CONTRACT DECLARATIONS AND EXECUTION

RFP or Informal Solicitation #	Contract #
N/A	MED-19-010

Title of Contract
Dental Care Coverage for the Healthy and Well Kids in Iowa (***hawk-i***)

This Contract must be signed by all parties before the Contractor provides any Deliverables. The Agency is not obligated to make payment for any Deliverables provided by or on behalf of the Contractor before the Contract is signed by all parties. This Contract is entered into by the following parties:

Agency of the State (hereafter "Agency")	
Name/Principal Address of Agency: Iowa Department of Human Services 1305 E. Walnut Des Moines, IA 50319-0114	**Agency Billing Contact Name / Address:** Heather Miller 100 Army Post Road Des Moines, IA 50319 **Phone:** 515-256-4650
Agency Contract Manager (hereafter "Contract Manager") /Address ("Notice Address"): Heather Miller 100 Army Post Road Des Moines, IA 50319	**Agency Contract Owner (hereafter "Contract Owner") / Address:** Michael Randol 100 Army Post Road Des Moines, IA 50315
E-Mail: hmiller@dhs.state.ia.us	**E-Mail:** mrandol@dhs.state.ia.us
Phone: 515-256-4650	
Contractor: (hereafter "Contractor")	
Legal Name: Delta Dental of Iowa	**Contractor's Principal Address:** 9000 Northpark Drive Johnston, IA 50131
Tax ID #: [redacted]	**Organized under the laws of:** State of IA
Contractor's Contract Manager Name/Address ("Notice Address"): Gretchen Hageman 9000 Northpark Drive Johnston, IA 50131	**Contractor's Billing Contact Name/Address:** Gretchen Hageman 9000 Northpark Drive Johnston, IA 50131 **Phone:** (515) 261-5645
Phone: (515) 261-5645	
E-Mail: ghageman@deltadentalia.com	

Contract Information	
Start Date: 08/01/18	**End Date of Base Term of Contract:** 06/30/19
Possible Extension(s): The Agency shall have the option to extend this Contract up to 5 additional 1-year extensions.	
Contractor a Business Associate? Yes	**Contractor subject to Iowa Code Chapter 8F?** No
Contract Include Sharing SSA Data? No	**Contractor a Qualified Service Organization?** Yes
Contract Warranty Period (hereafter "Warranty Period"): The term of this Contract, including any extensions.	**Contract Contingent on Approval of Another Agency:** Yes **Which Agency?** ***hawk-i*** board
Security & Privacy Office Data Confirmation Number: ISOP-18-4	
Contract Payments include Federal Funds? Yes **The contractor for federal reporting purposes under this contract is a:** Vendor **DUNS #:** 847610995 **The Name of the Pass-Through Entity:** Iowa Department of Human Services	
CFDA #: 93.767 **Grant Name:** Children's Health Insurance Program	**Federal Awarding Agency Name:** Department of Health and Human Services/Centers for Medicare and Medicaid Services

Contract Execution

This Contract consists of this Contract Declarations and Execution Section, the attached Certifications (if any), Special Terms, General Terms for Services Contracts, and all Special Contract Attachments. In consideration of the mutual covenants in this Contract and for other good and valuable consideration, the receipt, adequacy and legal sufficiency of which are hereby acknowledged, the parties have entered into this Contract and have caused their duly authorized representatives to execute this Contract.

Contractor, Delta Dental of Iowa		**Agency, Iowa Department of Human Services**	
Signature of Authorized Representative:	Date:	Signature of Authorized Representative:	Date: 8-22-18
Printed Name: Jeffrey S. Russell		Printed Name: Jerry R. Foxhoven	
Title: President and CEO		Title: Director	

Certification and Disclosure Regarding Lobbying

Instructions:
Title 45 of the Code of Federal Regulations, Part 93 requires the Contractor to include a certification form, and to file a disclosure form, if required, as part of the Contract. Award of the federally-funded contract is a Covered Federal action.

1) The Contractor shall file with the Agency this certification form, as set forth in Appendix A of 45 CFR Part 93, certifying the Contractor, including any subcontractor(s) at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) have not made, and will not make, any payment prohibited under 45 CFR § 93.100.
2) The Contractor shall file with the Agency a disclosure form, set forth in Appendix B of 45 CFR Part 93, in the event the Contractor or subcontractor(s) at any tier (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) has made or has agreed to make any payment using non-appropriated funds, including profits from any covered Federal action, which would be prohibited under 45 CFR § 93.100 if paid for with appropriated funds. All disclosure forms shall be forwarded from tier to tier until received by the Contractor and shall be treated as a material representation of fact upon which all receiving tiers shall rely.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Statement for Loan Guarantees and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

Submission of this statement is a pre-requisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than $10,000 for each such failure.

I certify that the contents of this certification are true and accurate. I am checking the appropriate box below regarding disclosures required in Title 45 of the Code of Federal Regulations, Part 93.

☒ The Contractor is NOT including a disclosure form as referenced in this form's instructions because the Contractor is NOT required by law to do so.

☐ The Contractor IS filing a disclosure form with the Agency as referenced in this form's instructions because the Contractor IS required by law to do so.

Signature:	
Printed Name/Title:	Jeffrey S. Russell
Date:	

SECTION 1: SPECIAL TERMS

1.1 Special Terms and Definitions

Centers for Medicare and Medicaid Services (CMS) – means the federal agency in the U.S. Department of Health and Human Services responsible for administration of the Medicaid (Title XIX) and the State Children's Health Insurance (Title XXI) programs.

Covered Services – means those Dentally Necessary Services set forth under Section 1.3.1.4 and in Attachment 3.2. Covered Services refers to services that are covered under the program whether or not Contractor or the Agency ultimately pay the provider for the services.

Day - means calendar day, except where the term working day is expressly used.

Dentally Necessary Services - means a dental procedure or service as determined by the Plan, to either establish or maintain a patient's oral health. Such determinations are based on the professional diagnostic judgment of the Plan and the standards of care that prevail in the professional community.

Emergency Dental Condition – means those dental services delivered to address relief of significant pain, infection, bleeding or traumatic injury to the oral cavity and supporting structures. Examples of traumatic injury areavulsed teeth (knocked out), extruded teeth (forced out of position and loosened) or extruded teeth (extruded) or fractured teeth. Oral injuries are often painful and should be treated by a dentist as soon as possible.

Enrollee - means a child who has been certified by the Agency as eligible for the ***hawk-i*** program in accordance with Iowa Admin. Code ch. 441-86 and who is eligible to enroll in a participating Plan. Such child's name shall appear on the Plan enrollment information, which the Third Party Administrator for the Agency shall transmit, to the Plan in accordance with an established notification schedule.

Enrollment Area - means the county or counties or region or regions in which a Plan is licensed to operate by the State of Iowa and in which service capability exists as defined by the Agency and set forth in this Contract. An Enrollment Area shall not be less than an entire county but may be less than a region. The Agency shall establish regions.

hawk-i - means Healthy And Well Kids in Iowa, the Iowa program to provide health care coverage for uninsured children of eligible families as authorized by Title XXI of the federal Social Security Act.

hawk-i* Board** - means the seven-member board appointed by the Governor to make policy for and provide direction to the Agency for the administration of the ***hawk-i program.

Identification Card - means a card distributed by the Plan that identifies covered Enrollees as members of the ***hawk-i*** plan.

Medically Necessary Orthodontic Services – means an orthodontic procedure that addresses a harmful habit, is an anatomical qualifying clinical condition, or is a limited, interceptive, or comprehensive orthodontic procedures that treats a handicapping malocclusion with a Salzmann score of 26 or greater.

Non-Participating Provider - means a dentist who has not entered into a contract with the Plan to provide Covered Services to Enrollees.

Plan - means the health maintenance organization, organized delivery system, preferred provider organization, dental carrier, or other managed care organization with a certificate of authority to do business in Iowa, which is obligated under this Contract.

1.2 Contract Purpose

The parties have entered into this Contract for the purpose of retaining the Contractor to provide dental care coverage for the Healthy and Well Kids in Iowa (***hawk-i***) Program.

1.2.1 Contract Management

1.2.1 Monitoring, Review, and Problem Reporting.

1.2.1.1 Agency Monitoring Clause. The Contract Manager or designee will:

- Verify Invoices and supporting documentation itemizing work performed prior to payment;
- Determine compliance with general contract terms, conditions, and requirements; and
- Assess compliance with Deliverables, performance measures, or other associated requirements based on the following:

Performance monitoring and data analysis are critical components in assessing how well the Contractor is maintaining and improving the quality of care delivered to members. The Agency will use various performance targets, industry standards, national benchmarks and program-specific standards in monitoring the Contractor's performance and outcomes. The Agency reserves the right to publish Contractor performance. Additionally, once sufficient baseline data is available, the Agency intends to utilize performance outcomes as a factor for auto-assignments and enrollment materials developed to facilitate member choice of contractor enrollment. Failure to meet performance targets shall subject the Contractor to the corrective actions

1.2.1.2 Agency Review Clause. The Contract Manager or designee will use the results of monitoring activities and other relevant data to assess the Contractor's overall performance and compliance with the Contract. At a minimum, the Agency will conduct a review annually; however, reviews may occur more frequently at the Agency's discretion. As part of the review(s), the Agency may require the Contractor to provide additional data, may perform on-site reviews, and may consider information from other sources.

The Agency may require one or more meetings to discuss the outcome of a review. Meetings may be held in person. During the review meetings, the parties will discuss the Deliverables that have been provided or are in process under this Contract, achievement of the performance measures, and any concerns identified through the Agency's contract monitoring activities.

1.2.1.3 Problem Reporting. As stipulated by the Agency, the Contractor and/or Agency shall provide a report listing any problem or concern encountered. Records of such reports and other related communications issued in writing during the course of Contract performance shall be maintained by the parties. At the next scheduled meeting after a problem has been identified in writing, the party responsible for resolving the problem shall provide a report setting forth activities taken or to be taken to resolve the problem together with the anticipated completion dates of such activities. Any party may recommend alternative courses of action or changes that will facilitate problem resolution. The Contract Owner has final authority to approve problem-resolution activities.

The Agency's acceptance of a problem report shall not relieve the Contractor of any obligation under this Contract or waive any other remedy. The Agency's inability to identify the extent of a problem or the extent of damages incurred because of a problem shall not act as a waiver of performance or damages under this Contract.

1.2.1.4 Addressing Deficiencies. To the extent that Deficiencies are identified in the Contractor's performance and notwithstanding other remedies available under this Contract, the Agency may require the Contractor to develop and comply with a plan acceptable to the Agency to resolve the Deficiencies.

1.2.1.5 Contract Payment Clause.

1.2.1.5.1 Pricing. In accordance with the payment terms outlined in this section and Contractor's completion of the Scope of Work as set forth in this Contract, the Contractor will be compensated as set forth in the Payment Methodology clause.

1.2.1.5.2 Payment Methodology.

1.2.1.5.2.1 Capitation Rate Payments.

The Agency will pay the Contractor on a monthly basis using the capitation payment methodology for enrollees assigned to Contractor. Capitation rates applicable to each Contract term are set forth in the Capitation Rates table in the Special Contract Attachment Section 3.4. The capitation payment will constitute payment in full for the Contractor's coverage of the enrollees assigned to Contractor as listed in the monthly HIPAA 820 capitation file. Retroactive adjustments to reflect the actual cost of covered services are prohibited.

The Agency will pay any Contractor health insurer fee that may be owed pursuant to Section 9010 of the Affordable Care Act on a retrospective basis upon receipt of information regarding the amount of the fee paid by the Contractor for the premium earned under the terms of this Contract. The retrospective payment will include an adjustment for related income taxes and other adjustments, including tax credits. The Contractor shall submit any requested documentation to the Agency regarding the amount of the fee. A corporate officer for the Contractor shall attest to the accuracy of the documentation.

Contractor shall on a monthly basis reconcile the monthly HIPAA 820 capitation file with the Contractor's enrollment records. Any discrepancies found between the monthly HIPAA 820 capitation file and the Contractor's enrollment records shall be reported to the Agency within sixty (60) calendar days from the end of the quarter. No adjustment to the capitation payment shall be made for any discrepancies reported after the sixty (60) calendar day period other than as required to avoid Contractor retention of payment in excess of those permitted under Section 1.3(D).

The parties agree to work diligently and in good faith to establish and agree to capitation rates before the expiration of any rate period. If the parties are unable to establish new annual capitation rates for a subsequent rate period due to delays or disagreements, the Agency or Contractor may terminate the Contract upon ninety (90) days written notice from expiration of the current rate period and contract amendment term or, if notice is given after the expiration of the current rate period, ninety (90) days written notice from the date of the notice. Upon agreement to the capitation rates, the Agency will perform a reconciliation between the capitation rates paid and the newly agreed upon rates for the rate period. Any discrepancy will be reconciled through the capitation rate payment process.

By agreeing to the rates offered to Contractor through the Contract amendment process, Contractor irrevocably and unconditionally releases, acquits, and forever discharges the State of Iowa, the Agency, and all of the Agency's officers, directors, employees, agents, and attorneys, from any and all liability whatsoever from any and all claims, demands and causes of action of every nature whatsoever that Contractor may have or may ever claim to have now existing or hereafter arising that relate to or arise out of any assertion regarding the actuarial soundness of the agreed rates.

1.2.1.5.2.2 Medical Loss Ratio

Capitation payments made through the Contract shall be subject to the Medical Loss Ratio ("MLR") applicable to each Contract term are set forth in the Capitation Rates table in the Special Contract

Attachment section 3.1. Calculation of the MLR shall be in accordance with Section 1.3(D.4), as further clarified by Section 4 § 438.8 of this Contract. Payment of any remittance by Contractor pursuant to the MLR reporting obligation shall occur within the timeframe set forth in Section 1.3(D.4).

1.2.1.5.2.3 Withhold

The Agency will withhold a portion of the approved capitation payments from Contractor within each Contract period in accordance with the 2% Withhold Payment Obligations table in the Special Contract Attachment section 3.1 applicable to the specific Contract term. The withheld amount shall be two percent (2%) of the monthly capitation payment. The Contractor will be eligible to receive some or all of the withheld funds based on the Contractor's performance in the areas outlined in the applicable 2% Withhold Payment Obligations table. These performance standards require the Contractor to exceed the minimum performance standard required for Contract compliance and incentivize the Contractor to perform at a higher level in areas determined by the Agency to be critical for a successful program. The Contractor shall submit information to the Agency, in the format and timeframe specified by the Agency, with respect to each performance measure. Any data received after the required submission date will not be eligible for an incentive payment. Incentive payments will be payable in the form of release of funds withheld.

1.2.1.5.2.4 Reimbursable Expenses.

Unless otherwise agreed to by the parties in an amendment to the Contract that is executed by the parties, the Contractor shall not be entitled to receive any other payment or compensation from the State for any Deliverables provided by or on behalf of the Contractor pursuant to this Contract. The Contractor shall be solely responsible for paying all costs, expenses, and charges it incurs in connection with its performance under this Contract.

1.2.2 Insurance Coverage.

The Contractor and any subcontractor shall obtain the following types of insurance for at least the minimum amounts listed below:

Type of Insurance	Limit	Amount
General Liability (including contractual liability) written on occurrence basis	General Aggregate Product/Completed Operations Aggregate Personal Injury Each Occurrence	$2 Million $1 Million $1 Million $1 Million
Automobile Liability (including any auto, hired autos, and non-owned autos)	Combined Single Limit	$1 Million
Excess Liability, Umbrella Form	Each Occurrence Aggregate	$1 Million $1 Million
Workers' Compensation and Employer Liability	As required by Iowa law	As Required by Iowa law
Property Damage	Each Occurrence Aggregate	$1 Million $1 Million
Professional Liability	Each Occurrence Aggregate	$2 Million $2 Million

1.2.3 Business Associate Agreement. The Contractor, acting as the Agency's Business Associate, performs certain services on behalf of or for the Agency pursuant to this Contract that require the exchange of information that is protected by the Health Insurance Portability and Accountability Act of 1996, as amended, and the federal regulations published at 45 C.F.R. part 160 and 164. The Business Associate agrees to comply with the Business Associate Agreement Addendum (BAA), and any amendments thereof, as posted to the Agency's website: http://dhs.iowa.gov/HIPAA/baa. This BAA, and any amendments thereof, is incorporated into the Contract by reference.

By signing this Contract, the Business Associate consents to receive notice of future amendments to the BAA through electronic mail. The Business Associate shall file and maintain a current electronic mail address with the Agency for this purpose. The Agency may amend the BAA by posting an updated version of the BAA on the Agency's website at: http://dhs.iowa.gov/HIPAA/baa, and providing the Business Associate electronic notice of the amended BAA. The Business Associate shall be deemed to have accepted the amendment unless the Business Associate notifies the Agency of its non-acceptance in accordance with the Notice provisions of the Contract within 30 days of the Agency's notice referenced herein. Any agreed alteration of the then current Agency BAA shall have no force or effect until the agreed alteration is reduced to a Contract amendment that must be signed by the Business Associate, Agency Director, and the Agency Security and Privacy Officer.

1.2.4 Qualified Service Organization. The Contractor acknowledges that it will be receiving, storing, processing, or otherwise dealing with confidential patient records from programs covered by 42 C.F.R. part 2, and the Contractor acknowledges that it is fully bound by those regulations. The Contractor will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by 42 C.F.R. part 2. "Qualified Service Organization" as used in this Contract has the same meaning as the definition set forth in 42 C.F.R. § 2.11.

1.3 Scope of Work

A. Deliverables, Performance Measures and Monitoring Activities.

The Contractor shall provide the following:

A.1 Performance Measure

The plan shall demonstrate an increase in total number of children 1-18 years of age who had at least one preventive dental visit during the measurement year.

A.2 Enrollment in the Hawk-i program

A.2.1 Enrollment Area & Eligibility Determinations

The agency shall act as the agent for the Agency in the determination of eligibility and enrollment. The Agency shall determine eligibility of children to participate in the ***hawk-i*** program and shall notify the Plan of enrollment.

The Enrollment Area for which the Contractor agrees to provide services shall be the entire State of Iowa for which a valid certificate of authority has been issued by the Insurance Division of the Department of Commerce and for which the Agency has determined there is a sufficient panel of contracted providers able to meet the needs of enrollees. The Agency shall determine eligibility of patients to enroll in the ***hawk-i*** plan.

A.2.2 Choice of a Plan

Enrollees shall have the right to choose a Plan in those counties where a choice is available.

A.2.3 Plan Information

The Agency will provide the enrollee with information about all plans available to the enrollee. Such information shall be provided to the Agency by the Contractor. When requested, the Agency will assist

the enrollee in the selection of a plan when more than one plan is available. Such assistance will be provided in an unbiased manner.

A.2.4 12-Month Enrollment Period

Unless this Contract is terminated earlier, upon selection of a plan, the enrollee will remain enrolled in the selected plan for a period of twelve (12) months as long as the enrollee remains eligible for the ***hawk-i*** program, but subject to the right of disenrollment as specified in this Contract.

A.2.5 Enrollment File to the Plan

The Agency will transmit an enrollment file to the Contractor in a format as agreed upon by all parties as follows:

1. A daily enrollment file that:
   - Lists all new or renewed ***hawk-i*** enrollees for each month of coverage.
   - Lists ***hawk-i*** enrollees that have changed (i.e., name change, address change, etc.)
2. A monthly file that lists all ***hawk-i*** enrollees eligible for the programs for that month.

The Contractor shall accept as enrollees all persons who appear on the enrollment file without restriction.

A.2.6 Open Enrollment

Contractor shall maintain a continuous open enrollment period during which Contractor shall accept enrollees eligible for coverage under this Contract.

A.2.7 Receipt of Enrollment Files

Contractor shall download both the daily and the monthly enrollment files on a daily basis in the same order as transmitted by the Agency.

A.2.8 Periodic Reviews of Eligibility

The Agency shall periodically conduct a review of each enrollee's circumstances to establish the enrollee's continued eligibility to participate in the ***hawk-i*** program.

A.2.9 Request for Enrollment Information

Upon request, Contractor shall have the right to examine and inspect all information in the possession of the Agency regarding the enrollment process and the number of enrollees enrolled.

A.2.10 Covered Services

Contractor shall provide coverage of all services required by this Contract (Section 3.2). The Agency shall provide the Contractor with ninety (90) Days' advanced written notice preceding any change in covered services under this Contact unless such change is pursuant to a legislative or regulatory mandate, in which event, the Agency shall use best efforts to provide reasonable notice to the Contractor. In the event the Agency provides less than ninety (90) Days' advanced written notice to the Contractor, the Contractor shall comply with the change in covered services within ninety (90) Days from the date the notice is given. Contractor shall not avoid costs for services covered in this Contract by referring enrollees to publicly supported dental care resources in accordance with 42 C.F.R. § 457.950(a)(4).

The Contractor shall provide or arrange for the provision of:

a. Dentally necessary services, and
b. Orthodontic services as required by Iowa Admin. Code ch.441-86

A.2.11 Pre-existing Conditions

Contractor shall not deny reimbursement of Covered Services based on the presence of a pre-existing dental condition.

A.2.12 Enrollee Engagement

Contractor shall ensure the provision of enrollee engagement by utilizing partners to work with providers and enrollees to promote successful compliance with treatment plans and use of preventive care. This will include educating enrollees about good oral hygiene, prevention and maintenance of teeth and gums. The Contractor will work with key community service organizations including the Department of Public Health, to provide resources for community partners so they can assist in education and awareness activities at the local level and support enrollee education and compliance, including linking enrollees with participating dental providers.

A.3 Insurance Division Obligations

Contractor shall retain at all times during the period of this Contract a valid Certificate of Authority issued by the State of Iowa Office of the Commissioner of Insurance. The Contractor shall comply with all reporting requirements at Iowa Admin. Code r. § 191-40.14 and copy the Agency on all required filings with the Iowa Insurance Division. The Contractor shall submit certificates of insurance for required insurance no less than thirty (30) calendar days after the policy renewal effective date. The Contractor shall provide to the Agency all contracts of reinsurance or a summary of the plan of self-insurance which meet the requirements of Iowa law. As applicable, the Contractor shall report to the Agency, in the manner dictated by the Agency, all health care claims costs paid by the Contractor's commercial reinsurer due to meeting the reinsurance attachment point.

A.4 Enrollee Education and Outreach

The Contractor shall manage population health by focusing on restoring basic functionality for all enrollees and improving the oral health of enrollees over time through education, enrollee engagement and community support by such means as, but not limited to:

a. Increasing use of preventive services versus restorative services;
b. Educate enrollees on appropriate utilization of preventive dental services to maintain oral health;
c. Utilizing community resources and health and dental providers to educate enrollees of the importance of oral health care and treatment.

A.5 Benefits

The Plan shall cover Dentally Necessary Services and Medically Necessary Orthodontic Services. This includes preventive and restorative services. See Section 3.2, The Iowa ***hawk-i*** Dental Plan.

A.6 Information to Enrollees and Potential Enrollees

Contractor shall, upon request, make available to enrollees and potential enrollees in the Contractor's service area information concerning the following:

i. *Providers.* The identity, location, qualifications, and availability of dental care providers that participate with the Contractor.
ii. *Enrollee Rights and Responsibilities*. The rights and responsibilities of enrollees.
iii. *Grievance and appeal procedures*. The procedures available to an enrollee and a dental care provider to challenge or appeal the failure of the Contractor to cover a service.
iv. *Information on covered items and services*. All items and services that are available to enrollees under the Contract between the Agency and the Contractor that are covered either directly or through a method of referral and Prior Authorization.

A.7 Plan Information for Enrollees

The Contractor shall mail the enrollee identification cards within ten (10) working days and all other materials to enrollees within twenty (20) working days of Contractor's notification by the Agency that the enrollee is eligible. At a minimum, the materials shall include:

1. The phone number(s) that can be used for assistance to obtain information about emergency care, Prior Authorization, scheduling appointments, and standard benefit/service information;
2. Current provider directory, which must include the names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. This includes information on specialists. Provider directory will be available on Contractor website unless enrollee specifically requests a written copy. Instructions for how to locate a provider will be included in other mailed materials to the provider;
3. Hours of service of the Contractor;
4. Any restrictions on the enrollee's freedom of choice among network providers;
5. Grievance and appeal procedures, including the information required by Iowa Admin. Code § 441-86.15(7).
6. Policies on the use of emergency services;
7. Limited Contractor liability for services from non-participating providers;
8. Information on emergency care coverage, including the fact that prior authorization is not required for emergency services;
9. Enrollee rights and responsibilities, as specified in 42 C.F.R. § 438.100;
10. Accessing out of area services;
11. Procedures for notifying enrollees affected by changes in Covered Services or their Delivery;
12. Procedures for recommending changes in policies and services;
13. 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; and
14. Information on how and where to access any benefits that are available under the State plan but are not covered under the Contract, including any cost sharing. The Contractor shall provide copies of the enrollee information to the Agency by January 15th of each Contract year. In addition, should the Contractor adopt a policy in relation to any particular service, the Contractor shall provide the information to current enrollees within 30 Days and to all potential enrollees on a going forward basis.

A.8 Enrollee Rights

The Contractor shall have written policies outlining enrollee rights, including but not limited to the rights identified below. These policies shall be communicated to enrollees and shall be available to the Agency and providers.

1. *Receive Information.* The enrollee shall receive information in accordance with Section 1.3(C).
2. *Respect.* The enrollee shall be treated with respect and with due consideration for his or her dignity and privacy.
3. *Non-English Speaking Enrollees.* The Contractor shall assure that services are accessible to all enrollees, including those with limited English proficiency or reading skills, with diverse cultural and ethnic backgrounds, and with physical and mental disabilities.

   The Agency shall notify the Contractor in writing if ten (10) percent or more of the Contractor's ***hawk-i*** enrollees speak the same non-English language. Upon notification, the Contractor shall provide the identified enrollees information written in the applicable language regarding access of Covered Services and the mechanism to obtain further information about the Contractor in the enrollee's native language.

   Upon notification from the Agency, the Contractor shall ensure that non-English speaking enrollees are provided information on the benefits and restrictions associated with enrollment in the Contractor in the non-English language. At the time of this contract, the Agency is requiring materials be available in Spanish.

The Contractor shall make oral interpretation services available and to make those services available free to charge to each potential enrollee and enrollee. This applies to all non-English languages, not just those that the Agency identifies.

4. *Visually Impaired Enrollees.* For enrollees identified as visually impaired, the Contractor shall provide basic plan information in large print and Braille formats or through other means, including information regarding how to access services.
5. *Privacy and Confidentiality of Dental Records.* The Contractor shall assure confidentiality of enrollee's dental, health and medical records and other information in the Contractor's possession consistent with state and federal laws. The enrollee shall be guaranteed the right to request and receive a copy of his or her medical or dental records, and to request that they may be amended or corrected as specified in 45 C.F.R. part 164.
6. *Disclosure of Treatment Options.* The Contractor shall not prohibit, or otherwise restrict, a dental 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 enrollee's health status, dental care, or treatment options, including any alternative treatment that may be self-administered.
    - for any information the enrollee needs in order to decide among all relevant treatment options.

A.9 Cost Sharing

Annually, ***hawk-i*** enrollees are limited to Annual Benefit Maximum of $1,000 per calendar year (January1- December 31). If a member reaches the $1,000 ABM and receives additional services the member is responsible for payment of services. Dental services delivered to address an Emergency Dental Condition are covered even if the hawk-I plan member has exceeded their annual benefit maximum. In these situations, services will be Dentally Necessary and prior authorization is required.

A.10 Reduction of Administrative Burdens

The Contractor shall reduce administrative burdens for providers by ensuring that:

- Claims are paid timely;
- The billing system is easily utilized by providers; and
- An annual provider satisfaction survey is conducted.

A.11 Meeting with the Agency

Contractor shall meet with the Agency on a monthly basis to discuss reports and other Contract activities and Contractor's performance under this Contract. When the Agency identifies potential performance issues, the Contractor shall formally respond in writing to these issues within the timeframe required by the Agency. If the Contractor fails to provide a formal, written response to the feedback or fails to respond within the timeframe established by the Agency, the Agency may consider the Contractor noncompliant in its performance reporting and may implement corrective actions.

A.12 Reporting

The Contractor shall comply with all reporting requirements (monthly, quarterly and annually) and shall submit requested data completely and accurately within the requested timeframes and in the format identified by the Agency. The Agency reserves the right to require the Contractor to work with and submit data to third-party data warehouses or analytic vendors. The Contractor shall have policies, procedures and mechanisms in place to ensure that the financial and non-financial performance data submitted to the Agency is accurate.

The Agency may change the frequency of reports and may require additional reports and performance targets at any time. In these situations, the Agency will provide at least thirty (30) calendar days' notice to the Contractor before changing reporting requirements. The Agency may request ad hoc reports "as needed", with a turnaround time to average no more than 15 business days.

A.13 Approval of Contractor/Provider/Stakeholder Communication

All Contractor, Provider and Stakeholder developed communications shall be pre-approved by the Agency. Unless otherwise agreed to by the Agency, all material shall be submitted at least 15 calendar days prior to expected use and distribution. All substantive changes to previously approved communications shall also be submitted to the Agency for review and approval at least 15 calendar days prior to use. The Contractor shall comply with any of the Agency's processes implemented to facilitate submission and approval of materials. For example, the Agency may opt to mandate use of an inventory control number on all submissions or the use of specific cover sheets with document submission. Agency may waive the right to review and approve provider communications. Information that includes the states name and correspondence that may be sent to providers on behalf of the Agency shall also be submitted by the Contractor for the Agency review and approval. Any approval given for the Agency or other state Agency name or logo is specific to the use requested and shall not be interpreted as blanket approval. The Contractor shall include the state program logo in their provider communication materials upon the Agency request. The Agency reserves the right to mandate that specific language be included in provider communication materials the Contractor developed.

A.14 Media Contacts

The Contractor shall not provide information to the media or give media interviews concerning the ***hawk-i*** program or the Contract without the express consent of the Agency and shall refer any such contacts to the Agency.

B. Enrollment and Disenrollment

B.1 No Discrimination

B.1.01 Contractor shall accept new enrollment from individuals in the order in which they apply without restriction, unless authorized by CMS, up to the limits set under the Contract. See the additional obligations set forth in Section 4 § 438.3(d)(1).

B.1.02 Contractor shall not discriminate against individuals eligible to enroll on the basis of health status or need for health care services. See the additional obligations set forth in Section 4 § 438.3(d)(3)

B.1.03 Contractor shall not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability. See the additional obligations as set forth in Section 4 § 438.3(d)(4).

B.1.04 Contractor shall not use any policy or practice that has the effect of discriminating against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability. See the additional obligations as set forth in Section 4 § 438.3(d)(4).

B.1.05 Reserved (N/A).

B.2 Choice of Doctor

B.2.01 For enrollees who qualify under the rural resident exception (under which a state may limit a rural area resident to a single managed care plan, the limitation on the enrollee's freedom to change between primary care providers can only be as restrictive as the limitations on disenrollment from the managed care plan as requested by the enrollee in accordance with Section 4 § 438.56(c). See the additional obligations as set forth in Section 4 § 438.52(b) – (d) and Section 4 § 438.56(c).

B.2.02 Contractor shall allow each enrollee to choose his or her network provider to the extent possible and appropriate. See the additional obligations as set forth in Section 4 § 438.3(l).

B.3 Opt Out

B.3.01 Enrollment with Contractor is voluntary, except when CMS has approved federal authority allowing the Agency to mandate enrollment. See Section 4 § 438.3(d)(2).

B.4 Reenrollment

B.4.01 Contractor shall accept the enrollee's automatic reenrollment when that enrollee has been disenrolled solely because he or she has lost Medicaid eligibility for a period of 2 months or less.

B.5 Disenrollment

B.5.01 The reasons for which Contractor may request disenrollment of an enrollee are set forth in Section 4 § 438.56(b)(1).

B.5.02 – B.5.05 Contractor shall not request disenrollment because of:

1. An adverse change in the enrollee's health status
2. The enrollee's utilization of medical services.
3. The enrollee's diminished mental capacity.
4. The enrollee's uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment seriously impairs Contractor's ability to furnish services to the enrollee or other enrollees.

See the additional obligations as set forth in Section 4 § 438.56(b)(2) and section 1903(m)(2)(A)(iv) of the Social Security Act.

B.5.06 Contractor shall comply with Section 4 § 438.56(b)(3), assuring the Agency that it does not request disenrollment for reasons other than those permitted under this Contract.

B.5.07 – B.5.10 Enrollees have a right under this Contract to disenroll from Contractor:

1. For cause, at any time;
2. Without cause 90 days after initial enrollment or during the 90 days following notification of enrollment, whichever is later;
3. Without cause at least once every 12 months; and
4. Without cause upon reenrollment if a temporary loss of enrollment has caused the enrollee to miss the annual disenrollment period.

See the additional obligations as set forth in Section 4 § 438.3(q)(5), Section 4 § 438.56(c)(1); Section 4 § 438.56(c)(2)(i) – (iii).

B.5.11 Reserved.

B.5.12 – B.5.13 Enrollees may request disenrollment if:

1. The enrollee moves out of the service area.
2. Contractor does not cover the services the enrollee seeks, because of moral or religious objections.

See the additional obligations as set forth in Section 4 § 438.56(d)(2)(i) – (ii).

B.5.14 Enrollees may request disenrollment if the enrollee needs related services to be performed at the same time and not all related services are available within the provider network. The enrollee's PCP or other provider must determine that receiving the services separately would

subject the enrollee to unnecessary risk. See the additional obligations as set forth in Section 4 § 438.56(d)(2)(iii).

B.5.15 *Reserved (not applicable to a dental-only PAHP).*

B.5.16 Enrollees may request disenrollment for other reasons, including poor quality of care, lack of access to services covered under the Contract, or a lack of access to providers experienced in dealing with the enrollee's care needs. See the additional obligations as set forth in Section 4 § 438.56(d)(2)(v).

BS.5.01 The Agency will make all decisions regarding the disenrollment of an enrollee from the Contractor and notify the Contractor of the disenrollment.

B.6 Disenrollment Request Process

B.6.01 A recipient, or his or her representative, must request disenrollment by submitting an oral or written request to the Contractor. See the additional obligations as set forth in Section 4 § 438.56(d)(1)(i) – (ii).

B.6.02 Contractor shall address the recipient's request for disenrollment through the Contractor's grievance process. If the recipient remains dissatisfied following the conclusion of the grievance process, Contractor shall forward the recipient's request to the Agency. See the additional obligations as set forth in Section 4 § 438.56(d)(3)(i).

B.6.03 The effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment. See the additional obligations as set forth in Section 4 § 438.56(e)(1) – (2), Section 4 § 438.56(d)(3)(ii), Section 4 § 438.3(q), and Section 4 § 438.56(c).

B.6.04 If the Agency fails to make a disenrollment determination within the specified timeframes (i.e., the first day of the second month following the month in which the enrollee requests disenrollment), the disenrollment is considered approved for the effective date that would have been established had the Agency made a determination in the specified timeframe. See the additional obligations as set forth in Section 4 § 438.56(e)(1) – (2), Section 4 § 438.56(d)(3)(ii), Section 4 § 438.3(q), and Section 4 § 438.56(c).

B.7 Special Rules for American Indians

B.7.01 If Contractor is an Indian managed care entity, Contractor may restrict enrollment of Indians in the same manner as Indian Health Programs may restrict the delivery of services to Indians. See the additional obligations as set forth in the Social Security Act section 1932(h)(3) and Section 4 § 438.14(d).

B.7.02 If Contractor is not an Indian managed care entity, any Indian enrolled with Contractor and eligible to receive services from an Indian health care provider (IHCP) PCP participating as a network provider, is permitted to choose that IHCP as their PCP, as long as that provider has capacity to provide services. See the additional obligations as set forth in the American Reinvestment and Recovery Act section 5006(d) and Section 4 § 438.14(b)(3).

C. Notifications

C.1 Language and Format

C.1.01 Contractor shall provide information to enrollees and potential enrollees in a manner and format that may be easily understood and is readily accessible by such enrollees and potential enrollees. See the additional obligations as set forth in Section 4 § 438.10(c)(1).

CS.1.01All notices, information materials, and instructional materials related to enrollees and potential enrollees must be written in a manner and format that may be easily understood and written at a maximum sixth grade reading level. Information that includes the State's name and correspondence that may be sent to participants on behalf of the Agency shall also be submitted

by the Contractor to the Agency for review and approval. Any approval given for the Agency or other State agency name or logo is specific to the use requested, and shall not be interpreted as blanket approval. The Contractor shall include the State program logo(s) in its marketing or other enrollee communication materials upon the Agency request. The Agency reserves the right to mandate that specific language be included in member communication materials.

C.1.02 Contractor shall have in place mechanisms to help enrollees and potential enrollees understand the requirements and benefits of their plan. See the additional obligations as set forth in Section 4 § 438.10(c)(7).

C.1.03 Contractor shall make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices available in the prevalent non-English languages in its particular service area. See the additional obligations as set forth in Section 4 § 438.10(d)(3).

C.1.04 – C.1.06 Contractor's written materials must:

1. Be available in alternative formats upon request of the potential enrollee or enrollee at no cost.

2. Include taglines in the prevalent non-English languages in the state, as well as large print, explaining the availability of written translation or oral interpretation to understand the information provided.

3. Include taglines in the prevalent non-English languages in the state, as well as large print, explaining the availability of the toll-free and Teletypewriter Telephone/Text Telephone (TTY/TDY) telephone number of the Contractor's member/customer service unit.

See the additional obligations as set forth in Section 4 § 438.10(d)(3).

C.1.07 Contractor shall make auxiliary aids and services available upon request of the potential enrollee or enrollee at no cost. See the additional obligations as set forth in Section 4 § 438.10(d)(3).

C.1.08 Contractor shall make interpretation services, including oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language (ASL), free of charge to each enrollee. See the additional obligations as set forth in Section 4 § 438.10(d)(4).

C.1.09 – C.1.11 Contractor shall notify its enrollees that:

1. Oral interpretation is available for any language, and how to access those services.

2. Written translation is available in prevalent languages, and how to access those services.

3. Auxiliary aids and services are available upon request at no cost for enrollees with disabilities, and how to access those services.

See the additional obligations as set forth in Section 4 § 438.10(d)(5)(i) - (iii).

C.1.12 Contractor shall provide all written materials for potential enrollees and enrollees in an easily understood language and format. See the additional obligations as set forth in Section 4 § 438.10(d)(6)(i).

C.1.13 – C.1.16 Contractor shall:

1. Provide all written materials for potential enrollees and enrollees in a font size no smaller than 12 point.

2. Make written materials for potential enrollees and enrollees available in alternative formats in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

3. Make written materials for potential enrollees and enrollees available through 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.

4. Include on all written materials a large print tagline and information on how to request auxiliary aids and services, including materials in alternative formats.

See the additional obligations as set forth in Section 4 § 438.10(d)(6)(ii) - (iv).

C.2 Enrollee Handbook

C.2.01 Contractor shall use the Agency developed model enrollee handbook. See the additional obligations as set forth in Section 4 § 438.10(c)(4)(ii).

C.2.02 Contractor shall provide each enrollee an enrollee handbook, which serves as a summary of benefits and coverage, within a reasonable time after receiving notice of the beneficiary's enrollment. See the additional obligations as set forth in Section 4 § 438.10(g)(1) and 45 C.F.R. § 147.200(a).

C.2.03 Contractor shall include in the enrollee handbook information that enables the enrollee to understand how to effectively use the managed care program. See the additional obligations as set forth in Section 4 § 438.10(g)(2).

C.2.04 – C.2.07 Contractor shall utilize the model enrollee handbook developed by the Agency that includes information:

1. On benefits provided by Contractor. This includes information about the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit and how to access component services if individuals under age 21 entitled to the EPSDT benefit are enrolled in the Contractor.

2. About how and where to access any benefits provided by the Agency, including EPSDT benefits delivered outside Contractor, if any.

3. About cost sharing on any benefits carved out of the Contractor contract and provided by the Agency.

4. About how transportation is provided for any benefits carved out of this Contract and provided by the Agency.

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(i) - (ii).

C.2.08 – C.2.09 Contractor shall utilize the model enrollee handbook developed by the Agency that includes detail that in the case of a counseling or referral service that Contractor does not cover because of moral or religious objections, the Contractor informs enrollees:

1. That the service is not covered by the Contractor.

2. How they can obtain information from the Agency about how to access those services.

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(ii)(A) - (B) and Section 4 § 438.102(b)(2).

C.2.10 – C.2.11 Contractor shall utilize the model enrollee handbook developed by the Agency that includes:

1. 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.

2. 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 PCP.

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(iii) - (iv).

C.2.12 Contractor shall utilize the model enrollee handbook developed by the Agency that includes the extent to which, and how, after-hours care is provided. See the additional obligations as set forth in Section 4 § 438.10(g)(2)(v).

C.2.13 – C.2.17 Contractor shall utilize the model enrollee handbook developed by the Agency that includes:

1. How emergency care is provided.

2. Information regarding what constitutes an emergency medical condition.

3. Information regarding what constitutes an emergency service.

4. The fact that prior authorization is not required for emergency services.

5. The fact that the enrollee has a right to use any hospital or other setting for emergency care.

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(v).

C.2.18 – C.2.19 Contractor shall utilize the model enrollee handbook developed by the Agency that includes:

1. Any restrictions on the enrollee's freedom of choice among network providers.

2. *Reserved (not applicable to a dental-only PAHP).*

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(vi) - (vii).

C.2.20 *Reserved (not applicable to a dental-only PAHP).*

C.2.21 Contractor shall utilize the model enrollee handbook developed by the Agency that includes cost sharing for services furnished by Contractor, if any is imposed under the State Plan. See the additional obligations as set forth in Section 4 § 438.10(g)(2)(viii).

C.2.22 – C.2.27 Contractor shall utilize the model enrollee handbook developed by the Agency that includes enrollee rights and responsibilities, including the enrollee's right to:

1. Receive information on beneficiary and plan information.

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

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

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

5. Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation.

6. Request and receive a copy of their medical records and request that they be amended or corrected.

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(ix)and Section 4 § 438.100(b)(2)(i) - (vi).

C.2.28 Contractor shall utilize the model enrollee handbook developed by the Agency that includes enrollee rights and responsibilities, including the enrollee's right to obtain available and accessible health care services covered under this Contract. See the additional obligations as set forth in Section 4 § 438.10(g)(2)(ix) and Section 4 § 438.100(b)(3).

C.2.29 Contractor shall utilize the model enrollee handbook developed by the Agency that includes the process of selecting and changing the enrollee's PCP. See the additional obligations as set forth in Section 4 § 438.10(g)(2)(x).

C.2.30 Contractor shall utilize the model enrollee handbook developed by the Agency that includes grievance, appeal, and fair hearing procedures and timeframes in a state-developed or state-approved description. See the additional obligations as set forth in Section 4 § 438.10(g)(2)(xi).

