.3.16. Information required by this paragraph to be provided by the TPA will be considered to be provided if the TPA:
  - 11.3.16.1. Mails a printed copy of the information to the enrollee's mailing address;
  - 11.3.16.2. Provides the information by email after obtaining the enrollee's agreement to receive the information by email;
  - 11.3.16.3. Posts the information on the website of the TPA and advises the enrollee in paper or electronic form that the information is available on the Internet and includes the applicable Internet address provided that enrollees with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or

11.3.16.4. Provides the information by any other method that can reasonably be expected to result in the enrollee receiving that information.

**11.4. Changes to the Enrollee Handbook.** The TPA must give each enrollee notice of any change to the enrollee handbook that the State defines as significant at least 30 days before the intended effective date of the change.

**11.5. Enrollee Materials: General Requirements.** Provide, and require the TPA to provide, all written materials for and enrollees consistent with the following:

11.5.1. Use easily understood language and format;

11.5.2. Use a font size no smaller than 12 point;

11.5.3. Be available in alternative formats and through the provision of auxiliary aids and services in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

11.5.4. Include a large print tagline and information on how to request auxiliary aids and services, including the provision of the materials in alternative formats. Large print means printed in a font size no smaller than 18 pt.

**11.6. Notifying Enrollees Communication Assistance.** The State shall notify enrollees, and require the TPA to notify its enrollees:

11.6.1. That oral interpretation is available for any language and written information is available in prevalent languages;

11.6.2. That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

11.6.3. How to access those services.

**11.7. Assistance for Non-English Language Needs.** The State through its contract with the TPA must:

11.7.1. Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in the TPA's service area.

11.7.2. Make available oral and written information in each prevalent non-English language. All written materials for enrollees must include taglines in each prevalent non-English language as well as large print explaining the availability of written translations or oral interpretation to understand the information

provided and the toll-free telephone number of the entity providing choice counseling services. Large print means printed in a font size no smaller than 18 pt.

- 11.7.3. Make its written materials, including, at a minimum, provider directories, member handbooks, appeal and grievance notices and other notices that are critical to obtaining services, available in the prevalent non-English languages in its particular service area. Written materials must also be made available in alternative formats and auxiliary aids and services should be made available upon request of the potential enrollee or enrollee at no cost. Written materials must also , include taglines in each prevalent non-English language as well as large print explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free and TTY/TDY telephone number of the TPA's member/customer service unit.

**11.8. Notifying Enrollees of Provider Terminations.** The State through its contract with the TPA must make a good faith effort to give written notice of termination of a contracted provider, within 15 calendar days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

## 12. Provider Directory Information Requirements

**12.1. Provider Directory Information.** The State through its contract with the TPA must make available, to enrollees, in electronic or paper form, the following information about its network providers:

- 12.1.1. The provider's name as well as any group affiliation.
- 12.1.2. Street address(es).
- 12.1.3. Telephone number(s).
- 12.1.4. Website URL as appropriate.
- 12.1.5. Specialty, if appropriate.
- 12.1.6. Whether the provider will accept new enrollees.

**12.2. Provider Directory: Provider Types.** The provider directory must include the information for each of the following provider types covered under the contract:

- 12.2.1. Physicians including specialists.
- 12.2.2. Hospitals.

12.2.3. Behavioral health providers.

**12.3. Future Requirements for Provider Directory Information.** The State must ensure through its contract with the TPA that the TPA complies with any provider directory information in 42 CFR 438 that are more comprehensive than these STCs.

### 13. Health Information Systems and Post-Adjudicated Claims Data Requirements

**13.1. Health Information Systems: General Requirements.** The State must ensure, through its contracts that the TPA maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this waiver. The systems must provide information on areas including, but not limited to, utilization, claims, and grievances and appeals.

**13.2. Health Information Systems: Specific Requirements.** The State must require, at a minimum, that the TPA, and any subcontractors, comply with the following:

13.2.1. Section 6504(a) of the Affordable Care Act, which requires that State claims processing and retrieval systems are able to collect data elements necessary to enable the mechanized claims processing and information retrieval systems in operation by the State to meet the requirements of section 1903(r)(1)(F) of the Act.

13.2.2. Collect data on enrollee and provider characteristics as specified by the State, and on all services furnished to enrollees through a post-adjudicated claims data system or other methods as may be specified by the State.

13.2.3. Ensure that data received from providers is accurate and complete by:

13.2.3.1. Verifying the accuracy and timeliness of reported data, including data from network providers the TPA is compensating on the basis of capitation payments.

13.2.3.2. Screening the data for completeness, logic, and consistency.

13.2.3.3. Collecting data from providers in standardized formats to the extent feasible and appropriate, including secure information exchanges and technologies utilized for State Medicaid quality improvement and care coordination efforts.