C.2.31 – C.2.36 Contractor shall utilize the model enrollee handbook developed by the Agency that:

1. Includes the enrollee's right to file grievances and appeals.

2. Includes the requirements and timeframes for filing a grievance or appeal.

3. Includes information on the availability of assistance in the filing process for grievances.

4. Includes information on the availability of assistance in the filing process for appeals.

5. Includes the enrollee's right to request a state fair hearing after the Contractor has made a determination on an enrollee's appeal which is adverse to the enrollee.

6. Specifies that, when requested by the enrollee, benefits that the Contractor 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, and that the enrollee may, consistent with Agency 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.

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(xi)(A) - (E).

C.2.37 – *Reserved (not applicable to a dental-only PAHP).*

C.2.38 *Reserved (not applicable to a dental-only PAHP).*

C.2.39 – C.2.44 Contractor shall utilize the model enrollee handbook developed by the Agency that includes:

1. How to access auxiliary aids and services, including additional information in alternative formats or languages.

2. The toll-free telephone number for member services.

3. The toll-free telephone number for dental management.

4. The toll-free telephone number for any other unit providing services directly to enrollees.

5. Information on how to report suspected fraud or abuse.

6. Any other content required by the Agency.

See the additional obligations as set forth in Section 4 § 438.10(g)(2)(xiii) - (xvi).

C.2.45 Contractor shall provide each enrollee notice of any significant change, as defined by the state, in the information specified in the enrollee handbook at least 30 days before the intended effective date of the change. See the additional obligations as set forth in Section 4 § 438.10(g)(4).

C.2.46 The Contractor shall utilize the model enrollee handbook and notices that describe the transition of care policies for enrollees and potential enrollees. See the additional obligations as set forth in Section 4 § 438.62(b)(3).

C.3 Enrollee Handbook Dissemination

C.3.01 Handbook information provided to the enrollee is considered to be provided if Contractor:

1. Mails a printed copy of the information to the enrollee's mailing address.

2. Provides the information by email after obtaining the enrollee's agreement to receive the information by email.

3. Posts the information on its website 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

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

See the additional obligations as set forth in Section 4 § 438.10(g)(3)(i) - (iv).

C.4 Network Provider Directory

C.4.01 – C.4.08 For provider types covered under the Contract, Contractor shall make the following information on the Contractor's network providers available to the enrollee in paper form upon request and electronic form:

1. Names, as well as any group affiliations.

2. Street addresses.

3. Telephone numbers.

4. Website URLs, as appropriate.

5. Specialties, as appropriate.

6. Whether network providers will accept new enrollees.

7. The cultural and linguistic capabilities of network providers, including languages (including ASL) offered by the provider or a skilled medical interpreter at the provider's office, and whether the provider has completed cultural competence training.

8. Whether network providers' offices/facilities have accommodations for people with physical disabilities, including offices, exam room(s) and equipment.

See the additional obligations as set forth in Section 4 § 438.10(h)(1)(i) - (viii) and Section 4 § 438.10(h)(2).

C.4.09 – C.4.10 Contractor's provider network information included in:

1. A paper provider directory must be updated at least monthly.

2. An electronic provider directory must be updated no later than 30 calendar days after the Contractor receives updated provider information.

See the additional obligations as set forth in Section 4 § 438.10(h)(3).

C.4.11 Contractor shall make its provider directories available on the Contractor's website in a machine readable file and format as specified by the Secretary. See the additional obligations as set forth in Section 4 § 438.10(h)(4).

C.5 Formulary

C.5.01 – C.5.03 *Reserved (not applicable to a dental-only PAHP. Pharmaceuticals are covered under the enrollee's medical services).*

C.6 Provider Terminations and Incentives

C.6.01 Contractor shall 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. See the additional obligations as set forth in Section 4 § 438.10(f)(1).

C.6.02 Contractor shall make available, upon request, any physician incentive plans in place. See the additional obligations as set forth in Section 4 § 438.10(f)(3) and Section 4 § 438.3(i).

C.7 Marketing

C.7.01 – C.7.04 Contractor:

1. Shall not distribute marketing materials without first obtaining Agency approval.

2. Shall distribute marketing materials to its entire service area as indicated in the Contract.

3. Shall not seek to influence enrollment in conjunction with the sale or offering of any private insurance.

4. Shall not directly or indirectly engaging in door-to-door, telephone, e-mail, texting, or other cold-call marketing activities.

See the additional obligations as set forth in Section 4 § 438.104(b)(1)(i) - (ii), and Section 4 § 438.104(b)(1)(iv) - (v).

C.7.05 – C.7.07

1. Contractor shall obtain prior Agency approval for any of its marketing materials, and its marketing, including plans and materials, must be accurate and not mislead, confuse, or defraud the recipients or the Agency.

2. Contractor's materials cannot contain any assertion or statement (whether written or oral) that the recipient must enroll in the Contractor to obtain benefits or to not lose benefits.

3. Contractor's materials cannot contain any assertion or statement (whether written or oral) that the Contractor is endorsed by CMS, the Federal or state government, or a similar entity.

See the additional obligations as set forth in Section 4 § 438.104(b)(2)(i) - (ii).

C.8 General Information Requirements

C.8.01 – C.8.06 If Contractor chooses to provide required information electronically to enrollees

1. It must be in a format that is readily accessible.

2. The information must be placed in a location on the Contractor's website that is prominent and readily accessible.

3. The information must be provided in an electronic form which can be electronically retained and printed.

4. The information is consistent with content and language requirements.

5. The Contractor must notify the enrollee that the information is available in paper form without charge upon request.

6. The Contractor must provide, upon request, information in paper form within 5 business days.

See the additional obligations as set forth in Section 4 § 438.10(c)(6)(i) - (v).

C.8.07 *Reserved (not applicable to a dental-only PAHP).*

C.8.08 Contractor shall reflect changes in state law in its written advance directives information as soon as possible, but no later than 90 days after the effective date of the change. See the additional obligations as set forth in Section 4 § 438.3(j)(4).

C.8.09 Contractor shall notify enrollees when it adopts a policy to discontinue coverage of a counseling or referral service based on moral or religious objections at least 30 day prior to the effective date of the policy for any particular service. See the additional obligations as set forth in Section 4 § 438.102(b)(1)(i)(B), and Section 4 § 438.10(g)(4).

C.8.10 – C.8.29 Contractor shall use the Agency-developed definition for the following terms: appeal; durable medical equipment; emergency medical condition; emergency medical transportation; emergency room care; emergency services; grievance; habilitation services and devices; home health care; hospice services; hospitalization; hospital outpatient care; physician services; prescription drug coverage; prescription drugs; primary care physician; PCP; rehabilitation services and devices; skilled nursing care; and specialist. See the additional obligations as set forth in Section 4 § 438.10(c)(4)(i).

C.8.30 – C.8.41 Contractor shall use the Agency-developed definition for the following terms: co-payment; excluded services; health insurance; medically necessary; network; non-participating provider; plan; preauthorization; participating provider; premium; provider; urgent care. See the additional obligations as set forth in Section 4 § 438.10(c)(4)(i).

C.8.42 Contractor shall disseminate practice guidelines to enrollees and potential enrollees upon request. See the additional obligations as set forth in Section 4 § 438.236(c).

C.8.43 Contractor shall use Agency developed enrollee notices. See the additional obligations as set forth in Section 4 § 438.10(c)(4)(ii).

C.8.44 Contractor shall provide timely notice to the enrollee of the enrollee's right to pursue a state fair hearing. See the additional obligations as set forth in Section 4 § 438.228(b).

C.9 Sales and Transactions

C.9.01 *Reserved (not applicable to a dental-only PAHP).*

D Payment

D.1 General

D.1.01 The final capitation rates for the Contract are set forth in Special Contract Attachments designated in Section 3.1 for each Contract term, which establish the capitation rates and other payment obligations for this Contract. See the additional obligations as set forth in Section 4 § 438.3(c)(1)(i), and Special Terms section 1.2.1.5.

D.1.02 Capitation payments may only be made by the Agency and retained by Contractor for Medicaid-eligible enrollees. See the additional obligations as set forth in Section 4 § 438.3(c)(2).

D.1.03 All applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, are described in the Contract in Section 1.2.1.5 of the Special Terms. See the additional obligations as set forth in Section 4 § 438.6(b)(1).

D.1.04 All delivery system and payment initiatives, if any, that are permitted by 42 C.F.R. § 438.6(c) will be set forth in the Contract's Special Terms and shall not be of any force or effect under this Contract until the initiative has received prior CMS approval. See the additional obligations as set forth in Section 4 § 438.6(c).

D.1.05 Reserved.

D.2 Incentive Arrangements

D.2.01 Any and all incentive arrangements identified in the Contract's Special Terms shall be for a fixed period of time. See the additional obligations as set forth in Section 4 § 438.6(b)(2)(i).

D.2.02 All performance for all incentive arrangements under this Contract will be measured during the rating period under the Contract in which the incentive arrangement is applied. See the additional obligations as set forth in Section 4 § 438.6(b)(2)(i).

D.2.03 – D.2.05 Any and all Incentive arrangements under the Contract:

1. Are not renewed automatically.

2. Are made available to both public and private contractors under the same terms of performance.

3. Do not condition Contractor participation in the incentive arrangement on the Contractor entering into or adhering to intergovernmental transfer agreements.

See the additional obligations as set forth in Section 4 § 438.6(b)(2)(ii) - (iv).

D.2.06 All incentive arrangements are necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the Agency's quality strategy. See the additional obligations as set forth in Section 4 § 438.6(b)(2)(v) and Section 4 § 438.340.

D.3 Withhold Arrangements

D.3.01 – D.3.06 For all withhold arrangements described in the Contract:

1. The arrangement is for a fixed period of time.

2. Performance is measured during the rating period under the Contract in which the withhold arrangement is applied.

3. The arrangement will not to be renewed automatically.

4. The arrangement is made available to both public and private contractors under the same terms of performance.

5. The arrangement does not condition Contractor participation in the withhold arrangement on the Contractor's entering into or adhering to intergovernmental transfer agreements.

6. The arrangement is necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the Agency's quality strategy.

See the additional obligations as set forth in Section 4 § 438.6(b)(3)(i) - (v) and Section 4 § 438.340.

DS.3.01 – The withhold applicable to this Contract is set forth in Section 3.1 of the Special Contract Attachments and further described in Section 1.2.1.5 of the Special Terms.

D.4 Medical Loss Ratio (MLR)

D.4.01 Contractor shall calculate/report a MLR for each MLR reporting year, consistent with MLR standards. See the additional obligations as set forth in Section 4 § 438.8(a).

D.4.02 The minimum MLR for this Contract shall be no less than 88%. See the additional obligations as set forth in Section 4 § 438.8(c).

DS.4.02 The MLR applicable to each Contract term is set forth in the applicable Special Contract Section 3.1.

D.4.03 Contractor's MLR calculation in a MLR reporting year is the ratio of the numerator (as defined in accordance with Section 4 § 438.8(e)) to the denominator (as defined in accordance with Section 4 § 438.8(f)). See the additional obligations as set forth in Section 4 § 438.8(d) - (f).

D.4.04 – D.4.05 Contractor shall:

1. Include each expense included in the MLR be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.

2. Report on a pro rata basis all expenditures that benefit multiple contracts or populations, or contracts other than those being reported.

See the additional obligations as set forth in Section 4 § 438.8(g)(1)(i) - (ii).

D.4.06 – D.4.08 Contractor shall abide by the following obligations when reporting MLRs under this Contract:

1. Expense allocation must be based on a generally accepted accounting method that is expected to yield the most accurate results.

2. Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.

3. Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.

See the additional obligations as set forth in Section 4 § 438.8(g)(2)(i) - (iii).

D.4.09 – D.4.12

1. Contractor may add a credibility adjustment to a calculated MLR if the MLR reporting year experience is partially credible.

2. The credibility adjustment is added to the reported MLR calculation before calculating any remittances, if required by the Agency.

3. Contractor may not add a credibility adjustment to a calculated MLR if the MLR reporting year experience is fully credible.

4. If Contractor's experience is non-credible, it is presumed to meet or exceed the MLR calculation standards.

See the additional obligations as set forth in Section 4 § 438.8(h)(1) - (3).

D.4.13 Contractor shall aggregate data for all Medicaid eligibility groups covered under the Contract with the Agency. See the additional obligations as set forth in Section 4 § 438.8(i).

D.4.14 Contractor shall provide a remittance for a MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 88 percent or higher. See the additional obligations as set forth in Section 4 § 438.8(j) and Section 4 § 438.8(c).

DS.4.14 The MLR applicable to each Contract term is set forth in the Special Contract Attachment 3.1 applicable to the rating period.

D.4.15 – D.4.29 Contractor shall submit a MLR report to the Agency that includes, for each MLR reporting year:

1. Total incurred claims.
2. Expenditures on quality improving activities.
3. Expenditures related to activities compliant with program integrity requirements.
4. Non-claims costs.
5. Premium revenue.
6. Taxes.
7. Licensing fees.
8. Regulatory fees.
9. Methodology(ies) for allocation of expenditures.
10. Any credibility adjustment applied.
11. The calculated MLR.
12. Any remittance owed to the Agency, if applicable.
13. A comparison of the information reported with the audited financial report.
14. A description of the aggregation method used to calculate total incurred claims.
15. The number of member months.

See the additional obligations as set forth in Section 4 § 438.8(k)(1)(i) - (xiii), Section 4 § 438.608(a)(1) - (5), Section 4 § 438.608(a)(7) - (8), Section 4 § 438.608(b), Section 4 § 438.3(m), and Section 4 § 438.8(i).

D.4.30 Contractor shall submit the MLR report in a timeframe and manner determined by the Agency, which must be within 12 months of the end of the MLR reporting year. See the additional obligations as set forth in Section 4 § 438.8(k)(2) and Section 4 § 438.8(k)(1).

DS.4.30 Contractor shall submit the MLR report no later than 12 months of the end of the MLR reporting year.

D.4.31 Contractor shall require any third party vendor providing claims adjudication activities to provide all underlying data associated with MLR reporting to Contractor within 180 days of the end of the MLR reporting year or within 30 days of being requested by the Contractor, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting. See the additional obligations as set forth in Section 4 § 438.8(k)(3).

D.4.32 – D.4.33 In any instance where the Agency makes a retroactive change to the capitation payments for a MLR reporting year where the MLR report has already been submitted to the Agency, Contractor must:

1. Re-calculate the MLR for all MLR reporting years affected by the change.
2. Submit a new MLR report meeting the applicable requirements.

See the additional obligations as set forth in Section 4 § 438.8(m) and Section 4 § 438.8(k).

D.4.34 Contractor shall attest to the accuracy of the calculation of the MLR in accordance with the MLR standards when submitting required MLR reports. See the additional obligations as set forth in Section 4 § 438.8(n) and Section 4 § 438.8(k).

D.5 Payment for Indian Health Care Providers (IHCP)

D.5.01 If Contractor contracts with Indian Health Care Providers (IHCPs), Contractor shall meet the requirements of FFS timely payment for all Indian Tribe, Tribal Organization, or Urban Indian Organization (I/T/U) providers in its network, including the paying of 90% of all clean claims from practitioners (i.e. those who are in individual or group practice or who practice in shared health facilities) within 30 days of the date of receipt; and paying 99 percent of all clean claims from practitioners (who are in individual or group practice or who practice in shared health facilities) within 90 days of the date of receipt. See the additional obligations as set forth in Section 4 § 438.14(b)(2)(iii) and ARRA 5006(d); 42 C.F.R. § 447.45; 42 C.F.R. § 447.46; SMDL 10-001).

D.5.02 IHCPs that are enrolled in Medicaid as Federally Qualified Health Centers (FQHC) but are not participating providers of Contractor must be paid an amount equal to the amount the Contractor would pay a FQHC that is a network provider but is not an IHCP, including any supplemental payment from the Agency to make up the difference between the amount the Contractor pays and what the IHCP FQHC would have received under Fee For Service (FFS). See the additional obligations as set forth in Section 4 § 438.14(c)(1).

D.5.03 When an IHCP is not enrolled in Medicaid as a FQHC, regardless of whether it participates in the Contractor's network, it has the right to receive its applicable encounter rate published annually in the Federal Register by the Indian Health Service (IHS), or in the absence of a published encounter rate, the amount it would receive if the services were provided under the state plan's FFS payment methodology. See the additional obligations as set forth in Section 4 § 438.14(c)(2).

D.6 Timely Payment

D.6.01 Contractor meet the requirements of FFS timely payment, including the paying of 90% of all clean claims from practitioners (i.e. those who are in individual or group practice or who practice in shared health facilities) within 30 days of the date of receipt; and paying 99% of all clean claims from practitioners (who are in individual or group practice or who practice in shared health facilities) within 90 days of the date of receipt. See the additional obligations as set forth in 42 C.F.R. §§ 447.45(d)(2) - (3), 42 C.F.R. § 447.46; and sections 1902(a)(37)(A) and 1932(f) of the Social Security Act.

D.6.02 Reserved.

D.7 Pass-through Payments

DS.7.01 Contractor shall make no pass-through payments to providers under this Contract even if such payments are permissible pursuant to 42 C.F.R. § 438.6(d).

E Providers and Provider Network

E.1 Network Adequacy

E.1.01 – E.1.02 Contractor shall:

1. Provide reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

2. Make arrangements with or referrals to, a sufficient number of physicians and other practitioners to ensure that the services under the Contract can be furnished promptly and without compromising the quality of care.

See the additional obligations as set forth in Section 4 § 438.3(q)(1), and Section 4 § 438.3(q)(3).

E.1.03 Contractor shall maintain and monitor a network of appropriate providers that is supported by written agreements. See the additional obligations as set forth in Section 4 § 438.206(b)(1).

E.1.04 Contractor shall maintain and monitor a network of appropriate providers that is sufficient to provide adequate access to all services covered under this Contract for all enrollees, including those with limited English proficiency or physical or mental disabilities. See the additional obligations as set forth in Section 4 § 438.206(b)(1).

E.1.05 *Reserved (not applicable to a dental-only PAHP).*

E.1.06 Contractor shall give assurances and provide supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the Agency's standards for access and timeliness of care. See the additional obligations as set forth in Section 4 § 438.207(a), Section 4 § 438.68; and Section 4 § 438.206(c)(1).

E.1.07 Contractor shall submit documentation to the Agency, in a format specified by the Agency, to demonstrate that it offers an appropriate range of preventive, primary care, specialty services that is adequate for the anticipated number of enrollees for the service area, to the extent such services are covered under the Contract. See the additional obligations as set forth in Section 4 § 438.207(b)(1).

E.1.08 Contractor shall submit documentation to the Agency, in a format specified by the Agency, to demonstrate that it 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. See the additional obligations as set forth in Section 4 § 438.207(b)(2).

E.1.09 Contractor shall submit documentation as specified by the Agency, but no less frequently than the following: 1) at the time it enters into a contract with the Agency; 2) on an annual basis; 3) at any time there has been a significant change (as defined by the Agency) in the Contractor's operations that would affect the adequacy of capacity and services, including changes in Contractor services, benefits, geographic service area, composition of or payments to its provider network, or at the enrollment of a new population in Contractor. See the additional obligations as set forth in Section 4 § 438.207(b) - (c).

E.1.10 Reserved.

ES.1.01 Contractor shall offer to contract with all federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) located in Iowa. The Contractor may establish quality standards that FQHCs and RHCs shall meet to be offered network participation, subject to Agency review and approval. The Contractor shall reimburse all FQHCs and RHCs the Prospective Payment System (PPS) rate in effect on the date of service for each encounter. The Contractor shall not enter into alternative reimbursement arrangements with FQHCs or RHCs without prior approval from the State.

ES.1.08 The Contractor shall ensure that enrollees have adequate access to dentists. Adequate access to a dentist shall be defined as either thirty (30) miles or thirty (30) minutes for urban areas

and sixty (60) miles or sixty (60) minutes in rural areas from the ***hawk-i*** enrollee place of residence.

E.2 Discrimination

E.2.01 Contractor shall not discriminate against any provider (limiting their participation, reimbursement or indemnification) 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. See the additional obligations as set forth in Section 4 § 438.12(a)(1).

E.3 Provider Selection

E.3.01 Contractor shall give written notice of the reason for its decision when it declines to include individual or groups of providers in its provider network. See the additional obligations as set forth in Section 4 § 438.12(a)(1).

E.3.02 Contractor shall implement written policies and procedures for selection and retention of network providers. See the additional obligations as set forth in Section 4 § 438.12(a)(2) and Section 4 § 438.214(a).

E.3.03 Contractor shall follow the Agency's uniform credentialing policy that addresses acute, primary, behavioral, substance use disorder, and LTSS providers, as appropriate. See the additional obligations as set forth in Section 4 § 438.12(a)(2) and Section 4 § 438.214(b)(1).

E.3.04 Contractor shall follow a documented process for credentialing and recredentialing of network providers. See the additional obligations as set forth in Section 4 § 438.12(a)(2) and Section 4 § 438.214(b)(2).

E.3.05 Contractor's selection policies and procedures shall not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment. See the additional obligations as set forth in Section 4 § 438.12(a)(2) and Section 4 § 438.214(c)

E.3.06 Contractor shall comply with any additional provider selection requirements established by the Agency. See the additional obligations as set forth in Section 4 § 438.12(a)(2) and Section 4 § 438.214(e).

E.3.07 Nothing in this Contract requires Contractor to contract with more providers than necessary to meet the needs of its enrollees. See the additional obligations as set forth in Section 4 § 438.12(b)(1).

E.3.08 Contractor is not precluded from using different reimbursement amounts for different specialties or for different practitioners in the same specialty. See the additional obligations as set forth in Section 4 § 438.12(b)(2).

E.3.09 Contractor is not precluded from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees. See the additional obligations as set forth in Section 4 § 438.12(b)(3).

E.3.10 Contractor shall demonstrate that its network providers are credentialed as required under 42 C.F.R. § 438.214. See the additional obligations as set forth in Section 4 § 438.206(b)(6).

E.4 Anti-gag

E.4.01 – E.4.04 Contractor shall not prohibit or restrict a provider acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient regarding:

1. The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

2. Any information the enrollee needs to decide among all relevant treatment options.

3. The risks, benefits, and consequences of treatment or non-treatment.

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.

See the additional obligations as set forth in Section 4 § 438.102(a)(1)(i) - (iv) and section 1932(b)(3)(A) of the Social Security Act.

E.4.05 Contractor shall take no punitive action against a provider who either requests an expedited resolution or supports an enrollee's appeal. See the additional obligations as set forth in Section 4 § 438.410(b).

E.5 Network Adequacy Standards

E.5.01 – E.5.06

1. Contractor and its network providers shall meet the Agency standards for timely access to care and services, taking into account the urgency of need for services.

2. The Contractor's network providers shall offer hours of operation that are no less than the hours offered to commercial enrollees or are comparable to Medicaid FFS, if the provider serves only Medicaid enrollees.

3. The Contractor shall make services available 24 hours a day, 7 days a week, when medically necessary.

4. The Contractor shall establish mechanisms to ensure that its network providers comply with the timely access requirements.

5. The Contractor shall monitor network providers regularly to determine compliance with the timely access requirements.

6. The Contractor shall take corrective action if it, or its network providers, fail to comply with the timely access requirements.

See the additional obligations as set forth in Section 4 § 438.206(c)(1)(i) - (vi).

E.5.07 Contractor shall ensure that network providers provide physical access, reasonable accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities. See the additional obligations as set forth in Section 4 § 438.206(c)(3).

E.5.08 – E.5.33 Contractor shall adhere to the time and distance standards developed by the Agency for the following provider types, if the provider type is covered under the Contract:

1. Adult PCPs.
2. Pediatric PCPs.
3. Obstetrics and Gynecology (OB/GYN) providers.
4. Adult mental health providers.
5. Adult substance use disorder providers.
6. Pediatric mental health providers.
7. Pediatric substance use disorder providers.
8. Adult specialist providers.

9. Pediatric specialist providers.

10. Hospitals.

11. Pharmacies.

12. Pediatric dental providers.

13. Any additional provider types when it promotes the objectives of the Medicaid program for the provider type to be subject to time and distance access standards, as determined by CMS.

See the additional obligations as set forth in Section 4 § 438.68(b)(1)(i) - (viii).

E.5.34 – E.5.35 *Reserved (not applicable to a dental-only PAHP).*

E.5.36 *Reserved (not applicable to a dental-only PAHP).*

E.5.37 – E.5.47 Contractor shall meet relevant Agency network adequacy standards in all geographic areas in which the Contractor operates for the following provider types, if the provider type is covered under the Contract:

1. Adult PCPs.

2, Pediatric PCPs.

3. OB/GYN providers.

4. Adult behavioral health (mental health and substance use disorder) providers.

5. Pediatric behavioral health (mental health and substance use disorder) providers.

6. Adult specialist providers.

7. Pediatric specialist providers.

8. Hospitals.

9. Pharmacies.

10. Pediatric dental providers.

11. Any additional provider types when it promotes the objectives of the Medicaid program as determined by CMS.

Contractor may be permitted to have varying standards for the same provider type based on geographic areas. See the additional obligations as set forth in Section 4 § 438.68(b)(3) and Section 4 § 438.68(b)(1)(i) - (viii).

E.5.48 *Reserved (not applicable to a dental-only PAHP).*

E.5.49 If the Agency has developed an exceptions process for managed care contractors for the Agency-developed provider network standards, the Contract will be amended to describe the standards by which any exceptions to the Agency-developed provider network standards will be evaluated and approved. See the additional obligations as set forth in Section 4 § 438.68(d)(1).

E.6 Provider Notification of Grievance and Appeal Rights

E.6.01 – E.6.03 Contractor shall inform providers and subcontractors, at the time they enter into a contract, about:

1. Enrollee grievance, appeal, and fair hearing procedures and timeframes as specified in Section 4 § 438.400 through Section 4 § 438.424 and described in the Grievance and Appeals section herein.

2. The enrollee's right to file grievances and appeals and the requirements and timeframes for filing.

3. The availability of assistance to the enrollee with filing grievances and appeals.

See the additional obligations as set forth in Section 4 § 438.414 and Section 4 § 438.10(g)(2)(xi)(A) - (C).

E.6.04 Contractor shall inform providers and subcontractors, at the time they enter into a contract, about the enrollee's right to request a state fair hearing after the Contractor has made a determination on an enrollee's appeal which is adverse to the enrollee. See the additional obligations as set forth in Section 4 § 438.414 and Section 4 § 438.10(g)(2)(xi)(D).

ES.6.04 Contractor shall inform providers and subcontractors, at the time they enter into a contract, that providers and subcontractors do not have a right to request a state fair hearing to address a payment dispute between the provider or subcontractor and Contractor after services have been rendered. See the additional obligations as set forth in Section 4 § 438.402(c)(1)(ii).

E.6.05 Contractor shall inform providers and subcontractors, at the time they enter into a contract, about the enrollee's right to request continuation of benefits that the Contractor seeks to reduce or terminate during an appeal or state fair hearing filing, if filed within the allowable timeframes, although the enrollee may be liable for the cost of any continued benefits while the appeal or state fair hearing is pending if the final decision is adverse to the enrollee. See the additional obligations as set forth in Section 4 § 438.414 and Section 4 § 438.10(g)(2)(xi)(E).

E.7 Balance Billing

E.7.01 Contractor shall require that subcontractors and referral providers not bill enrollees, for covered services, any amount greater than would be owed if the entity provided the services directly (i.e., no balance billing by providers). See the additional obligations as set forth in Section 4 § 438.3(k), Section 4 § 438.230(c)(1) - (2), and Section 1932(b)(6) of the Social Security Act.

ES. 7.01 In addition to prohibiting balance billing, Contractor shall ensure that members of its provider panel only hold ***hawk-i*** Medicaid members financially responsible when expressly permitted by this Contract or when permitted by applicable federal law.

E.8 Physician Incentive Plan

E.8.01 Contractor may only operate a physician incentive plan if no specific payment can be made directly or indirectly under a physician incentive plan to a physician or physician group as an incentive to reduce or limit medically necessary services to an enrollee. See the additional obligations as set forth in Section 4 § 438.3(i), 42 C.F.R. § 422.208(c)(1), and Section 1903(m)(2)(A)(x) of the Social Security Act.

ES.8.01 – Contractor shall obtain prior Agency approval of any physician incentive plan before implementing the plan. Contractor shall address in any such plan how the plan will educate and engage dental providers in aligning with ***hawk-i*** goals.

E.8.02 If Contractor puts a physician/physician group at substantial financial risk for services not provided by the physician/physician group, Contractor must ensure that the physician/physician group has adequate stop-loss protection. See the additional obligations as set forth in Section 4 § 438.3(i), 42 C.F.R. § 422.208(c)(2), and Section 1903(m)(2)(A)(x) of the Social Security Act.

E.9 Network Requirements Involving Indians, Indian Health Care Providers (IHCPs), and Indian Managed Care Entities (IMCEs).

E.9.01 Contractor shall demonstrate that there are sufficient IHCPs participating in the provider network to ensure timely access to services available under this Contract from such providers for

Indian enrollees who are eligible to receive services. See the additional obligations as set forth in Section 4 § 438.14(b)(1) and Section 4 § 438.14(b)(5).

E.9.02 Contractor shall pay IHCPs, whether participating or not, for covered services provided to Indian enrollees, who are eligible to receive services at a negotiated rate between Contractor and IHCP or, in the absence of a negotiated rate, at a rate not less than the level and amount of payment the managed care entity would make for the services to a participating provider that is not an IHCP. See the additional obligations as set forth in Section 4 § 438.14(b)(2)(i) - (ii).

E.9.03 Contractor shall permit Indian enrollees to obtain covered services from out-of-network IHCPs from whom the enrollee is otherwise eligible to receive such services. See the additional obligations as set forth in Section 4 § 438.14(b)(4).

E.9.04 Contractor shall permit an out-of-network IHCP to refer an Indian enrollee to a network provider. See the additional obligations as set forth in Section 4 § 438.14(b)(6).

E.10 Practice Guidelines

E.10.01 Contractor shall disseminate practice guidelines to all affected providers. See the additional obligations as set forth in Section 4 § 438.236(c).

F Coverage

F.1 Emergency and Post-Stabilization Services

F.1.01 – F.1.02 Contractor shall cover and pay for:

1. Emergency services.
2. Post-stabilization care services.

See the additional obligations as set forth in Section 4 § 438.114(b), Section 4 § 422.113(c), and section 1852(d)(2) of the Social Security Act.

F.1.03 Contractor shall pay non-contracted providers for emergency services no more than the amount that would have been paid if the service had been provided under the Agency's FFS Medicaid program. See section 1932(b)(2)(D) of the Social Security Act & SMDL 06-010.

F.1.04 – F.1.06 Contractor shall:

1. Cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with Contractor.
2. Not deny payment for treatment obtained when an enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not result in placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.
3. Not deny payment for treatment obtained when a representative of the Contractor instructs the enrollee to seek emergency services.

See the additional obligations as set forth in Section 4 § 438.114(c)(1)(i), Section 4 § 438.114(c)(1)(ii)(A) - (B), and section 1932(b)(2) of the Social Security Act.

F.1.07 Reserved

F.1.08 – F.1.09 Contractor shall not:

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

2. Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's PCP, Contractor, or applicable state entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

See the additional obligations as set forth in Section 4 § 438.114(d)(1)(i) - (ii).

F.1.10 Contractor shall not hold an enrollee who has an emergency medical condition liable for payment of subsequent screening and treatment needed to diagnose or stabilize the specific condition. See the additional obligations as set forth in Section 4 § 438.114(d)(2).

F.1.11 – F.1.12

1. Contractor is responsible for coverage and payment of services until the attending emergency physician, or the provider actually treating the enrollee, determines that the enrollee is sufficiently stabilized for transfer or discharge.

2. The determination of the attending emergency physician, or the provider actually treating the enrollee, of when the enrollee is sufficiently stabilized for transfer or discharge is binding on the Contractor and Agency for coverage and payment of emergency and post stabilization services.

See the additional obligations as set forth in Section 4 § 438.114(d)(3).

F.1.13 – F.1.17 Contractor shall cover post-stabilization care services:

1. Obtained within or outside the Contractor network that is:

a. Pre-approved by a Contractor plan provider or representative.

b. Not pre-approved by a Contractor provider or representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the Contractor for pre-approval of further post-stabilization care services.

2. Administered to maintain, improve, or resolve the enrollee's stabilized condition without preauthorization, and regardless of whether the enrollee obtains the services within the Contractor network when the Contractor:

a. Did not respond to a request for pre-approval within 1 hour.

b. Could not be contacted.

c. Representative and the treating physician could not reach agreement concerning the enrollee's care and a Contractor physician was not available for consultation.

See the additional obligations as set forth in Section 4 § 438.114(e), 422.113(c)(2)(i) - (ii); 422.113(c)(2)(iii)(A) - (C).

F.1.18 Contractor shall limit charges to enrollees for post-stabilization care services to an amount no greater than what the Contractor would charge the enrollee if he or she obtained the services through the Contractor. See the additional obligations as set forth in Section 4 § 438.114(e), and Section 4 § 438.10 (c)(2)(iv).

F.1.19 – F.1.22 The Contractor's financial responsibility for post-stabilization care services if has not pre-approved ends when:

1. A Contractor physician with privileges at the treating hospital assumes responsibility for the enrollee's care.

2. A Contractor physician assumes responsibility for the enrollee's care through transfer.

3. A Contractor representative and the treating physician reach an agreement concerning the enrollee's care.

4. The enrollee is discharged.

See the additional obligations as set forth in Section 4 § 438.114(e), and Section 422.113(c)(3)(i) - (iv).

F.2 Family Planning

F.2.01 Reserved (*not applicable to a dental-only PAHP).*

F.3 Abortions

F.3.01 *Reserved (not applicable to a dental-only PAHP).*

F.4 Delivery Network

F.4.01 *Reserved (not applicable to a dental-only PAHP).*

F.4.02 Contractor shall provide for a second opinion from a network provider, or arrange for the enrollee to obtain a second opinion outside the network, at no cost to the enrollee. See the additional obligations as set forth in Section 4 § 438.206(b)(3).

F.4.03 If Contractor's provider network is unable to provide necessary medical services covered under this Contract to a particular enrollee, the Contractor must adequately and timely cover the services out of network, for as long as the Contractor's provider network is unable to provide them. See the additional obligations as set forth in Section 4 § 438.206(b)(4).

F.4.04 Contractor shall coordinate payment with out-of-network providers and ensure the cost to the enrollee is no greater than it would be if the services were furnished within the network. See the additional obligations as set forth in Section 4 § 438.206(b)(5).

F.4.05 *Reserved (not applicable to a dental-only PAHP).*

F.5 Services Not Covered Based on Moral Objections

F.5.01 If Contractor elects not to provide, reimburse for, or provide coverage of, a counseling or referral service because of an objection on moral or religious grounds, Contractor shall furnish information about the services it does not cover to the Agency with its application for a Medicaid contract. See the additional obligations as set forth in Section 4 § 438.102(b)(1)(i)(A)(1) and section 1932(b)(3)(B)(i) of the Social Security Act.

F.5.02 If Contractor elects not to provide, reimburse for, or provide coverage of, a counseling or referral service because of an objection on moral or religious grounds, Contractor shall furnish information about the services it does not cover to the Agency whenever it adopts such a policy during the term of the Contract. See the additional obligations as set forth in Section 4 § 438.102(b)(1)(i)(A)(2) and section 1932(b)(3)(B)(i) of the Social Security Act.

F.6 Amount, Duration and Scope

F.6.01 The contract identifies, defines, and specifies the amount, duration, and scope of each service the Contractor is required to offer. See the additional obligations as set forth in Section 4 § 438.210(a)(1). Specific amount, duration, and scope limitations are set forth in Special Contract Section 3.2.

F.6.02 For each service that Contractor is required to provide to children shall be furnished in an amount, duration and scope that is no less than the amount, duration and scope for the same services provided under FFS Medicaid, unless otherwise specified in an approved State Plan waiver. See the additional obligations as set forth in Section 4 § 438.210(a)(2).

F.6.03 Contractor shall provide services for enrollees under the age of 21 to the same extent that services are furnished to individuals under the age of 21 under FFS Medicaid. See the additional obligations as set forth in Section 4 § 438.210(a)(2).

F.6.04 Contractor shall ensure that services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished. See the additional obligations as set forth in Section 4 § 438.210(a)(3)(i).

F.6.05 Contractor shall not arbitrarily denying or reducing the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition of the enrollee. See the additional obligations as set forth in Section 4 § 438.210(a)(3)(ii).

F.6.06 Contractor may place appropriate limits on a service on the basis of criteria applied under the Medicaid State Plan (MSP), such as medical necessity or as otherwise permitted under an approved State Plan waiver. See the additional obligations as set forth in Section 4 § 438.210(a)(4)(i).

F.6.07 Contractor may place appropriate limits on a service for utilization control, provided the services furnished can reasonably achieve their purpose. See the additional obligations as set forth in Section 4 § 438.210(a)(4)(ii)(A).

F.6.08 Contractor may place appropriate limits on a service for utilization control, provided the services supporting individuals with ongoing or chronic conditions or who require LTSS are authorized in a manner that reflects the enrollee's ongoing need for such services and supports. See the additional obligations as set forth in Section 4 § 438.210(a)(4)(ii)(B).

F.6.09 *Reserved (not applicable to a dental-only PHAP)*

F.6.10 The Contractor must specify what constitutes "medically necessary services" in a manner that is no more restrictive than the state Medicaid program, including Quantitative and Non-Quantitative Treatment Limits (QTL) (NQTL), as indicated in state statutes and regulations, the MSP, and other state policies and procedures. See the additional obligations as set forth in Section 4 § 438.210(a)(5)(i).

F.6.11 The contract must specify what constitutes "medically necessary services" in a manner that addresses the extent to which the Contractor is responsible for covering services that address the prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability. See the additional obligations as set forth in Section 4 § 438.210(a)(5)(ii)(A).

F.6.12 The contract must specify what constitutes "medically necessary services" in a manner that addresses the extent to which the Contractor is responsible for covering services related to the ability for an enrollee to achieve age-appropriate growth and development. See the additional obligations as set forth in Section 4 § 438.210(a)(5)(ii)(B).

F.6.13 The contract must specify what constitutes "medically necessary services" in a manner that addresses the extent to which the Contractor is responsible for covering services related to the ability for an enrollee to attain, maintain, or regain functional capacity. See the additional obligations as set forth in Section 4 § 438.210(a)(5)(ii)(C).

F.6.14 The contract must specify what constitutes "medically necessary services" in a manner that addresses the extent to which the Contractor is responsible for covering services related to the opportunity for an enrollee receiving LTSS to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice. See the additional obligations as set forth in Section 4 § 438.210(a)(5)(ii)(D).

F.6.15 *Reserved (not applicable to a dental-only PAHP).*

F.6.16 – F.6.20 Contractor may cover services or settings for enrollees that are in lieu of those covered under the state plan if:

1. The Agency determines that the alternative service or setting is a medically appropriate substitute for the covered service or setting under the state plan.

2. The Agency determines that the alternative service or setting is a cost effective substitute for the covered service or setting under the state plan.

3. The enrollee is not required by Contractor to use the alternative service or setting.

4. The approved in lieu of services are authorized and identified in this Contract.

5. The approved in lieu of services are offered to enrollees at the option of the Contractor.

See the additional obligations as set forth in Section 4 § 438.3(e)(2)(i) - (iii).

F.7 Provider Preventable Conditions

F.7.01 Contractor shall not make payment to a provider for provider-preventable conditions that meet the following criteria:

1. The condition is identified in the state plan.

2. The condition has been found by the Agency, based upon a review of medical literature by qualified professionals, to be reasonably preventable through the application of procedures supported by evidence-based guidelines.

3. The condition has a negative consequence for the beneficiary.

4. The condition is auditable.

5. The condition arises from, at a minimum, wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part; surgical or other invasive procedure performed on the wrong patient.

See the additional obligations as set forth in Section 4 § 438.3(g), 42 C.F.R. § 434.6(a)(12)(i), and 42 C.F.R. § 447.26(b).

F.7.02 Contractor shall require all providers to report provider-preventable conditions associated with claims for payment or enrollee treatments for which payment would otherwise be made. See the additional obligations as set forth in Section 4 § 438.3(g), 42 C.F.R. § 434.6(a)(12)(ii), and 42 C.F.R. § 447.26(d).

F.7.03 Contractor shall report all identified provider-preventable conditions in a form or frequency, which may be specified by the Agency. See the additional obligations as set forth in Section 4 § 438.3(g).

FS.7.03 – Contractor shall report all identified provider-preventable conditions in accordance with the obligations set forth in the reporting templates.

F.8 Cost Sharing

F.8.01 Any cost sharing imposed on Medicaid enrollees shall be in accordance with Medicaid FFS requirements at 42 C.F.R. § 447.50 through 42 C.F.R. § 447.82. See the additional obligations as set forth in Section 4 § 438.108, State Medicaid Director Letter (SMDL), #06-015 dated 6/16/06, and sections 1916(a)(2)(D) and 1916(b)(2)(D) of the Social Security Act.

F.8.02 Contractor shall exempt from premiums any Indian who is eligible to receive or has received an item or service furnished by an IHCP or through referral under contract health

services. See the additional obligations as set forth in 42 C.F.R. § 447.52(h), 42 C.F.R. § 447.56(a)(1)(x), 42 C.F.R. § 447.51(a)(2), ARRA 5006(a), and SMDL #10-001.

F.8.03 Contractor shall exempt from all cost sharing any Indian who is currently receiving or has ever received an item or service furnished by an IHCP or through referral under contract health services. See the additional obligations as set forth in 42 C.F.R. § 447.52(h), 42 C.F.R. § 447.56(a)(1)(x), 42 C.F.R. § 447.51(a)(2), ARRA 5006(a), and SMDL 10-001.

FS.8.01 – Any cost sharing or co-payment will not be the responsibility of Contractor and Contractor may not charge a co-payment or premium.

FS.8.02 The basis of payment for services rendered by providers of services participating in the medical assistance program is either a system based on the provider's allowable costs of operation or a fee schedule. Generally, institutional types of providers such as hospitals and nursing facilities are reimbursed on a cost-related basis, and practitioners such as physicians, dentists, optometrists, and similar providers are reimbursed on the basis of a fee schedule. Providers of service must accept reimbursement based upon the department's methodology without making any additional charge to the member.

F.9 Nonpayment

F.9.01 *Reserved (not applicable to a dental-only PAHP).*

F.9.02 – F.9.06 *Reserved (not applicable to a dental-only PAHP).*

F.10 Federally Qualified Health Center (FQHC) Payments

F.10.01 *Reserved (not applicable to a dental-only PAHP).*

F.11 Outpatient/Prescription Drugs

F.11.01 – F.11.07 *Reserved (not applicable to a dental-only PAHP).*

F.12 Parity in Mental Health and Substance Use Disorder (MH/SUD) Benefits

F.12.01 – F.12.08 *Reserved (not applicable to a dental-only PAHP).*

F.13 Long-Term Services and Supports (LTSS)

F.13.01 - F.13.03 *Reserved (not applicable to a dental-only PAHP.*

F.14 Advance Directives

F.14.01 – F.14.03 *Reserved (not applicable to a dental-only PAHP).*

F.15 Moral Objections

F.15.01 Contractor is not required to provide, reimburse for, or provide coverage of a counseling or referral service if Contractor objects to the service on moral or religious grounds. See the additional obligations as set forth in Section 4 § 438.102(a)(2), and section 1932(b)(3)(B)(i) of the Social Security Act.

F.16 Enrollee Rights

F.16.01 The Contractor shall have written policies guaranteeing each enrollee's right to receive information on the managed care program and plan into which he/she is enrolled. See the additional obligations as set forth in Section 4 § 438.100(a)(1), and Section 4 § 438.100(b)(2)(i).

F.16.02 The Contractor shall have written policies guaranteeing each enrollee's right to be treated with respect and with due consideration for his or her dignity and privacy. See the additional obligations as set forth in Section 4 § 438.100(a)(1) and Section 4 § 438.100(b)(2)(ii).

F.16.03 Contractor shall have written policies guaranteeing each enrollee's right to receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. See the additional obligations as set forth in Section 4 § 438.100(a)(1), and Section 4 § 438.100(b)(2)(iii).

F.16.04 Contractor shall have written policies guaranteeing each enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment. See the additional obligations as set forth in Section 4 § 438.100(a)(1), and Section 4 § 438.100(b)(2)(iv).

F.16.05 Contractor shall have written policies guaranteeing each enrollee's right to be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation. See the additional obligations as set forth in Section 4 § 438.100(a)(1), and Section 4 § 438.100(b)(2)(v).

F.16.06 Contractor shall have written policies guaranteeing each enrollee's right to request and receive a copy of his or her medical records, and to request that they be amended or corrected. See the additional obligations as set forth in Section 4 § 438.100(a)(1), and Section 4 § 438.100(b)(2)(vi).

F.16.07 Contractor shall ensure that each enrollee is free to exercise his or her rights without the Contractor or its network providers treating the enrollee adversely. See the additional obligations as set forth in Section 4 § 438.100(a)(1), and Section 4 § 438.100(c).

G. Quality and Utilization Management

G.1 External Quality Review (EQR)

G.1.01 Contractor shall undergo annual, external independent reviews of the quality, timeliness, and access to the services covered under each contract. See the additional obligations as set forth in Section 4 § 438.350.

GS.1.01 The Contractor shall provide all information required for the external quality reviews in the timeframe and format requested by the External Quality Review Organization (EQRO). The Contractor shall incorporate and address findings from these external quality reviews in the QM/QI program. The Contractors shall collaborate with the EQRO to develop studies, surveys and other analytic activities to assess the quality of care and services provided to members and to identify opportunities for Contractor improvement. The Contractor shall also work collaboratively with the Agency and the EQRO to annually measure identified performance measures to assure quality and accessibility of health care in the appropriate setting to members, including the validation of performance improvement projects (PIPs) and performance measures. The Contractor shall respond to recommendations made by the EQRO within the timeframe established by the EQRO, the Agency or its designee.

G.2 Care Coordination

G.2.01 – G.2.02 Contractor shall:

1. Implement procedures to ensure that each enrollee has an ongoing source of care appropriate to their needs.

2. Formally designate a person or entity as primarily responsible for coordinating services accessed by the enrollee.

See the additional obligations as set forth in Section 4 § 438.208(b)(1).

G.2.03 Contractor shall provide all enrollees information on how to contact their designated person or entity. See the additional obligations as set forth in Section 4 § 438.208(b)(1).

G.2.04 Contractor shall implement procedures to coordinate the services Contractor furnishes to the enrollee between settings of care, including appropriate discharge planning for short-term and long-term hospital and institutional stays. See the additional obligations as set forth in Section 4 § 438.208(b)(2)(i).

G.2.05 Contractor shall implement procedures to coordinate services Contractor furnishes to the enrollee with the services the enrollee receives from any other MCO, PIHP, or PAHP. See the additional obligations as set forth in Section 4 § 438.208(b)(2)(ii).

G.2.06 Contractor shall implement procedures to coordinate the services Contractor furnishes to the enrollee with the services the enrollee receives in FFS Medicaid. See the additional obligations as set forth in Section 4 § 438.208(b)(2)(iii).

G.2.07 Contractor shall implement procedures to coordinate the services Contractor furnishes to the enrollee with the services the enrollee receives from community and social support providers. See the additional obligations as set forth in Section 4 § 438.208(b)(2)(iv).

G.2.08 – G.2.09 Contractor shall:

1. Make a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees.

2. Make subsequent attempts to conduct an initial screening of each enrollee's needs if the initial attempt to contact the enrollee is unsuccessful.

See the additional obligations as set forth in Section 4 § 438.208(b)(3).

G.2.10 Contractor shall share with the Agency or other MCOs, PIHPs, and PAHPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities. See the additional obligations as set forth in Section 4 § 438.208(b)(4).

G.2.11 Contractor shall ensure that each provider furnishing services to enrollees maintains and shares an enrollee health record in accordance with professional standards. See the additional obligations as set forth in Section 4 § 438.208(b)(5).

G.2.12 Contractor shall use and disclose individually identifiable health information, such as medical records and any other health or enrollment information that identifies a particular enrollee, in accordance with the confidentiality requirements in 45 C.F.R. parts 160 and 164. See the additional obligations as set forth in Section 4 § 438.208(b)(6), Section 4 § 438.224, 45 C.F.R. part 164, and 45 C.F.R. part 164.

G.2.13 Contractor shall implement a transition of care policy that is consistent with federal requirements and at least meets the Agency defined transition of care policy. See the additional obligations as set forth in Section 4 § 438.62(b)(1) - (2).

G.3 Authorization and Utilization Management

G.3.01 Contractor and its subcontractors shall have in place and follow written policies and procedures for processing requests for initial and continuing authorizations of services. See the additional obligations as set forth in Section 4 § 438.210(b)(1).

G.3.02 Contractor shall have in effect mechanisms to ensure consistent application of review criteria for authorization decisions. See the additional obligations as set forth in Section 4 § 438.210(b)(2)(i).

G.3.03 Contractor shall consult with the requesting provider for medical services when appropriate. See the additional obligations as set forth in Section 4 § 438.210(b)(2)(ii).

G.3.04 *Reserved (not applicable to a dental-only PAHP).*

G.3.05 Contractor shall ensure 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, will be made by an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health,

or long- term services and supports needs. See the additional obligations as set forth in Section 4 § 438.210(b)(3).

G.3.06 *Reserved (not applicable to a dental-only PAHP).*

G.3.07 For standard authorization decisions, Contractor shall provide notice as expeditiously as the enrollee's condition requires and within Agency-established timeframes that may not exceed 14 calendar days after receipt of request for service, with a possible extension of 14 days if the enrollee or provider requests an extension or Contractor justifies the need for additional information and how the extension is in the enrollee's interest. See the additional obligations as set forth in Section 4 § 438.210(d)(1).

G.3.08 When a provider indicates, or Contractor determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, Contractor shall 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. See the additional obligations as set forth in Section 4 § 438.210(d)(2).

G.3.09 *Reserved (not applicable to a dental-only PAHP).*

G.3.10 Contractor shall not structure compensation to individuals or entities that conduct utilization management activities so as to provide incentives for denying, limiting, or discontinuing medically necessary services to any enrollee. See the additional obligations as set forth in Section 4 § 438.210(e).

G.4 Staffing Training

G.4.01 Contractor shall adopt practice guidelines that are based on valid and reliable clinical evidence or a consensus of providers in the particular field. See the additional obligations as set forth in Section 4 § 438.236(b)(1).

G.4.02 Contractor shall adopt practice guidelines that consider the needs of the enrollees. See the additional obligations as set forth in Section 4 § 438.236(b)(2).

G.4.03 Contractor shall adopt practice guidelines in consultation with contracting health care professionals. See the additional obligations as set forth in Section 4 § 438.236(b)(3).

G.4.04 Contractor shall review and update practice guidelines periodically as appropriate. See the additional obligations as set forth in Section 4 § 438.236(b)(4).

G.4.05 Contractor's decisions regarding utilization management, enrollee education, coverage of services, and other areas to which practice guidelines apply shall be consistent with such practice guidelines. See the additional obligations as set forth in Section 4 § 438.236(d).

G.5 Quality

G.5.01 Contractor shall establish and implement an ongoing Comprehensive Quality Assessment and Performance Improvement (QAPI) program for the services it furnishes to its enrollees. See the additional obligations as set forth in Section 4 § 438.330(a)(1), Section 4 § 438.330(a)(3).

G.5.02 Contractor's comprehensive QAPI program shall include Performance Improvement Projects (PIP), including any required by the Agency or CMS, that focus on clinical and non-clinical areas. See the additional obligations as set forth in Section 4 § 438.330(b)(1), Section 4 § 438.330(d)(1), and Section 4 § 438.330(a)(2).

G.5.03 Contractor shall including in its comprehensive QAPI program collection and submission of performance measurement data, including any required by the Agency or CMS. See the additional obligations as set forth in Section 4 § 438.330(b)(2), Section 4 § 438.330(c), Section 4 § 438.330(a)(2).

G.5.04 Contractor's comprehensive QAPI program shall include mechanisms to detect both underutilization and overutilization of services. See the additional obligations as set forth in Section 4 § 438.330(b)(3).

G.5.05 Contractor's comprehensive QAPI program must include mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the Agency in the quality strategy. See the additional obligations as set forth in Section 4 § 438.330(b)(4), Section 4 § 438.340.

G.5.06 – G.5.07 *Reserved (not applicable to a dental-only PAHP).*

G.5.08 *Reserved (not applicable to a dental-only PAHP).*

G.5.09 Annually, Contractor shall: measure and report to the Agency on its performance, using the standard measures required by the Agency; submit to the Agency data, specified by the Agency, which enables the Agency to calculate the Contractor's performance using the standard measures identified by the Agency under paragraph (c)(1); OR perform a combination of these activities. See the additional obligations as set forth in Section 4 § 438.330(c)(1) and (2).

G.5.10 Each of Contractor's PIPs shall be designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction. See the additional obligations as set forth in Section 4 § 438.330(d)(2).

G.5.11 Each of Contractor's PIPs shall include measurement of performance using objective quality indicators. See the additional obligations as set forth in Section 4 § 438.330(d)(2)(i).

G.5.12 Each of Contractor's PIPs shall include implementation of interventions to achieve improvement in the access to and quality of care. See the additional obligations as set forth in Section 4 § 438.330(d)(2)(ii).

G.5.13 Each of Contractor's PIPs shall include an evaluation of the effectiveness of the interventions based on the performance measures collected as part of the PIP. See the additional obligations as set forth in Section 4 § 438.330(d)(2)(iii).

G.5.14 Each of Contractor's PIPs shall include planning and initiation of activities for increasing or sustaining improvement. See the additional obligations as set forth in Section 4 § 438.330(d)(2)(iv).

G.5.15 Contractor shall report the status and results of each performance improvement project to the Agency as requested, but not less than once per year. See the additional obligations as set forth in Section 4 § 438.330(d)(1) and (3).

G.5.16 *Reserved (not applicable to a dental-only PAHP).*

G.5.17 Contractor shall develop a process to evaluate the impact and effectiveness of its own QAPI. See the additional obligations as set forth in Section 4 § 438.330(e)(2) and §438.310(c)(2).

G.6 Cultural Competence

G.6.01 Contractor shall participate in the Agency'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. See the additional obligations as set forth in Section 4 § 438.206(c)(2).

G.7 Special Health Care Needs: Assessment and Treatment Plans

G.7.01 Contractor shall implement mechanisms to comprehensively assess each Medicaid enrollee identified by the Agency or the Contractor as having special health care needs to identify

any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. See the additional obligations as set forth in Section 4 § 438.208(c)(2).

G.7.02 – G.7.04 *Reserved (not applicable to a dental-only PAHP).*

G.7.05 Contractor shall use diligent efforts to identify Enrollees with special health care needs. This can be performed through an assessment of the Enrollee's health status upon enrollment or through identification by primary care providers. When found, the Contractor shall produce such a treatment or service plan for enrollees with special health care needs that are determined through assessment to need a course of treatment or regular care monitoring. See the additional obligations as set forth in Section 4 § 438.208(c)(3).

G.7.06 – G.7.10 *Reserved (not applicable to a dental-only PAHP).*

G.7.11 – G.7.13 For enrollees with special health care needs as required by the Agency:

1. The Contractor's treatment or service plan shall be approved by the Contractor in a timely manner, if this approval is required by the Contractor.

2. The Contractor's plan shall be developed in accordance with any applicable Agency quality assurance and utilization review standards.

3. The Contractor's treatment or service plan be reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly, or at the request of the enrollee.

See the additional obligations as set forth in Section 4 § 438.208(c)(3)(iii) - (v) and Section 4 § 441.301(c)(3).

G.7.14 For enrollees with special health care needs determined through an assessment to need a course of treatment or regular care monitoring, Contractor shall have a mechanism in place to allow enrollees to directly access a specialist as appropriate for the enrollee's condition and identified needs. See the additional obligations as set forth in Section 4 § 438.208(c)(4).

GS.7.01 The Contractor shall use diligent efforts to identify enrollees with special health care needs. This can be performed through an assessment of the enrollee's health status upon enrollment or though identification by primary care providers. When enrollees are identified, the Contractor shall develop a treatment plan, if the Agency requires the Contractor to develop such a plan, in conjunction with the primary care provider to determine the necessity of additional care management to meet the needs of the enrollee. If it is determined that services of a specialist physician are necessary to perform care facilitation, the Contractor shall allow direct access to such a provider without referral or through a mechanism of a standing referral or defined number of visits.

G.8 Accreditation

G.8.01 Contractor shall inform the Agency as to whether it has been accredited by a private independent accrediting entity. See the additional obligations as set forth in Section 4 § 438.332(a).

G.8.02 – G.8.04 If Contractor has received accreditation by a private independent accrediting entity, Contractor shall authorize the private independent accrediting entity to provide the Agency a copy of its most recent accreditation review, including:

1. Its accreditation status, survey type, and level (as applicable);

2. Recommended actions or improvements, corrective action plans, and summaries of findings; and

3. The expiration date of the accreditation.

See the additional obligations as set forth in Section 4 § 438.332(b)(1) - (3).

H Grievances and Appeals

H.1 Grievance and Appeals System

HS.1.01 Contractor is responsible for providing all support at all states of the grievance and appeal process, including but not limited to providing the necessary factual and expert testimony necessary to support the Contractor's position taken in relation to an enrollee's claim, including providing any support required by the Attorney General's Office in relation to a judicial review proceeding arising out of the state fair hearing process. Contractor shall be responsible for any award of attorneys' fees and costs provided at any stage of state fair hearing or judicial review of a Contractor decision.

H.1.01 Contractor shall have a grievance and appeal system in place for enrollees. See the additional obligations as set forth in Section 4 § 438.402(a) and Section 4 § 438.228(a).

H.1.02 Contractor shall have only one level of appeal for enrollees within the PAHP. See the additional obligations as set forth in Section 4 § 438.402(b), and Section 4 § 438.228(a).

H.1.03 Contractor shall give enrollees any reasonable assistance in completing grievance and appeal forms and 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 with Teletypewriter Telephone/Telecommunication Device for the Deaf (TTY/TDD) and interpreter capability. See the additional obligations as set forth in Section 4 § 438.406(a), and Section 4 § 438.228(a).

H.1.04 Contractor shall acknowledge receipt of each grievance and appeal of adverse benefit determinations. See the additional obligations as set forth in Section 4 § 438.406(b)(1), and Section 4 § 438.228(a).

H.1.05 – H.1.06 Contractor shall ensure that decision makers on grievances and appeals of adverse benefit determinations were not:

1. Involved in any previous level of review or decision-making.

2. Subordinates of any individual who was involved in a previous level of review or decision-making.

See the additional obligations as set forth in Section 4 § 438.406(b)(2)(i), and Section 4 § 438.228(a).

H.1.07 – H.1.09 Contractor shall ensure that decision makers on grievances and appeals of adverse benefit determinations are individuals with appropriate clinical expertise, as determined by the Agency, in treating the enrollee's condition or disease:

1. If the decision involves an appeal of a denial based on lack of medical necessity.

2. If the decision involves a grievance regarding denial of expedited resolution of an appeal.

3. If the decision involves a grievance or appeal involving clinical issues.

See the additional obligations as set forth in Section 4 § 438.406(b)(2)(ii)(A) - (C), and Section 4 § 438.228(a).

H.1.10 Contractor shall ensure that decision makers on grievances and appeals of adverse benefit determinations take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination. See the additional obligations as set forth in Section 4 § 438.406(b)(2)(iii) and Section 4 § 438.228(a).

H.1.11 Contractor shall address any enrollee disenrollment request through its grievance process and complete review of the grievance in time to permit the disenrollment to be effective no later than the first day of the second month following the month in which the enrollee requests disenrollment. See the additional obligations as set forth in Section 4 § 438.56(d)(5)(ii), Section 4 § 438.56(e)(1), and Section 4 § 438.228(a).

H.2 Notice of Adverse Benefit Determination Requirements

H.2.01 Contractor's notice of adverse benefit determination shall explain the adverse benefit determination the Contractor has made or intends to make. See the additional obligations as set forth in Section 4 § 438.404(b)(1).

H.2.02 Contractor's notice of adverse benefit determination shall explain 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. See the additional obligations as set forth in Section 4 § 438.404(b)(2).

H.2.03 Contractor's notice of adverse benefit determination shall explain the enrollee's right to request an appeal of the Contractor's adverse benefit determination, including information on exhausting the Contractor's one level of appeal and the right to request a state fair hearing after receiving notice that the adverse benefit determination is upheld. See the additional obligations as set forth in Section 4 § 438.404(b)(3), and Section 4 § 438.402(b) - (c).

H.2.04 Contractor's notice of adverse benefit determination shall explain the procedures for exercising the enrollee's rights to appeal. See the additional obligations as set forth in Section 4 § 438.404(b)(4).

H.2.05 Contractor's notice of adverse benefit determination shall explain the circumstances under which an appeal process can be expedited and how to request it. See the additional obligations as set forth in Section 4 § 438.404(b)(5).

H.2.06 Contractor's notice of adverse benefit determination shall explain the enrollee's right to have benefits continue pending the resolution of the appeal, how to request that benefits be continued, and the circumstances, consistent with state policy, under which the enrollee may be required to pay the costs of continued services. See the additional obligations as set forth in Section 4 § 438.404(b)(6).

H.3 Notice of Adverse Benefit Determination Timing

H.3.01 Contractor shall mail the notice of adverse benefit determination at least 10 days before the date of action, when the action is a termination, suspension, or reduction of previously authorized Medicaid-covered services. See the additional obligations as set forth in Section 4 § 438.404(c)(1), and Section 431.211.

H.3.02 Contractor may mail the notice of adverse benefit determination as few as 5 days prior to the date of action if the agency has facts indicating that action should be taken because of probable fraud by the beneficiary, and the facts have been verified, if possible, through secondary sources. See the additional obligations as set forth in Section 4 § 438.404(c)(1), and 42 C.F.R. § 431.214.

H.3.03 Contractor shall mail the notice of adverse benefit determination by the date of the action when any of the following occur:

1. The recipient has died.
2. The enrollee submits a signed written statement requesting service termination.

3. The enrollee submits a signed written statement including information that requires service termination or reduction and indicates that he understands that service termination or reduction will result.

4. The enrollee has been admitted to an institution where he or she is ineligible under the plan for further services.

5. The enrollee's address is determined unknown based on returned mail with no forwarding address.

6. The enrollee is accepted for Medicaid services by another local jurisdiction, state, territory, or commonwealth.

7. A change in the level of medical care is prescribed by the enrollee's physician.

8. The notice involves an adverse determination with regard to preadmission screening requirements of section 1919(e)(7) of the Act.

9. The transfer or discharge from a facility will occur in an expedited fashion.

See the additional obligations as set forth in Section 4 § 438.404(c)(1); 42 C.F.R. § 431.213; 42 C.F.R. § 431.231(d); section 1919(e)(7) of the Social Security Act; 42 C.F.R. § 483.12(a)(5)(i); and 42 C.F.R. § 483.12(a)(5)(ii).

H.3.04 Contractor shall give notice of adverse benefit determination on the date of determination when the action is a denial of payment. See the additional obligations as set forth in Section 4 § 438.404(c)(2).

H.3.05 Contractor shall give notice of adverse benefit determination as expeditiously as the enrollee's condition requires within Agency-established timeframes that may not exceed 14 calendar days following receipt of the request for service, for standard authorization decisions that deny or limit services. See the additional obligations as set forth in Section 4 § 438.210(d)(1), and Section 4 § 438.404(c)(3).

H.3.06 Contractor shall extend the 14 calendar day notice of adverse benefit determination timeframe for standard authorization decisions that deny or limit services up to 14 additional calendar days if the enrollee or the provider requests extension. See the additional obligations as set forth in Section 4 § 438.404(c)(4), and Section 4 § 438.210(d)(1)(i).

H.3.07 Contractor shall extend the 14 calendar day notice of adverse benefit determination timeframe for standard authorization decisions that deny or limit services up to 14 additional calendar days if the Contractor justifies a need (to the state Agency, upon request) for additional information and shows how the extension is in the enrollee's best interest. See the additional obligations as set forth in Section 4 § 438.210(d)(1)(ii) and Section 4 § 438.404(c)(4).

H.3.08 Contractor shall extend the 14 calendar day notice of adverse benefit determination timeframe for standard authorization decisions that deny or limit services, it must give the enrollee written notice of the reason for the extension and inform the enrollee of the right to file a grievance if he/she disagrees with the decision. See the additional obligations as set forth in Section 4 § 438.210(d)(1)(ii), and Section 4 § 438.404(c)(4)(i).

H.3.09 Contractor shall extend the 14 calendar day notice of adverse benefit determination timeframe for standard authorization decisions that deny or limit services, it must issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires. See the additional obligations as set forth in Section 4 § 438.210(d)(1)(ii), and Section 4 § 438.404(c)(4)(ii).

H.3.10 For cases in which a provider indicates, or the Contractor determines, that following the standard authorization timeframe could seriously jeopardize the enrollee's life or health or his/her ability to attain, maintain, or regain maximum function, the Contractor shall make an expedited service 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. See the additional obligations as set forth in Section 4 § 438.210(d)(2)(i), and Section 4 § 438.404(c)(6).

H.3.11 Contractor may extend the 72 hour expedited service authorization decision time period by up to 14 calendar days if the enrollee requests an extension, or if the Contractor justifies (to the state Agency, upon request) a need for additional information and how the extension is in the enrollee's interest. See the additional obligations as set forth in Section 4 § 438.210(d)(2)(ii), and Section 4 § 438.404(c)(6).

H.3.12 Contractor shall give notice on the date that the timeframes expire, when service authorization decisions are not reached within the applicable timeframes for either standard or expedited service authorizations. See the additional obligations as set forth in Section 4 § 438.404(c)(5).

H.4 Who May File Appeals and Grievances

H.4.01 Contractor shall allow enrollees to file appeals, grievances, and state fair hearing requests after receiving notice that an adverse benefit determination is upheld. See the additional obligations as set forth in Section 4 § 438.402(c)(1) and Section 4 § 438.408.

H.4.02 If the Agency chooses to offer and arrange for an external medical review, that complies with Section 42 § C.F.R. § 438.402(c)(1)(i)(B), the process for such review and the Contractor's obligation to comply with such review is outlined in the Contract. See the additional obligations as set forth in Section 4 § 438.402(c)(1)(i)(B).

H.4.03 Contractor shall allow providers, or authorized representatives, acting on behalf of the enrollee and with the enrollee's written consent, to request an appeal, file a grievance, or request a state fair hearing request. See the additional obligations as set forth in Section 4 § 438.402(c)(1)(i) - (ii) and Section 4 § 438.408.

HS.4.03 Contractor shall not allow providers or subcontractors to seek a state fair hearing to address payment disputes between Contractor and the provider or subcontractor after services have been rendered. See the additional obligations as set forth in Section 4 § 438.402(c)(1)(ii).

H.5 Timeframes for Filing Appeals

H.5.01 If Contractor fails to adhere to notice and timing requirements, the enrollee is deemed to have exhausted Contractor's appeals process, and the enrollee may initiate a state fair hearing. See the additional obligations as set forth in Section 4 § 438.408 and Section 4 § 438.402(c)(1)(i)(A).

H.5.02 Contractor shall allow the enrollee to file an appeal to the Contractor within 60 calendar days from the date on the adverse benefit determination notice. See the additional obligations as set forth in Section 4 § 438.402(c)(2)(ii).

H.5.03 Contractor shall allow the provider or authorized representative acting on behalf of the enrollee, to the extent state law permits, to file an appeal to the Contractor within 60 calendar days from the date on the adverse benefit determination notice. See the additional obligations as set forth in Section 4 § 438.402(c)(2)(ii).

H.6 Process for Filing an Appeal or Expedited Appeal Request

H.6.01 Contractor shall allow the enrollee to request an appeal either orally or in writing. See the additional obligations as set forth in Section 4 § 438.402(c)(3)(ii).

H.6.02 Contractor shall allow the provider or authorized representative acting on behalf of the enrollee, as state law permits, to request an appeal either orally or in writing. See the additional obligations as set forth in Section 4 § 438.402(c)(3)(ii) and Section 4 § 438.402(c)(1)(ii).

H.6.03 Unless an expedited resolution is requested by the enrollee, Contractor shall require that an enrollee's oral filing of an appeal to be followed by a written, signed appeal. See the additional obligations as set forth in Section 4 § 438.402(c)(3)(ii).

H.6.04 Contractor shall ensure that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals, and confirmed in writing unless the enrollee or the provider requests expedited resolution. See the additional obligations as set forth in Section 4 § 438.406(b)(3).

H.6.05 Contractor shall provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments. See the additional obligations as set forth in Section 4 § 438.406(b)(4).

H.6.06 Contractor shall provide the enrollee and his or her representative 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 Contractor (or at the direction of the Contractor)) in connection with the appeal of the adverse benefit determination. See the additional obligations as set forth in Section 4 § 438.406(b)(5).

H.6.07 Contractor shall provide the enrollee and his or her representative the enrollee's case file free of charge and sufficiently in advance of the resolution timeframe for standard and expedited appeal resolutions. For standard resolution of an appeal and notice to the affected parties, the Contractor must comply with the Agency-established timeframe that is no longer than 30 calendar days from the day the Contractor receives the appeal. For expedited resolution of an appeal and notice to affected parties, the Contractor must comply with the Agency-established timeframe that is no longer than 72 hours after the Contractor receives the appeal. See the additional obligations as set forth in Section 4 § 438.406(b)(5) and Section 4 § 438.408(b) - (c).

H.6.08 Contractor shall consider the enrollee, his/her representative, or the legal representative of a deceased enrollee's estate as parties to an appeal. See the additional obligations as set forth in Section 4 § 438.406(b)(6).

H.6.09 Contractor shall establish and maintain an expedited review process for appeals, when the Contractor determines (for a request from the enrollee) or when 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. See the additional obligations as set forth in Section 4 § 438.410(a).

H.6.10 Contractor shall inform enrollees of the limited time available to present evidence and testimony, in person and in writing, and make legal and factual arguments in the case of an expedited appeal resolution. Contractor shall inform enrollees of this sufficiently in advance of the resolution timeframe for appeals. See the additional obligations as set forth in Section 4 § 438.406(b)(4), Section 4 § 438.408(b) and Section 4 § 438.408(c).

H.6.11 If Contractor denies a request for expedited resolution of an appeal, it must transfer the appeal to the standard timeframe of no longer than 30 calendar days from the day the Contractor receives the appeal (with a possible 14-day extension). See the additional obligations as set forth in Section 4 § 438.410(c), Section 4 § 438.408(b)(2), and Section 4 § 438.408(c)(2).

H.7 Timeframes for Resolving Appeals and Expedited Appeals

H.7.01 Contractor shall resolve each appeal and provide notice, as expeditiously as the enrollee's health condition requires, within 30 calendar days from the day the Contractor receives the appeal. See the additional obligations as set forth in Section 4 § 438.408(a) and Section 4 § 438.408(b)(2).

H.7.02. – H.7.03 Contractor may extend the timeframe for processing an appeal by up to 14 calendar days if the enrollee requests the extension, or if the Contractor shows that there is need for additional information and that the delay is in the enrollee's interest (upon Agency request). See the additional obligations as set forth in Section 4 § 438.408(c)(1) and Section 4 § 438.408(b)(2).

H.7.04 – H.7.06 If Contractor extends the timeline for an appeal not at the request of the enrollee, it must:

1. Make reasonable efforts to give the enrollee prompt oral notice of the delay.

2. Give the enrollee written notice, within 2 calendar days, 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.

3. Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

See the additional obligations as set forth in Section 4 § 438.408(c)(2)(i) - (iii) and Section 4 § 438.408(b)(2).

H.7.07 Contractor shall resolve each expedited appeal and provide notice, as expeditiously as the enrollee's health condition requires, within Agency-established timeframes not to exceed 72 hours after the Contractor receives the expedited appeal request. See the additional obligations as set forth in Section 4 § 438.408(a) and Section 4 § 438.408(b)(3).

H.7.08 – H.7.09 Contractor may extend the timeframe for processing an expedited appeal by up to 14 calendar days:

1. If the enrollee requests the extension; or

2. If the Contractor shows that there is need for additional information and that the delay is in the enrollee's interest (upon Agency request).

See the additional obligations as set forth in Section 4 § 438.408(c)(1)(i) - (ii) and Section 4 § 438.408(b)(3).

H.7.10 – H.7.12 Contractor shall extend the timeline for processing an expedited appeal not at the request of the enrollee, it must:

1. Make reasonable efforts to give the enrollee prompt oral notice of the delay.

2. Give the enrollee written notice, within 2 calendar days, 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.

3. Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

See the additional obligations as set forth in Section 4 § 438.408(c)(2)(i) - (iii) and Section 4 § 438.408(b)(3).

H.8 Notice of Resolution for Appeals

H.8.01 – H.8.04 Contractor shall provide written notice of the resolution of the appeals process:

1. In a format and language that, at a minimum, meets applicable notification standards.

2. And include the results of the appeal resolution.

3. And include the date of the appeal resolution.

For appeal decisions not wholly in the enrollee's favor, Contractor shall include the following in the written resolution notice:

1. The right to request a state fair hearing.

2. How to request a state fair hearing.

3. The right to request and receive benefits pending a hearing.

4. How to request the continuation of benefits.

4. Notice that the enrollee may, consistent with state policy, be liable for the cost of any continued benefits if the Contractor's adverse benefit determination is upheld in the hearing.

See the additional obligations as set forth in Section 4 § 438.408(d)(2)(i), Section 4 § 438.10 and Section 4 § 438.408(e)(1) - (2).

H.8.05 Contractor shall provide written notice, and make reasonable efforts to provide oral notice, of the resolution of an expedited appeal. See the additional obligations as set forth in Section 4 § 438.408(d)(2)(ii).

H.9 Continuation of Benefits

H.9.01 Contractor shall continue the enrollee's benefits while an appeal is in process if all of the following occur:

1. The enrollee files the request for an appeal within 60 calendar days following the date on the adverse benefit determination notice.

2. The appeal involves the termination, suspension, or reduction of a previously authorized service.

3. The enrollee's services were ordered by an authorized provider.

4. The period covered by the original authorization has not expired.

5. The request for continuation of benefits is filed on or before the later of the following:

- Within 10 calendar days of the Contractor sending the notice of adverse benefit determination, or
- The intended effective date of the Contractor's proposed adverse benefit determination.

See the additional obligations as set forth in Section 4 § 438.420(a), Section 4 § 438.420(b)(1) - (5), and Section 4 § 438.402(c)(2)(ii).

H.9.02 If, at the enrollee's request, Contractor continues or reinstates the enrollee's benefits while the appeal or state fair hearing is pending, the benefits must be continued until one of the following occurs:

1. The enrollee withdraws the appeal or request for state fair hearing.

2. The enrollee does not request a state fair hearing and continuation of benefits within 10 calendar days from the date the Contractor sends the notice of an adverse appeal resolution.

3. A state fair hearing decision adverse to the enrollee is issued.

See the additional obligations as set forth in Section 4 § 438.420(c)(1)-(3), and Section 4 § 438.408(d)(2).

H.9.03 Contractor may recover the cost of continued services furnished to the enrollee while the appeal or state fair hearing was pending if the final resolution of the appeal or state fair hearing upholds the Contractor's adverse benefit determination. See the additional obligations as set forth in Section 4 § 438.420(d), and 42 C.F.R. § 431.230(b).

H.9.04 Contractor shall 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) if the services were not furnished while the appeal was pending and if the Contractor or state fair hearing officer reverses a decision to deny, limit, or delay services. See the additional obligations as set forth in Section 4 § 438.424(a).

H.9.05 Contractor shall pay for disputed services received by the enrollee while the appeal was pending, unless Agency policy and regulations provide for the Agency to cover the cost of such services, when the Contractor or state fair hearing officer reverses a decision to deny authorization of the services. See the additional obligations as set forth in Section 4 § 438.424(b).

H.9.06 Contractor shall notify the requesting provider and give the enrollee written notice of any decision to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. See the additional obligations as set forth in Section 4 § 438.210(c), and Section 4 § 438.404.

H.10 Grievances

H.10.01An enrollee may file a grievance with Contractor at any time. See the additional obligations as set forth in Section 4 § 438.402(c)(2)(i).

H.10.02An enrollee may file a grievance either orally or in writing. See the additional obligations as set forth in Section 4 § 438.402(c)(3)(i).

H.10.03 Enrollees may only file grievances with the Contractor. See the additional obligations as set forth in Section 4 § 438.402(c)(3)(i).

H.10.04Contractor shall resolve each grievance and provide notice, as expeditiously as the enrollee's health condition requires, within Agency-established timeframes not to exceed 90 calendar days from the day the Contractor receives the grievance. See the additional obligations as set forth in Section 4 § 438.408(a) and Section 4 § 438.408(b)(1).

H.10.05 – H.10.06 Contractor may extend the timeframe for processing a grievance by up to 14 calendar days:

1. If the enrollee requests the extension; or

2. If the Contractor shows that there is need for additional information and that the delay is in the enrollee's interest (upon Agency request).

See the additional obligations as set forth in Section 4 § 438.408(c)(1)(i) - (ii); § 438.408(b)(1).

H.10.07 – H.10.08 If Contractor extends the timeline for a grievance not at the request of the enrollee, it must:

1. Make reasonable efforts to give the enrollee prompt oral notice of the delay.

2. Give the enrollee written notice, within 2 calendar days, 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.

See the additional obligations as set forth in Section 4 § 438.408(c)(2)(i) - (ii) and Section 4 § 438.408(b)(1).

H.10.09The Contractor must provide an enrollee with written notice of the resolution of a grievance consistent with, at a minimum, the standards described at Section 4 § 438.10. See the additional obligations as set forth in Section 4 § 438.408(d)(1) and Section 4 § 438.10.

H.11 Grievance and Appeal Recordkeeping Requirements

H.11.01Contractor shall maintain records of grievances and appeals. See the additional obligations as set forth in Section 4 § 438.416(a).

H.11.02 – H.11.07 Contractor's record of each grievance or appeal include:

1. A general description of the reason for the appeal or grievance.
2. The date received.
3. The date of each review or, if applicable, review meeting.
4. Resolution information for each level of the appeal or grievance, if applicable.
5. The date of resolution at each level, if applicable.
6. The name of the covered person for whom the appeal or grievance was filed.

See the additional obligations as set forth in Section 4 § 438.416(b)(1) - (6).

H.11.08Contractor's record of each grievance or appeal be accurately maintained in a manner accessible to the Agency and available upon request to CMS. See the additional obligations as set forth in Section 4 § 438.416(c).

I. Program Integrity

I.1 Exclusions

I.1.01 Contractor shall not employ or contract with providers excluded from participation in Federal health care programs. See the additional obligations as set forth in Section 4 § 438.214(d)(1).

I.1.02 Contractor shall not be controlled by a sanctioned individual under section 1128(b)(8) of the Social Security Act. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(1); 42 C.F.R. § 431.55(h); section 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1001.1901(c); 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09.

I.1.03 Contractor shall not have a contract for the administration, management, or provision of medical services (or the establishment of policies or provision of operational support for such services), either directly or indirectly, with an individual convicted of crimes described in section 1128(b)(8)(B) of the Social Security Act. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(2); 42 C.F.R. § 431.55(h); section 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1001.1901(c); 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09.

I.1.04 Contractor shall not have a contract for the administration, management, or provision of medical services (or the establishment of policies or provision of operational support for such services), either directly or indirectly, with any individual or entity that is (or is affiliated with a person/entity that is) debarred, suspended, or excluded from participating in procurement activities under the Federal Acquisition Regulation (FAR) or from participating in non-

procurement activities under regulation issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(2); 42 C.F.R. § 438.610(a); 42 C.F.R. § 431.55(h); section 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1001.1901(c); 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09; Exec. Order No. 12549.

I.1.05 Contractor shall not have a contract for the administration, management, or provision of medical services (or the establishment of policies or provision of operational support for such services), either directly or indirectly, with any individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Social Security Act. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(2); 42 C.F.R. § 438.610(b); 42 C.F.R. § 431.55(h); section 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1001.1901(c); 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09.

I.1.06 Contractor shall not employ or contract, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services with any individual or entity that is (or is affiliated with a person/entity that is) debarred, suspended, or excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in non-procurement activities under regulation issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(3)(i), Section 4 § 438.610(a); 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1001.1901(c); 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09; Exec. Order No. 12549.

I.1.07 Contractor shall not employ or contract, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services with any individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Social Security Act. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(3)(i), Section 4 § 438.610(b); section 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09.

I.1.08 Contractor shall not employ or contract, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services with any individual or entity that would (or is affiliated with a person/entity that would) provide those services through an individual or entity debarred, suspended, or excluded from participating in procurement activities under the FAR or from participating in non- procurement activities under regulation issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(3)(ii), Section 4 § 438.610(a); section 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1001.1901(c); 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09; Exec. Order No. 12549.

I.1.09 Contractor shall not employ or contract, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services with any individual or entity that would provide those services through an individual or entity excluded from participation in any Federal health care program under section 1128 or 1128A of the Social Security Act. See the additional obligations as set forth in Section 4 § 438.808(a), Section 4 § 438.808(b)(3)(ii), Section 4 § 438.610(b); section 1903(i)(2) of the Social Security Act; 42 C.F.R. § 1001.1901(c); 42 C.F.R. § 1002.3(b)(3); SMDL 6/12/08; SMDL 1/16/09.

I.2 Requirements, Procedures and Reporting

I.2.01 Contractor shall submit encounter data to the Agency. See the additional obligations as set forth in Section 4 § 438.604(a)(1), Section 4 § 438.606, and Section 4 § 438.818.

I.2.02 Contractor shall submit data on the basis of which the Agency certifies the actuarial soundness of capitation rates to Contractor, including base data that is generated by the Contractor. See the additional obligations as set forth in Section 4 § 438.604(a)(2), Section 4 § 438.606, Section 4 § 438.3, and Section 4 § 438.5(c).

I.2.03 Contractor shall submit data on the basis of which the Agency determines the compliance of Contractor with the MLR requirement. See the additional obligations as set forth in Section 4 § 438.604(a)(3), Section 4 § 438.606, and Section 4 § 438.8.

I.2.04 Contractor shall submit data on the basis of which the Agency determines that Contractor has made adequate provision against the risk of insolvency. See the additional obligations as set forth in Section 4 § 438.604(a)(4), Section 4 § 438.606, and Section 4 § 438.116.

I.2.05 Contractor shall submit documentation on which the Agency bases its certification that Contractor complied with the Agency's requirements for availability and accessibility of services, including the adequacy of the provider network. See the additional obligations as set forth in Section 4 § 438.604(a)(5), Section 4 § 438.606, Section 4 § 438.207(b), and Section 4 § 438.206.

I.2.06 – I.2.12 Contractor shall submit:

1. The name and address of any person (individual or corporation) with an ownership or control interest in the managed care entity and its subcontractors. The address for corporate entities must include as applicable primary business address, every business location, and P.O. Box address.

2. The date of birth and Social Security Number (SSN) of any individual with an ownership or control interest in Contractor and its subcontractors.

3. Other tax identification number of any corporation with an ownership or control interest in Contractor and any subcontractor in which Contractor has a 5 percent or more interest.

4. Information on whether an individual or corporation with an ownership or control interest in Contractor is related to another person with ownership or control interest in Contractor as a spouse, parent, child, or sibling.

5. Information on whether a person or corporation with an ownership or control interest in any subcontractor in which Contractor has a 5 percent or more interest is related to another person with ownership or control interest in Contractor as a spouse, parent, child, or sibling.

6. The name of any other disclosing entity in which an owner of Contractor has an ownership or control interest.

7. The name, address, date of birth, and SSN of any managing employee of the Contractor.

See the additional obligations as set forth in Section 4 § 438.604(a)(6), Section 4 § 438.606; Section 4 § 438.230, Section 4 § 438.608(c)(2), 42 C.F.R. § 455.104(b)(1)(i) - (iii); and 42 C.F.R. § 455.104(b)(2) - (4).

I.2.13 Contractor shall submit any other data, documentation, or information relating to the performance of the entity's obligations as required by the Agency or Secretary. See the additional obligations as set forth in Section 4 § 438.604(b) and Section 4 § 438.606.

I.2.14 The individual who submits data to the Agency shall provide a certification, which attests, based on best information, knowledge and belief that the data, documentation and information are accurate, complete and truthful. See the additional obligations as set forth in Section 4 § 438.604 and Section 4 § 438.606(b).

I.2.15 Data, documentation, or information submitted to the Agency by Contractor must be certified by one of the following:

1. The Contractor's Chief Executive Officer (CEO).

2. The Contractor's Chief Financial Officer (CFO).

3. An individual who reports directly to the CEO or CFO with delegated authority to sign for the CEO or CFO so that the CEO or CFO is ultimately responsible for the certification.

See the additional obligations as set forth in Section 4 § 438.604 and Section 4 § 438.606(a).

I.2.16 Contractor shall submit certification concurrently with the submission of data, documentation, or information. See the additional obligations as set forth in Section 4 § 438.606(c) and Section 4 § 438.604(a) - (b).

I.2.17 – I.2.24 Contractor shall not knowingly have:

1. A director, officer, or partner who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

2. A person with ownership of 5% or more of Contractor's equity who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

3. A network provider who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

4. An employment, consulting, or other agreement for the provision of Contractor contract items or services with a person who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

See the additional obligations as set forth in Section 4 § 438.610(a)(1) - (2), Section 4 § 438.610(c)(1), 438.610(c)(3) - (4), Section 1932(d)(1) of the Social Security Act; SMDL 6/12/08; SMDL 1/16/09; Exec. Order No. 12549.