13.2.4. Make all collected data available to the State, and upon request to CMS.

**13.3. Post-Adjudicated Claims Data: General Requirement.** The State must require the TPA to submit to the State post-adjudicated claims data that complies with the form,

format and manner for data as required in in 42 CFR 438.242. Contracts between a State and the TPA must provide for:

- 13.3.1. Collection and maintenance of sufficient post-adjudicated claims data to identify the provider who delivers any item(s) or service(s) to enrollees.
- 13.3.2. Submission of post-adjudicated claims data to the State at a frequency and level of detail to allow the submission of all post-adjudicated claims data that the State is required to report to CMS.

**13.4. Post-Adjudicated Claims Data and Availability of FFP.** FFP is available for expenditures associated with the TPA contract and covered services provided under the TPA contract only if the State meets the following conditions for providing sufficient and timely post-adjudicated claims data to CMS:

- 13.4.1. The State shall submit post-adjudicated claims data to CMS consistent with the data reporting requirements of the Medicaid Statistical Information System or any successor system.
- 13.4.2. The State shall ensure that post-adjudicated claims data is validated for accuracy and completeness before each data submission.
- 13.4.3. The State must require that the data, documentation and information that the TPA submits to the State related to post-adjudicated claims data be certified by either the TPA's Chief Executive Officer or Chief Financial Officer and that such data documentation and information is accurate, complete and truthful.
- 13.4.4. The State shall require the TPA to submit the certification concurrently with the submission of the data, documentation, or information.

**13.5. CMS Review of Post-Adjudicated Claims Data.** CMS will assess the State's submission to determine if it complies with current criteria for accuracy and completeness.

- 13.5.1. If, after being notified of compliance issues the State is unable to make a data submission compliant, CMS will take appropriate steps to defer and/or disallow FFP on all or part of the TPA contract and covered services provided under the TPA contract in a manner based on the enrollee and specific service type of the noncompliant data.

#### 14. Program Integrity Requirements

**14.1. Procedures to Detect Fraud Waste and Abuse.** The State, through its contract with the TPA, must require that the TPA, or subcontractor to the extent that the subcontractor is delegated responsibility by the TPA for coverage of services and payment of claims

under the contract between the State and the TPA, 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:

- 14.1.1. A compliance program that includes, at a minimum, all of the following elements:
  - 14.1.1.1. Written policies, procedures, and standards of conduct that articulate the TPA's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and State requirements.
  - 14.1.1.2. The designation of a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the Chief Executive Officer and the board of directors.
  - 14.1.1.3. The establishment of a Regulatory Compliance Committee at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.
  - 14.1.1.4. A system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.
  - 14.1.1.5. Effective lines of communication between the compliance officer and the organization's employees.
  - 14.1.1.6. Enforcement of standards through well-publicized disciplinary guidelines.
- 14.1.2. Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract.

- 14.1.3. Provision for prompt reporting of all improper payments identified or recovered, specifying the improper payments due to potential fraud, to the State or law enforcement.
- 14.1.4. 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 including all of the following:
  - 14.1.4.1. Changes in the enrollee's residence; or
  - 14.1.4.2. The death of an enrollee.
- 14.1.5. Provision for notification to the State when it receives information about a change in a provider's circumstances that may affect the provider's eligibility to participate in the Medicaid program, including the termination of the provider agreement with the TPA.
- 14.1.6. 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.
- 14.1.7. Written policies for all employees of the entity, and of any contractor or agent, providing 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 are in place.
- 14.1.8. Provision for the prompt referral of any potential fraud, waste, or abuse that the TPA identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit.
- 14.1.9. Provision for the TPA'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.

**14.2. Prohibited Relationships.** The TPA, or a subcontractor of the TPA, may not knowingly have a relationship with 1) an individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549; or 2) an individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in this paragraph for any of the following:

- 14.2.1. A director, officer, or partner of the TPA.
- 14.2.2. A subcontractor of the TPA, as governed by § 438.230.
- 14.2.3. A person with beneficial ownership of 5 percent or more of the TPA's equity.
- 14.2.4. A network provider or persons with an employment, consulting or other arrangement with the TPA for the provision of items and services that are significant and material to the TPA's obligations under its contract with the State.
- 14.2.5. An individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.
- 14.2.6. An individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

**14.3. Prohibition Relationship with Excluded Individuals and Entities.** The TPA may not have a relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Act.

**14.4. Non-Compliance with Prohibited Relationship.** If a State finds that the TPA is not in compliance with the Prohibited Relationship STCs, the State:

- 14.4.1. Must notify CMS of the noncompliance.
- 14.4.2. May continue an existing agreement with the TPA entity unless CMS directs otherwise.
- 14.4.3. May not renew or otherwise extend the duration of an existing agreement with the TPA.

**14.5. Other Program Integrity Requirements.** The State must ensure, through its contracts, that the TPA, and any subcontractors:

- 14.5.1. Provides written disclosure of any prohibited relationships described in the STCs.
- 14.5.2. Provides written disclosures of information on ownership and control required under 42 CFR 455.104.
- 14.5.3. Reports to the State within 60 calendar days when it has identified any payments in excess of amounts specified in the contract.



**14.6. Other Remedies Available.** Nothing in these STCs must be construed to limit or otherwise affect any remedies available to the U.S. under sections 1128, 1128A or 1128B of the Social Security Act.