I.2.25 – I.2.26 Contractor shall not knowingly having a subcontractor of the Contractor who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non- procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549. See the additional obligations as set forth in Section 4 § 438.610(a)(1) - (2), Section 4 § 438.610(c)(2), Section 1932(d)(1) of the Social Security Act; and Exec. Order No. 12549.

I.2.27 – I.2.37 Contractor shall provide written disclosure of any:

1. Director, officer, or partner who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under

Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

2. Subcontractor of the Contractor who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

3. Person with ownership of 5% or more of the Contractor's equity who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

4. Network provider who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

5. Employment, consulting, or other agreement for the provision of Contract items or services with a person who is (or is affiliated with a person/entity that is) debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

6. An individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Social Security Act.

See the additional obligations as set forth in Section 4 § 438.608(c)(1), 438.610(a)(1) - (2), 438.610(b), 438.610(c)(1) - (4), SMDL 6/12/08; SMDL 1/16/09; Exec. Order No. 12549, and Section 1932(d)(1) of the Social Security Act.

I.2.38 Contractor shall ensure that all network providers are enrolled with the Agency as Medicaid providers consistent with provider disclosure, screening, and enrollment requirements. See the additional obligations as set forth in Section 4 § 438.608(b); 42 C.F.R. §§ 455.100-106; 42 C.F.R. §§ 455.400 – 455.470.

I.2.39 Contractor and any subcontractor shall report to the Agency within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in this Contract. See the additional obligations as set forth in Section 4 § 438.608(c)(3).

I.2.40 Contractor shall submit audited financial reports specific to this Contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards. See the additional obligations as set forth in Section 4 § 438.3(m).

I.3 Disclosure

I.3.01 Contractor and any subcontractor shall disclose to the Agency any persons or corporations with an ownership or control interest in the Contractor that:

1. Has direct, indirect, or combined direct/indirect ownership interest of 5% or more of the Contractor's equity;

2. Owns 5% or more of any mortgage, deed of trust, note, or other obligation secured by the Contractor if that interest equals at least 5% of the value of the Contractor's assets;

3. Is an officer or director of a managed care plan organized as a corporation; or

4. Is a partner in a managed care plan organized as a partnership.

See the additional obligations as set forth in Section 4 § 438.608(c)(2), 42 C.F.R. §§ 455.100 – 104, Section 1124(a)(2)(A) of the Social Security Act, and Section 1903(m)(2)(A)(viii) of the Social Security Act.

I.3.02 Contractor and its subcontractors shall disclose information on individuals or corporations with an ownership or control interest in the Contractor to the Agency at the following times:

1. When the Contractor submits a proposal in accordance with the state's procurement process.

2. When the Contractor executes a contract with the Agency.

3. When the Agency renews or extends the Contractor contract.

4. Within 35 days after any change in ownership of the Contractor.

See the additional obligations as set forth in Section 4 § 438.608(c)(2), 42 C.F.R. §§ 455.100 – 103, 42 C.F.R. § 455.104(c)(3), Section 1124(a)(2)(A) of the Social Security Act, and section 1903(m)(2)(A)(viii) of the Social Security Act.

I.3.03 Reserved

I.4 Reporting Transactions (Not applicable to a PAHP only)

I.4.01 Reserved.

I.5 Compliance Program

I.5.01 – I.5.07 Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall implement and maintain a compliance program that must include:

1. Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the Contract, and all applicable Federal and state requirements.

2. A Compliance Officer (CO) 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 CEO and the Board of Directors (BoD).

3. A Regulatory Compliance Committee (RCC) on the BoD and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the Contract.

4. A system for training and education for the CO, the organization's senior management, and the organization's employees for the federal and state standards and requirements under the Contract.

5. Effective lines of communication between the CO and the organization's employees.

6. Enforcement of standards through well-publicized disciplinary guidelines.

7. The 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.

See the additional obligations as set forth in Section 4 § 438.608(a), Section 4 § 438.608(a)(1)(i) - (vii).

I.5.08 Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall implement and maintain arrangements or procedures for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the Agency. See the additional obligations as set forth in Section 4 § 438.608(a)(2).

I.5.09 – I.5.10 Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall implement and maintain arrangements or procedures for prompt notification to the Agency when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including changes in the enrollee's residence or the death of the enrollee. See the additional obligations as set forth in Section 4 § 438.608(a)(3).

I.5.11 Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contract for coverage of services and payment of claims under this Contract, shall implement and maintain arrangements or procedures for notification to the Agency 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 Contractor. See the additional obligations as set forth in Section 4 § 438.608(a)(4).

I.5.12 Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall implement and maintain arrangements or procedures that include provisions 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. See the additional obligations as set forth in Section 4 § 438.608(a)(5).

I.5.13 If Contractor makes or receives annual payments under the Contract of at least $5,000,000, Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall implement and maintain written policies for all employees of the entity, and of any contractor or agent, that provide detailed information about the False Claims Act (FCA) and other Federal and state laws, including information about rights of employees to be protected as whistleblowers. See the additional obligations as set forth in Section 4 § 438.608(a)(6), Section 1902(a)(68) of the Social Security Act.

I.5.14 Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall implement and maintain arrangements or procedures that include provision for the prompt referral of any potential fraud, waste, or abuse that the Contractor identifies to the Agency Medicaid program integrity unit or any potential fraud directly to the state Medicaid Fraud Control Unit. See the additional obligations as set forth in Section 4 § 438.608(a)(7).

I.5.15 Contractor or subcontractor, to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall implement and maintain arrangements or procedures that include provision for the Contractor's suspension of payments to a network provider for which the Agency determines there is a credible allegation of fraud. See the additional obligations as set forth in Section 4 § 438.608(a)(8); 42 C.F.R. § 455.23.

I.6 Treatment of Recoveries

I.6.01 Contractor shall comply with the retention policies for the treatment of recoveries of all overpayments from the Contractor to a provider, including specifically the retention policies for the treatment of recoveries of overpayments due to fraud, waste, or abuse. See the additional obligations as set forth in Section 4 § 438.608(d)(1)(i).

I.6.02 Contractor shall comply with the process, timeframes, and documentation required for reporting the recovery of all overpayments as set forth in Section 4 § 438.608(d)(1)(ii).

I.6.03 Contractor shall comply with the process, timeframes, and documentation required for payment of recoveries of overpayments to the Agency in situations where the Contractor is not permitted to retain some or all of the recoveries of overpayments. See the additional obligations as set forth in Section 4 § 438.608(d)(1)(iii).

I.6.04 Contractor shall have, and require the use of, a mechanism for a network provider to report to the Contractor when it has received an overpayment, to return the overpayment to the Contractor within 60 calendar days after the date on which the overpayment was identified, and to notify the Contractor in writing of the reason for the overpayment. See the additional obligations as set forth in Section 4 § 438.608(d)(2).

I.6.05 Contractor shall submit the annual report of overpayment recoveries. See the additional obligations as set forth in Section 4 § 438.604(a)(7), Section 4 § 438.606, and Section 4 § 438.608(d)(3).

I.7 Additional Program Integrity Requirements

In addition to the requirements of I-1 through and including I-6, the following are required by this Contract.

I.7.01 *Designation of SIU Manager.* The Contractor shall employ an SIU Manager. The Contractor shall:

1. ensure that the SIU Manager is dedicated full-time to the Contractor's Iowa Medicaid product lines;

2. require the SIU Manager to be located in Iowa;

3. require that the qualifications of the SIU Manager are equal to those of the Agency Program Integrity Director; and

4. ensure that the SIU Manager responsibilities include:

(a) directing the activities of Special Investigation Unit staff;

(b) attending meetings with the State, including meeting with the State as the State directs, but no less than meeting on a monthly basis;

(c) acting as a subject matter expert for Medicaid program integrity; and

(d) reducing or eliminating wasteful, fraudulent, or abusive healthcare billings and services.

I.7.02 *SIU Staff.*

1. In addition to employing the SIU Manager, the Contractor shall employ one full-time dedicated SIU staff member for each 100,000 members assigned to the Contractor under this Contract.

2. The Contractor shall require the SIU staff to review and investigate Contractor's providers and members to identify fraud, waste, and abuse.

3. The Contractor shall ensure that a majority of the SIU staff work in Iowa.

I.7.03 *Program Integrity Activity Reporting*

1. Monthly Reporting. In addition to any reporting required by the federal regulations, including 42 C.F.R. § 438.608(d)(3), the Contractor shall provide the Agency with a monthly Program Integrity Activity Report outlining the Contractor's program integrity activities for the previous calendar month. To the extent that the federal regulations require reporting less frequently than the provisions in this Contract, the reporting requirements of this Contract are in addition to the less frequent reporting requirements under the federal regulations.

In the monthly Program Integrity Activity Report, the Contractor shall provide the information requested by the Agency, in the format requested by the Agency, including, but not limited to:

(a) A list of the Contractor's program integrity related activities for the month.

(b) Identification of the Contractor's progress in meeting the program integrity goals and objectives of the Contractor's program integrity work plan.

(c) Identification of the recoupment totals for the reporting period.

(d) A summary of state fiscal year to date information with the respect to program integrity.

(e) With respect to each provider reviewed:

1) The name and NPI of the provider.

2) The data source, referral, or other reason for the review.

3) Identification of any action taken by the Contractor, including, but not limited to, suspension, termination, recoupment, payment reduction, denial of enrollment or reenrollment, identification as excluded pursuant to 42 C.F.R. § 455.

4) Identification of the reason for the action and, if a payment or recoupment is involved, all of the relevant financial information related to the action.

2. Quarterly Audit Report. In addition to any reporting required by the federal regulations, including 42 C.F.R. § 438.608(d)(3), the Contractor shall provide the Agency with a quarterly audit report. To the extent that the federal regulations require reporting less frequently than the provisions of this Contract, the reporting requirements of this Contract are in addition to the less frequent reporting requirements under the federal regulations.

On a quarterly basis the Contractor shall submit a detailed audit report to the Agency which outlines the Contractor's program integrity related activities, as well as identifies the Contractor's progress in meeting program integrity related goals and objectives. The audit report should also specify individual provider recoupment, repayment schedules, and actions taken for each audit or investigation. The Agency shall review and approve, approve with modifications, or reject the audit report and specify the grounds for rejection. Recoupment totals and summaries for each reporting period (quarterly unless otherwise specified by the Agency) must also be submitted in the audit report.

3. Reporting Suspected Fraud, Waste, or Abuse. The Contractor shall report possible fraud or abuse activity to the Agency. The Contractor shall initiated an immediate investigation to gather facts regarding the possible fraud or abuse. Documentation of the findings of the investigation shall be delivered to the Agency within two (2) days of the identification of suspected fraud or abuse activity. In addition, the Contractor shall provide reports of its investigative, corrective, and legal activities with respect to fraud and abuse to the Agency in accordance with contractual and regulatory requirements. The Contractor and its subcontractors shall cooperate fully in any Agency reviews or investigations and in any subsequent legal action. The Contractor shall implement corrective actions in instances of fraud and abused detected by the State agency or other authorized agencies or entities. The Contractor shall report

to the Agency the following information monthly and in the manner required by the Agency: (i) the number of complaints of fraud and abused made to the Agency that warrant preliminary investigation; and (ii) for each complaint which warrants investigation: (a) the name and ID number; (b) source of the complaint; (c) type of provider; (d) nature of the complaint; (e) approximate dollars involved; (f) disposition of the case; (g) service type; and (i) any other relevant information requested by the Agency.

I.7.04 Required Fraud, Waste, and Abuse Activities.

1. The Contractor shall conduct regular review and audits of its operations, including incorporation of Correct Coding Initiative editing in the Contractor's claims adjudication process.

2. The Contractor shall assess and strengthen internal controls to ensure claims are submitted and paid properly.

3. The Contractor shall educate employees, providers, and members about fraud and abuse and how to report it.

4. The Contractor shall ensure accuracy, completeness, and truthfulness of claims and payment data as required by 42 C.F.R. Part 438, Subpart H and 42 C.F.R. § 457.950(a)(2).

5. The Contractor shall ensure sufficient organizational resources to effectively respond to complaints of fraud and abuse.

6. The Contractor shall effectively process fraud and abuse complaints.

7. The Contractor shall report information to the Agency in a format and timeframe designated by the Agency. Information shall be reported to the Agency monthly.

8. The Contractor shall monitor data and shall collect information related to utilization and service patterns of potential overpayments made to providers, subcontractors, and members and compile that information including, but not limited to, the following compilations:

   (a) A list of automated pre-payment claims edits.

   (b) A list of automated post-payment claims edits.

   (c) A list of desk audits on post-processing review of claims.

   (d) A list of reports of provider profiling and credentialing created in conducting program and payment integrity reviews.

9. The Contractor shall also collect and compile the following information:

   (a) A list of surveillance and utilization management protocols used to safeguard unnecessary or inappropriate use of Medicaid systems.

   (b) A list of provisions in the subcontractor and provider agreements that ensure the integrity of provider credentials.

   (c) A list of references in provider and member material regarding fraud and abuse referrals.

   (d) Any claims algorithms, use of predictive modeling, or editing required by the Agency.

10. The Contractor shall develop data mining techniques and conduct on-site audits.

I.7.05 Coordination of Program Integrity Efforts. The Contractors shall coordinate any and all program integrity efforts with IME personnel, IDPH personnel, and Iowa's Medicaid Fraud Control Unit (MFCU), located within the Iowa Department of Inspections and Appeals. At minimum, the Contractor shall:

1. Meet no less than once per month and as otherwise required with the Agency Program Integrity Unit, IDPH staff, and MFCU staff.

2. Provide any and all documentation or information upon request to the Agency, the MFCU, the HHS-OIG or the US Department of Justice related to any aspect of the Contract, including but not limited to, policies, procedures, subcontracts, provider agreements, claims data, encounter data, provider records and report on recoupment actions and receivables.

3. Coordinate program integrity activities with other contractors as directed by the Agency.

I.7.06 Verification of Services Provided. The Contractor shall have in place a method and procedures to verify whether services reimbursed by the Contractor were actually furnished to members as billed by providers.

I.7.07 Program Integrity Payment Related Issues.

1. Credible Allegation of Fraud Temporary Suspension of Payment.

The Contractor shall comply with 42 C.F.R. § 455.23 and § 438.608(a)(8) by suspending all payments to a provider after the Agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program against an individual or entity unless the Agency or law enforcement (including but not limited to MFCU) has identified in writing good cause for not suspending payments or to suspend payments only in part. The Contractor shall issue notice of payments suspension that comports in all respects with the obligations set forth in 42 C.F.R. § 455.23(b) and maintain the suspension for the durational period set forth in 42 C.F.R. § 455.23(c). In addition, the notice of payment suspension shall state that payments are being withheld in accordance with 42 C.F.R. § 455.23. The Contractor shall not suspend payments without consulting first with the MFCU and second with the Agency. The Contractor shall maintain all materials related to payment suspensions for a minimum of five (5) years in compliance with the obligations set forth in 42 C.F.R. § 455.23(g). The Contractor shall afford a grievance process to providers for whom payments have been suspended by the Contractor under this section.

2. Overpayments. The Contractor shall maintain policies and procedures to ensure that providers comply with Iowa Code Chapter 249A Subchapter II – Program Integrity, including but not limited to application of interest related to provider overpayments.

3. Circumstances Whereby the Contractor May Not Recoup or Withhold Improperly Paid Funds. The Contractor is prohibited from taking any actions to recoup or withhold improperly paid funds already paid or potentially due to a provider when the issues, services or claim upon which the withhold or recoupment are based meet one or more of the following criteria:

a) The improperly paid funds have already been recovered by the State of Iowa directly or through resolution of a State or federal investigation and/or lawsuit, including but not limited to false claims act cases;

b) The funds have already been recovered by the Recovery Audit Contractor; or

c) When the issues, services or claims that are the basis fof the recoupment or withhold are currently being investigated by the State of Iowa, are the subject of pending federal or State litigation or investigation, or are being audited by the Iowa RAC.

The prohibition described above shall be limited to a specific provider(s) for specific dates, and for specific issues, services, or claims. The Contractor shall check with IME Program Integrity Unit before initiating any recoupment or withhold of any program integrity related funds to ensure that the recoupment or withhold is permissible. In the event that the Contractor obtains funds in cases where recoupment or withhold is prohibited under this section, the Contractor shall return the funds to the provider.

4. Recovery of Payments.

(a) The Contractor shall recover improper payments and overpayments attributable to claims paid by the Contractor as identified by the Contractor or the Agency.

(b) The Contractor may retain overpayments attributable to claims paid by the Contractor.

(c) The State shall transmit recovery of an overpayment attributable to claims paid by the Contractor on or before the 60th day following receipt of the overpayment.

(d) The Contractor shall report improper payments and overpayments in accordance with the reporting requirements in this Contract.

(e) The provisions above do not apply to any amount of recovery to be retained under the False Claims Act cases or through other investigations.

I.7.08 Contractor Reporting Obligations for Adverse Actions Taken on Provider Applications for Program Integrity Reasons; 42 C.F.R. § 1002.3. The Contractor shall not permit the provider into the provider network if the Agency or the Contractor determines that any person who has ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid, or CHIP, or if the Agency or Contractor determine that the provider did not fully and accurately make any disclosure required pursuant to 42 C.F.R. § 1001.1001(a)(1).

I.7.09 Termination of Providers. The Contractor shall comply with all requirements for provider disenrollment and termination as required by 42 C.F.R. §455.416.

I.7.10 Enforcement of Iowa Medicaid Program Rules.

The Contractor and the Agency shall develop a process for referral of providers to the Agency for sanction under 441 Iowa Administrative Code § 79.2 The Contractor shall vigorously pursue fraud, waste and abuse in the Medicaid Program and notify the Agency PI of any provider activity which would incur a sanction under 441 Iowa Administrative Code § 79.2(249A).

J. General Terms and Conditions

J.1 Inspection

J.1.01 The Agency, CMS, the Office of the Inspector General (OIG), the Comptroller General, and their designees shall be allowed to inspect and audit any records or documents of the Contractor at any time. See the additional obligations as set forth in Section 4 § 438.3(h).

J.1.02 The Agency, CMS, the OIG, the Comptroller General, and their designees shall be allowed to inspect and audit any records or documents of the Contractor's subcontractors at any time. See the additional obligations as set forth in Section 4 § 438.3(h).

J.1.03 The Agency, CMS, the OIG, the Comptroller General, and their designees shall be allowed to inspect the premises, physical facilities, and equipment where Medicaid-related activities are conducted at any time. See the additional obligations as set forth in Section 4 § 438.3(h).

J.1.04 – J.1.05 The Agency, CMS, the OIG, the Comptroller General and their designees have the right to audit records or documents of the Contractor or the Contractor's subcontractors for 10 years from the final date of the Contract period or from the date of completion of any audit, whichever is later. See the additional obligations as set forth in Section 4 § 438.3(h).

J.1.06 The Secretary, the Department of Health and Human Services, and the Agency (or any person or organization designated by either) have the right to audit and inspect any books or records of the Contractor or its subcontractors pertaining to:

1. The ability of the Contractor to bear the risk of financial losses.

2. Services performed or payable amounts under the Contract.

See the additional obligations as set forth in Section 1903(m)(2)(A)(iv) of the Social Security Act.

J.1.07 Contractor and the Contractor's subcontractors shall retain, as applicable, enrollee grievance and appeal records in 42 C.F.R. § 438.416, base data in 42 C.F.R. § 438.5(c), MLR reports in 42 C.F.R. § 438.8(k), and the data, information, and documentation specified in 42 C.F.R. § 438.604, 438.606, 438.608, and 438.610 for a period of no less than 10 years. See the additional obligations as set forth in Section 4 § 438.3(u).

J.2 Compliance with State and Federal Laws

J.2.01 Contractor shall comply with all applicable Federal and state laws and regulations including:

1. Title VI of the Civil Rights Act (CRA) of 1964.

2. The Age Discrimination Act of 1975.

3. The Rehabilitation Act of 1973.

4. Title IX of the Education Amendments of 1972 (regarding education programs and activities).

5. The Americans with Disabilities Act.

6. Section 1557 of the Patient Protection and Affordable Care Act (ACA).

See the additional obligations as set forth in Section 4 § 438.3(f)(1) and Section 4 § 438.100(d).

J.2.02 Contractor shall comply with any applicable Federal and state laws that pertain to enrollee rights and ensure that its employees and contracted providers observe and protect those rights. See the additional obligations as set forth in Section 4 § 438.100(a)(2).

J.3 Subcontracts

J.3.01 Contractor shall maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the Agency, notwithstanding any relationship(s) that the Contractor may have with any subcontractor. See the additional obligations as set forth in Section 4 § 438.230(b)(1), and Section 4 § 438.3(k).

J.3.02 – J.3.03 If Contractor's activities or obligations under the Contract with the Agency are delegated to a subcontractor, Contractor shall ensure that:

1. The activities and obligations, and related reporting responsibilities, are specified in the Contract or written agreement between the Contractor and the subcontractor.

2. The contract or written arrangement between the Contractor and the subcontractor must either provide for revocation of the delegation of activities or obligations, or specify other remedies in instances where the Agency or the Contractor determines that the subcontractor has not performed satisfactorily.

See the additional obligations as set forth in Section 4 § 438.230(c)(1)(i) - (iii) and Section 4 § 438.3(k).

J.3.04 Contracts between the Contractor and subcontractors must require the subcontractor to comply with all applicable Medicaid laws, regulations, including applicable subregulatory guidance and contract provisions. See the additional obligations as set forth in Section 4 § 438.230(c)(2) and Section 4 § 438.3(k).

J.3.05 Contracts between the Contractor and subcontractors must require the subcontractor to agree that the Agency, CMS, the DHHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, records, contracts, computer or other electronic systems of the subcontractor, or of the subcontractor's contractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the Contractor's contract with the Agency. See the additional obligations as set forth in Section 4 § 438.230(c)(3)(i), and Section 4 § 438.3(k).

J.3.06 Contracts between the Contractor and subcontractors must require the subcontractor to make available, for the purposes of an audit, evaluation, or inspection by the Agency, CMS, the DHHS Inspector General, the Comptroller General or their designees, its premises, physical facilities, equipment, books, records, contracts, computer, or other electronic systems relating to its Medicaid enrollees. See the additional obligations as set forth in Section 4 § 438.230(c)(3)(ii), and Section 4 § 438.3(k).

J.3.07 Contracts between the Contractor and subcontractors must require the subcontractor to agree that the right to audit by the state, CMS, the DHHS Inspector General, the Comptroller General or their designees, 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. See the additional obligations as set forth in Section 4 § 438.230(c)(3)(iii), and Section 4 § 438.3(k).

J.3.08 Contracts between the Contractor and subcontractors require that if the Agency, CMS, or the DHHS Inspector General determine that there is a reasonable possibility of fraud or similar risk, the state, CMS, or the DHHS Inspector General may inspect, evaluate, and audit the subcontractor at any time. See the additional obligations as set forth in Section 4 § 438.230(c)(3)(iv), and Section 4 § 438.3(k).

J.4 Third Party Liability (TPL) Activities

JS.4.01 Third Party Liability is defined as any individual, entity, or program that is or may be liable to pay all or part of the health care expenses of a Medicaid beneficiary. Under Section 1902(a)(25) of the Social Security Act, the State is required to take all reasonable measures to identify legally liable third parties and treat Third Party Liability as a resource of the Medicaid beneficiary. Contractor may retain its third party collections. The capitated rates have been adjusted down by the amount of the Contractor's expected collections.

JS.4.02 Pursuant to applicable law, the Agency is the payer of last resort for all covered services. The Contractor shall exercise full assignment rights as applicable and shall make every reasonable effort to determine the liability of third parties to pay for services rendered to members under the Contract and cost avoid and/or recover any such liability from the third party. The Contractor shall develop and implement policies and procedures, subject to Agency review and approval, to meet its obligations regarding third party liability when the third party pays a cash benefit to the member, regardless of services used, or does not allow the member to assign his/her benefits. When there is third party liability, the Contractor shall pay the member's coinsurance, deductibles, co-payments and other cost-sharing expenses up to the Contractor's allowed amount. The Contractor's total liability shall not exceed the Contractor's allowed amount minus the amount paid by the primary payer. The Contractor shall follow all activities laid out in the Agency, Medicaid TPL Action Plan, revised 2015.

See the additional obligations as set forth in 42 C.F.R. part 433 subpart D and 42 C.F.R. § 447.20.

JS.4.03 Reports include, but are not limited to:

1. Monthly amounts billed and collected, current and year-to-date.

2. Recoveries and unrecoverable amounts by carrier, type of coverage, and reason (quarterly).

3. TPL activity reports (quarterly).

4. Internal reports used to investigate possible third-party liability when paid claims contain a TPL amount and no resource information is on file.

5. Monthly quality assurance sample to the Department verifying the accuracy of the TPL updated applied during the previous month.

6. Monthly pay-and-chase carrier bills.

J.5 Sanctions

J.5.01 – J.5.09 Reserved

J.5.10 The Agency may impose additional sanctions provided for under state statutes or regulations to address Contractor noncompliance. See the additional obligations as set forth in Section 4 § 438.702(b).

J.5.11 – J.5.20 Reserved

J.6 Termination

J.6.01 Reserved

J.7 Insolvency

J.7.01 Medicaid enrollees may not held liable for the Contractor's debts, in the event the Contractor becomes insolvent. See the additional obligations as set forth in Section 4 § 438.106(a) and Section 1932(b)(6) of the Social Security Act.

J.7.02 – J.7.03 Medicaid enrollees may not be held liable for covered services provided to the enrollee, for which the Agency does not pay the Contractor, or for which the Agency or Contractor does not pay the provider that furnished the service under a contractual, referral, or other arrangement. See the additional obligations as set forth in Section 4 § 438.106(b)(1) - (2), Section 4 § 438.3(k), Section 4 § 438.230; and Section 1932(b)(6) of the Social Security Act.

JS.7.02 Notwithstanding Section J.7.02 - J.7.03, a Medicaid enrollee can be held liable for services provided to the enrollee that normally are covered services under the Contract but which were provided to an enrollee who has met or exceeded their ABM. However, the enrollee may only be held liable for such services if the enrollee was informed of the liability before services were delivered to the enrollee and the enrollee expressly accepted the liability in writing, noting expressly that the enrollee would be accepting liability because of exceeding the ABM.

JS.7.03 The phrase "covered services" as used in section J.7.02-J.7.03 means those services provided to Medicaid beneficiaries through this Contract whether or not the Contractor or the Agency ultimately pay the provider for the services.

J.7.04 Medicaid enrollees may not be held liable for covered services furnished under a contract, referral, or other arrangement to the extent that those payments are in excess of the amount the enrollee would owe if the Contractor covered the services directly. See the additional obligations as set forth in Section 4 § 438.106(c), Section 4 § 438.3(k), Section 4 § 438.230, and Section 1932(b)(6) of the Social Security Act.

J.7.05 Contractor shall provide assurances satisfactory to the Agency that its provision against the risk of insolvency is adequate to ensure that Medicaid enrollees will not be liable for the

Contractor's debt if the Contractor becomes insolvent. See the additional obligations as set forth in Section 4 § 438.116(a).

J.7.06 Reserved

K. Health Information Systems and Enrollee Data

K.01 Contractor shall maintain a health information system that collects, analyzes, integrates, and reports data. See the additional obligations as set forth in Section 4 § 438.242(a).

K.02 Contractor's health information system must provide information on areas including, but not limited to, utilization, claims, grievances and appeals, and disenrollment for reasons other than loss of Medicaid eligibility. See the additional obligations as set forth in Section 4 § 438.242(a).

K.03 Contractor shall comply with Section 6504(a) of the Affordable Care Act (ACA), which requires that Agency 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 Agency to meet the requirements of section 1903(r)(1)(F) of the Social Security Act. See the additional obligations as set forth in Section 4 § 438.242(b)(1), Section 6504(a) of the ACA, and Section 1903(r)(1)(F) of the Social Security Act.

K.04 Contractor shall collect data on enrollee and provider characteristics as specified by the Agency and on all services furnished to enrollees through an encounter data system or other methods as may be specified by the Agency. See the additional obligations as set forth in Section 4 § 438.242(b)(2).

K.05 Contractor shall verify the accuracy and timeliness of data reported by providers, including data from network providers the Contractor is compensating on the basis of capitation payments. See the additional obligations as set forth in Section 4 § 438.242(b)(3)(i).

K.06 Contractor shall screen the data received from providers for completeness, logic, and consistency. See the additional obligations as set forth in Section 4 § 438.242(b)(3)(ii).

K.07 Contractor shall collect data from providers in standardized formats to the extent feasible and appropriate, including secure information exchanges and technologies utilized for Agency Medicaid quality improvement and care coordination efforts. See the additional obligations as set forth in Section 4 § 438.242(b)(3)(iii).

K.08 Contractor shall make all collected data available to the Agency and upon request to CMS. See the additional obligations as set forth in Section 4 § 438.242(b)(4).

K.09 – K.12 Contractor shall:

1. Collect and maintain sufficient enrollee encounter data to identify the provider who delivers any item(s) or service(s) to enrollees.

2. Submit enrollee encounter data to the Agency at a frequency and level of detail to be specified by CMS and the Agency, based on program administration, oversight, and program integrity needs.

3. Submit all enrollee encounter data that the Agency is required to report to CMS.

4. Submit encounter data to the Agency in standardized Accredited Standards Committee (ASC) X12N 837 and National Council for Prescription Drug Programs (NCPDP) formats, and the ASC X12N 835 format as appropriate.

See the additional obligations as set forth in Section 4 § 438.242(c)(1) - (4), and Section 4 § 438.818.

KS.01 Reporting Format and Batch Submission Schedule

The Contractor shall submit encounter claims in an electronic format that adheres to the data Specifications set forth by the Agency and in any State or federally mandated electronic claims submission standards. The Agency will have all of the remedies provided to it under the Contract, including liquidated damages, for failure to comply with these requirements. Encounter data shall be submitted by the 20th of the month subsequent to the month for which data are reflected. All corrections to the monthly encounter data submission shall be finalized within forty-five (45) days from the date the initial error report for the month was sent to the Contractor or fifty-nine (59) days from the date the initial encounter data were due. The error rate for encounter data cannot exceed one percent (1%). The source of the error can be identified by system edits and/or analysis of the encounter data. The Agency will notify the Contractor of changes made to calculate encounter data timeliness, accuracy, and quality sixty (60) days prior to implementation.

KS. 01.01 Encounter Claims Policies

The Contractor shall develop written policies and procedures to address its submission of encounter claims to the State.

KS. 01.02 Accuracy of Encounter Claims

The Contractor shall implement policies and procedures to ensure that encounter claims submissions are accurate. The Agency reserves the right to monitor encounter claims for accuracy against Contractor internal criteria as well as State and Federal requirements. The Agency will regularly monitor the Contractor's accuracy by reviewing the Contractor's compliance with its internal policies and procedures for accurate encounter claims submissions and by random sample audits of claims. The Agency will implement a quarterly Encounter Utilization Monitoring report and review process to be implanted in the first quarter following the contract effective date. The Contractor shall submit timely and accurate reports in the format and timeframe designated by the Agency. The Contractor shall investigate root cause of report inaccuracies and submit a revised report in the timeframe designated by the Agency. The Contractor shall fully comply with requirements of these audits and provide all requested Documentation, including, but not limited to, applicable medical records and prior authorizations. The Agency will require the Contractor to submit a corrective action plan and will require non-compliance remedies for Contractor failure to comply with accuracy of these reporting requirements.

KS. 01.03 Encounter Data Completeness

The Contractor shall have in place a system for monitoring and reporting the completeness of claims and encounter data received from providers. For every service provided, providers must submit corresponding claim or encounter data with claim detail identical to that required for fee-for-service claims submissions. The Contractor shall also have in place a system for verifying and ensuring that providers are not submitting claims or encounter data for services that were not provided. The Contractor shall demonstrate its internal standards for measuring completeness, the results of any completeness studies, and any corrective action plans developed to address areas of non-compliance. The Agency may require the Contractor to demonstrate, through report or audit, that this monitoring system is in place and that the Contractor is regularly monitoring the completeness of claims and encounter data and ensuring that the Contractor is meeting the Agency completeness requirements.

KS.02 The Contractor shall institute a system that integrates information about enrollees in order to facilitate positive enrollee outcomes through education and outreach. The system shall have the ability to track the results of the initial oral health screening, comprehensive oral health risk assessment, enrollee outcomes and have the ability to share information with the Enrollee, his or her authorized representatives, and all relevant treatment providers, including, but not limited to primary care providers and specialists. The Contractor shall submit regular reporting regarding the selection criteria, strategies & outcomes of education and outreach programs as prescribed in the reporting template.

L. Agency Obligations

L.1 Enrollee and Potential Enrollee Information

L.1.01 The prevalent non-English languages spoken by enrollees and potential enrollees in the Agency and each Contractor service area will be identified by the Agency. See the additional obligations as set forth in Section 4 § 438.10(d)(1).

L.1.02 If the Contractor does not cover counseling or referral services because of moral or religious objections and chooses not to furnish information on how and where to obtain such services, the Agency will provide that information to potential enrollees. See the additional obligations as set forth in Section 4 § 438.10(e)(2)(v)(C).

L.2 Contract Sanctions and Terminations

L.2.01 – L2.13 *Reserved (not applicable to a PAHP).*

LS.2.01 -- The Agency retains authority to impose sanctions under State statutes or State regulations that address areas of noncompliance specified in 42 C.F.R. § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

LS.2.02 If the Contractor fails to comply in any way with encounter data submission requirements as described in Section K, the Agency cam impose liquidated damages of $5,000 per accounting period (for encounters submitted monthly beginning October 1, 2018).

L.3 Payment

L.3.01 Contractor shall make no payment to a network provider other than by the Contractor for services covered under the Contract between the Agency and the Contractor, except when these payments are specifically required to be made by the Agency in Title XIX of the Act, in 42 C.F.R., or when the Agency makes direct payments to network providers for graduate medical education costs approved under the state plan. See the additional obligations as set forth in Section 4 § 438.60.

L.3.02 When the amount the IHCP receives from Contractor is less than the amount the IHCP would have received under FFS or the applicable encounter rate published annually in the Federal Register by the IHS, the Agency must make a supplemental payment to the IHCP to make up the difference between the amount the Contractor pays and the amount the IHCP would have received under FFS or the applicable encounter rate. See the additional obligations as set forth in Section 4 § 438.14(c)(3).

L.4 Identifying Special Healthcare Needs or Who Need LTSS

L.4.01 The Agency, the enrollment broker, or the Contractor may identify persons with special health care needs as defined by the Agency. See the additional obligations as set forth in Section. 4 § 438.208(c)(1).

L.4.02 *Reserved (not applicable to a dental-only PAHP).*

L.5 Data Collection

L.5.01 – L.5.02 The Agency will collect the following information from the Contractor to improve the performance of its managed care program:

1. Enrollment and disenrollment data from the Contractor.
2. Member grievance and appeal logs from the Contractor.

See the additional obligations as set forth in Section 4 § 438.66(c)(1) - (2).

L.5.03 The Agency will collect provider complaint and appeal logs from the Contractor to improve the performance of its managed care program. See the additional obligations as set forth in Section 4 § 438.66(c)(3).

L.5.04 – L.5.05 The Agency will collect the following information to improve the performance of its managed care program:

1. The results of any enrollee satisfaction survey conducted by the Contractor.
2. The results of any provider satisfaction survey conducted by the Contractor.

See the additional obligations as set forth in Section 4 § 438.66(c)(5).

L.5.06 – L.5.08 The Agency will collect the following information to improve the performance of its managed care program:

1. Performance on required quality measures from the Contractor.
2. Medical management committee reports and minutes from the Contractor.
3. The Contractor's annual quality improvement plan.

See the additional obligations as set forth in Section 4 § 438.66(c)(6) - (8).

L.5.09 – L.5.11 The Agency will collect the following information to improve the performance of its managed care program:

1. Audited financial and encounter data from the Contractor.
2. The MLR summary reports from the Contractor.
3. Customer service performance data from the Contractor.

See the additional obligations as set forth in Section 4 § 438.66(c)(9) - (11), and Section 4 § 438.8.

L.5.12 *Reserved (not applicable to a dental-only PAHP).*

L.6 Program Integrity

L.6.01 If the Agency learns that Contractor has a prohibited relationship with an individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549, or if the Contractor has a relationship with an individual who is an affiliate of such an individual, the Agency may continue an existing agreement with the Contractor unless the Secretary directs otherwise. See the additional obligations as set forth in Section 4 § 438.610(d)(2), Section 4 § 438.610(a), and Exec. Order No. 12549.

L.6.02 If the Agency learns that Contractor has a prohibited relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Social Security Act, the Agency may continue an existing agreement with the

Contractor unless the Secretary directs otherwise. See the additional obligations as set forth in Section 4 § 438.610(d)(2), and Section 4 § 438.610(b).

L.6.03 If the Agency learns that Contractor has a prohibited relationship with an individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the FAR or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549, or if Contractor has relationship with an individual who is an affiliate of such an individual, the Agency may not renew or extend the existing agreement with Contractor unless the Secretary provides to the Agency and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliation. See the additional obligations as set forth in Section 4 § 438.610(d)(3), Section 4 § 438.610(a), and Exec. Order No. 12549.

L.6.04 If the Agency learns that Contractor has a prohibited relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Social Security Act, the Agency may not renew or extend the existing agreement with the Contractor unless the Secretary provides to the Agency and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliation. See the additional obligations as set forth in Section 4 § 438.610(d)(3), and Section 4 § 438.610(b).

L.6.05 The Agency will screen and enroll, and periodically revalidate all Contractor network providers as Medicaid providers. See the additional obligations as set forth in Section 4 § 438.602(b)(1).

L.6.06 Contractor may execute network provider agreements, pending the outcome of screening, enrollment, and revalidation, of up to 120 days but must terminate a network provider immediately upon notification from the Agency that the network provider cannot be enrolled, or the expiration of one 120 day period without enrollment of the provider, and notify affected enrollees. See the additional obligations as set forth in Section 4 § 438.602(b)(2).

L.6.07 The Agency will review the ownership and control disclosures submitted by the Contractor and any of the Contractor's subcontractors. See the additional obligations as set forth in Section 4 § 438.602(c) and Section 4 § 438.608(c).

L.6.08 The Agency will ensure that the Contractor is not located outside of the United States. See the additional obligations as set forth in Section 4 § 438.602(i).

SECTION 2. GENERAL TERMS FOR SERVICES CONTRACTS

2.1 Definitions. Definitions in this section correspond with capitalized terms in the Contract.

"Acceptance" means that the Agency has determined that one or more Deliverables satisfy the Agency's Acceptance Tests. Final Acceptance means that the Agency has determined that all Deliverables satisfy the Agency's Acceptance Tests. Non-acceptance means that the Agency has determined that one or more Deliverables have not satisfied the Agency's Acceptance Tests.
"Acceptance Criteria" means the Specifications, goals, performance measures, testing results and/or other criteria designated by the Agency and against which the Deliverables may be evaluated for purposes of Acceptance or Non-acceptance thereof.
"Acceptance Tests" or "Acceptance Testing" mean the tests, reviews, and other activities that are performed by or on behalf of the Agency to determine whether the Deliverables meet the Acceptance Criteria or otherwise satisfy the Agency, as determined by the Agency in its sole discretion.
"Applicable Law" means all applicable federal, state, and local laws, rules, ordinances, regulations, orders, guidance, and policies in place at Contract execution as well as any and all future amendments, changes, and additions to such laws as of the effective date of such change. Applicable Law includes, without limitation, all laws that pertain to the prevention of discrimination in employment and in the provision of services (e.g., Iowa Code ch. 216 and Iowa Code § 19B.7). For employment, this would include equal employment opportunity and affirmative action, and the use of targeted small businesses as subcontractors of suppliers. The term Applicable Law also encompasses the applicable provisions of Section 508 of the Rehabilitation Act of 1973, as amended, and all standards and requirements established by the Architectural and Transportation Barriers Access Board and the Iowa Office of the Chief Information Officer.
"Bid Proposal" or "Proposal" means the Contractor's proposal submitted in response to the Solicitation, if this Contract arises out of a competitive process.
"Business Days" means any day other than a Saturday, Sunday, or State holiday as specified by Iowa Code §1C.2.
"Confidential Information" means, subject to any applicable State and federal laws and regulations, including but not limited to Iowa Code Chapter 22, any confidential or proprietary information or trade secrets disclosed by either party (a "Disclosing Party") to the other party (a "Receiving Party") that, at the time of disclosure, is designated as confidential (or like designation), is disclosed in circumstances of confidence, or would be understood by the parties, exercising reasonable business judgment, to be confidential. Regardless of whether or not the following information is designated as confidential, the term Confidential Information includes information that could be used to identify recipients or applicants of Agency services and recipients of Contract services including Protected Health Information (45 C.F.R. § 160.103) and Personal Information (Iowa Code § 715C.1(11)), Agency security protocols and procedures, Agency system architecture, information that could compromise the security of the Agency network or systems, and information about the Agency's current or future competitive procurements, including the evaluation process prior to the formal announcement of results.

Confidential Information does not include any information that: (1) was rightfully in the possession of the Receiving Party from a source other than the Disclosing Party prior to the time of disclosure of the information by the Disclosing Party to the Receiving Party; (2) was known to the Receiving Party prior to the disclosure of the information by the Disclosing Party; (3) was disclosed to the Receiving Party without restriction by an independent third party having a legal right to disclose the information; (4) is in the public domain or shall have become publicly available other than as a result of disclosure by the Receiving Party in violation of this Agreement or in breach of any other agreement with the Disclosing Party; (5) is

independently developed by the Receiving Party without any reliance on Confidential Information disclosed by the Disclosing Party; or (6) is disclosed by the Receiving Party with the written consent of the Disclosing Party.

"Contract" means the collective documentation memorializing the terms of the agreement between the Agency and the Contractor identified in the Contract Declarations and Execution Section and includes the signed Contract Declarations and Execution Section, the General Terms for Services Contracts, the Special Terms, and any Special Contract Attachments, as these documents may be amended from time to time.

"Deficiency" means a defect, flaw, anomaly, failure, omission, interruption of service, or other problem of any nature whatsoever with respect to a Deliverable, including, without limitation, any failure of a Deliverable to conform to or meet an applicable specification. Deficiency also includes the lack of something essential or necessary for completeness or proper functioning of a Deliverable.

"Deliverables" means all of the services, goods, products, work, work product, data, items, materials and property to be created, developed, produced, delivered, performed, or provided by or on behalf of, or made available through, the Contractor (or any agent, contractor or subcontractor of the Contractor) in connection with this Contract. This includes data that is collected on behalf of the Agency.

"Documentation" means any and all technical information, commentary, explanations, design documents, system architecture documents, database layouts, test materials, training materials, guides, manuals, worksheets, notes, work papers, and all other information, documentation and materials related to or used in conjunction with the Deliverables, in any medium, including hard copy, electronic, digital, and magnetically or optically encoded media.

"Force Majeure" means an event that no human foresight could anticipate or which if anticipated, is incapable of being avoided. Circumstances must be abnormal and unforeseeable, so that the consequences could not have been avoided through the exercise of all due care. The delay or impossibility of performance must be beyond the control and without the fault or negligence of the parties. Force Majeure does not include: financial difficulties of the Contractor or any parent, subsidiary, affiliated or associated company of the Contractor; claims or court orders that restrict the Contractor's ability to deliver the Deliverables contemplated by this Contract; strikes; labor unrest; or supply chain disruptions.

"Invoice" means a Contractor's claim for payment. At the Agency's discretion, claims may be submitted on an original invoice from the Contractor or may be submitted on a claim form acceptable to the Agency, such as a General Accounting Expenditure (GAX) form.

"Solicitation" means the formal or informal procurement (and any Addenda thereto) identified in the Contracts Declarations and Execution Section that was issued to solicit the Bid Proposal leading to this Contract.

"Special Contract Attachments" means any attachment to this Contract.

"Special Terms" means the Section of the Contract entitled "Special Terms" that contains terms specific to this Contract, including but not limited to the Scope of Work and contract payment terms. If there is a conflict between the General Terms for Services Contracts and the Special Terms, the Special Terms shall prevail.

"Specifications" means all specifications, requirements, technical standards, performance standards, representations, and other criteria related to the Deliverables stated or expressed in this Contract, the Documentation, the Solicitation, and the Bid Proposal. Specifications shall include the Acceptance Criteria and any specifications, standards, or criteria stated or set forth in any applicable state, federal, foreign, and local laws, rules and regulations. The Specifications are incorporated into this Contract by reference as if fully set forth in this Contract.

"State" means the State of Iowa, the Agency, and all State of Iowa agencies, boards, and commissions, and when this Contract is available to political subdivisions, any political subdivisions of the State of Iowa.

2.2 Duration of Contract. The term of the Contract shall begin and end on the dates specified in the Contract Declarations and Execution Section, unless extended or terminated earlier in accordance with the termination provisions of this Contract. The Agency may, in its sole discretion, amend the end date of this Contract by exercising any applicable extension by giving the Contractor a written extension at least

sixty (60) days prior to the expiration of the initial term or renewal term.

2.3 Scope of Work. The Contractor shall provide Deliverables that comply with and conform to the Specifications. Deliverables shall be performed within the boundaries of the United States.

2.4 Compensation.

2.4.1 Withholding Payments. In addition to pursuing any other remedy provided herein or by law, the Agency may withhold compensation or payments to the Contractor, in whole or in part, without penalty to the Agency or work stoppage by the Contractor, in the event the Agency determines that: (1) the Contractor has failed to perform any of its duties or obligations as set forth in this Contract; (2) any Deliverable has failed to meet or conform to any applicable Specifications or contains or is experiencing a Deficiency; or (3) the Contractor has failed to perform Close-Out Event(s). No interest shall accrue or be paid to the Contractor on any compensation or other amounts withheld or retained by the Agency under this Contract.

2.4.2 Erroneous Payments and Credits. The Contractor shall promptly repay or refund the full amount of any overpayment or erroneous payment within thirty (30) Business Days after either discovery by the Contractor or notification by the Agency of the overpayment or erroneous payment.

2.4.3 Offset Against Sums Owed by the Contractor. In the event that the Contractor owes the State any sum under the terms of this Contract, any other contract or agreement, pursuant to a judgment, or pursuant to any law, the State may, in its sole discretion, offset any such sum against: (1) any sum Invoiced by, or owed to, the Contractor under this Contract, or (2) any sum or amount owed by the State to the Contractor, unless otherwise required by law. The Contractor agrees that this provision constitutes proper and timely notice under any applicable laws governing offset.

2.5 Termination.

2.5.1 Termination for Cause by the Agency. The Agency may terminate this Contract upon written notice for the breach by the Contractor or any subcontractor of any material term, condition or provision of this Contract, if such breach is not cured within the time period specified in the Agency's notice of breach or any subsequent notice or correspondence delivered by the Agency to the Contractor, provided that cure is feasible. In addition, the Agency may terminate this Contract effective immediately without penalty and without advance notice or opportunity to cure for any of the following reasons:

2.5.1.1 The Contractor furnished any statement, representation, warranty, or certification in connection with this Contract, the Solicitation, or the Bid Proposal that is false, deceptive, or materially incorrect or incomplete;

2.5.1.2 The Contractor or any of the Contractor's officers, directors, employees, agents, subsidiaries, affiliates, contractors or subcontractors has committed or engaged in fraud, misappropriation, embezzlement, malfeasance, misfeasance, or bad faith;

2.5.1.3 The Contractor or any parent or affiliate of the Contractor owning a controlling interest in the Contractor dissolves;

2.5.1.4 The Contractor terminates or suspends its business;

2.5.1.5 The Contractor's corporate existence or good standing in Iowa is suspended, terminated, revoked or forfeited, or any license or certification held by the Contractor related to the Contractor's performance under this Contract is suspended, terminated, revoked, or forfeited;

2.5.1.6 The Contractor has failed to comply with any applicable international, federal, state (including, but not limited to Iowa Code Chapter 8F), or local laws, rules, ordinances, regulations, or orders when performing within the scope of this Contract;

2.5.1.7 The Agency determines or believes the Contractor has engaged in conduct that: (1) has or may expose the Agency or the State to material liability; or (2) has caused or may cause a person's life, health, or safety to be jeopardized;

2.5.1.8 The Contractor infringes or allegedly infringes or violates any patent, trademark, copyright, trade dress, or any other intellectual property right or proprietary right, or the Contractor misappropriates or allegedly misappropriates a trade secret;

2.5.1.9 The Contractor fails to comply with any applicable confidentiality laws, privacy laws, or any provisions of this Contract pertaining to confidentiality or privacy; or

2.5.1.10 Any of the following has been engaged in by or occurred with respect to the Contractor or any corporation, shareholder or entity having or owning a controlling interest in the Contractor:

• Commencing or permitting a filing against it which is not discharged within ninety (90) days, of a case or other proceeding seeking liquidation, reorganization, or other relief with respect to itself or its debts under any bankruptcy, insolvency, or other similar law now or hereafter in effect; or filing an answer admitting the material allegations of a petition filed against it in any involuntary case or other proceeding commenced against it seeking liquidation, reorganization, or other relief under any bankruptcy, insolvency, or other similar law now or hereafter in effect with respect to it or its debts; or consenting to any such relief or to the appointment of or taking possession by any such official in any voluntary case or other proceeding commenced against it seeking liquidation, reorganization, or other relief under any bankruptcy, insolvency, or other similar law now or hereafter in effect with respect to it or its debts;
• Seeking or suffering the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its assets;
• Making an assignment for the benefit of creditors;
• Failing, being unable, or admitting in writing the inability generally to pay its debts or obligations as they become due or failing to maintain a positive net worth and such additional capital and liquidity as is reasonably adequate or necessary in connection with the Contractor's performance of its obligations under this Contract; or
• Taking any action to authorize any of the foregoing.

2.5.2 Termination Upon Notice. Following a thirty (30) day written notice, the Agency may terminate this Contract in whole or in part without penalty and without incurring any further obligation to the Contractor. Termination can be for any reason or no reason at all.

2.5.3 Termination Due to Lack of Funds or Change in Law. Notwithstanding anything in this Contract to the contrary, and subject to the limitations set forth below, the Agency shall have the right to terminate this Contract without penalty and without any advance notice as a result of any of the following:

2.5.3.1 The legislature or governor fail in the sole opinion of the Agency to appropriate funds sufficient to allow the Agency to either meet its obligations under this Contract or to operate as required and to fulfill its obligations under this Contract; or

2.5.3.2 If funds are de-appropriated, reduced, not allocated, or receipt of funds is delayed, or if any funds or revenues needed by the Agency to make any payment hereunder are insufficient or unavailable for any other reason as determined by the Agency in its sole discretion; or

2.5.3.3 If the Agency's authorization to conduct its business or engage in activities or operations related to the subject matter of this Contract is withdrawn or materially altered or modified; or

2.5.3.4 If the Agency's duties, programs or responsibilities are modified or materially altered; or

2.5.3.5 If there is a decision of any court, administrative law judge or an arbitration panel or any law, rule, regulation, or order is enacted, promulgated, or issued that materially or adversely affects the Agency's ability to fulfill any of its obligations under this Contract.

The Agency shall provide the Contractor with written notice of termination pursuant to this section.

2.5.4 Other remedies. The Agency's right to terminate this Contract shall be in addition to and not exclusive of other remedies available to the Agency, and the Agency shall be entitled to exercise any other rights and pursue any remedies, in law, at equity, or otherwise.

2.5.5 Limitation of the State's Payment Obligations. In the event of termination of this Contract for any reason by either party (except for termination by the Agency pursuant to Section 2.5.1, *Termination for Cause by the Agency*) the Agency shall pay only those amounts, if any, due and owing to the Contractor hereunder for Deliverables actually and satisfactorily provided in accordance with the provisions of this Contract up to and including the date of termination of this Contract and for which the Agency is obligated to pay pursuant to this Contract; provided however, that in the event the Agency terminates this Contract pursuant to Section 2.5.3, *Termination Due to Lack of Funds or Change in Law*, the Agency's obligation to pay the Contractor such amounts and other compensation shall be limited by, and subject to, legally available funds. Payment will be made only upon submission of Invoices and proper proof of the Contractor's claim. Notwithstanding the foregoing, this section in no way limits the rights or remedies available to the Agency and shall not be construed to require the Agency to pay any compensation or other amounts hereunder in the event of the Contractor's breach of this Contract or any amounts withheld by the Agency in

accordance with the terms of this Contract. The Agency shall not be liable, under any circumstances, for any of the following:
2.5.5.1 The payment of unemployment compensation to the Contractor's employees;
2.5.5.2 The payment of workers' compensation claims, which occur during the Contract or extend beyond the date on which the Contract terminates;
2.5.5.3 Any costs incurred by the Contractor in its performance of the Contract, including, but not limited to, startup costs, overhead, or other costs associated with the performance of the Contract;
2.5.5.4 Any damages or other amounts associated with the loss of prospective profits, anticipated sales, goodwill, or for expenditures, investments, or commitments made in connection with this Contract; or
2.5.5.5 Any taxes the Contractor may owe in connection with the performance of this Contract, including, but not limited to, sales taxes, excise taxes, use taxes, income taxes, or property taxes.
2.5.6 Contractor's Contract Close-Out Duties. Upon receipt of notice of termination, at expiration of the Contract, or upon request of the Agency (hereafter, "Close-Out Event"), the Contractor shall:
2.5.6.1 Cease work under this Contract and take all necessary or appropriate steps to limit disbursements and minimize costs, and furnish a report within thirty (30) days of the Close-Out Event, describing the status of all work performed under the Contract and such other matters as the Agency may require.
2.5.6.2 Immediately cease using and return to the Agency any property or materials, whether tangible or intangible, provided by the Agency to the Contractor.
2.5.6.3 Cooperate in good faith with the Agency and its employees, agents, and independent contractors during the transition period between the Close-Out Event and the substitution of any replacement service provider.
2.5.6.4 Immediately return to the Agency any payments made by the Agency for Deliverables that were not rendered or provided by the Contractor.
2.5.6.5 Immediately deliver to the Agency any and all Deliverables for which the Agency has made payment (in whole or in part) that are in the possession or under the control of the Contractor or its agents or subcontractors in whatever stage of development and form of recordation such property is expressed or embodied at that time.

2.5.7 Termination for Cause by the Contractor. The Contractor may only terminate this Contract for the breach by the Agency of any material term of this Contract, if such breach is not cured within sixty (60) days of the Agency's receipt of the Contractor's written notice of breach.

2.6 Change Order Procedure. The Agency may at any time request a modification to the Scope of Work using a change order. The following procedures for a change order shall be followed:
2.6.1 Written Request. The Agency shall specify in writing the desired modifications to the same degree of specificity as in the original Scope of Work.
2.6.2 The Contractor's Response. The Contractor shall submit to the Agency a firm cost proposal for the requested change order within five (5) Business Days of receiving the change order request.
2.6.3 Acceptance of the Contractor Estimate. If the Agency accepts the cost proposal presented by the Contractor, the Contractor shall provide the modified Deliverable subject to the cost proposal included in the Contractor response. The Contractor's provision of the modified Deliverables shall be governed by the terms and conditions of this Contract.
2.6.4 Adjustment to Compensation. The parties acknowledge that a change order for this Contract may or may not entitle the Contractor to an equitable adjustment in the Contractor's compensation or the performance deadlines under this Contract.
2.7 Indemnification.
2.7.1 By the Contractor. The Contractor agrees to indemnify and hold harmless the State and its officers, appointed and elected officials, board and commission members, employees, volunteers, and agents (collectively the "Indemnified Parties"), from any and all costs, expenses, losses, claims, damages, liabilities, settlements, and judgments (including, without limitation, the reasonable value of the time spent by the Attorney General's Office,) and the costs, expenses, and attorneys' fees of other counsel retained by the Indemnified Parties directly or indirectly related to, resulting from, or arising out of this Contract, including but not limited to any claims related to, resulting from, or arising out of:
2.7.1.1 Any breach of this Contract;
2.7.1.2 Any negligent, intentional, or wrongful act or omission of the Contractor or any agent or subcontractor utilized or employed by the Contractor;

2.7.1.3 The Contractor's performance or attempted performance of this Contract, including any agent or subcontractor utilized or employed by the Contractor;
2.7.1.4 Any failure by the Contractor to make all reports, payments, and withholdings required by federal and state law with respect to social security, employee income and other taxes, fees, or costs required by the Contractor to conduct business in the State of Iowa;
2.7.1.5 Any claim of misappropriation of a trade secret or infringement or violation of any intellectual property rights, proprietary rights, or personal rights of any third party, including any claim that any Deliverable or any use thereof (or the exercise of any rights with respect thereto) infringes, violates, or misappropriates any patent, copyright, trade secret, trademark, trade dress, mask work, utility design, or other intellectual property right or proprietary right of any third party.

2.8 Insurance.
2.8.1 Insurance Requirements. At the Contractor's expense, the Contractor shall maintain insurance in full force and effect covering its work during the entire term of this Contract, which includes any extensions or renewals thereof. The Contractor shall ensure that any subcontractor also complies with the provision of this Section. Insurance shall be provided through companies licensed by the State of Iowa, through statutorily authorized self-insurance programs, through local government risk pools, or through any combination of these. The Contractor's insurance shall, among other things, be occurrence based and shall insure against any loss or damage resulting from or related to the Contractor's performance of this Contract regardless of the date the claim is filed or expiration of the policy. The State of Iowa and the Agency shall be named as additional insureds or loss payees, or the Contractor shall obtain an endorsement to the same effect, as applicable.
2.8.1.2. Name the State of Iowa and the Agency as additional insureds or loss payees on the policies for all coverages required by this Contract, with the exception of Workers' Compensation, or the Contractor shall obtain an endorsement to the same effect; and
2.8.1.3 Provide a waiver of any subrogation rights that any of its insurance carriers might have against the State on the policies for all coverages required by this Contract, with the exception of Workers' Compensation.
The requirements set forth in this section shall be indicated on the certificates of insurance coverage supplied to the Agency.
2.8.2 Types and Amounts of Insurance Required. Unless otherwise requested by the Agency in writing, the Contractor shall cause to be issued insurance coverages insuring the Contractor and/or subcontractors against all general liabilities, product liability, personal injury, property damage, and (where applicable) professional liability in the amount specified in the Special Terms for each occurrence. In addition, the Contractor shall ensure it has any necessary workers' compensation and employer liability insurance as required by Iowa law.
2.8.3 Certificates of Coverage. The Contractor shall submit certificates of the insurance, which indicate coverage and notice provisions as required by this Contract, to the Agency upon execution of this Contract. The Contractor shall maintain all insurance policies required by this Contract in full force and effect during the entire term of this Contract, which includes any extensions or renewals thereof, and shall not permit such policies to be canceled or amended except with the advance written approval of the Agency. The insurer shall state in the certificate that no cancellation of the insurance will be made without at least a thirty (30) day prior written notice to the Agency. The certificates shall be subject to approval by the Agency. Approval of the insurance certificates by the Agency shall not relieve the Contractor of any obligation under this Contract.
2.8.4 Notice of Claim. Contractor shall provide prompt notice to the Agency of any claim related to the contracted services made by a third party. If the claim matures to litigation, the Contractor shall keep the Agency regularly informed of the status of the lawsuit, including any substantive rulings. The Contractor shall confer directly with the Agency about and before any substantive settlement negotiations.

2.9 Ownership and Security of Agency Information.
2.9.1 Ownership and Disposition of Agency Information. Any information either supplied by the Agency to the Contractor, or collected by the Contractor on the Agency's behalf in the course of the performance of this Contract, shall be considered the property of the Agency ("Agency Information").

The Contractor will not use the Agency Information for any purpose other than providing services under the Contract, nor will any part of the information and records be disclosed, sold, assigned, leased, or otherwise provided to third parties or commercially exploited by or on behalf of the Contractor. The Agency shall own all Agency Information that may reside within the Contractor's hosting environment and/or equipment/media.

2.9.2 Foreign Hosting and Storage Prohibited. Agency Information shall be hosted and/or stored within the continental United States only.

2.9.3 Access to Agency Information that is Confidential Information. The Contractor's employees, agents, and subcontractors may have access to Agency Information that is Confidential Information to the extent necessary to carry out responsibilities under the Contract. Access to such Confidential Information shall comply with both the State's and the Agency's policies and procedures. In all instances, access to Agency Information from outside of the United States and its protectorates, either by the Contractor, including a foreign office or division of the Contractor or its affiliates or associates, or any subcontractor, is prohibited.

2.9.4 No Use or Disclosure of Confidential Information. Confidential Information collected, maintained, or used in the course of performance of the Contract shall only be used or disclosed by the Contractor as expressly authorized by law and only with the prior written consent of the Agency, either during the period of the Contract or thereafter. The Contractor shall immediately report to the Agency any unauthorized use or disclosure of Confidential Information. The Contractor may be held civilly or criminally liable for improper use or disclosure of Confidential Information.

2.9.5 Contractor Breach Notification Obligations. The Contractor agrees to comply with all applicable laws that require the notification of individuals in the event of unauthorized use or disclosure of Confidential Information or other event(s) requiring notification in accordance with applicable law. In the event of a breach of the Contractor's security obligations or other event requiring notification under applicable law, the Contractor agrees to follow Agency directives, which may include assuming responsibility for informing all such individuals in accordance with applicable laws, and to indemnify, hold harmless, and defend the State of Iowa against any claims, damages, or other harm related to such breach.

2.9.6 Compliance of Contractor Personnel. The Contractor and the Contractor's personnel shall comply with the Agency's and the State's security and personnel policies, procedures, and rules, including any procedure which the Agency's personnel, contractors, and consultants are normally asked to follow. The Contractor agrees to cooperate fully and to provide any assistance necessary to the Agency in the investigation of any security breaches that may involve the Contractor or the Contractor's personnel. All services shall be performed in accordance with State Information Technology security standards and policies as well as Agency security protocols and procedures. By way of example only, see Iowa Code 8B.23, http://secureonline.iowa.gov/links/index.html, and https://ocio.iowa.gov/home/standards.

2.9.7 Subpoena. In the event that a subpoena or other legal process is served upon the Contractor for records containing Confidential Information, the Contractor shall promptly notify the Agency and cooperate with the Agency in any lawful effort to protect the Confidential Information.

2.9.8 Return and/or Destruction of Information. Upon expiration or termination of the Contract for any reason, the Contractor agrees to comply with all Agency directives regarding the return or destruction of all Agency Information and any derivative work. Delivery of returned Agency Information must be through a secured electronic transmission or by parcel service that utilizes tracking numbers. Such information must be provided in a format useable by the Agency. Following the Agency's verified receipt of the Agency Information and any derivative work, the Contractor agrees to physically and/or electronically destroy or erase all residual Agency Information regardless of format from the entire Contractor's technology resources and any other storage media. This includes, but is not limited to, all production copies, test copies, backup copies and /or printed copies of information created on any other servers or media and at all other Contractor sites. Any permitted destruction of Agency Information must occur in such a manner as to render the information incapable of being reconstructed or recovered. The Contractor will provide a record of information destruction to the Agency for inspection and records retention no later than thirty (30) days after destruction.

2.9.9 Contractor's Inability to Return and/or Destroy Information. If for any reason the Agency Information cannot be returned and/or destroyed upon expiration or termination of the Contract, the Contractor agrees to notify the Agency with an explanation as to the conditions which make return and/or destruction not possible or feasible. Upon mutual agreement by both parties that the return and/or destruction of the information is not possible or feasible, the Contractor shall make the Agency Information inaccessible. The Contractor shall not use or disclose such retained Agency Information for any purposes other than those expressly permitted by the Agency. The Contractor shall provide to the Agency a detailed description as to the procedures and methods used to make the Agency Information inaccessible no later than thirty (30) days after making the information inaccessible. If the Agency provides written permission for the Contractor to retain the Agency Information in the Contractor's information systems, the Contractor will extend the protections of this Contract to such information and limit any further uses or disclosures of such information.

2.9.10 Contractors that are Business Associates. If the Contractor is the Agency's Business Associate, and there is a conflict between the Business Associate Agreement and this Section 2.9, the provisions in the Business Associate Agreement shall control.

2.10 Intellectual Property.

2.10.1 Ownership and Assignment of Other Deliverables. The Contractor agrees that the State and the Agency shall become the sole and exclusive owners of all Deliverables. The Contractor hereby irrevocably assigns, transfers and conveys to the State and the Agency all right, title and interest in and to all Deliverables and all intellectual property rights and proprietary rights arising out of, embodied in, or related to such Deliverables, including copyrights, patents, trademarks, trade secrets, trade dress, mask work, utility design, derivative works, and all other rights and interests therein or related thereto. The Contractor represents and warrants that the State and the Agency shall acquire good and clear title to all Deliverables, free from any claims, liens, security interests, encumbrances, intellectual property rights, proprietary rights, or other rights or interests of the Contractor or of any third party, including any employee, agent, contractor, subcontractor, subsidiary, or affiliate of the Contractor. The Contractor (and Contractor's employees, agents, contractors, subcontractors, subsidiaries and affiliates) shall not retain any property interests or other rights in and to the Deliverables and shall not use any Deliverables, in whole or in part, for any purpose, without the prior written consent of the Agency and the payment of such royalties or other compensation as the Agency deems appropriate. Unless otherwise requested by the Agency, upon completion or termination of this Contract, the Contractor will immediately turn over to the Agency all Deliverables not previously delivered to the Agency, and no copies thereof shall be retained by the Contractor or its employees, agents, subcontractors, or affiliates, without the prior written consent of the Agency.

2.10.2 Waiver. To the extent any of the Contractor's rights in any Deliverables are not subject to assignment or transfer hereunder, including any moral rights and any rights of attribution and of integrity, the Contractor hereby irrevocably and unconditionally waives all such rights and enforcement thereof and agrees not to challenge the State's rights in and to the Deliverables.

2.10.3 Further Assurances. At the Agency's request, the Contractor will execute and deliver such instruments and take such other action as may be requested by the Agency to establish, perfect, or protect the State's rights in and to the Deliverables and to carry out the assignments, transfers and conveyances set forth in Section 2.10, *Intellectual Property*.

2.10.4 Publications. Prior to completion of all services required by this Contract, the Contractor shall not publish in any format any final or interim report, document, form, or other material developed as a result of this Contract without the express written consent of the Agency. Upon completion of all services required by this Contract, the Contractor may publish or use materials developed as a result of this Contract, subject to confidentiality restrictions, and only after the Agency has had an opportunity to review and comment upon the publication. Any such publication shall contain a statement that the work was done pursuant to a contract with the Agency and that it does not necessarily reflect the opinions, findings, and conclusions of the Agency.

2.10.5 Federal License. As this Contract is at least partially federally funded, the federal government reserves a royalty-free, nonexclusive, and irrevocable

license to reproduce, publish, or otherwise use and to authorize others to use for federal government purposes, software and associated documentation designed, developed or installed in whole or in part with federal funds pursuant to this Contract. This clause does not apply when the Agency does not directly pay a contractor for designing, developing or installing software or associated documentation. When the Agency only pays a contractor a capitated rate, the Agency is not paying Contractor for designing, developing or installing software.

2.11 Warranties.

2.11.1 Construction of Warranties Expressed in this Contract with Warranties Implied by Law. Warranties made by the Contractor in this Contract, whether: (1) this Contract specifically denominates the Contractor's promise as a warranty; or (2) the warranty is created by the Contractor's affirmation or promise, by a description of the Deliverables to be provided, or by provision of samples to the Agency, shall not be construed as limiting or negating any warranty provided by law, including without limitation, warranties that arise through the course of dealing or usage of trade. The warranties expressed in this Contract are intended to modify the warranties implied by law only to the extent that they expand the warranties applicable to the Deliverables provided by the Contractor. With the exception of Subsection 2.11.3, the provisions of this section apply during the Warranty Period as defined in the Contract Declarations and Execution Section.

2.11.2 Contractor represents and warrants that:

2.11.2.1 All Deliverables shall be wholly original with and prepared solely by the Contractor; or it owns, possesses, holds, and has received or secured all rights, permits, permissions, licenses, and authority necessary to provide the Deliverables to the Agency hereunder and to assign, grant and convey the rights, benefits, licenses, and other rights assigned, granted, or conveyed to the Agency hereunder or under any license agreement related hereto without violating any rights of any third party;

2.11.2.2 The Contractor has not previously and will not grant any rights in any Deliverables to any third party that are inconsistent with the rights granted to the Agency herein; and

2.11.2.3 The Agency shall peacefully and quietly have, hold, possess, use, and enjoy the Deliverables without suit, disruption, or interruption.

2.11.3 The Contractor represents and warrants that:

2.11.3.1 The Deliverables (and all intellectual property rights and proprietary rights arising out of, embodied in, or related to such Deliverables); and

2.11.3.2 The Agency's use of, and exercise of any rights with respect to, the Deliverables (and all intellectual property rights and proprietary rights arising out of, embodied in, or related to such Deliverables), do not and will not, under any circumstances, misappropriate a trade secret or infringe upon or violate any copyright, patent, trademark, trade dress or other intellectual property right, proprietary right or personal right of any third party. The Contractor further represents and warrants there is no pending or threatened claim, litigation, or action that is based on a claim of infringement or violation of an intellectual property right, proprietary right or personal right or misappropriation of a trade secret related to the Deliverables. The Contractor shall inform the Agency in writing immediately upon becoming aware of any actual, potential, or threatened claim of or cause of action for infringement or violation or an intellectual property right, proprietary right, or personal right or misappropriation of a trade secret. If such a claim or cause of action arises or is likely to arise, then the Contractor shall, at the Agency's request and at the Contractor's sole expense:

- Procure for the Agency the right or license to continue to use the Deliverable at issue;
- Replace such Deliverable with a functionally equivalent or superior Deliverable free of any such infringement, violation, or misappropriation;
- Modify or replace the affected portion of the Deliverable with a functionally equivalent or superior Deliverable free of any such infringement, violation, or misappropriation; or
- Accept the return of the Deliverable at issue and refund to the Agency all fees, charges, and any other amounts paid by the Agency with respect to such Deliverable. In addition, the Contractor agrees to indemnify, defend, protect, and hold harmless the State and its officers, directors, employees, officials, and agents as provided in the Indemnification Section of this Contract, including for any breach of the representations and warranties made by the Contractor in this section.

The warranty provided in this Section 2.11.3 shall be perpetual, shall not be subject to the contractual

Warranty Period, and shall survive termination of this Contract. The foregoing remedies provided in this subsection shall be in addition to and not exclusive of other remedies available to the Agency and shall survive termination of this Contract.

2.11.4 The Contractor represents and warrants that the Deliverables shall:

2.11.4.1 Be free from material Deficiencies; and

2.11.4.2 Meet, conform to, and operate in accordance with all Specifications and in accordance with this Contract during the Warranty Period, as defined in the Contract Declarations and Execution Section. During the Warranty Period the Contractor shall, at its expense, repair, correct or replace any Deliverable that contains or experiences material Deficiencies or fails to meet, conform to or operate in accordance with Specifications within five (5) Business Days of receiving notice of such Deficiencies or failures from the Agency or within such other period as the Agency specifies in the notice. In the event the Contractor is unable to repair, correct, or replace such Deliverable to the Agency's satisfaction, the Contractor shall refund the fees or other amounts paid for the Deliverables and for any services related thereto. The foregoing shall not constitute an exclusive remedy under this Contract, and the Agency shall be entitled to pursue any other available contractual, legal, or equitable remedies. The Contractor shall be available at all reasonable times to assist the Agency with questions, problems, and concerns about the Deliverables, to inform the Agency promptly of any known Deficiencies in any Deliverables, repair and correct any Deliverables not performing in accordance with the warranties contained in this Contract, notwithstanding that such Deliverables may have been accepted by the Agency, and provide the Agency with all necessary materials with respect to such repaired or corrected Deliverable.

2.11.5 The Contractor represents, warrants and covenants that all services to be performed under this Contract shall be performed in a professional, competent, diligent, and workmanlike manner by knowledgeable, trained, and qualified personnel, all in accordance with the terms and Specifications of this Contract and the standards of performance considered generally acceptable in the industry for similar tasks and projects. In the absence of a Specification for the performance of any portion of this Contract, the parties agree that the applicable Specification shall be the generally accepted industry standard. So long as the Agency notifies the Contractor of any services performed in violation of this standard, the Contractor shall re-perform the services at no cost to the Agency, such that the services are rendered in the above-specified manner, or if the Contractor is unable to perform the services as warranted, the Contractor shall reimburse the Agency any fees or compensation paid to the Contractor for the unsatisfactory services.

2.11.6 The Contractor represents and warrants that the Deliverables will comply with all Applicable Law.

2.11.7 Obligations Owed to Third Parties. The Contractor represents and warrants that all obligations owed to third parties with respect to the activities contemplated to be undertaken by the Contractor pursuant to this Contract are or will be fully satisfied by the Contractor so that the Agency will not have any obligations with respect thereto.

2.12 Acceptance of Deliverables.

2.12.1 Acceptance of Written Deliverables. For the purposes of this section, written Deliverables means documents including, but not limited to project plans, planning documents, reports, or instructional materials ("Written Deliverables"). Although the Agency determines what Written Deliverables are subject to formal Acceptance, this section generally does not apply to routine progress or financial reports. Absent more specific Acceptance Criteria in the Special Terms, following delivery of any Written Deliverable pursuant to the Contract, the Agency will notify the Contractor whether or not the Deliverable meets contractual specifications and requirements. Written Deliverables shall not be considered accepted by the Agency, nor does the Agency have an obligation to pay for such Deliverables, unless and until the Agency has notified the Contractor of the Agency's Final Acceptance of the Written Deliverables. In all cases, any statements included in such Written Deliverables that alter or conflict with any contractual requirements shall in no way be considered as changing the contractual requirements unless and until the parties formally amend the Contract.

2.12.2 Acceptance of Software Deliverables. Except as otherwise specified in the Scope of Work, all Deliverables that are custom developed software ("Software Deliverables") shall be subject to the Agency's Acceptance Testing and Acceptance, unless otherwise specified in the Scope of Work. Upon completion of all work to be performed by the

Contractor with respect to any Software Deliverable, the Contractor shall deliver a written notice to the Agency certifying that the Software Deliverable meets and conforms to applicable Specifications and is ready for the Agency to conduct Acceptance Testing; provided, however, that the Contractor shall pretest the Software Deliverable to determine that it meets and operates in accordance with applicable Specifications prior to delivering such notice to the Agency. At the Agency's request, the Contractor shall assist the Agency in performing Acceptance Tests at no additional cost to the Agency. Within a reasonable period of time after the Agency has completed its Acceptance Testing, the Agency shall provide the Contractor with written notice of Acceptance or Non-acceptance with respect to each Software Deliverable that was evaluated during such Acceptance Testing. In the event the Agency provides notice of Non-acceptance to the Contractor with respect to any Software Deliverable, the Contractor shall correct and repair such Software Deliverable and submit it to the Agency within ten (10) days of the Contractor's receipt of notice of Non-acceptance so that the Agency may re-conduct its Acceptance Tests.

In the event the Agency determines, after re-conducting its Acceptance Tests with respect to any Software Deliverable that the Contractor has attempted to correct or repair pursuant to this section, that such Software Deliverable fails to satisfy its Acceptance Tests, then the Agency shall have the continuing right, at its sole option, to: (1) require the Contractor to correct and repair such Software Deliverable within such period of time as the Agency may specify in a written notice to the Contractor; (2) refuse to accept such Software Deliverable without penalty and without any obligation to pay any fees or other amounts associated with such Software Deliverable (or receive a refund of any fees or amounts already paid with respect to such Software Deliverable); (3) accept such Software Deliverable on the condition that any fees or other amounts payable with respect thereto shall be reduced or discounted to reflect, to the Agency's satisfaction, the Deficiencies present therein and any reduced value or functionality of such Software Deliverable or the costs likely to be incurred by the Agency to correct such Deficiencies; or (4) terminate this Contract and/or seek any and all available remedies, including damages. Notwithstanding the provisions of Section 2.5.1, *Termination for Cause by the Agency*, of this Contract, the Agency may terminate this Contract pursuant to this section without providing the Contractor with any notice or opportunity to cure provided for in the termination provisions of this Contract. The Agency's right to exercise the foregoing rights and remedies, including termination of this Contract, shall remain in effect until Acceptance Tests are successfully completed to the Agency's satisfaction and the Agency has provided the Contractor with written notice of Final Acceptance.

2.12.3 Notice of Acceptance and Future Deficiencies. The Contractor's receipt of any notice of Acceptance, including Final Acceptance, with respect to any Deliverable shall not be construed as a waiver of any of the Agency's rights to enforce the terms of this Contract or require performance in the event the Contractor breaches this Contract or any Deficiency is later discovered with respect to such Deliverable.

2.13 Contract Administration.

2.13.1 Independent Contractor. The status of the Contractor shall be that of an independent contractor. The Contractor, its employees, agents, and any subcontractors performing under this Contract are not employees or agents of the State or any agency, division, or department of the State simply by virtue of work performed pursuant to this Contract. Neither the Contractor nor its employees shall be considered employees of the Agency or the State for federal or state tax purposes simply by virtue of work performed pursuant to this Contract. The Agency will not withhold taxes on behalf of the Contractor (unless required by law).

2.13.2 Incorporation of Documents. To the extent this Contract arises out of a Solicitation, the parties acknowledge that the Contract consists of these contract terms and conditions as well as the Solicitation and the Bid Proposal. The Solicitation and the Bid Proposal are incorporated into the Contract by reference. If the Contractor proposed exceptions or modifications to the Sample Contract attached to the Solicitation or to the Solicitation itself, these proposed exceptions or modifications shall not be incorporated into this Contract unless expressly set forth herein. If there is a conflict between the Contract, the Solicitation, and the Bid Proposal, the conflict shall be resolved according to the following priority, ranked in descending order:

(1) the Contract; (2) the Solicitation; (3) the Bid Proposal.

2.13.3 Intent of References to Bid Documents. To the extent this Contract arises out of a Solicitation, the references to the parties' obligations, which are contained in this Contract, are intended to supplement or clarify the obligations as stated in the Solicitation and the Bid Proposal. The failure of the parties to make reference to the terms of the Solicitation or the Bid Proposal in this Contract shall not be construed as creating a conflict and will not relieve the Contractor of the contractual obligations imposed by the terms of the Solicitation and the Contractor's Bid Proposal. Terms offered in the Bid Proposal, which exceed the requirements of the Solicitation, shall not be construed as creating an inconsistency or conflict with the Solicitation or the Contract. The contractual obligations of the Agency are expressly stated in this document. The Bid Proposal does not create any express or implied obligations of the Agency.

2.13.4 Compliance with the Law. The Contractor, its employees, agents, and subcontractors shall comply at all times with all Applicable Law. All such Applicable Law is incorporated into this Contract as of the effective date of the Applicable Law. The Contractor and Agency expressly reject any proposition that future changes to Applicable Law are inapplicable to this Contract and the Contractor's provision of Deliverables and/or performance in accordance with this Contract. When providing Deliverables pursuant to this Contract the Contractor, its employees, agents, and subcontractors shall comply with all Applicable Law.

2.13.4.1 The Contractor, its employees, agents, and subcontractors shall not engage in discriminatory employment practices which are forbidden by Applicable Law. Upon the State's written request, the Contractor shall submit to the State a copy of its affirmative action plan, containing goals and time specifications, and non-discrimination and accessibility plans and policies regarding services to clients as required under 11 Iowa Admin. Code chapter 121.

2.13.4.2 In the event the Contractor contracts with third parties for the performance of any of the Contractor obligations under this Contract as set forth in Section 2.13.9, the Contractor shall take such steps as necessary to ensure such third parties are bound by the terms and conditions contained in this Section 2.13.4.

2.13.4.3 Notwithstanding anything in this Contract to the contrary, the Contractor's failure to fulfill any requirement set forth in this Section 2.13.4 shall be regarded as a material breach of this Contract and the State may cancel, terminate, or suspend in whole or in part this Contract. The State may further declare the Contractor ineligible for future state contracts in accordance with authorized procedures or the Contractor may be subject to other sanctions as provided by law or rule.

2.13.4.4 The Contractor, its employees, agents, and subcontractors shall also comply with all Applicable Law regarding business permits and licenses that may be required to carry out the work performed under this Contract.

2.13.4.5 If all or a portion of the funding used to pay for the Deliverables is being provided through a grant from the Federal Government, the Contractor acknowledges and agrees that pursuant to applicable federal laws, regulations, circulars, and bulletins, the awarding agency of the Federal Government reserves certain rights including, without limitation, a royalty-free, non-exclusive and irrevocable license to reproduce, publish or otherwise use, and to authorize others to use, for Federal Government purposes, the Deliverables developed under this Contract and the copyright in and to such Deliverables.

2.13.5 Procurement. The Contractor shall use procurement procedures that comply with all applicable federal, state, and local laws and regulations.

2.13.6 Non-Exclusive Rights. This Contract is not exclusive. The Agency reserves the right to select other contractors to provide Deliverables similar or identical to those described in the Scope of Work during the entire term of this Contract, which includes any extensions or renewals thereof.

2.13.7 Amendments. This Contract may only be amended by mutual written consent of the parties, with the exception of (1) the Contract end date, which may be extended under the Agency's sole discretion, and (2) the Business Associate Agreement, which may be modified or replaced on notice pursuant to Section 1.5, *Business Associate Agreement.* Amendments shall be executed on a form approved by the Agency that expressly states the intent of the parties to amend this Contract. This Contract shall not be amended in any way by use of terms and conditions in an Invoice or other ancillary transactional document. To the extent that language in a transactional document conflicts with the terms

of this Contract, the terms of this Contract shall control.

2.13.8 No Third Party Beneficiaries. There are no third party beneficiaries to this Contract. This Contract is intended only to benefit the State and the Contractor.

2.13.9 Use of Third Parties. The Agency acknowledges that the Contractor may contract with third parties for the performance of any of the Contractor's obligations under this Contract. The Contractor shall notify the Agency in writing of all subcontracts relating to Deliverables to be provided under this Contract prior to the time the subcontract(s) become effective. The Agency reserves the right to review and approve all subcontracts. The Contractor may enter into these contracts to complete the project provided that the Contractor remains responsible for all Deliverables provided under this Contract. All restrictions, obligations, and responsibilities of the Contractor under this Contract shall also apply to the subcontractors and the Contractor shall include in all of its subcontracts a clause that so states. The Agency shall have the right to request the removal of a subcontractor from the Contract for good cause.

2.13.10 Choice of Law and Forum. The laws of the State of Iowa shall govern and determine all matters arising out of or in connection with this Contract without regard to the conflict of law provisions of Iowa law. Any and all litigation commenced in connection with this Contract shall be brought and maintained solely in Polk County District Court for the State of Iowa, Des Moines, Iowa, or in the United States District Court for the Southern District of Iowa, Central Division, Des Moines, Iowa, wherever jurisdiction is appropriate. This provision shall not be construed as waiving any immunity to suit or liability including without limitation sovereign immunity in State or Federal court, which may be available to the Agency or the State of Iowa.

2.13.11 Assignment and Delegation. The Contractor may not assign, transfer, or convey in whole or in part this Contract without the prior written consent of the Agency. For the purpose of construing this clause, a transfer of a controlling interest in the Contractor shall be considered an assignment. Except as provided in Section 2.13.9, the Contractor may not delegate any of its obligations or duties under this Contract without the prior written consent of the Agency. The Contractor may not assign, pledge as collateral, grant a security interest in, create a lien against, or otherwise encumber any payments that may or will be made to the Contractor under this Contract.

2.13.12 Integration. This Contract represents the entire Contract between the parties. The parties shall not rely on any representation that may have been made which is not included in this Contract.

2.13.13 No Drafter. No party to this Contract shall be considered the drafter of this Contract for the purpose of any statute, case law, or rule of construction that would or might cause any provision to be construed against the drafter.

2.13.14 Headings or Captions. The paragraph headings or captions used in this Contract are for identification purposes only and do not limit or construe the contents of the paragraphs.

2.13.15 Not a Joint Venture. Nothing in this Contract shall be construed as creating or constituting the relationship of a partnership, joint venture, (or other association of any kind or agent and principal relationship) between the parties hereto. No party, unless otherwise specifically provided for herein, has the authority to enter into any contract or create an obligation or liability on behalf of, in the name of, or binding upon another party to this Contract.

2.13.16 Joint and Several Liability. If the Contractor is a joint entity, consisting of more than one individual, partnership, corporation, or other business organization, all such entities shall be jointly and severally liable for carrying out the activities and obligations of this Contract, for any default of activities and obligations, and for any fiscal liabilities.

2.13.17 Supersedes Former Contracts or Agreements. This Contract supersedes all prior contracts or agreements between the Agency and the Contractor for the Deliverables to be provided in connection with this Contract.

2.13.18 Waiver. Except as specifically provided for in a waiver signed by duly authorized representatives of the Agency and the Contractor, failure by either party at any time to require performance by the other party or to claim a breach of any provision of the Contract shall not be construed as affecting any subsequent right to require performance or to claim a breach.

2.13.19 Notice. With the exception of the Business Associate Agreement, as set forth in Section 1.5, *Business Associate Agreement*, any notices required by the Contract shall be given in writing by registered or certified mail, return receipt requested, by

receipted hand delivery, by Federal Express, courier or other similar and reliable carrier which shall be addressed to each party's Contract Manager as set forth in the Contract Declarations and Execution Section. From time to time, the parties may change the name and address of a party designated to receive notice. Such change of the designated person shall be in writing to the other party.
Each such notice shall be deemed to have been provided:

- At the time it is actually received in the case of hand delivery;
- Within one (1) day in the case of overnight delivery, courier or services such as Federal Express with guaranteed next-day delivery; or
- Within five (5) days after it is deposited in the U.S. Mail.

2.13.20 Cumulative Rights. The various rights, powers, options, elections, and remedies of any party provided in this Contract, shall be construed as cumulative and not one of them is exclusive of the others or exclusive of any rights, remedies or priorities allowed either party by law, and shall in no way affect or impair the right of any party to pursue any other equitable or legal remedy to which any party may be entitled.
2.13.21 Severability. If any provision of this Contract is determined by a court of competent jurisdiction to be invalid or unenforceable, such determination shall not affect the validity or enforceability of any other part or provision of this Contract.
2.13.22 Time is of the Essence. Time is of the essence with respect to the Contractor's performance of the terms of this Contract. The Contractor shall ensure that all personnel providing Deliverables to the Agency are responsive to the Agency's requirements and requests in all respects. Notwithstanding the foregoing or any term or condition herein that is or may appear to be to the contrary, Contractor shall not be liable or responsible for any delay caused by the Agency, and Contractor's time for performance shall be extended to the extent of any delay caused by the Agency."?
2.13.23 Authorization. The Contractor represents and warrants that:
2.13.23.1 It has the right, power, and authority to enter into and perform its obligations under this Contract.
2.13.23.2 It has taken all requisite action (corporate, statutory, or otherwise) to approve execution, delivery, and performance of this Contract and this Contract constitutes a legal, valid, and binding obligation upon itself in accordance with its terms.
2.13.24 Successors in Interest. All the terms, provisions, and conditions of the Contract shall be binding upon and inure to the benefit of the parties hereto and their respective successors, assigns, and legal representatives.
2.13.25 Records Retention and Access.
2.13.25.1 Financial Records. The Contractor shall maintain accurate, current, and complete records of the financial activity of this Contract which sufficiently and properly document and calculate all charges billed to the Agency during the entire term of this Contract, which includes any extensions or renewals thereof, and for a period of at least seven (7) years following the date of final payment or completion of any required audit (whichever is later). If any litigation, claim, negotiation, audit, or other action involving the records has been started before the expiration of the seven (7) year period, the records must be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular seven (7) year period, whichever is later. The Contractor shall permit the Agency, the Auditor of the State of Iowa or any other authorized representative of the State and where federal funds are involved, the Comptroller General of the United States or any other authorized representative of the United States government, to access and examine, audit, excerpt and transcribe any directly pertinent books, documents, papers, electronic or optically stored and created records, or other records of the Contractor relating to orders, Invoices or payments, or any other Documentation or materials pertaining to this Contract, wherever such records may be located. The Contractor shall not impose a charge for audit or examination of the Contractor's books and records. Based on the audit findings, the Agency reserves the right to address the Contractor's board or other managing entity regarding performance and expenditures. When state or federal law or the terms of this Contract require compliance with the OMNI Circular, or other similar provision addressing proper use of government funds, the Contractor shall comply with these additional records retention and access requirements:
2.13.25.1.1 Records of financial activity shall include records that adequately identify the source and application of funds. When the terms of this Contract require matching funds, cash contributions made by

the Contractor and third-party in-kind (property or service) contributions, these funds must be verifiable from the Contractor's records. These records must contain information pertaining to contract amount, obligations, unobligated balances, assets, liabilities, expenditures, income, and third-party reimbursements.

2.13.25.1.2 The Contractor shall maintain accounting records supported by source documentation that may include but are not limited to cancelled checks, paid bills, payroll, time and attendance records, and contract award documents.

2.13.25.1.3 The Contractor, in maintaining project expenditure accounts, records and reports, shall make any necessary adjustments to reflect refunds, credits, underpayments or overpayments, as well as any adjustments resulting from administrative or compliance reviews and audits. Such adjustments shall be set forth in the financial reports filed with the Agency.

2.13.25.1.4 The Contractor shall maintain a sufficient record keeping system to provide the necessary data for the purposes of planning, monitoring, and evaluating its program.

2.13.25.2 The Contractor shall retain all non-medical and medical client records for a period of seven (7) years from the last date of service for each patient; or in the case of a minor patient or client, for a period consistent with that established by Iowa Code § 614.1(9), whichever is greater.

2.13.26 Audits. Local governments and non-profit subrecipient entities that expend $750,000 or more in a year in federal awards (from all sources) shall have a single audit conducted for that year in accordance with the provisions of the OMNI Circular, OMB Uniform Guidance: Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 C.F.R. 200. A copy of the final audit report shall be submitted to the Agency if either the schedule of findings and questioned costs or the summary schedule of prior audit findings includes any audit findings related to federal awards provided by the Agency. If an audit report is not required to be submitted per the criteria above, the subrecipient must provide written notification to the Agency that the audit was conducted in accordance with Government Auditing Standards and that neither the schedule of findings and questioned costs nor the summary schedule of prior audit findings includes any audit findings related to federal awards provided by the Agency. See the OMNI Circular, Section 200.330, Subrecipient and Contractor Determinations for a discussion of subrecipient versus contractor (vendor) relationships. The Contractor shall provide the Agency with a copy of any written audit findings or reports, whether in draft or final form, within two (2) Business Days following receipt by the Contractor. The requirements of this paragraph shall apply to the Contractor as well as any subcontractors.

2.13.27 Reimbursement of Audit Costs. If the Auditor of the State of Iowa notifies the Agency of an issue or finding involving the Contractor's noncompliance with laws, rules, regulations, and/or contractual agreements governing the funds distributed under this Contract, the Contractor shall bear the cost of the Auditor's review and any subsequent assistance provided by the Auditor to determine compliance. The Contractor shall reimburse the Agency for any costs the Agency pays to the Auditor for such review or audit.

2.13.28 Staff Qualifications and Background Checks. The Contractor shall be responsible for assuring that all persons, whether they are employees, agents, subcontractors, or anyone acting for or on behalf of the Contractor, are properly licensed, certified, or accredited as required under applicable state law and the Iowa Administrative Code. The Contractor shall provide standards for service providers who are not otherwise licensed, certified, or accredited under state law or the Iowa Administrative Code.

The Agency reserves the right to conduct and/or request the disclosure of criminal history and other background investigation of the Contractor, its officers, directors, shareholders, and the Contractor's staff, agents, or subcontractors retained by the Contractor for the performance of Contract services.

2.13.29 Solicitation. The Contractor represents and warrants that no person or selling agency has been employed or retained to solicit and secure this Contract upon an agreement or understanding for commission, percentage, brokerage, or contingency excepting bona fide employees or selling agents maintained for the purpose of securing business.

2.13.30 Obligations Beyond Contract Term. All obligations of the Agency and the Contractor incurred or existing under this Contract as of the date of expiration or termination will survive the expiration or termination of this Contract. Contract sections that survive include, but are not necessarily limited to, the following: (1) Section 2.4.2, *Erroneous Payments and Credits*; (2) Section 2.5.5,

Limitation of the State's Payment Obligations; (3) Section 2.5.6, *Contractor's Contract Close-Out Duties*; (4) Section 2.7, *Indemnification*, and all subparts thereof; (5) Section 2.9, *Ownership and Security of Agency Information*, and all subparts thereof; (6) Section 2.10, *Intellectual Property*, and all subparts thereof; (7) Section 2.13.10, *Choice of Law and Forum*; (8) Section 2.13.16, *Joint and Several Liability*; (9) Section 2.13.20, *Cumulative Rights*; (10) Section 2.13.24 *Successors In Interest*; (11) Section 2.13.25, *Records Retention and Access*, and all subparts thereof; (12) Section 2.13.26, *Audits*; (13) Section 2.13.27, *Reimbursement of Audit Costs*; (14) Section 2.13.35, *Repayment Obligation*; and (15) Section 2.13.39, *Use of Name or Intellectual Property*.

2.13.31 Counterparts. The parties agree that this Contract has been or may be executed in several counterparts, each of which shall be deemed an original and all such counterparts shall together constitute one and the same instrument.

2.13.32 Delays or Potential Delays of Performance. Whenever the Contractor encounters any difficulty which is delaying or threatens to delay the timely performance of this Contract, including but not limited to potential labor disputes, the Contractor shall immediately give notice thereof in writing to the Agency with all relevant information with respect thereto. Such notice shall not in any way constitute a basis for an extension of the delivery schedule or be construed as a waiver by the Agency or the State of any rights or remedies to which either is entitled by law or pursuant to provisions of this Contract. Failure to give such notice, however, may be grounds for denial of any request for an extension of the delivery schedule because of such delay. Furthermore, the Contractor will not be excused from failure to perform that is due to a Force Majeure unless and until the Contractor provides notice pursuant to this provision.

2.13.33 Delays or Impossibility of Performance Based on a Force Majeure. Neither party shall be in default under the Contract if performance is prevented, delayed, or made impossible to the extent that such prevention, delay, or impossibility is caused by a Force Majeure. If a delay results from a subcontractor's conduct, negligence or failure to perform, the Contractor shall not be excused from compliance with the terms and obligations of the Contract unless the subcontractor or supplier is prevented from timely performance by a Force Majeure as defined in this Contract.

If a Force Majeure delays or prevents the Contractor's performance, the Contractor shall immediately use its best efforts to directly provide alternate, and to the extent possible, comparable performance. Comparability of performance and the possibility of comparable performance shall be determined solely by the Agency.

The party seeking to exercise this provision and not perform or delay performance pursuant to a Force Majeure shall immediately notify the other party of the occurrence and reason for the delay. The parties shall make every effort to minimize the time of nonperformance and the scope of work not being performed due to the unforeseen events. Dates by which performance obligations are scheduled to be met will be extended only for a period of time equal to the time lost due to any delay so caused.

2.13.34 Right to Address the Board of Directors or Other Managing Entity. The Agency reserves the right to address the Contractor's board of directors or other managing entity of the Contractor regarding performance, expenditures, and any other issue the Agency deems appropriate.

2.13.35 Repayment Obligation. In the event that any State and/or federal funds are deferred and/or disallowed as a result of any audits or expended in violation of the laws applicable to the expenditure of such funds, the Contractor shall be liable to the Agency for the full amount of any claim disallowed and for all related penalties incurred. The requirements of this paragraph shall apply to the Contractor as well as any subcontractors.

2.13.36 Reporting Requirements. If this Contract permits other State agencies and political subdivisions to make purchases off of the Contract, the Contractor shall keep a record of the purchases made pursuant to the Contract and shall submit a report to the Agency on a quarterly basis. The report shall identify all of the State agencies and political subdivisions making purchases off of this Contract and the quantities purchased pursuant to the Contract during the reporting period.

2.13.37 Immunity from Liability. Every person who is a party to the Contract is hereby notified and agrees that the State, the Agency, and all of their employees, agents, successors, and assigns are immune from liability and suit for or from the Contractor's and/or subcontractors' activities involving third parties and arising from the Contract.

2.13.38 Public Records. The laws of the State require procurement and contract records to be made public unless otherwise provided by law.
2.13.39 Use of Name or Intellectual Property. The Contractor agrees it will not use the Agency and/or State's name or any of their intellectual property, including but not limited to, any State, state agency, board or commission trademarks or logos in any manner, including commercial advertising or as a business reference, without the expressed prior written consent of the Agency and/or the State.
2.13.40 Taxes. The State is exempt from Federal excise taxes, and no payment will be made for any taxes levied on the Contractor's employees' wages. The State is exempt from State and local sales and use taxes on the Deliverables.
2.13.41 No Minimums Guaranteed. The Contract does not guarantee any minimum level of purchases or any minimum amount of compensation.

2.14 Contract Certifications. The Contractor will fully comply with obligations herein. If any conditions within these certifications change, the Contractor will provide written notice to the Agency within twenty-four (24) hours from the date of discovery.
2.14.1 Certification of Compliance with Pro-Children Act of 1994. The Contractor must comply with Public Law 103-227, Part C Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act). This Act requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted by an entity and used routinely or regularly for the provision of health, day care, education, or library services to children under the age of 18, if the Deliverables are funded by federal programs either directly or through State or local governments. Federal programs include grants, cooperative agreements, loans or loan guarantees, and contracts. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities (other than clinics) where Women, Infants, and Children (WIC) coupons are redeemed.

The Contractor further agrees that the above language will be included in any subawards that contain provisions for children's services and that all subgrantees shall certify compliance accordingly. Failure to comply with the provisions of this law may result in the imposition of a civil monetary penalty of up to $1,000.00 per day.
2.14.2 Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions
By signing this Contract, the Contractor is providing the certification set out below:
2.14.2.1 The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the Contractor knowingly rendered an erroneous certification, in addition to other remedies available to the federal government, the Agency or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
2.14.2.2 The Contractor shall provide immediate written notice to the Agency if at any time the Contractor learns that its certification was erroneous when submitted or had become erroneous by reason of changed circumstances.
2.14.2.3 The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principle, proposal, and voluntarily excluded, as used in this clause, have the meaning set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. Contact the Agency for assistance in obtaining a copy of those regulations.
2.14.2.4 The Contractor agrees by signing this Contract that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the Agency or agency with which this transaction originated.
2.14.2.5 The Contractor further agrees by signing this Contract that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transaction," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

2.14.2.6 A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. A participant may, but is not required to, check the List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

2.14.2.7 Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

2.14.2.8 Except for transactions authorized under Section 2.14.2.4 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the federal government, the Agency or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

2.14.2.9 The Contractor certifies, by signing this Contract, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

Where the Contractor is unable to certify to any of the statements in this certification, such Contractor shall attach an explanation to this Contract.

2.14.3 Restriction on Lobbying.

This section is applicable to all federally-funded contracts.

Title 45 of the Code of Federal Regulations, Part 93 sets conditions on the use of Federal funds supporting this Contract. The Contractor shall comply with all requirements of CFR Part 93 which is incorporated herein as if fully set forth. No appropriated funds supporting this Contract may be expended by the Contractor for payment of any person for influencing or attempting to influence an employee of the agency (as defined in 5 U.S.C.552(f)), a member of Congress in connection with the award of this Contract, the making of any federal funding grant award connected to this Contract, the making of any Federal loan connected to this Contract, the entering into any cooperative agreement connected to this Contract, and the extension, continuation, or modification of this Contract.

2.14.3.1 The Contractor shall file with the Agency a certification form, set forth in Appendix A of 45 CFR Part 93, certifying the Contractor, including any subcontractor(s) at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) have not made, and will not make, any payment prohibited under 45 CFR § 93.100.

2.14.3.2 The Contractor shall file with the Agency a disclosure form, set forth in Appendix B of 45 CFR Part 93, in the event the Contractor or subcontractor(s) at any tier (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) has made or has agreed to make any payment using non-appropriated funds, including profits from any covered Federal action, which would be prohibited under 45 CFR §93.100 if paid for with appropriated funds. All disclosure forms shall be forwarded from tier to tier until received by the Contractor and shall be treated as a material representation of fact upon which all receiving tiers shall rely.

2.14.3.3 The Contractor shall file with the Agency subsequent disclosure forms at the end of each calendar quarter in which there occurs any event that requires disclosure or materially affects the accuracy of the information contained in any disclosure form previously filed. Such events include:

2.14.3.3.1 A cumulative increase of $25,000 or more in the amount paid or expected to be paid to influence a covered Federal action;

2.14.3.3.2 A change in the person(s) or individual(s) influencing or attempting to influence a covered Federal action; and

2.14.3.3.3 A change in the officer(s), employee(s), or Member(s) contacted to influence or attempt to influence a covered Federal action.

2.14.3.4 The Contractor may be subject to civil penalties if the Contractor fails to comply with the requirements of 45 CFR Part 93. An imposition of a civil penalty does not prevent the Agency from taking appropriate enforcement actions which may

include, but not necessarily be limited to, termination of the Contract.

2.14.4 Certification Regarding Drug Free Workplace

2.14.4.1 Requirements for Contractors Who are Not Individuals. If the Contractor is not an individual, the Contractor agrees to provide a drug-free workplace by:

2.14.4.1.1 Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance is prohibited in the Contractor's workplace and specifying the actions that will be taken against employees for violations of such prohibition;

2.14.4.1.2 Establishing a drug-free awareness program to inform employees about:

- The dangers of drug abuse in the workplace;
- The Contractor's policy of maintaining a drug- free workplace;
- Any available drug counseling, rehabilitation, and employee assistance programs; and
- The penalties that may be imposed upon employees for drug abuse violations;

2.14.4.1.3 Making it a requirement that each employee to be engaged in the performance of such contract be given a copy of the statement required by Subsection 2.14.4.1.1;

2.14.4.1.4 Notifying the employee in the statement required by Subsection 2.14.4.1.1 that as a condition of employment on such contract, the employee will:

- Abide by the terms of the statement; and
- Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five (5) days after such conviction;

2.14.4.1.5 Notifying the contracting agency within ten (10) days after receiving notice under the second unnumbered bullet of Subsection 2.14.4.1.4 from an employee or otherwise receiving actual notice of such conviction;

2.14.4.1.6 Imposing a sanction on, or requiring the satisfactory participation in a drug abuse assistance or rehabilitation program by, any employee who is so convicted, as required by 41 U.S.C. § 703; and

2.14.4.1.7 Making a good faith effort to continue to maintain a drug-free workplace through implementation of this section.

2.14.4.2 Requirement for Individuals. If the Contractor is an individual, by signing the Contract, the Contractor agrees not to engage in the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance in the performance of the Contract.

2.14.4.3 Notification Requirement. The Contractor shall, within thirty (30) days after receiving notice from an employee of a conviction pursuant to 41 U.S.C. § 701(a)(1)(D)(ii) or 41 U.S.C. § 702(a)(1)(D)(ii):

2.14.4.3.1 Take appropriate personnel action against such employee up to and including termination; or

2.14.4.3.2 Require such employee to satisfactorily participate in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency.

2.14.5 Conflict of Interest. The Contractor represents, warrants, and covenants that no relationship exists or will exist during the Contract period between the Contractor and the Agency that is a conflict of interest. No employee, officer, or agent of the Contractor or subcontractor shall participate in the selection or in the award or administration of a subcontract if a conflict of interest, real or apparent, exists. The provisions of Iowa Code chapter 68B shall apply to this Contract. The Contractor shall establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by the desire for private gain for themselves or others with whom they have family, business, or other ties.

In the event the Contractor becomes aware of any circumstances that may create a conflict of interest the Contractor shall immediately take such actions to mitigate or eliminate the risk of harm caused by the conflict or appearance of conflict. The Contractor shall promptly, fully disclose and notify the Agency of any circumstances that may arise that may create a conflict of interest or an appearance of conflict of interest. Such notification shall be submitted to the Agency in writing within seven (7) Business Days after the conflict or appearance of conflict is discovered.

In the event the Agency determines that a conflict or appearance of a conflict exists, the Agency may take any action that the Agency determines is necessary to mitigate or eliminate the conflict or appearance of a conflict. Such actions may include, but are not limited to:

2.14.5.1 Exercising any and all rights and remedies under the Contract, up to and including terminating the Contract with or without cause; or
2.14.5.2 Directing the Contractor to implement a corrective action plan within a specified time frame to mitigate, remedy and/or eliminate the circumstances which constitute the conflict of interest or appearance of conflict of interest; or
2.14.5.3 Taking any other action the Agency determines is necessary and appropriate to ensure the integrity of the contractual relationship and the public interest.
The Contractor shall be liable for any excess costs to the Agency as a result of the conflict of interest.
2.14.6 Certification Regarding Sales and Use Tax. By executing this Contract, the Contractor certifies it is either (1) registered with the Iowa Department of Revenue, collects, and remits Iowa sales and use taxes as required by Iowa Code chapter 423; or (2) not a "retailer" or a "retailer maintaining a place of business in this state" as those terms are defined in Iowa Code § 423.1(42) and (43). The Contractor also acknowledges that the Agency may declare the Contract void if the above certification is false. The Contractor also understands that fraudulent certification may result in the Agency or its representative filing for damages for breach of contract.
2.14.7 Certification Regarding Iowa Code Chapter 8F. If the Contractor is or becomes subject to Iowa Code chapter 8F during the entire term of this Contract, which includes any extensions or renewals thereof, the Contractor shall comply with the following:
2.14.7.1 As a condition of entering into this Contract, the Contractor shall certify that it has the information required by Iowa Code § 8F.3 available for inspection by the Agency and the Legislative Services Agency.
2.14.7.2 The Contractor agrees that it will provide the information described in this section to the Agency or the Legislative Services Agency upon request. The Contractor shall not impose a charge for making information available for inspection or providing information to the Agency or the Legislative Services Agency.
2.14.7.3 Pursuant to Iowa Code § 8F.4, the Contractor shall file an annual report with the Agency and the Legislative Services Agency within ten (10) months following the end of the Contractor's fiscal year (unless the exceptions provided in Iowa Code § 8F.4(1)(b) apply). The annual report shall contain:
2.14.7.3.1 Financial information relative to the expenditure of state and federal moneys for the prior year pursuant to this Contract. The financial information shall include but is not limited to budget and actual revenue and expenditure information for the year covered.
2.14.7.3.2 Financial information relating to all service contracts with the Agency during the preceding year, including the costs by category to provide the contracted services.
2.14.7.3.3 Reportable conditions in internal control or material noncompliance with provisions of laws, rules, regulations, or contractual agreements included in external audit reports of the Contractor covering the preceding year.
2.14.7.3.4 Corrective action taken or planned by the Contractor in response to reportable conditions in internal control or material noncompliance with laws, rules, regulations, or contractual agreements included in external audit reports covering the preceding year.
2.14.7.3.5 Any changes in the information submitted in accordance with Iowa Code §8F.3
2.14.7.3.6 A certification signed by an officer and director, two directors, or the sole proprietor of the Contractor, whichever is applicable, stating the annual report is accurate and the recipient entity is in full compliance with all laws, rules, regulations, and contractual agreements applicable to the recipient entity and the requirements of Iowa Code chapter 8F.
2.14.7.3.7 In addition, the Contractor shall comply with Iowa Code chapter 8F with respect to any subcontracts it enters into pursuant to this Contract. Any compliance documentation, including but not limited to certifications, received from subcontractors by the Contractor shall be forwarded to the Agency.
2.14.8 Reserved. ***(Food and Nutrition Services Funded Contract).***

SECTION 3: SPECIAL CONTRACT ATTACHMENTS

The Special Contract Attachments in this section are a part of the Contract.

3.1 Rate Sheets

A. 7/1/2018 – 6/30/2019 Rate Sheets

3.1(A) Rate Sheet for rating period 7/1/2018 through 6/30/2019

Capitation Rates

State of Iowa Department of Human Services SFY 2019 *hawk-i* Dental Capitation Rate Development Gross and Net Capitation Rates		
Rate Cell	**SFY 2019 Gross Rate**	**SFY 2019 Net 2% Withhold Rate**
CHIP hawk-i	$ 23.26	$22.79

Medical Loss Ratio
The Medical Loss Ratio applicable to the rating period is as follows:

Date Range	Applicable MLR
7/1/2018 – 6/30/2019	88%

2% Withhold Payment Obligations:

Performance Measure	Required Contractual Standard	Withhold Payment Obligation	
		Perf. Level	**Percentage of Withhold Payable**
Preventive Dental Visits	Increase in total number of children 1-18 years of age who had at least one preventive dental visit during the measurement year.	**30% or above**	**50%**
		29%	**40%**
		28%	**30%**
		27%	**20%**
		26%	**10%**
		25% or below	**0%**

Section 3.2

The Iowa hawk-i Dental Plan

Covered Benefits

Table of Contents

The Iowa *hawk-i* Dental Plan

Section 1 - Basic Services

The following is a list of services that are payable under the Iowa ***hawk-i*** Dental Plan. The list includes those services most commonly provided to covered individuals. It is not an all-inclusive list of covered services.

Code	Diagnostic and Treatment Services
D0120	Periodic oral evaluation - Limited to twice per benefit period.*
D0140	Limited oral evaluation - problem focused - Limited to twice per benefit period.*
D0150	Comprehensive oral evaluation – Limited to twice per benefit period.* Also limited to once per dentist in a three-year period when the recipient has not seen that dentist during the previous three years
D0160	Detailed and extensive oral evaluation – Limited to twice per benefit period.*
D0180	Comprehensive periodontal evaluation – Limited to twice per benefit period.* Also limited to once per dentist in a three-year period when the recipient has not seen that dentist during the previous three years
D0210	Intraoral – complete series (including bitewings) 1 every 5 consecutive years.**
D0220	Intraoral - periapical first film
D0230	Intraoral - periapical - each additional film
D0240	Intraoral – occlusal film
D0270	Bitewing - single film - 1 set per benefit period; 2 sets for "At High Risk" Members***
D0272	Bitewings - two films - 1 set per benefit period; 2 sets for "At High Risk" Members***
D0273	Bitewings - three films - 1 set per benefit period; 2 sets for "At High Risk" Members***
D0274	Bitewings – four films – 1 set per benefit period; 2 sets for "At High Risk" Members***
D0277	Vertical bitewings – 7 to 8 films – 1 set per benefit period; 2 sets for "At High Risk" Members***
D0330	Panoramic film – 1 every 5 consecutive years.**
D0484	Consultation on slides prepared elsewhere – Limited to twice per benefit period
Code	**Preventive Services**
D1120	Prophylaxis – Child - Limited to twice per benefit period.
D1110	Prophylaxis – Adult – Limited to twice per benefit period.
D1206	Topical fluoride varnish – Limited to twice per benefit period; additional application for "At High Risk" Members***
D1208	Topical fluoride application; excluding varnish – Limited to twice per benefit period: additional application for "At High Risk" Members***
D1351	Sealant - per tooth - unrestored permanent molars - 1 sealant per tooth every 3 consecutive years.
D1352	Preventive resin restoration in moderate to high caries risk children – permanent tooth. Limited to permanent unrestored molars and not paid in conjunction with a sealant
D1353	Sealant repair – per tooth – previously sealed permanent molars – 1 sealant repair per tooth every 3 years (benefit starts 2 years after the initial sealant is placed)
D1354	Interim caries arresting medicament application
D1510	Space maintainer – fixed – unilateral
D1515	Space maintainer – fixed – bilateral
D1520	Space maintainer - removable – unilateral
D1525	Space maintainer - removable – bilateral
D1550	Re-cementation or re-bond space maintainer
D1555	Removal of fixed space maintainer

Code	Additional Procedures covered as Basic Services
D9110	Palliative treatment of dental pain – minor procedure

- * The twice per benefit period frequency limitation is inclusive for all oral evaluations, including consultations.
- **The once every 5 consecutive year frequency limitation is inclusive for complete series x-ray and/or panoramic films.
- ***"At Risk" Members –will be identified through provider documentation using a caries risk assessment form

Section 2 - Intermediate Services

The following is a list of services that are payable under the Iowa ***hawk-i*** Dental Plan. The list includes those services most commonly provided to covered individuals. It is not an all-inclusive list of covered services.

Code	Minor Restorative Services
D2140	Amalgam - one surface, primary or permanent
D2150	Amalgam - two surfaces, primary or permanent
D2160	Amalgam - three surfaces, primary or permanent
D2161	Amalgam - four or more surfaces, primary or permanent
D2330	Resin–based composite - one surface, anterior
D2331	Resin-based composite - two surfaces, anterior
D2332	Resin-based composite - three surfaces,
D2335	Resin-based composite - four or more surfaces or involving incisal angle (anterior)
D2910	Re-cement or re-bond inlay or onlay
D2920	Re-cement or re-bond crown
D2930	Prefabricated stainless steel crown - primary tooth
D2931	Prefabricated stainless steel crown - permanent tooth
D2951	Pin retention - per tooth, in addition to restoration
Code	**Endodontic Services**
D3220	Therapeutic pulpotomy (excluding final restoration) - If a root canal is within 45 days of the pulpotomy, total benefit for the root canal will include the allowance given for the pulpotomy.
D3222	Partial pulpotomy for apexogenesis - permanent tooth with incomplete root development If a root canal is within 45 days of the pulpotomy, total benefit for the root canal will include the allowance given for the partial pulpotomy.
D3230	Pulpal therapy (resorbable filling) - anterior, primary tooth (excluding final restoration)
D3240	Pulpal therapy (resorbable filling) - posterior, primary tooth excluding final restoration
Code	**Periodontal Services**
D4341	Periodontal scaling and root planning-four or more teeth per quadrant – Limited to 1 per quadrant every 24 consecutive months
D4342	Periodontal scaling and root planning-one to three teeth, per quadrant – Limited to 1 per quadrant every 24 consecutive months
D4910	Periodontal maintenance – Limited to no more than 4 in the first benefit period, combined with adult prophylaxis, after the completion of active periodontal therapy. Limited to twice per benefit period thereafter.
Code	**Prosthodontic Services**
D5410	Adjust complete denture – maxillary – Limited to twice per denture per benefit period after

	6 months have elapsed since initial placement.
D5411	Adjust complete denture – mandibular – Limited to twice per denture per benefit period after 6 months have elapsed since initial placement.
D5421	Adjust partial denture – maxillary – Limited to twice per denture per benefit period after 6 months have elapsed since initial placement.
D5422	Adjust partial denture - mandibular – Limited to twice per denture per benefit period after 6 months have elapsed since initial placement.
D5510	Repair broken complete denture base
D5520	Replace missing or broken teeth - complete denture (each tooth)
D5610	Repair resin denture base
D5620	Repair cast framework
D5630	Repair or replace broken clasp
D5640	Replace broken teeth - per tooth
D5650	Add tooth to existing partial denture
D5660	Add clasp to existing partial denture
D5710	Rebase complete maxillary denture
D5711	Rebase complete mandibular denture.
D5720	Rebase maxillary partial
D5721	Rebase mandibular partial denture
D5730	Reline complete maxillary denture (chairside) -
D5731	Reline complete mandibular denture (chairside) -
D5740	Reline maxillary partial denture (chairside)
D5741	Reline mandibular partial denture (chairside)
D5750	Reline complete maxillary denture (laboratory) -
D5751	Reline complete mandibular denture (laboratory) -
D5760	Reline maxillary partial denture (laboratory)
D5761	Reline mandibular partial denture (laboratory)
D5850	Tissue conditioning (maxillary) - Limited to twice per denture every 36 consecutive months.
D5851	Tissue conditioning (mandibular) – Limited to twice per denture every 36 consecutive months.
D6930	Recement or re-bond fixed partial denture
D6980	Fixed partial denture repair, by report
Code	**Oral Surgery**
D7140	Extraction, erupted tooth or exposed root (elevation and/or forceps removal)
D7210	Surgical removal of erupted tooth requiring elevation of mucoperiosteal flap and removal of bone and/or section of tooth
D7220	Removal of impacted tooth - soft tissue
D7230	Removal of impacted tooth – partially bony
D7240	Removal of impacted tooth - completely bony
D7241	Removal of impacted tooth - completely bony with unusual surgical complications
D7250	Surgical removal of residual tooth roots (cutting procedure)
D7270	Tooth reimplantation and/or stabilization of accidentally evulsed or displaced tooth
D7280	Surgical access of an unerupted tooth
D7285	Incisional biopsy of oral tissue – hard (bone, tooth)
D7286	Incisional biopsy of oral tissue – soft
D7310	Alveoloplasty in conjunction with extractions - per quadrant
D7311	Alveoloplasty in conjunction with extractions-1-3 teeth or tooth spaces, per quadrant
D7320	Alveoloplasty not in conjunction with extractions - per quadrant

D7321	Alveoloplasty not in conjunction with extractions-1-3 three teeth or tooth spaces, per quad
D7471	Removal of exostosis
D7530	Removal of foreign body
D7971	Excision of pericoronal gingiva
D9951	Occlusal adjustment – limited – Limited to twice every 12 consecutive months

Section 3 - Major Services

The following is a list of services that are payable under the Iowa ***hawk-i*** Dental Plan. The list includes those services most commonly provided to covered individuals. It is not an all-inclusive list of covered services.

Code	Major Restorative Services * Limited to once per tooth every 5 consecutive years, unless otherwise noted
D2410	Gold Foil - one surface – An alternate benefit will be provided.
D2420	Gold Foil – two surfaces – An alternate benefit will be provided.
D2430	Gold Foil – three surfaces – An alternate benefit will be provided.
D2510	Inlay - metallic – one surface – An alternate benefit will be provided
D2520	Inlay - metallic – two surfaces – An alternate benefit will be provided
D2530	Inlay - metallic – three surfaces – An alternate benefit will be provided
D2542	Onlay - metallic - two surfaces
D2543	Onlay - metallic - three surfaces
D2544	Onlay - metallic - four or more surfaces
D2740	Crown - porcelain/ceramic substrate
D2750	Crown - porcelain fused to high noble metal
D2751	Crown - porcelain fused to predominately base metal
D2752	Crown - porcelain fused to noble metal
D2780	Crown - 3/4 cast high noble metal
D2781	Crown - 3/4 cast predominately base metal
D2783	Crown - 3/4 porcelain/ceramic
D2790	Crown - full cast high noble metal
D2791	Crown - full cast predominately base metal
D2792	Crown - full cast noble metal
D2794	Crown – titanium
D2950	Core buildup, including any pins
D2954	Prefabricated post and core, in addition to crown
D2955	Post removal
D2980	Crown repair, by report
Code	**Endodontic Services**
D3310	Anterior root canal (excluding final restoration)
D3320	Bicuspid root canal (excluding final restoration)
D3330	Molar root canal (excluding final restoration)
D3346	Retreatment of previous root canal therapy-anterior
D3347	Retreatment of previous root canal therapy-bicuspid
D3348	Retreatment of previous root canal therapy-molar
D3351	Apexification/recalcification – initial visit (apical closure/calcific repair of perforations, root resorption, etc.)
D3352	Apexification/recalcification – interim medication replacement (apical closure/calcific repair of perforations, root resorption, etc.)

D3353	Apexification/recalcification - final visit (includes completed root canal therapy, apical closure/calcific repair of perforations, root resorption, etc.)
D3410	Apicoectomy/periradicular surgery - anterior
D3421	Apicoectomy/periradicular surgery - bicuspid (first root)
D3425	Apicoectomy/periradicular surgery - molar (first root)
D3426	Apicoectomy/periradicular surgery (each additional root)
D3450	Root amputation - per root
D3920	Hemisection (including any root removal) - not including root canal therapy
D3950	Canal preparation
Code	**Periodontal Services**
D4210	Gingivectomy or gingivoplasty – four or more teeth Limited to 1 per quadrant per benefit period.
D4211	Gingivectomy or gingivoplasty – one to three teeth – Limited to 1 per quadrant per benefit period.
D4240	Gingival flap procedure, four or more teeth – Limited to 1 per quadrant per benefit period.
D4241	Gingival flap procedure, one to three teeth – Limited to 1 per quadrant per benefit period.
D4249	Clinical crown lengthening-hard tissue
D4260	Osseous surgery (including flap entry and closure), four or more contiguous teeth or bounded teeth spaces per quadrant – Limited to 1 per quadrant per benefit period.
D4261	Osseous surgery (including flap entry and closure) – one to three teeth – Limited to 1 per quadrant per benefit period.
D4270	Pedicle soft tissue graft procedure
D4271	Free soft tissue graft procedure (including donor site surgery)
D4273	Subepithelial connective tissue graft procedures (including donor site surgery)
D4355	Full mouth debridement to enable comprehensive evaluation and diagnosis – Limited to 1 per lifetime after 36 months have elapsed since last dental cleaning (prophylaxis).
Code	**Prosthodontic Services** * Limited to once every 5 consecutive years, unless otherwise noted.
D5110	Complete denture - maxillary
D5120	Complete denture - mandibular
D5130	Immediate denture - maxillary
D5140	Immediate denture - mandibular
D5211	Maxillary partial denture - resin base (including any conventional clasps, rests and teeth)
D5212	Mandibular partial denture - resin base (including any conventional clasps, rests and teeth)
D5213	Maxillary partial denture - cast metal framework with resin denture base (including any conventional clasps, rests and teeth)
D5214	Mandibular partial denture - cast metal framework with resin denture base (including any conventional clasps, rests and teeth)
D5281	Removable unilateral partial denture-one piece cast metal (including clasps and teeth)
D5862	Precision attachment
D6241	Pontic - porcelain fused to predominately base metal
D6242	Pontic - porcelain fused to noble metal
D6245	Pontic - porcelain/ceramic
D6519	Inlay/onlay – porcelain/ceramic
D6520	Inlay – metallic – two surfaces
D6530	Inlay – metallic – three or more surfaces
D6543	Onlay – metallic – three surfaces
D6544	Onlay – metallic – four or more surfaces

D6545	Retainer - cast metal for resin bonded fixed prosthesis
D6548	Retainer - porcelain/ceramic for resin bonded fixed prosthesis
D6740	Crown - porcelain/ceramic
D6750	Crown - porcelain fused to high noble metal
D6751	Crown - porcelain fused to predominately base metal -
D6752	Crown - porcelain fused to noble metal
D6780	Crown - 3/4 cast high noble metal
D6781	Crown - 3/4 cast predominately base metal
D6782	Crown - 3/4 cast noble metal
D6783	Crown - 3/4 porcelain/ceramic
D6790	Crown - full cast high noble metal
D6791	Crown - full cast predominately base metal
D6792	Crown - full cast noble metal
D6920	Connector bar
D6940	Stress breaker
D6950	Precision attachment
D6973	Core buildup for retainer, including any pins
Code	**Emergency Dental Services**
D2940	Protective Restoration
D4320	Provisional splinting – intracoronal – benefit is subject to review as an emergency dental service.
D4321	Provisional splinting – extracoronal – benefit is subject to review as an emergency dental service.
D7910	Suture of recent small wounds up to 5 cm. Benefit is subject to review as an emergency dental service.
D5810	Complete denture upper (interim)) – benefit subject to review as an emergency dental service.[1]
D5811	Complete denture lower (interim)) – benefit subject to review as an emergency dental service.
D5820	Partial denture upper (interim)) – benefit subject to review as an emergency dental service.
D5821	Partial denture lower (interim)) – benefit subject to review as an emergency dental service.
D7510	Incision and drainage of abscess - intraoral soft tissue – benefit subject to review as an emergency dental service.
D7911	Complicated sutures up to 5 cm. - benefit subject to review as an emergency dental service.
D7912	Complicated sutures greater than 5 cm.- benefit subject to review as an emergency dental service.

Section 4 - Orthodontic Coverage

Orthodontic procedures require prior authorization and will be approved when "medically necessary" as defined below. A "handicapping" malocclusion is a condition that constitutes a hazard to the maintenance of oral health and interferes with the well-being of the recipient by causing:

- Impaired mastication,
- Dysfunction of the temporomandibular articulation,

[1] Deletion of D2970 made in the First Amendment.

- Susceptibility to periodontal disease,
- Susceptibility to dental caries, and
- Impaired speech due to malpositions of the teeth.

Medically necessary orthodontic service is an orthodontic procedure that addresses a harmful habit (e.g. tongue thrust) that is causing deformative changes to the teeth and/or jaw structure, or is one of the automatically qualifying clinical conditions (cleft palate or craniofacial deformity), or is a limited, interceptive, or comprehensive orthodontic treatment that treats a handicapping malocclusion with a Salzmann score of 26 or greater. Assessment of the most handicapping malocclusion is determined by the magnitude of the following variables: degree of mal-alignment, missing teeth, angle classification, overjet and overbite, open bite, and crossbite. A Salzmann Index score of 26 or greater will be used as criteria for "medically necessary" orthodontic benefits.

Approval for treatment will be assessed in a manner consistent with "Handicapping Malocclusion Assessment to Establish Treatment Priority," by J. A. Salzmann, DDS, American Journal of Orthodontics, October 1968. Approval may be made for a complete comprehensive case of active orthodontic treatment.

Provider's request for prior authorization shall be accompanied by:

- An interpreted cephalometric radiograph (either a full series of radiographs or panograph film).
- Study models trimmed so that the models simulate centric occlusion of the recipient when the models are placed on their heels.
- A written plan of treatment.

Post treatment records or a randomized record audit may be requested.

MINOR TREATMENT TO CONTROL HARMFUL HABITS

D8210 Removable appliance therapy. Requires prior authorization.
D8220 Fixed appliance therapy. Requires prior authorization.

- These procedures will be approved for a finger, lip, or tongue habit that has deformative impact on the teeth and/or jaw structures. Requests for approval shall be accompanied by documentation of the nature and scope of the deleterious habit.

LIMITED OR INTERCEPTIVE TREATMENT

D8020 Limited orthodontic treatment of the transitional dentition
D8060 Interceptive orthodontic treatment of the transitional dentition

- These procedures will be approved for certain limited and interceptive cases that are associated with handicapping malocclusions. Requests for approval should demonstrate an overjet of 6mm or greater, an ANB angle of 4 degrees or more, or an ANB angle of 0 degrees or less.

COMPREHENSIVE ORTHODONTIC TREATMENT OF PERMANENT DENTITION

D8070 / D8080 / D8680 / D8999

These procedures require prior authorization. Orthodontic procedures will be approved for handicapping malocclusions that meet a Salzmann Index score of 26 or greater. The request for prior authorization shall be accompanied by:

- An interpreted cephalometric radiograph (either a full series of radiographs or pantograph film),
- Study models trimmed so that the models simulate centric occlusion of the recipient when the models are placed on their heels, and
- A written plan of treatment.

Code Procedure Comment

Code	Description
D0140	Limited oral evaluation – problem focused
D8020	Limited orthodontic treatment of the transitional dentition
D8060	Interceptive orthodontic treatment of the transitional dentition
**D8070	Comprehensive treatment of transitional dentition
**D8080	Comprehensive treatment of adolescent dentition
D8210	Removable Appliance Therapy – harmful habit
D8220	Fixed Appliance Therapy – harmful habit
*D8660	Pre-orthodontic treatment visit
D8680	Orthodontic retention
D8690	Active treatment, transfers (Use when recipient transfers from one provider to another)
D8999	Unspecified orthodontic procedure

* Code used for diagnostic records (radiographs, casts, photos, etc)
** Inclusive of D0140, D8660, and D8680 procedures when provided by the same dentist in the same course of treatment.

Section 5 – Emergency Dental Services Beyond the Annual Benefit Maximum

Dental services delivered to address an Emergency Dental Condition are covered even if the ***hawk-i***plan member has exceeded their annual benefit maximum. For applicable instances, services will be Dentally Necessary and prior authorization is required. Treatment of Emergency Dental Conditions beyond the annual benefit maximum are covered by participating and non-participating dentists inside and outside of the Plan's Enrollment Area. The Plan shall directly reimburse the Provider rendering emergency services to the Enrollee.

Funding is intended to address urgent clinical problems to allow a member to return to normal, pain and infection-free oral functioning and not to provide for definitive therapy.

Covered services must meet one or more of the following emergent/urgent criteria:

- Services related to the relief of significant pain or to eliminate acute infection
- Services to treat traumatic clinical conditions
- Services that allow a patient to attain the basic human functions (eg eating, speech, etc)
- Services that prevent a condition from seriously jeopardizing one's health/functioning or deteriorating in an imminent time frame to a more serious and costly dental problem

Section 6 – Services Not Covered

The following is a list of services that are *not payable* under the Iowa ***hawk-i*** Dental Plan.

Please Note: Even if a service is not specifically listed as an exclusion, it may not be covered under this plan. Contact the dental carrier if you are unsure a certain service is covered. Experimental or investigational services are not a covered benefit of the Plan.

Code	Services Not Covered
D0320	TMJ arthrogram
D0321	Other TMJ films
D0322	Tomographic survey
D0351	3D photographic image
D0360	Cone Beam CT
D0362	Cone Beam multiple images 2 dim.
D0363	Cone Beam multiple images 3 dim.
D0416	Viral culture
D0418	Analysis of saliva example chemical or biological analysis of saliva for diagnostic purposes.
D0425	Caries test
D0431	Adjunctive pre-diagnostic test
D0475	Declassification procedure
D0476	Special stains for microorganisms
D0477	Special stains not for microorganisms
D0478	Immunohistochemical stains
D0479	Tissue in-situ-hybridization
D0481	Electron microscopy
D0482	Direct immunofluorescence
D0483	In-direct immunofluorescence
D0485	Consultation including preparation of slides
D0486	Brush biopsy sample
D1310	Nutritional counseling
D1320	Tobacco counseling
D1330	Oral Hygiene Instruction
D7292	Surgical replacement screw retained
D7293	Surgical replacement w/surgical flap
D7294	Surgical replacement without the surgical flap
D7880	TMJ Appliance
D7899	TMJ Therapy
D7997	Appliance Removal
D7998	Intraoral placement of a fixation device
D2799	Provisional Crown
D2975	Coping
D3460	Endodontic Implant
D3470	Intentional reimplantation
D3910	Surgical procedure for isolation of tooth
D4230	Anatomical crown exposure 4 or more teeth
D4231	Anatomical crown exposure 1-3 teeth
D5867	Replacement Precision Attachment
D5986	Fluoride Gel Carrier
D6057	Custom abutment
D6253	Provisional Pontic
D6975	Coping – metal
D9210	Local Anesthesia not in conjunction with operative or surgical procedures
D9211	Regional Block Anesthesia
D9212	Trigeminal Division Block Anesthesia
D9215	Local Anesthesia
D9219	Evaluation for deep sedation or general anesthesia
D9230	Analgesia, anxiolysis, inhalation of nitrous oxide
D9248	Non-intravenous conscious sedation

D9410	House / extended care facility call
D9420	Hospital Call
D9450	Case presentation
D9630	Other drugs and or medicaments
D9920	Behavior Management
D9940	Occlusal guard, by report
D9941	Fabrication of athletic mouthguard
D9950	Occlusion analysis - mounted case
D9952	Occlusal adjustment - complete
D9970	Enamel microabrasion
D9971	Odontoplasty 1-2 teeth
D9972	External bleaching - per arch
D9973	External bleaching - per tooth
D9974	Internal bleaching - per tooth
D0310	Sialography
D0472	Oral Pathology lab
D0473	Oral Pathology lab
D0474	Oral Pathology lab
D0480	Oral Pathology lab
D0502	Oral Pathology lab
D5911	Facial Moulage (sectional)
D5912	Facial Moulage (complete)
D5913	Nasal Prosthesis
D5914	Auricular Prosthesis
D5915	Orbital Prosthesis
D5916	Ocular Prosthesis
D5919	Facial Prosthesis
D5922	Nasal Septal Prosthesis
D5923	Ocular Prosthesis (interim)
D5924	Cranial Prosthesis
D5925	Facial Augmentation implant
D5926	Nasal Prosthesis (replacement)
D5927	Auricular Prosthesis (replacement)
D5928	Orbital Prosthesis (replacement)
D5929	Facial Prosthesis (replacement)
D5931	Obturator Prosthesis (surgical)
D5932	Obturator Prosthesis (definitive)
D5933	Obturator Prosthesis (modification)
D5934	Mandibular resection Prosthesis w/guide flange
D5935	Mandibular resection Prosthesis w/out guide flange
D5936	Obturator Prosthesis (interim)
D5937	Trismus Appliance
D5951	Feeding Aid
D5952	Speech Aid prosthesis (pediatric)
D5953	Speech Aid prosthesis (adult)
D5954	Palatal Augmentation Prosthesis
D5955	Palatal Lift Prosthesis (definitive)
D5958	Palatal Lift Prosthesis (interim)
D5959	Palatal Lift Prosthesis (modification)
D5960	Speech Aid Prosthesis (modification)
D5982	Surgical Stent

D5983	Radiation Carrier
D5984	Radiation Shield
D5985	Radiation Cone locator
D5987	Commissure Splint
D5988	Surgical Splint
D7410	Lesion up to 1.25 (benign)
D7411	Lesion greater than 1.25 (benign)
D7412	Complicated lesion (benign)
D7413	Lesion up to 1.25 (malignant)
D7414	Lesion greater than 1.25 (malignant)
D7415	Complicated lesion (malignant)
D7440	Lesion diameter up to 1.25 (malignant)
D7441	Lesion diameter greater than 1.25 (malignant)
D7460	Removal of Benign lesion up to 1.25
D7461	Removal of Benign lesion greater than 1.25
D7465	Destruction of lesion (by report)
D7490	Radical resection upper/lower
D7540	Removal of reaction producing the foreign body
D7550	Partial Ostectomy
D7560	Maxillary Sinusotomy
D7610	Upper open reduction
D7620	Upper closed reduction
D7630	Lower open reduction (simple)
D7640	Lower closed reduction (simple)
D7650	Open reduction (simple)
D7660	Closed reduction (simple)
D7670	Alveolus closed reduction (simple)
D7671	Alveolus open reduction (simple)
D7680	Facial bones (simple)
D7710	Upper open reduction (compound)
D7720	Upper closed reduction (compound)
D7730	Lower open reduction (compound)
D7740	Lower closed reduction (compound)
D7750	Malar and/or zygomatic arch open red.(compound)
D7760	Malar and/or zygomatic arch closed red.(compound)
D7770	Alveolus open red.(compound - stabilization of teeth)
D7771	Alveolus closed red. (compound – stabilization of teeth)
D7780	Facial bones (compound)
D7810	TMJ open reduction
D7820	TMJ closed reduction
D7830	TMJ manipulation
D7840	Condylectomy
D7850	Surgical discectomoy
D7852	Disc repair
D7854	Synovectomy
D7856	Myotomy
D7858	Joint reconstruction
D7860	Arthrotomy
D7865	Arthroplasty
D7870	Arthrocentesis
D7871	Non-Arthroscopic

D7872	Arthroscopy with or without a biopsy
D7873	Arthoscopy surgical adhesions
D7874	Arthoscopy surgical disc
D7875	Arthoscopy surgical synovectomy
D7876	Arthoscopy surgical discectomy
D7877	Arthoscopy surgical debridement
D7920	Skin graft
D7940	Osteoplasty deformities
D7941	Osteotomy lower rami
D7943	Osteotomy lower rami with bone graft
D7944	Osteotomy segmented
D7945	Osteotomy body of mandible
D7946	Lefort I upper total
D7947	Lefort I upper segmented
D7948	Lefort II or Lefort III without bone graft
D7949	Lefort II or Lefort III with bone graft
D7950	Bone graft - mandible or face
D7955	Repair of Maxillofacial soft or hard tissue
D7980	Sialolithotomy
D7981	Excision of salivary gland
D7982	Sialodochoplasty
D7983	Closure of salivary fistula
D7990	Emergency tracheotomy
D7991	Coronoidectomy
D7995	Synthetic graft
D7996	Implant lower for augmentation purposes

3.3 Complaint/Appeal Reporting Form

COMPLAINT/APPEAL REPORTING FORM

(Use to record each complaint/appeal)

Date Complaint/Appeal Received		
hawk-I ID		
Last name, First name		
City, zip code		
Gender **M**- male **F**- female		
A- Appeal **C**- Complaint		
Problem as described by the Enrollee:		
FINAL RESOLUTION SUMMARY:	Resolution Date (mm/dd/yy)	Enter: 1- if to Enrollee's satisfaction 2 -if not to Enrollee's satisfaction
Administrative resolution/system error		
Contacting physician/provider in question		
Other		
DENIAL OF PAYMENT (reason)		Enter: 1 - if denial upheld 2 - if denial reversed
System/Processing Error		
Service Not Covered		
Service Not Payable		
Services Not Received by Network Provider		
No prior authorization for services utilized		
Other		
QUALITY OF CARE		
Poor quality of care received		
Poor health education		
Poor communication of treatment needs by provider		
Poor provider/patient relationship		
Other		
ACCESS TO SERVICES		
Could not find a dentist to provide care		
Difficulty getting an appointment		
Long office wait times for the scheduled appt.		

Provider too far/travel time too long		
Problems obtaining services outside regular hours		
Denied services thought needed		
Cannot obtain services recommended by the provider through the program		
Cannot get referral to a specialist thought needed		
Afraid to access emergency care for fear of having to pay for it		
Other		
COMMUNICATION		
Lack of respect since joining the program (culturally specific)		
Lack of respect since joining the program		
Cannot understand how to get services through the program		
Getting services process too complicated		
Difficulties communicating with providers (language problem)		
Difficulties communicating with providers (general)		
Other		

3.4. Capitation Payment

For the time period of August 1, 2018 through June 30, 2019

The Contractor shall be paid a monthly capitation payment of $23.26 ($22.79 with 2% hold) per member per month.

For Orthodontic Services

The Contractor shall submit a monthly invoice to the Agency for payment of approved orthodontic services. The invoice should include a summary listing the services and the amount to be paid. Payment for covered services shall be the lesser of the amount billed or the maximum allowed amount in accordance with the following schedule:

Code	Nomenclature	Maximum Allowed Amount
D0140	Limited oral evaluation – problem focused	$35.00
D8020	Limited orthodontic treatment of the transitional dentition	$250.00
D8060	Interceptive orthodontic treatment of the transitional dentition	$375.00
D8070*	Comprehensive orthodontic treatment of the transitional dentition	$4,300.00
D8080*	Comprehensive orthodontic treatment of the adolescent dentition	$4,300.00
D8210	Removable appliance therapy	$400.00
D8220	Fixed appliance therapy	$450.00
D8660**	Pre-orthodontic treatment visit	$200.00
D8690	Orthodontic treatment (alternative billing to a contract fee)	Prorated Allowed Amount #
D8999	Unspecified orthodontic procedure, by report	$125.00
	Administrative fee for each approved treatment	$180.00

*The maximum allowed amount of $4,300.00 includes D0140, D8660, D8680 procedures when provided by the same dentist in the same course of treatment.

**Use this procedure code for diagnostic procedures (radiographs, films, photos, casts, etc.).

#The maximum allowed amount is determined by the Contractor. This is used when a child transfers from one dentist/orthodontist during the treatment phase.

SECTION 4: FEDERAL REGULATORY TERMS

Subpart A—General Provisions

§ 438.1 Basis and scope.

This Section of the Contract sets forth federal requirements, prohibitions, and procedures for the provision of Medicaid services through Contractor. These provisions are drawn directly from the federal regulatory provisions applicable to Contractor's scope of services. The intent of the parties through the inclusion of these provisions is to clearly require compliance with the relevant federal obligations at a minimum, with clarification or addition to these obligations set forth either in these restated regulations or within the scope of work.

§ 438.2 Definitions.

As used in this Contract—

Abuse means as the term is defined in 42 C.F.R. § 455.2.

Actuary means an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board. In this Contract, Actuary refers to an individual who is acting on behalf of the State when used in reference to the development and certification of capitation rates.

Capitation payment means a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the State plan. The State makes the payment regardless of whether the particular beneficiary receives services during the period covered by the payment.

Choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions; it includes answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP.

Comprehensive risk contract means a risk contract between the State and an MCO that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) Federally Qualified Health Center (FQHC) services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

Enrollee means a Medicaid beneficiary who is currently enrolled with the Contractor. The term "Member" and "Enrollee" may be used interchangeably in this Contract.

Enrollee encounter data means the information relating to the receipt of any item(s) or service(s) by an enrollee under this Contract that is subject to the requirements of 42 C.F.R. §§ 438.242 and 438.818.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the Public Health Service Act.

Fraud means as the term is defined in 42 C.F.R. § 455.2.

Health insuring organization (HIO) means a county operated entity, that in exchange for capitation payments, covers services for beneficiaries—

(1) Through payments to, or arrangements with, providers;

(2) Under a comprehensive risk contract with the State; and

(3) Meets the following criteria—

(i) First became operational prior to January 1, 1986; or

(ii) Is described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990 and section 205 of the Medicare Improvements for Patients and Providers Act of 2008).

Long-term services and supports (LTSS) means services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under 42 C.F.R. part 438, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of 42 C.F.R. subpart I of part 489; or

(2) Any public or private entity that meets the advance directives requirements and is determined by the Secretary to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid beneficiaries within the area served by the entity.

(ii) Meets the solvency standards of 42 C.F.R. § 438.116.

Managed care program means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Social Security Act.

Material adjustment means an adjustment that, using reasonable actuarial judgment, has a significant impact on the development of the capitation payment such that its omission or misstatement could impact a determination whether the development of the capitation rate is consistent with generally accepted actuarial principles and practices.

Network provider means any provider, group of providers, or entity that has a network provider agreement with Contractor, or a subcontractor, and receives Medicaid funding directly or indirectly to order, refer or render covered services as a result of the Contract. A network provider is not a subcontractor by virtue of the network provider agreement.

Nonrisk contract means a contract between the State and a PAHP under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in 42 C.F.R. § 447.362; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Overpayment means any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled to under Title XIX of the Social Security Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not entitled to under Title XIX of the Social Security Act.

Potential enrollee means a Medicaid beneficiary who is subject to mandatory enrollment or may voluntarily elect to enroll in a given MCO, PIHP, PAHP, PCCM or PCCM entity, but is not yet an enrollee of a specific MCO, PIHP, PAHP, PCCM, or PCCM entity.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of capitation payments, or other payment arrangements that do not use State plan payment rates.

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.

Rate cell means a set of mutually exclusive categories of enrollees that is defined by one or more characteristics for the purpose of determining the capitation rate and making a capitation payment; such characteristics may include age, gender, eligibility category, and region or geographic area. Each enrollee should be categorized in one of the rate cells for each unique set of mutually exclusive benefits under the contract.

Rating period means a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by 42 C.F.R. § 438.7(a).

Risk contract means a contract between the State and Contractor under which the Contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

State means the Single State agency as specified in 42 C.F.R. § 431.10. For purposes of this Contract, the term "State" means the State of Iowa, and the term "Single State Agency" means the Iowa Department of Human Services.

Subcontractor means an individual or entity that has a contract with Contractor that relates directly or indirectly to the performance of the Contractor's obligations under its contract with the State. A network provider is not a subcontractor by virtue of the network provider agreement with the Contractor.

§ 438.3 Standard contract requirements.

(a) *CMS review.* This Contract is contingent upon CMS review and approval.

(b) *Reserved.*

(c) *Payment.* The following requirements apply to the final capitation rate and the receipt of capitation payments under the Contract:

(1) The final capitation rate under this Contract for Contractor will be:

(i) Specifically identified in the applicable contract submitted for CMS review and approval.

(ii) The final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the requirements of 42 C.F.R. par 438, subpart K (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the Contractor to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

(2) Capitation payments may only be made by the State and retained by the Contractor for Medicaid-eligible enrollees.

(d) *Enrollment discrimination prohibited.*

(1) Contractor 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.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in 42 C.F.R. § 438.50(a).

(3) Contractor will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) Contractor 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, or national origin, sex, sexual orientation gender identity, or disability.

(e) *Services that may be covered by Contractor.* (1) Contractor may cover, for enrollees, services that are in addition to those covered under the State plan as follows:

(i) Any services that the Contractor voluntarily agree to provide, although the cost of these services cannot be included when determining the payment rates under paragraph (c) of this section.

(ii) *Reserved (not applicable to a dental-only PAHP).*

(2) Contractor may cover, for enrollees, services or settings that are in lieu of services or settings covered under the State plan as follows:

(i) The State determines that the alternative service or setting is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the Contractor to use the alternative service or setting;

(iii) The approved in lieu of services are authorized and identified in this Contract, and will be offered to enrollees at the option of the Contractor; and

(iv) The utilization and actual cost of in lieu of services is taken into account in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise.

(f) *Compliance with applicable laws and conflict of interest safeguards.* Contractor shall:

(1) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in 42 C.F.R. § 438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Social Security Act applicable to contracting officers, employees, or independent contractors.

(g) *Provider-preventable condition requirements.* Contractor shall 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 C.F.R. § 434.6(a)(12) and 42 C.F.R. § 447.26. Contractor must report all identified provider-preventable conditions in a form and frequency as specified by the State.

(h) *Inspection and audit of records and access to facilities.* The State, CMS, the Office of the Inspector General, the Comptroller General, and their designees may, at any time, inspect and audit any records or documents of the Contractor, or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(i) *Physician incentive plans.* (1) Contractor shall provide for compliance with the requirements set forth in 42 C.F.R. §§ 422.208 and 422.210.

(2) 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 "Contractor," "State," and "Medicaid beneficiaries," respectively.

(j) *Advance directives.* (1) *Reserved (not applicable to a dental-only PAHP).*

(2) *Reserved (not applicable to a dental-only PAHP).*

(3) *Reserved (not applicable to a dental-only PAHP).*

(4) *Reserved (not applicable to a dental-only PAHP).*

(k) *Subcontracts.* All subcontracts must fulfill the requirements of 42 C.F.R. part 438 for the service or activity delegated under the subcontract in accordance with 42 C.F.R. § 438.230.

(l) *Choice of network provider.* The Contractor shall allow each enrollee to choose his or her network provider to the extent possible and appropriate.

(m) *Audited financial reports.* Contractor shall submit audited financial reports specific to the Medicaid contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(n) *Parity in mental health and substance use disorder benefits.* (1) To the extent that Contractor provides services to MCO enrollees, Contractor shall provide for services to be delivered in compliance with the requirements of 42 C.F.R. part 438, subpart K insofar as those requirements are applicable.

(2) *Reserved.*

(o) *Reserved.*

(p) *Reserved.*

(q) *Reserved.*

(r) *Reserved.*

(s) *Requirements for MCOs, PIHPs, or PAHPs that provide covered outpatient drugs.* Reserved.

(t) *Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.* Reserved.

(u) *Recordkeeping requirements.* Contractor shall retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in 42 C.F.R. § 438.416, base data in 42 C.F.R. §

438.5(c), MLR reports in 42 C.F.R. § 438.8(k), and the data, information, and documentation specified in 42 C.F.R. §§ 438.604, 438.606, 438.608, and 438.610 for a period of no less than 10 years.

(v) *Applicability date.* Reserved.

§ 438.4 Actuarial soundness.

(a) *Actuarially sound capitation rates defined.* Actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the Contractor for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements in paragraph (b) of this section.

(b) *CMS review and approval of actuarially sound capitation rates.* Capitation rates for Contractor will be reviewed and approved by CMS as actuarially sound. To be approved by CMS, the Agency must show that the capitation rates:

(1) Have been developed in accordance with standards specified in 42 C.F.R. § 438.5 and generally accepted actuarial principles and practices. Any proposed differences among capitation rates according to covered populations must be based on valid rate development standards and not based on the rate of Federal financial participation associated with the covered populations.

(2) Are appropriate for the populations to be covered and the services to be furnished under the contract.

(3) Are adequate to meet the requirements on Contractor in 42 C.F.R. §§ 438.206, 438.207, and 438.208.

(4) Are specific to payments for each rate cell under the Contract.

(5) Do not cross-subsidize and are not cross-subsidized by payments for any other rate cell.

(6) Are certified by an actuary as meeting the applicable requirements of 42 C.F.R. part 438, including that the rates have been developed in accordance with the requirements specified in 42 C.F.R. § 438.3(c)(1)(ii) and (e).

(7) Meet any applicable special contract provisions as specified in 42 C.F.R. § 438.6.

(8) Are provided to CMS in a format and within a timeframe that meets requirements in 42 C.F.R. § 438.7.

(9) Are developed in such a way that the Contractor would reasonably achieve a medical loss ratio standard, as calculated under 42 C.F.R. § 438.8, of at least 85 percent for the rate year. The capitation rates may be developed in such a way that the Contractor would reasonably achieve a medical loss ratio standard greater than 85 percent, as calculated under 42 C.F.R. § 438.8, as long as the capitation rates are adequate for reasonable, appropriate, and attainable non-benefit costs.

§ 438.5 Rate development standards.

(a) *Definitions.* As used in this section and 42 C.F.R. § 438.7(b), the following terms have the indicated meanings:

Budget neutral means a standard for any risk sharing mechanism that recognizes both higher and lower expected costs among contracted MCOs, PIHPs, or PAHPs under a managed care program and does not create a net aggregate gain or loss across all payments under that managed care program.

Prospective risk adjustment means a methodology to account for anticipated variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from historical experience of the contracted MCOs, PIHPs, or PAHPs and applied to rates for the rating period for which the certification is submitted.

Retrospective risk adjustment means a methodology to account for variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from experience concurrent with the rating period of the contracted MCOs, PIHPs, or PAHPs subject to the adjustment and calculated at the expiration of the rating period.

Risk adjustment is a methodology to account for the health status of enrollees via relative risk factors when predicting or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the State.

(b) *Process and requirements for setting actuarially sound capitation rates.* In setting actuarially sound capitation rates, the Agency will follow the steps below, in an appropriate order, in accordance with this section, or explain why they are not applicable:

(1) Consistent with paragraph (c) of this section, identify and develop the base utilization and price data.

(2) Consistent with paragraph (d) of this section, develop and apply trend factors, including cost and utilization, to base data that are developed from actual experience of the Medicaid population or a similar population in accordance with generally accepted actuarial practices and principles.

(3) Consistent with paragraph (e) of this section, develop the non-benefit component of the rate to account for reasonable expenses related to MCO, PIHP, or PAHP administration; taxes; licensing and regulatory fees; contribution to reserves; risk margin; cost of capital; and other operational costs associated with the MCO's, PIHP's, or PAHP's provision of State plan services to Medicaid enrollees.

(4) Consistent with paragraph (f) of this section, make appropriate and reasonable adjustments to account for changes to the base data, programmatic changes, non-benefit components, and any other adjustment necessary to establish actuarially sound rates.

(5) Take into account the MCO's, PIHP's, or PAHP's past medical loss ratio, as calculated and reported under 42 C.F.R. § 438.8, in the development of the capitation rates, and consider the projected medical loss ratio in accordance with 42 C.F.R. § 438.4(b)(9).

(6) Consistent with paragraph (g) of this section, if risk adjustment is applied, select a risk adjustment methodology that uses generally accepted models and apply it in a budget neutral manner across all MCOs, PIHPs, or PAHPs in the program to calculate adjustments to the payments as necessary.

(c) *Base data.* (1) The Agency will provide all the validated encounter data, FFS data (as appropriate), and audited financial reports (as defined in 42 C.F.R. § 438.3(m)) that demonstrate experience for the populations to be served by the MCO, PIHP, or PAHP to the actuary developing the capitation rates for at least the three most recent and complete years prior to the rating period.

(2) The Agency and its actuaries will use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates. Such base data must be derived from the Medicaid population, or, if data on the Medicaid population is not available, derived from a similar population and adjusted to make the utilization and price data comparable to data from the Medicaid population. Data will be in accordance with actuarial standards for data quality and an explanation of why that specific data is used must be provided in the rate certification.

(3) *Exception.* (i) If the Agency is unable to base its rates on data meeting the qualifications in paragraph (c)(2) of this section that the basis of the data be no older than from the 3 most recent and complete years prior to the rating period may request approval for an exception; the request will describe why an exception is necessary and describe the actions the Agency intends to take to come into compliance with those requirements.

(ii) If the Agency requests an exception from the base data standards established in this section, the Agency will set forth a corrective action plan to come into compliance with the base data standards no later than 2 years from the rating period for which the deficiency was identified.

(d) *Trend.* Each trend will be reasonable and developed in accordance with generally accepted actuarial principles and practices. Trend will be developed primarily from actual experience of the Medicaid population or from a similar population.

(e) *Non-benefit component of the rate.* The development of the non-benefit component of the rate will include reasonable, appropriate, and attainable expenses related to MCO, PIHP, or PAHP administration, taxes, licensing and regulatory fees, contribution to reserves, risk margin, cost of capital, and other operational costs associated with the provision of services identified in 42 C.F.R. § 438.3(c)(1)(ii) to the populations covered under the Contract.

(f) *Adjustments.* Each adjustment will reasonably support the development of an accurate base data set for purposes of rate setting, address appropriate programmatic changes, reflect the health status of the enrolled population, or reflect non-benefit costs, and be developed in accordance with generally accepted actuarial principles and practices.

(g) *Risk adjustment.* Prospective or retrospective risk adjustment methodologies will be developed in a budget neutral manner consistent with generally accepted actuarial principles and practices.

§ 438.6 Special contract provisions related to payment.

(a) *Definitions.* As used in this Contract, the following terms have the indicated meanings:

Base amount is the starting amount, calculated according to paragraph (d)(2) of this section, available for pass-through payments to hospitals in a given contract year subject to the schedule in paragraph (d)(3) of this section.

Incentive arrangement means any payment mechanism under which Contractor may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

Pass-through payment is any amount required by the Agency to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate, between the Contractor and hospitals, physicians, or nursing facilities that is not for the following purposes: A specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under paragraphs (c)(1)(i) through (iii) of this section for services and enrollees covered under the Contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the Contract; GME payments; or FQHC or RHC wrap around payments.

Risk corridor means a risk sharing mechanism in which the Agency and the Contractor may share in profits and losses under the contract outside of a predetermined threshold amount.

Withhold arrangement means any payment mechanism under which a portion of a capitation rate is withheld from Contractor and a portion of or all of the withheld amount will be paid to the Contractor for meeting targets specified in the Contract. The targets for a withhold arrangement are distinct from general operational requirements under the Contract. Arrangements that withhold a portion of a capitation rate for noncompliance with general operational requirements are a penalty and not a withhold arrangement.

(b) *Basic requirements.* (1) If used in the payment arrangement between the Agency and the Contractor, all applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be described in the Contract, and will be developed in accordance with 42 C.F.R. § 438.4, the rate development standards in 42 C.F.R. § 438.5, and generally accepted actuarial principles and practices.

(2) Any incentive arrangements permitted under the Contract may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound. For all incentive arrangements, the arrangement must be—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the incentive arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition Contractor participation in the incentive arrangement on the Contractor entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy at 42 C.F.R. § 438.340.

(3) Any withhold arrangement will ensure that the capitation payment minus any portion of the withhold that is not reasonably achievable is actuarially sound as determined by an actuary. The total amount of the withhold, achievable or not, must be reasonable and take into consideration the Contractor's financial operating needs accounting for the size and characteristics of the populations covered under the Contract, as well as the Contractor's capital reserves as measured by the risk-based capital level, months of claims reserve, or other appropriate measure of reserves. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable will be submitted as part of the documentation required under 42 C.F.R. § 438.7(b)(6). For all withhold arrangements, the arrangement will be—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the withhold arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition Contractor participation in the withhold arrangement on the Contractor entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy under 42 C.F.R. § 438.340.

(c) *Delivery system and provider payment initiatives under the Contract*—(1) *General rule.* Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation implementing a Title XIX provision related to payments to providers, that is applicable to managed care programs, the Agency will not direct Contractor's expenditures under the Contract.

(i) The State may require Contractor to implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.

(ii) The State may require Contractor to participate in a multi-payer or Medicaid-specific delivery system reform or performance improvement initiative.

(iii) The State may require Contractor to:

(A) Adopt a minimum fee schedule for network providers that provide a particular service under the contract; or

(B) Provide a uniform dollar or percentage increase for network providers that provide a particular service under the contract.

(C) Adopt a maximum fee schedule for network providers that provide a particular service under the Contract, so long as the Contractor retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(2) *Process for approval.* (i) All Contract arrangements that direct the Contractor's expenditures under paragraphs (c)(1)(i) through (iii) of this section will be developed in accordance with 42 C.F.R. § 438.4, the standards specified in 42 C.F.R. § 438.5, generally accepted principles and practices, and have written approval

prior to implementation. To obtain written approval, the Agency will demonstrate, in writing, that the arrangement—

(A) Is based on the utilization and delivery of services;

(B) Directs expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;

(C) Expects to advance at least one of the goals and objectives in the quality strategy in 42 C.F.R. § 438.340;

(D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the quality strategy in 42 C.F.R. § 438.340;

(E) Does not condition network provider participation in contract arrangements under paragraphs (c)(1)(i) through (iii) of this section on the network provider entering into or adhering to intergovernmental transfer agreements; and

(F) May not be renewed automatically.

(ii) Any Contract arrangements that direct the Contractor's expenditures under paragraphs (c)(1)(i) or (c)(1)(ii) of this section will also demonstrate, in writing, that the arrangement—

(A) Makes participation in the value-based purchasing initiative, delivery system reform or performance improvement initiative available, using the same terms of performance, to a class of providers providing services under the Contract related to the reform or improvement initiative;

(B) Uses a common set of performance measures across all of the payers and providers;

(C) Will not set the amount or frequency of the expenditures; and

(D) Does not allow the State to recoup any unspent funds allocated for these arrangements from the Contractor.

(d) *Pass-through payments under the Contract. Reserved. (Pass-through payments are not permitted under the Contract.)*

(e) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease. Reserved.*

§ 438.7 Rate certification submission.

(a) *CMS review and approval of the rate certification.* The Agency will submit to CMS for review and approval, all Contract rate certifications concurrent with the review and approval process for the Contract as specified in 42 C.F.R. § 438.3(a).

(b) *Documentation.* The rate certification will contain the following information:

(1) *Base data.* A description of the base data used in the rate setting process (including the base data requested by the actuary, the base data that was provided by the Agency, and an explanation of why any base data requested was not provided by the Agency) and of how the actuary determined which base data set was appropriate to use for the rating period.

(2) *Trend.* Each trend factor, including trend factors for changes in the utilization and price of services, applied to develop the capitation rates must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(i) The calculation of each trend used for the rating period and the reasonableness of the trend for the enrolled population.

(ii) Any meaningful difference in how a trend differs between the rate cells, service categories, or eligibility categories.

(3) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense that is included in the rate and evaluate the reasonableness of the cost assumptions underlying each expense. The actuary may document the non-benefit costs according to the types of non-benefit costs under 42 C.F.R. § 438.5(e).

(4) *Adjustments.* All adjustments used to develop the capitation rates must be adequately described with enough detail so that CMS, or an actuary applying generally accepted actuarial principles and practices, can understand and evaluate all of the following:

(i) How each material adjustment was developed and the reasonableness of the material adjustment for the enrolled population.

(ii) The cost impact of each material adjustment and the aggregate cost impact of non-material adjustments.

(iii) Where in the rate setting process the adjustment was applied.

(iv) A list of all non-material adjustments used in the rate development process.

(5) *Risk adjustment.* (i) All prospective risk adjustment methodologies will be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The data, and any adjustments to that data, to be used to calculate the adjustment.

(B) The model, and any adjustments to that model, to be used to calculate the adjustment.

(C) The method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk factors of the respective populations.

(D) The magnitude of the adjustment on the capitation rate per MCO, PIHP, or PAHP.

(E) An assessment of the predictive value of the methodology compared to prior rating periods.

(F) Any concerns the actuary has with the risk adjustment process.

(ii) All retrospective risk adjustment methodologies will be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The party calculating the risk adjustment.

(B) The data, and any adjustments to that data, to be used to calculate the adjustment.

(C) The model, and any adjustments to that model, to be used to calculate the adjustment.

(D) The timing and frequency of the application of the risk adjustment.

(E) Any concerns the actuary has with the risk adjustment process.

(iii) Application of an approved risk adjustment methodology to capitation rates does not require a revised rate certification because payment of capitation rates as modified by the approved risk adjustment methodology must be within the scope of the original rate certification. The Agency will provide to CMS the payment terms updated by the application of the risk adjustment methodology consistent with 42 C.F.R. § 438.3(c).

(6) *Special contract provisions.* A description of any of the special contract provisions related to payment in 42 C.F.R. § 438.6 that are applied in the Contract.

(c) *Rates paid under risk contracts.* The Agency, through its actuary, will certify the final capitation rate paid per rate cell under each risk contract and document the underlying data, assumptions and methodologies supporting that specific capitation rate.

(1) The Agency may pay Contractor a capitation rate under the Contract that is different from the capitation rate paid to another PAHP, so long as each capitation rate per rate cell that is paid is independently developed and set in accordance with 42 C.F.R. part 438.

(2) If the Agency determines that a retroactive adjustment to the capitation rate is necessary, the retroactive adjustment will be supported by a rationale for the adjustment and the data, assumptions and methodologies used to develop the magnitude of the adjustment must be adequately described with enough detail to allow CMS or an actuary to determine the reasonableness of the adjustment. These retroactive adjustments will be certified by an actuary in a revised rate certification and submitted as a Contract amendment to be approved by CMS. All such adjustments are also subject to Federal timely claim filing requirements.

(3) The Agency may increase or decrease the capitation rate per rate cell, as required in paragraph (c) of this section and 42 C.F.R. § 438.4(b)(4), up to 1.5 percent without submitting a revised rate certification, as required under paragraph (a) of this section. Such changes of the capitation rate within the permissible 1.5 percent range will be consistent with a modification of the Contract as required in 42 C.F.R. § 438.3(c).

(d) *Provision of additional information.* The Agency will, upon CMS' request, provide additional information, whether part of the rate certification or additional supplemental materials, if CMS determines that information is pertinent to the approval of the certification under 42 C.F.R. part 438. The Agency will identify whether the information provided in addition to the rate certification is proffered by the Agency, the actuary, or another party.

§ 438.8 Medical loss ratio (MLR) standards.

(a) *Basic rule.* Contractor shall calculate and report a MLR in accordance with this section for all Contract years beginning with the 2018 State Fiscal Year (beginning July 1, 2018).

(b) *Definitions.* As used in this section, the following terms have the indicated meanings:

Credibility adjustment means an adjustment to the MLR for a partially credible MCO, PIHP, or PAHP to account for a difference between the actual and target MLRs that may be due to random statistical variation.

Full credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR with a minimal chance that the difference between the actual and target medical loss ratio is not statistically significant. An MCO, PIHP, or PAHP that is assigned full credibility (or is fully credible) will not receive a credibility adjustment to its MLR.

Member months mean the number of months an enrollee or a group of enrollees is covered by Contractor over a specified time period, such as a year.

MLR reporting year means a period of 12 months consistent with the State fiscal year.

No credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be insufficient for the calculation of a MLR. An MCO, PIHP, or PAHP that is assigned no credibility (or is non-credible) will not be measured against any MLR requirements.

Non-claims costs means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e)(2) of this section); expenditures on activities that improve health care quality (as defined in paragraph (e)(3) of this section); or licensing and regulatory fees, or Federal and State taxes (as defined in paragraph (f)(2) of this section).

Partial credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR but with a non-negligible chance that the difference between the actual

and target medical loss ratios is statistically significant. An MCO, PIHP, or PAHP that is assigned partial credibility (or is partially credible) will receive a credibility adjustment to its MLR.

(c) *MLR requirement.* A minimum MLR equal to or higher than 85 percent must be calculated and reported for each MLR reporting year by the Contractor consistent with this section.

(d) *Calculation of the MLR.* The MLR experienced for Contractor in a MLR reporting year is the ratio of the numerator (as defined in paragraph (e) of this section) to the denominator (as defined in paragraph (f) of this section). A MLR may be increased by a credibility adjustment, in accordance with paragraph (h) of this section.

(e) *Numerator*—(1) *Required elements.* The numerator of Contractor's MLR for a MLR reporting year is the sum of Contractor's incurred claims (as defined in (e)(2) of this section); the Contractor's expenditures for activities that improve health care quality (as defined in paragraph (e)(3) of this section); and fraud reduction activities (as defined in paragraph (e)(4) of this section).

(2) *Incurred claims.* (i) Incurred claims must include the following:

(A) Direct claims that the Contractor paid to providers (including under capitated contracts with network providers) for services or supplies covered under the contract and services meeting the requirements of 42 C.F.R. § 438.3(e) provided to enrollees.

(B) Unpaid claims liabilities for the MLR reporting year, including claims reported that are in the process of being adjusted or claims incurred but not reported.

(C) Withholds from payments made to network providers to the extent that such withholds have been finalized to be paid or have been paid.

(D) Claims that are recoverable for anticipated coordination of benefits.

(E) Claims payments recoveries received as a result of subrogation.

(F) Incurred but not reported claims based on past experience, and modified to reflect current conditions, such as changes in exposure or claim frequency or severity.

(G) Changes in other claims-related reserves.

(H) Reserves for contingent benefits and the medical claim portion of lawsuits.

(ii) Amounts that must be deducted from incurred claims include the following:

(A) Overpayment recoveries received from network providers.

(B) Prescription drug rebates received and accrued.

(iii) Expenditures that must be included in incurred claims include the following:

(A) The amount of incentive and bonus payments to network providers to the extent that such bonus payments have been finalized to be paid or have been paid.

(B) The amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses. The amount of fraud reduction expenses must not include activities specified in paragraph (e)(4) of this section.

(iv) Amounts that must either be included in or deducted from incurred claims include, respectively, net payments or receipts related to State mandated solvency funds.

(v) Amounts that must be excluded from incurred claims:

(A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:

(*1*) Amounts paid to third party vendors for secondary network savings.

(*2*) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.

(*3*) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in 42 C.F.R. § 438.3(e) and provided to an enrollee. Payments under this subsection (3) are only to be considered incurred claims if the following four-factor test is met:

> I. The entity contracts with an issuer to deliver, provide, or arrange for the delivery and provision of clinical services to the issuer's enrollees but the entity is not the issuer with respect to those services;
>
> II. The entity contractually bears financial and utilization risk for the delivery, provision, or arrangement of specific clinical services to enrollees;
>
> III. The entity delivers, provides, or arranges for the delivery and provision of clinical services through a system of integrated care delivery that, as appropriate, provides for the coordination of care and sharing of clinical information, and which includes programs such as provider performance reviews, tracking clinical outcomes, communicating evidence-based guidelines to the entity's clinical providers, and other, similar care delivery efforts; and
>
> IV. Functions other than clinical services that are included in the payment (capitated or fee-for-service) must be reasonably related or incident to the clinical services, and must be performed on behalf of the entity or the entity's providers.

(*4*) Fines and penalties assessed by regulatory authorities.

(B) Amounts paid to the Agency as remittance under paragraph (j) of this section.

(C) Amounts paid to network providers under to 42 C.F.R. § 438.6(d).

(vi) Incurred claims paid by one PAHP that is later assumed by another entity must be reported by the assuming PAHP for the entire MLR reporting year and no incurred claims for that MLR reporting year may be reported by the ceding PAHP.

(3) *Activities that improve health care quality.* Activities that improve health care quality are limited to 2% of capitation payments and must be in one of the following categories:

(i) A Contractor activity that meets the requirements of 45 C.F.R. § 158.150(b) and is not excluded under 45 C.F.R. § 158.150(c).

(ii) A Contractor activity related to any EQR-related activity as described in 42 C.F.R. § 438.358(b) and (c).

(iii) Any Contractor expenditure that is related to Health Information Technology and meaningful use, meets the requirements placed on issuers found in 45 C.F.R. § 158.151, and is not considered incurred claims, as defined in paragraph (e)(2) of this section.

(4) *Fraud prevention activities.* Contractor's expenditures on activities related to fraud prevention as adopted for the private market at 45 C.F.R. part 158. Expenditures under this paragraph must not include expenses for fraud reduction efforts in paragraph (e)(2)(iii)(B) of this section.

(f) *Denominator*—(1) *Required elements.* The denominator of Contractor's MLR for a MLR reporting year must equal the adjusted premium revenue. The adjusted premium revenue is the Contractor's premium revenue

(as defined in paragraph (f)(2) of this section) minus the Contractor's Federal, State, and local taxes and licensing and regulatory fees (as defined in paragraph (f)(3) of this section) and is aggregated in accordance with paragraph (i) of this section.

(2) *Premium revenue.* Premium revenue includes the following for the MLR reporting year:

(i) Agency capitation payments, developed in accordance with 42 C.F.R. § 438.4, to the Contractor for all enrollees under a risk contract approved under 42 C.F.R. § 438.3(a), excluding payments made under to 42 C.F.R. § 438.6(d).

(ii) Agency-developed one time payments, for specific life events of enrollees.

(iii) Other payments to the Contractor approved under 42 C.F.R. § 438.6(b)(3).

(iv) Unpaid cost-sharing amounts that the Contractor could have collected from enrollees under the Contract, except those amounts the Contractor can show it made a reasonable, but unsuccessful, effort to collect.

(v) All changes to unearned premium reserves.

(vi) Net payments or receipts related to risk sharing mechanisms developed in accordance with 42 C.F.R. § 438.5 or 42 C.F.R. § 438.6.

(3) *Federal, State, and local taxes and licensing and regulatory fees.* Taxes, licensing and regulatory fees for the MLR reporting year include:

(i) Statutory assessments to defray the operating expenses of any State or Federal department.

(ii) Examination fees in lieu of premium taxes as specified by State law.

(iii) Federal taxes and assessments allocated to Contractor, excluding Federal income taxes on investment income and capital gains and Federal employment taxes.

(iv) State and local taxes and assessments including:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State or locality directly.

(B) Guaranty fund assessments.

(C) Assessments of State or locality industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State or locality income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

(E) State or locality premium taxes plus State or locality taxes based on reserves, if in lieu of premium taxes.

(v) Payments made by Contractor that are otherwise exempt from Federal income taxes, for community benefit expenditures as defined in 45 C.F.R. § 158.162(c), limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by Contractor's earned premium in the State.

(4) *Denominator when Contractor is assumed.* The total amount of the denominator for Contractor if Contractor is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no amount under this paragraph for that year may be reported by the ceding PAHP.

(g) *Allocation of expense*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.

(ii) Expenditures that benefit multiple contracts or populations, or contracts other than those being reported, must be reported on a pro rata basis.

(2) *Methods used to allocate expenses.* (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.

(iii) Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.

(h) *Credibility adjustment.* (1) Contractor may add a credibility adjustment to a calculated MLR if the MLR reporting year experience is partially credible. The credibility adjustment must be added to the reported MLR calculation before calculating any remittances.

(2) Contractor may not add a credibility adjustment to a calculated MLR if the MLR reporting year experience is fully credible.

(3) If Contractor's experience is non-credible, it is presumed to meet or exceed the MLR calculation standards in this section.

(4) On an annual basis, CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the following methodology:

(i) CMS will use the most recently available and complete managed care encounter data or FFS claims data, and enrollment data, reported by the states to CMS. This data may cover more than 1 year of experience.

(ii) CMS will calculate the credibility adjustment so that a MCO, PIHP, or PAHP receiving a capitation payment that is estimated to have a medical loss ratio of 85 percent would be expected to experience a loss ratio less than 85 percent 1 out of every 4 years, or 25 percent of the time.

(iii) The minimum number of member months necessary for a MCO's PIHP's, or PAHP's medical loss ratio to be determined at least partially credible will be set so that the credibility adjustment would not exceed 10 percent for any partially credible MCO, PIHP, or PAHP. Any MCO, PIHP, or PAHP with enrollment less than this number of member months will be determined non-credible.

(iv) The minimum number of member months necessary for a MCO's PIHP's, or PAHP's medical loss ratio to be determined fully credible will be set so that the minimum credibility adjustment for any partially credible MCO, PIHP, or PAHP would be greater than 1 percent. Any MCO, PIHP, or PAHP with enrollment greater than this number of member months will be determined to be fully credible.

(v) A MCO, PIHP, or PAHP with a number of enrollee member months between the levels established for non-credible and fully credible plans will be deemed partially credible, and CMS will develop adjustments, using linear interpolation, based on the number of enrollee member months.

(vi) CMS may adjust the number of enrollee member months necessary for an MCO's, PIHP's, or PAHP's experience to be non-credible, partially credible, or fully credible so that the standards are rounded for the purposes of administrative simplification. The number of member months will be rounded to 1,000 or a different degree of rounding as appropriate to ensure that the credibility thresholds are consistent with the objectives outlined herein.

(i) *Aggregation of data.* Contractor shall aggregate data for all Medicaid eligibility groups covered under the Contract with the State unless the State requires separate reporting and a separate MLR calculation for specific populations.

(j) *Remittance to the Agency if specific MLR is not met.* Contractor shall provide a remittance for an MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 85 percent or higher as set forth in this Contract. Contractor shall remit payment to the Agency within 90 days of submission of the MLR report for any MLR falling below the MLR standard.

(k) *Reporting requirements.* (1) Contractor shall submit a report to the Agency that includes at least the following information for each MLR reporting year:

(i) Total incurred claims with IBNR reported separately.

(ii) Expenditures on quality improving activities.

(iii) Expenditures related to activities compliant with 42 C.F.R. § 438.608(a)(1) through (5), (7), (8) and (b).

(iv) Non-claims costs.

(v) Premium revenue.

(vi) Taxes, licensing and regulatory fees.

(vii) Methodology(ies) for allocation of expenditures.

(viii) Any credibility adjustment applied.

(ix) The calculated MLR.

(x) Any remittance owed to the Agency, if applicable.

(xi) A comparison of the information reported in this paragraph with the audited financial report required under 42 C.F.R. § 438.3(m).

(xii) A description of the aggregation method used under paragraph (i) of this section.

(xiii) The number of member months.

(2) Contractor shall submit the report required in paragraph (k)(1) of this section in a timeframe and manner determined by the State, which must be within 12 months of the end of the MLR reporting year.

(3) Contractor shall require any third party vendor providing claims adjudication activities to provide all underlying data associated with MLR reporting to Contractor within 180 days of the end of the MLR reporting year or within 30 days of being requested by the Contractor, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting.

(l) *Newer experience.* The Agency, in its discretion, may exclude a Contractor that is newly contracted with the Agency from the requirements in this section for the first year of the Contractor's operation. Contractor must be required to comply with the requirements in this section during the next MLR reporting year in which the Contractor is in business with the Agency, even if the first year was not a full 12 months.

(m) *Recalculation of MLR.* In any instance where the Agency makes a retroactive change to the capitation payments for a MLR reporting year where the report has already been submitted to the Agency, the Contractor shall re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.

(n) *Attestation.* Contractor shall attest to the accuracy of the calculation of the MLR in accordance with requirements of this section when submitting the report required under paragraph (k) of this section.

§ 438.9 Provisions that apply to non-emergency medical transportation.

Contractor shall assist in the coordination of enrollee transportation with the enrollee's medical managed care organization.

§ 438.10 Information requirements.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Limited English proficient (LEP) means potential enrollees and enrollees who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English may be LEP and may be eligible to receive language assistance for a particular type of service, benefit, or encounter.

Prevalent means a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient.

Readily accessible means electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.

(b) *Applicability.* The provisions of this section apply to all managed care programs which operate under any authority in the Social Security Act.

(c) *Basic rules.* (1) Contractor shall provide all required information in this section to enrollees and potential enrollees in a manner and format that may be easily understood and is readily accessible by such enrollees and potential enrollees.

(2) The Agency will utilize its beneficiary support system required in 42 C.F.R. § 438.71.

(3) The Agency will operate a Web site that provides the content, either directly or by linking to individual PAHP Web sites, specified in paragraphs (g), (h), and (i) of this section.

(4) For consistency in the information provided to enrollees, the Agency will develop and require Contractor to use:

(i) Definitions for managed care terminology, including appeal, co-payment, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services and devices, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, medically necessary, network, non-participating provider, physician services, plan, preauthorization, participating provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, rehabilitation services and devices, skilled nursing care, specialist, and urgent care; and

(ii) Model enrollee handbooks and enrollee notices.

(5) Contractor shall provide the required information in this section to each enrollee.

(6) Enrollee information required in this section may not be provided electronically by the Agency, or Contractor unless all of the following are met:

(i) The format is readily accessible;

(ii) The information is placed in a location on the Agency or Contractor's Web site that is prominent and readily accessible;

(iii) The information is provided in an electronic form which can be electronically retained and printed;

(iv) The information is consistent with the content and language requirements of this section; and

(v) The enrollee is informed that the information is available in paper form without charge upon request and provides it upon request within 5 business days.

(7) Contractor shall have in place mechanisms to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(d) *Language and format.* The Agency will:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each of Contractor's service areas.

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. All written materials for potential enrollees must include taglines in the prevalent non-English languages in the State, 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 as required by 42 C.F.R. § 438.71(a). Large print means printed in a font size no smaller than 18 point.

(3) Require Contractor to make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, available in the prevalent non-English languages in its particular service area. Written materials must also be made available in alternative formats upon request of the potential enrollee or enrollee at no cost. Auxiliary aids and services must also be made available upon request of the potential enrollee or enrollee at no cost. Written materials must include taglines in the prevalent non-English languages in the state, as well as large print, explaining the availability of written translation or oral interpretation to understand the information provided and the toll-free and TTY/TDY telephone number of Contractor's member/customer service unit. Large print means printed in a font size no smaller than 18 point.

(4) Make interpretation services available to each potential enrollee and require Contractor to make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language. Oral interpretation requirements apply to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify potential enrollees, and require Contractor to notify its enrollees—

(i) That oral interpretation is available for any language and written translation is available in prevalent languages;

(ii) That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

(iii) How to access the services in paragraphs (d)(5)(i) and (ii) of this section.

(6) Provide, and require Contractor to provide, all written materials for potential enrollees and enrollees consistent with the following:

(i) Use easily understood language and format.

(ii) Use a font size no smaller than 12 point.

(iii) 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.

(iv) 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 point.

(e) *Information for potential enrollees.* (1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee, either in paper or electronic form as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary managed care program, or is first required to enroll in a mandatory managed care program; and

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available PAHPs.

(2) The information for potential enrollees must include, at a minimum, all of the following:

(i) Information about the potential enrollee's right to disenroll consistent with the requirements of 42 C.F.R. § 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;

(ii) The basic features of managed care;

(iii) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program. For mandatory and voluntary populations, the length of the enrollment period and all disenrollment opportunities available to the enrollee must also be specified;

(iv) The service area covered by each PAHP.

(v) Covered benefits including:

(A) Which benefits are provided by Contractor; and

(B) Which, if any, benefits are provided directly by the State.

(C) For a counseling or referral service that Contractor does not cover because of moral or religious objections, the Agency will provide information about where and how to obtain the service;

(vi) The provider directory and formulary information required in paragraphs (h) and (i) of this section;

(vii) Any cost-sharing that will be imposed by Contractor consistent with those set forth in the State plan;

(viii) The requirements for each PAHP to provide adequate access to covered services, including the network adequacy standards established in 42 C.F.R. § 438.68;

(ix) The Contractor's responsibilities for coordination of enrollee care; and

(x) To the extent available, quality and performance indicators for each PAHP, including enrollee satisfaction.

(f) *Information for all enrollees of Contractor: General requirements.* (1) Contractor shall 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.

(2) The Agency will notify all enrollees of their right to disenroll consistent with the requirements of 42 C.F.R. § 438.56 at least annually. Such notification must clearly explain the process for exercising this disenrollment right, as well as the alternatives available to the enrollee based on their specific circumstance. The Agency will send the notice no less than 60 calendar days before the start of each enrollment period.

(3) Contractor shall make available, upon request, any physician incentive plans in place as set forth in 42 C.F.R. § 438.3(i).

(g) *Information for enrollees of Contractor—Enrollee handbook.* (1) Contractor shall provide each enrollee an enrollee handbook, within a reasonable time after receiving notice of the beneficiary's enrollment, which serves a similar function as the summary of benefits and coverage described in 45 C.F.R. § 147.200(a).

(2) The content of the enrollee handbook must include information that enables the enrollee to understand how to effectively use the managed care program. This information must include at a minimum:

(i) Benefits provided by the Contractor.

(ii) How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided.

(A) In the case of a counseling or referral service that Contractor does not cover because of moral or religious objections, the Contractor shall inform enrollees that the service is not covered by Contractor.

(B) Contractor shall inform enrollees how they can obtain information from the State about how to access the services described in paragraph (g)(2)(i)(A) of this section.

(iii) 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.

(iv) 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.

(v) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes an emergency medical condition and emergency services.

(B) The fact that prior authorization is not required for emergency services.

(C) 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.

(vi) Any restrictions on the enrollee's freedom of choice among network providers.

(vii) *Reserved (not applicable to a dental-only PAHP).*

(viii) Cost sharing, if any is imposed under the State plan.

(ix) Enrollee rights and responsibilities, including the elements specified in 42 C.F.R. § 438.100.

(x) The process of selecting and changing the enrollee's primary care provider.

(xi) Grievance, appeal, and fair hearing procedures and timeframes, consistent with 42 C.F.R. part 438, subpart F, in a State-developed or State-approved description. Such information must include:

(A) The right to file grievances and appeals.

(B) The requirements and timeframes for filing a grievance or appeal.

(C) The availability of assistance in the filing process.

(D) The right to request a State fair hearing after Contractor has made a determination on an enrollee's appeal which is adverse to the enrollee.

(E) The fact that, when requested by the enrollee, benefits that Contractor 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, and that 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.

(xii) *Reserved (not applicable to a dental-only PAHP).*

(xiii) How to access auxiliary aids and services, including additional information in in alternative formats or languages.

(xiv) The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees.

(xv) Information on how to report suspected fraud or abuse;

(xvi) Any other content required by the State.

(3) Information required by this paragraph to be provided by Contractor will be considered to be provided if Contractor:

(i) Mails a printed copy of the information to the enrollee's mailing address;

(ii) Provides the information by email after obtaining the enrollee's agreement to receive the information by email;

(iii) Posts the information on the Contractor's Web site 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

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

(4) Contractor shall give each enrollee notice of any change that the State defines as significant in the information specified in this paragraph (g), at least 30 days before the intended effective date of the change.

(h) *Information for all enrollees of Contractor—Provider Directory.* (1) Contractor shall make available in paper form upon request and electronic form, the following information, as well as other information required by the Agency, about its network providers:

(i) The provider's name as well as any group affiliation.

(ii) Street address(es).

(iii) Telephone number(s).

(iv) Web site URL, as appropriate.

(v) Specialty, as appropriate.

(vi) Whether the provider will accept new enrollees.

(vii) The provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office, and whether the provider has completed cultural competence training.

(viii) Whether the provider's office/facility has accommodations for people with physical disabilities, including offices, exam room(s) and equipment.

(2) The provider directory must include the information in paragraph (h)(1) of this section for each of the following provider types if covered under the contract:

(i) Physicians, including specialists;

(ii) Hospitals;

(iii) Pharmacies;

(iv) Behavioral health providers; and

(v) LTSS providers, as appropriate.

(3) Information included in a paper provider directory must be updated at least monthly and electronic provider directories must be updated no later than 30 calendar days after the Contractor receives updated provider information.

(4) Provider directories must be made available on the Contractor's Web site in a machine readable file and format as specified by the Secretary.

(i) *Information for all enrollees of Contractor: Formulary. Reserved (not applicable to dental-only PAHPs because pharmaceuticals are covered by the enrollee's medical plan).*

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) Contractor shall 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 Contractor declines to include individual or groups of providers in its provider network, it shall give the affected providers written notice of the reason for its decision.

(2) In all contracts with network providers, Contractor shall comply with the requirements specified in 42 C.F.R. § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the Contractor to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the Contractor from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the Contractor from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

§ 438.14 Requirements that apply to PAHP contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs).

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Indian means any individual defined at 25 U.S.C. §§ 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 C.F.R. § 136.12. This means the individual:

(i) Is a member of a Federally recognized Indian tribe;

(ii) Resides in an urban center and meets one or more of the four criteria:

(A) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(D) Is determined to be an Indian under regulations issued by the Secretary;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(iv) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

Indian health care provider (IHCP) means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

Indian managed care entity (IMCE) means a MCO, PIHP, PAHP, PCCM, or PCCM entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C) of the Social Security Act) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of one or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

(b) *Network and coverage requirements.* Contractor shall:

(1) Demonstrate that there are sufficient IHCPs participating in the provider network of Contractor to ensure timely access to services available under the Contract from such providers for Indian enrollees who are eligible to receive services.

(2) Pay IHCPs for covered services provided to Indian enrollees who are eligible to receive services from such providers as follows:

(i) At a rate negotiated between the Contractor and the IHCP, or

(ii) In the absence of a negotiated rate, at a rate not less than the level and amount of payment that the Contractor would make for the services to a participating provider which is not an IHCP; and

(iii) Make payment to all IHCPs in its network in a timely manner as required for payments to practitioners in individual or group practices under 42 C.F.R. § 447.45 and 447.46.

(3) Permit any Indian who is enrolled with the Contractor and eligible to receive services from a IHCP primary care provider participating as a network provider, to choose that IHCP as his or her primary care provider, as long as that provider has capacity to provide the services.

(4) Permit Indian enrollees to obtain services covered under the Contract between the State and the Contractor from out-of-network IHCPs from whom the enrollee is otherwise eligible to receive such services.

(5) If timely access to covered services cannot be ensured due to few or no IHCPs, Contractor will be considered to have met the requirement in paragraph (b)(1) of this section if—

(i) Indian enrollees are permitted by the Contractor to access out-of-State IHCPs; or

(ii) If this circumstance is deemed to be good cause for disenrollment from both the Contractor and the State's managed care program in accordance with 42 C.F.R. § 438.56(c).

(6) Contractor shall permit an out-of-network IHCP to refer an Indian enrollee to a network provider.

(c) *Payment requirements.* (1) When an IHCP is enrolled in Medicaid as a FQHC but not a participating provider of the Contractor, it must be paid an amount equal to the amount the Contractor would pay a FQHC that is a network provider but is not an IHCP, including any supplemental payment from the State to make up the difference between the amount the Contractor pays and what the IHCP FQHC would have received under FFS.

(2) When an IHCP is not enrolled in Medicaid as a FQHC, regardless of whether it participates in the Contractor's network or not, it has the right to receive its applicable encounter rate published annually in the Federal Register by the Indian Health Service, or in the absence of a published encounter rate, the amount it would receive if the services were provided under the State plan's FFS payment methodology.

(3) When the amount a IHCP receives from Contractor is less than the amount required by paragraph (c)(2) of this section, the Agency will make a supplemental payment to the IHCP to make up the difference between the amount the Contractor pays and the amount the IHCP would have received under FFS or the applicable encounter rate.

(d) *Enrollment in IMCEs.* An IMCE may restrict its enrollment to Indians in the same manner as Indian Health Programs, as defined in 25 U.S.C. 1603(12), may restrict the delivery of services to Indians, without being in violation of the requirements in 42 C.F.R. § 438.3(d).

Subpart B—State Responsibilities

§ 438.50 State Plan requirements.

Reserved.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities.

(a) *General rule.*

(1) The Agency will ensure that beneficiaries are given a choice of at least two PAHPs.

(2) – (3) Reserved.

(b) *Exception for rural area residents.* (1) Under any managed care program authorized by any of the following, and subject to the requirements of paragraph (b)(2) of this section, the Agency will limit a rural area resident to a single PAHP:

(i) A State plan amendment under section 1932(a) of the Social Security Act.

(ii) A waiver under section 1115(a) of the Social Security Act.

(iii) A waiver under section 1915(b) of the Social Security Act.

(2) To comply with this paragraph (b), the Agency will permit the beneficiary—

(i) To choose from at least two primary care providers; and

(ii) To obtain services from any other provider under any of the following circumstances:

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

(B) The provider is not part of the network, but is the main source of a service to the beneficiary, provided that—

(*1*) The provider is given the opportunity to become a participating provider under the same requirements for participation in the Contractor's as other network providers of that type.

(*2*) 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).

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

(D) 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.

(E) The Agency determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph (b), "rural area" is any county designated as "micro," "rural," or "County with Extreme Access Considerations (CEAC)" in the Medicare Advantage Health Services Delivery (HSD) Reference file for the applicable calendar year.

(c) *Exception for certain health insuring organizations (HIOs).* Reserved.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single PAHP under paragraph (b) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under 42 C.F.R. § 438.56(c).

§ 438.54 Managed care enrollment.

Reserved.

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Reserved.*

(b) *Disenrollment requested by the Contractor.*

(1) Contractor shall only request disenrollment of an enrollee for reasons set forth in the Contract.

(2) Contractor may not request disenrollment because of 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 Contractor seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees).

(3) Contractor shall not request disenrollment for reasons other than those permitted under this Contract.

(c) *Disenrollment requested by the enrollee.* A beneficiary may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the beneficiary's initial enrollment into the Contractor, or during the 90 days following the date the State sends the beneficiary notice of that enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the beneficiary to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in 42 C.F.R. § 438.702(a)(4).

(d) *Procedures for disenrollment*—(1) *Request for disenrollment.* The beneficiary (or his or her representative) must submit an oral or written request—

(i) To the State (or its agent).

(ii) Reserved.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee moves out of the Contractor's service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the provider network; and the enrollee's

primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) *Reserved (not applicable to a dental-only PAHP).*

(v) Other reasons, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's care needs.

(3) *Contractor's action on request.* (i) When the Contractor receives a request for disenrollment, Contractor shall address the request through the Contractor's grievance process before referring the request to the Agency.

(ii) If the Agency fails to make a disenrollment determination so that the beneficiary can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the beneficiary, or one referred by the Contractor, the Agency will take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the Contractor at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the Contractor's grievance procedures.* (i) The Agency does require that the enrollee seek redress through the Contractor's grievance system before making a determination on the enrollee's request.

(ii) The grievance process must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in paragraph (e)(1) of this section.

(iii) If, as a result of the grievance process, the Contractor approves the disenrollment, the State agency must still make the final determination concerning disenrollment.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment or Contractor refers the request to the State.

(2) If the Agency fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved for the effective date that would have been established had the Agency complied with paragraph (e)(1) of this section.

(f) *Notice and appeals.* The Agency will:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period. The notice must include an explanation of all of the enrollee's disenrollment rights as specified in this section.

(2) Ensure timely access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* A beneficiary who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less will be automatically reenrolled in the same PAHP if eligibility is retained within that 2 month period.

§ 438.58 Conflict of interest safeguards.

The State does have 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 the enrollment processes specified in 42 C.F.R. § 438.54(b). These safeguards are at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Prohibition of additional payments for services covered under the Contract.

Contractor shall make no payment to a network provider other than by the Contractor for services covered under the Contract, except when these payments are specifically required to be made by the State in Title XIX of the Social Security Act, in 42 C.F.R. chapter IV, or when the State agency makes direct payments to network providers for graduate medical education costs approved under the State plan.

§ 438.62 Continued services to enrollees.

(a) The Agency will arrange for Medicaid services to be provided without delay to any Medicaid enrollee of Contractor the contract of which is terminated and for any Medicaid enrollee who is disenrolled from Contractor for any reason other than ineligibility for Medicaid.

(b) The Agency will have in effect a transition of care policy to ensure continued access to services during a transition from FFS to Contractor or transition from one PAHP to another when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization.

(1) The transition of care policy will include the following:

(i) The enrollee has access to services consistent with the access they previously had, and is permitted to retain their current provider for a period of time if that provider is not in the Contractor network.

(ii) The enrollee is referred to appropriate providers of services that are in the network.

(iii) The Agency, in the case of Contractor having previously provided services to an enrollee, will fully and timely comply with requests for historical utilization data from the new PAHP in compliance with Federal and State law.

(iv) Consistent with Federal and State law, the enrollee's new provider(s) will be able to obtain copies of the enrollee's medical records, as appropriate.

(v) The Agency will also implement any other necessary procedures as specified by the Secretary to ensure continued access to services to prevent serious detriment to the enrollee's health or reduce the risk of hospitalization or institutionalization.

(2) Contractor shall implement a transition of care policy consistent with the requirements in paragraph (b)(1) of this section and at least meets the Agency defined transition of care policy.

(3) The Agency will make its transition of care policy publicly available and provide instructions to enrollees and potential enrollees on how to access continued services upon transition. At a minimum, the transition of care policy must be described in the quality strategy, under 42 C.F.R. § 438.340, and explained to individuals in the materials to enrollees and potential enrollees, in accordance with 42 C.F.R. § 438.10.

(c) *Applicability date. Reserved.*

§ 438.66 State monitoring requirements.

(a) *General requirement.* Reserved.

(b) The Agency's managed care monitoring system addresses all aspects of the managed care program, including the performance of each PAHP in at least the following areas:

(1) Administration and management.

(2) Appeal and grievance systems.

(3) Claims management.

(4) Enrollee materials and customer services, including the activities of the beneficiary support system.

(5) Finance, including medical loss ratio reporting.

(6) Information systems, including encounter data reporting.

(7) Marketing.

(8) Medical management, including utilization management and case management.

(9) Program integrity.

(10) Provider network management, including provider directory standards.

(11) Availability and accessibility of services, including network adequacy standards.

(12) Quality improvement.

(13) Areas related to the delivery of LTSS not otherwise included in paragraphs (b)(1) through (12) of this section as applicable to the managed care program.

(14) All other provisions of the contract, as appropriate.

(c) The Agency will use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:

(1) Enrollment and disenrollment trends in each PAHP.

(2) Member grievance and appeal logs.

(3) Provider complaint and appeal logs.

(4) Findings from the Agency's External Quality Review process.

(5) Results from any enrollee or provider satisfaction survey conducted by the PAHP.

(6) Performance on required quality measures.

(7) Medical management committee reports and minutes.

(8) The annual quality improvement plan for each PAHP.

(9) Audited financial and encounter data submitted by each PAHP.

(10) The medical loss ratio summary reports required by 42 C.F.R. § 438.8.

(11) Customer service performance data submitted by each PAHP and performance data submitted by the beneficiary support system.

(12) Any other data related to the provision of LTSS not otherwise included in paragraphs (c)(1) through (11) of this section as applicable to the managed care program.

(d)(1) The Agency will assess the readiness of Contractor as follows:

(i) Prior to the Agency implementing a managed care program, whether the program is voluntary or mandatory.

(ii) When Contractor has not previously contracted with the Agency.

(iii) When any PAHP currently contracting with the Agency will provide or arrange for the provision of covered benefits to new eligibility groups.

(2) The Agency will conduct a readiness review of Contractor as follows:

(i) Started at least 3 months prior to the effective date of the events described in paragraph (d)(1) of this section.

(ii) Completed in sufficient time to ensure smooth implementation of an event described in paragraph (d)(1) of this section.

(iii) Submitted to CMS for CMS to make a determination that the Contract or Contract amendment associated with an event described in paragraph (d)(1) of this section is approved under 42 C.F.R. § 438.3(a).

(3) Readiness reviews described in paragraphs (d)(1)(i) and (ii) of this section will include both a desk review of documents and on-site reviews of Contractor. Readiness reviews described in paragraph (d)(1)(iii) of this section must include a desk review of documents and may, at the Agency's option, include an on-site review. On-site reviews will include interviews with Contractor staff and leadership that manage key operational areas.

(4) The Agency's readiness review will assess the ability and capacity of Contractor to perform satisfactorily for the following areas:

(i) Operations/Administration, including—

(A) Administrative staffing and resources.

(B) Delegation and oversight of Contractor responsibilities.

(C) Enrollee and provider communications.

(D) Grievance and appeals.

(E) Member services and outreach.

(F) Provider Network Management.

(G) Program Integrity/Compliance.

(ii) Service delivery, including—

(A) Case management/care coordination/service planning.

(B) Quality improvement.

(C) Utilization review.

(iii) Financial management, including—

(A) Financial reporting and monitoring.

(B) Financial solvency.

(iv) Systems management, including—

(A) Claims management.

(B) Encounter data and enrollment information management.

(e)(1) The Agency will submit to CMS no later than 180 days after each contract year, a report on each managed care program administered by the Agency, regardless of the authority under which the program operates.

(i) The initial report will be due after the contract year following the release of CMS guidance on the content and form of the report.

(ii) For States that operate their managed care program under section 1115(a) of the Social Security Act authority, submission of an annual report that may be required by the Special Terms and Conditions of the section

1115(a) demonstration program will be deemed to satisfy the requirement of this paragraph (e)(1) provided that the report includes the information specified in paragraph (e)(2) of this section.

(2) The program report will provide information on and an assessment of the operation of the managed care program on, at a minimum, the following areas:

(i) Financial performance of each PAHP, including MLR experience.

(ii) Encounter data reporting by each PAHP.

(iii) Enrollment and service area expansion (if applicable) of each PAHP.

(iv) Modifications to, and implementation of PAHP benefits covered under the contract with the State.

(v) Grievance, appeals, and State fair hearings for the managed care program.

(vi) Availability and accessibility of covered services within the PAHP contracts, including network adequacy standards.

(vii) Evaluation of Contractor's performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance.

(viii) Results of any sanctions or corrective action plans imposed by the Agency or other formal or informal intervention with a contracted PAHP to improve performance.

(ix) Activities and performance of the beneficiary support system.

(x) Any other factors in the delivery of LTSS not otherwise addressed in (e)(2)(i)-(ix) of this section as applicable.

(3) The program report required in this section will be:

(i) Posted on the Web site required under 42 C.F.R. § 438.10(c)(3).

(ii) Provided to the Medical Care Advisory Committee, required under 42 C.F.R. § 431.12.

(iii) Provided to the stakeholder consultation group specified in 42 C.F.R. § 438.70, to the extent that the managed care program includes LTSS.

(f) *Applicability.* Reserved.

§ 438.68 Network adequacy standards.

(a) *General rule.* The Agency will develop and enforce network adequacy standards consistent with this section.

(b) *Provider-specific network adequacy standards.* (1) The Agency will develop time and distance standards for the following provider types covered under the Contract:

(i) Primary care, adult and pediatric.

(ii) Reserved.

(iii) Reserved.

(iv) Specialist, adult and pediatric.

(v) Reserved.

(vi) Reserved.

(vii) Pediatric dental.

(viii) Additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS, for the provider type to be subject to time and distance access standards.

(2) *LTSS.* Reserved.

(3) *Scope of network adequacy standards.* Network standards established in accordance with paragraphs (b)(1) and (2) of this section will include all geographic areas covered by the managed care program or, if applicable, the Contract between the State and the Contractor. The Agency may have varying standards for the same provider type based on geographic areas.

(c) *Development of network adequacy standards.* (1) In developing network adequacy standards consistent with paragraph (b)(1) of this section, the Agency will consider, at a minimum, the following elements:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services.

(iii) The characteristics and health care needs of specific Medicaid populations covered in the PAHP contract.

(iv) The numbers and types (in terms of training, experience, and specialization) of network providers required to furnish the contracted Medicaid services.

(v) The numbers of network providers who are not accepting new Medicaid patients.

(vi) The geographic location of network providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees.

(vii) The ability of network providers to communicate with limited English proficient enrollees in their preferred language.

(viii) The ability of network providers to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(ix) The availability of triage lines or screening systems, as well as the use of telemedicine, e-visits, and/or other evolving and innovative technological solutions.

(2) *Reserved.*

(d) *Exceptions process.* (1) To the extent the Agency permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved will be:

(i) Specified in this Contract;

(ii) Based, at a minimum, on the number of providers in that specialty practicing in the Contractor's service area.

(2) If the Agency grants an exception in accordance with paragraph (d)(1) of this section to Contractor, the Agency will monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under 42 C.F.R. § 438.66.

(e) *Publication of network adequacy standards.* The Agency will publish the standards developed in accordance with paragraphs (b)(1) and (2) of this section on the Web site required by 42 C.F.R. § 438.10. Upon request, network adequacy standards will also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

§ 438.70 Stakeholder engagement when LTSS is delivered through a managed care program.

Reserved. (Not applicable to a dental-only PAHP).

§ 438.71 Beneficiary support system.

Reserved.

§ 438.74 State oversight of the minimum MLR requirement.

Reserved.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.*

(1) Contractor shall have written policies regarding the enrollee rights specified in this section; and

(2) Contractor shall comply with any applicable Federal and State laws that pertain to enrollee rights, and ensure that its employees and contracted providers observe and protect those rights.

(b) *Specific rights*—(1) *Basic requirement.* Contractor shall ensure that each of its enrollees is guaranteed the rights as specified in paragraphs (b)(2) and (3) of this section.

(2) An enrollee of Contractor has the following rights: The right to—

(i) Receive information in accordance with 42 C.F.R. § 438.10.

(ii) Be treated with respect and with due consideration for his or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in 42 C.F.R. § 438.10(g)(2)(ii)(A) and (B).)

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

(v) 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.

(vi) If the privacy rule, as set forth in 45 C.F.R. 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 C.F.R. §§ 164.524 and 164.526.

(3) An enrollee of Contractor has the right to be furnished health care services in accordance with 42 C.F.R. §§ 438.206 through 438.210, to the extent that such services are covered by the Contract.

(c) *Free exercise of rights.* Each enrollee is free to exercise his or her rights, and Contractor shall ensure that the enrollee's exercise of those rights will not have any effect on the way the Contractor and its network providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* Contractor shall comply with any other applicable Federal and State laws (including: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 C.F.R. part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 C.F.R. part 91; the Rehabilitation Act of 1973; Title IX of the Education Amendments of 1972 (regarding education programs and activities); Titles II and III of the Americans with Disabilities Act; and section 1557 of the Patient Protection and Affordable Care Act.

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) Contractor may not prohibit, or otherwise restrict, a provider 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:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or non-treatment.

(iv) 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.

(2) Subject to the information requirements of paragraph (b) of this section, if Contractor would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if Contractor objects to the service on moral or religious grounds.

(b) *Information requirements: Contractor responsibility.* (1)(i) If Contractor elects the option provided in paragraph (a)(2) of this section, it must furnish information about the services it does not cover as follows:

(A) To the State—

(*1*) With its application for a Medicaid contract.

(*2*) Whenever it adopts the policy during the term of the contract.

(B) Consistent with the provisions of 42 C.F.R. § 438.10, to enrollees, within 90 days after adopting the policy for any particular service.

(ii) Although this timeframe would be sufficient to entitle the Contractor to the option provided in paragraph (a)(2) of this section, the overriding rule in 42 C.F.R. § 438.10(g)(4) requires the Agency, its contracted representative, or the Contractor to furnish the information at least 30 days before the effective date of the policy.

(2) As specified in 42 C.F.R. § 438.10(g)(2)(ii)(A) and (B), the Contractor must inform enrollees how they can obtain information from the Agency about how to access the service excluded under paragraph (a)(2) of this section.

(c) *Information requirements: State responsibility.* For each service excluded Cotnractor under paragraph (a)(2) of this section, the State will provide information on how and where to obtain the service, as specified in 42 C.F.R. § 438.10.

(d) *Sanction. Reserved (not applicable to a dental-only PAHP).*

§ 438.104 Marketing activities.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the Contractor with a potential enrollee for the purpose of marketing as defined in this paragraph (a).

Marketing means any communication, from Contractor to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in Contractor's Medicaid product, or either to not enroll in or to disenroll from another PAHP's Medicaid product. Marketing does not include communication to a Medicaid beneficiary from the issuer of a qualified health plan, as defined in 45 C.F.R. § 155.20, about the qualified health plan.

Marketing materials means materials that—

(i) Are produced in any medium, by or on behalf of Contractor; and

(ii) Can reasonably be interpreted as intended to market the Contractor to potential enrollees.

PAHP and/or Contractor includes any of the entity's employees, network providers, agents, or contractors.

Private insurance does not include a qualified health plan, as defined in 45 C.F.R. § 155.20.

(b) *Contract requirements.*

(1) Contractor shall—

(i) Not distribute any marketing materials without first obtaining Agency approval.

(ii) Distribute the materials to its entire service area as indicated in the contract.

(iii) Comply with the information requirements of 42 C.F.R. § 438.10 to ensure that, before enrolling, the beneficiary receives, from the entity or the Agency, the accurate oral and written information he or she needs to make an informed decision on whether to enroll.

(iv) Not seek to influence enrollment in conjunction with the sale or offering of any private insurance.

(v) Not, directly or indirectly, engage in door-to-door, telephone, email, texting, or other cold-call marketing activities.

(2) Specify the methods by which the entity ensures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the beneficiaries or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The beneficiary must enroll in Contractor to obtain benefits or to not lose benefits; or

(ii) The Contractor is endorsed by CMS, the Federal or State government, or similar entity.

(c) *Agency review.* In reviewing the marketing materials submitted by the entity, the Agency will consult with the Medical Care Advisory Committee established under 42 C.F.R. § 431.12 or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Contractor's shall ensure that its Medicaid enrollees are not held liable for any of the following:

(a) The Contractor's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The Agency does not pay the Contractor; or

(2) The Agency, or the Contractor does not pay the individual or health care provider that furnished the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the Contractor covered the services directly.

§ 438.108 Cost sharing.

Any cost sharing imposed on Medicaid enrollees must be in accordance with 42 C.F.R. §§ 447.50 through 447.82.

§ 438.110 Member advisory committee.

(a) *General rule.* Reserved.

(b) *Committee composition.* Reserved.

§ 438.114 Emergency and poststabilization services.

(a) *Definitions.* As used in this section—

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:

(i) Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(ii) Serious impairment to bodily functions.

(iii) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are as follows:

(i) Furnished by a provider that is qualified to furnish these services under Title XIX.

(ii) Needed to evaluate or stabilize an emergency medical condition.

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 paragraph (e) of this section, to improve or resolve the enrollee's condition.

(b) *Coverage and payment: General rule.* For enrollees who have fee-for-service Medicaid, the Agency is responsible for coverage and payment of emergency services and poststabilization care services. For enrollees who are enrolled in a Medicaid MCO, the MCO is responsible for coverage and payment of emergency services and poststabilization care services.

(1) Reserved.

(2) Reserved.

(c) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, PCCM or PCCM entity; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) 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 paragraphs (1), (2), and (3) of the definition of emergency medical condition in paragraph (a) of this section.

(B) A representative of the MCO, PIHP, PAHP, PCCM, or PCCM entity instructs the enrollee to seek emergency services.

(2) *Reserved (not applicable to a dental-only PAHP).*

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

(i) Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, PIHP, PAHP or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) 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 entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at 42 C.F.R. § 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 Social Security Act and the States.

(f) *Applicability to Contractor.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the Contractor is responsible, the rules under this section apply.

§ 438.116 Solvency standards.

(a) *Requirement for assurances.* (1) Contractor must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the Contractor's debts if the entity becomes insolvent.

(2) Reserved.

Subpart D—MCO, PIHP and PAHP Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Contractor shall make all services covered under the State plan available and accessible to enrollees of Contractor in a timely manner. The Agency will ensure that Contractor provider networks for services covered under the Contract meet the standards developed by the Agency in accordance with 42 C.F.R. § 438.68.

(b) *Delivery network.* Contractor shall meet the following requirements:

(1) Maintains and monitors 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.

(2) *Reserved (not applicable to a dental-only PAHP).*

(3) Provides for a second opinion from a network provider, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the provider network is unable to provide necessary services, covered under the Contract, to a particular enrollee, Contractor must adequately and timely cover these services out of network for the enrollee, for as long as the Contractor's provider network is unable to provide them.

(5) Requires out-of-network providers to coordinate with Contractor for payment and ensures the cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its network providers are credentialed as required by 42 C.F.R. § 438.214.

(7) *Reserved (not applicable to a dental-only PAHP).*

(c) *Furnishing of services.*

(1) *Timely access.* Contractor shall:

(i) Meet and require its network providers to meet Agency standards for timely access to care and services, taking into account the urgency of the need for services.

(ii) 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 FFS, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by network providers.

(v) Monitor network providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply by a network provider.

(2) *Access and cultural considerations.* Contractor shall 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.

(3) *Accessibility considerations.* Contractor shall ensure that network providers provide physical access, reasonable accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(d) *Applicability date.* This Subpart D applies to this Contract beginning July 1, 2018. Until that applicability date, Contractor shall comply with 42 C.F.R. § 438.206 contained in the 42 C.F.R. parts 430 to 481, edition revised as of October 1, 2015.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* Contractor shall give assurances to the Agency and provide supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the Agency's standards for access to care under 42 C.F.R. part 438, including the standards at 42 C.F.R. § 438.68 and 42 C.F.R. § 438.206(c)(1).

(b) *Nature of supporting documentation.* Contractor shall submit documentation to the Agency, in a format specified by the Agency, to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of preventive, primary care, specialty services, and LTSS that is adequate for the anticipated number of enrollees for the service area (to the extent such services are covered under the Contract).

(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.

(c) *Timing of documentation.* Contractor shall submit the documentation described in paragraph (b) of this section as specified by the Agency, but no less frequently than the following:

(1) At the time it enters into a contract with the Agency.

(2) On an annual basis.

(3) At any time there has been a significant change (as defined by the Agency) in the Contractor's operations that would affect the adequacy of capacity and services, including—

(i) Changes in Contractor's services, benefits, geographic service area, composition of or payments to its provider network; or

(ii) Enrollment of a new population in the Contractor.

(d) *State review and certification to CMS.* After the Agency reviews the documentation submitted by the Contractor, the Agency will submit an assurance of compliance to CMS that the Contractor meets the Agency's requirements for availability of services, as set forth in 42 C.F.R. § 438.68 and 42 C.F.R. § 438.206. The submission to CMS will include documentation of an analysis that supports the assurance of the adequacy of the network for Contractor related to its provider network.

(e) *CMS' right to inspect documentation.* The Agency will make available to CMS, upon request, all documentation collected by the Agency from Contractor.

(f) *Applicability date.* This Section 438.207 applies to the Contract effective July 1, 2018. Until that applicability date, Contractor shall continue to comply with 42 C.F.R. § 438.207 contained in the 42 C.F.R. parts 430 to 481, edition revised as of October 1, 2015.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (3) of this section, Contractor shall comply with the requirements of this section.

(2) *PIHP and PAHP exception.* For PIHPs and PAHPs, the Agency determines, based on the scope of the entity's services, and on the way the Agency has organized the delivery of managed care services, whether a particular PIHP or PAHP is required to implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* Reserved.

(b) *Care and coordination of services for all Contractor enrollees.* Contractor shall implement procedures to deliver care to and coordinate services for all Contractor enrollees. These procedures must meet Agency requirements and must do the following:

(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. The enrollee must be provided information on how to contact their designated person or entity;

(2) Coordinate the services the Contractor furnishes to the enrollee:

(i) Between settings of care, including appropriate discharge planning for short term and long-term hospital and institutional stays;

(ii) With the services the enrollee receives from any other MCO, PIHP, or PAHP;

(iii) With the services the enrollee receives in FFS Medicaid; and

(iv) With the services the enrollee receives from community and social support providers.

(3) Provide that the Contractor makes a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful;

(4) Share with the State or other MCOs, PIHPs, and PAHPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities;

(5) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards; and

(6) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 C.F.R. parts 160 and 164 subparts A and E, to the extent that they are applicable.

(c) *Additional services for enrollees with special health care needs or who need LTSS*—(1) *Identification. Reserved (not applicable to a dental-only PAHP).*

(d) *Applicability date. Reserved.*

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Through this Contract:

(1) The Agency has identified, defined, and specified the amount, duration, and scope of each service that the Contractor is required to offer. The specific amount, duration, and scope requirements are set forth in Special Contract Attachments.

(2) The Agency hereby requires that Contractor provide such services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid, as set forth in 42 C.F.R. § 440.230, and for enrollees under the age of 21, as set forth in 42 C.F.R. subpart B of part 440.

(3) The Agency requires that Contractor:—

(i) Ensure that the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished.

(ii) 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.

(4) Only put in place appropriate limits on a service—

(i) On the basis of criteria applied under the State plan, such as medical necessity; or

(ii) For the purpose of utilization control, provided that—

(A) The services furnished can reasonably achieve their purpose, as required in paragraph (a)(3)(i) of this section;

(B) The services supporting individuals with ongoing or chronic conditions or who require long-term services and supports are authorized in a manner that reflects the enrollee's ongoing need for such services and supports; and

(C) *Reserved (not applicable to a dental-only PAHP).*

(5) Specify what constitutes "medically necessary services" in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program, including quantitative and non-quantitative treatment limits, as indicated in State statutes and regulations, the State Plan, and other Agency policy and procedures; and

(ii) Addresses the extent to which the Contractor is responsible for covering services that address:

(A) The prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability.

(B) The ability for an enrollee to achieve age-appropriate growth and development.

(C) The ability for an enrollee to attain, maintain, or regain functional capacity.

(D) *Reserved (not applicable to a dental-only PAHP).*

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, Contractor shall--

(1) have in place, and follow, written policies and procedures.

(2)

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions.

(ii) Consult with the requesting provider for medical services when appropriate.

(iii) *Reserved (not applicable to a dental-only PAHP).*

(3) 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 an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs.

(c) *Notice of adverse benefit determination.* Contractor shall notify the requesting provider, and give the enrollee written notice of any decision by the Contractor to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. The enrollee's notice must meet the requirements of 42 C.F.R. § 438.404.

(d) *Timeframe for decisions.*

(1) *Standard authorization decisions.* For standard authorization decisions, Contractor shall 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—

(i) The enrollee, or the provider, requests extension; or

(ii) The Contractor justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) *Expedited authorization decisions.* (i) For cases in which a provider indicates, or the Contractor 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 Contractor 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.

(ii) The Contractor may extend the 72 hour time period by up to 14 calendar days if the enrollee requests an extension, or if the Contractor justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(3) *Covered outpatient drug decisions. Reserved (not applicable to a dental-only PAHP).*

(e) *Compensation for utilization management activities.* Consistent with 42 C.F.R. § 438.3(i), and 42 C.F.R. § 422.208, Contractor shall not structure compensation to individuals or entities that conduct utilization management activities so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

§ 438.214 Provider selection.

(a) *General rules.* Contractor shall implement written policies and procedures for selection and retention of network providers and that those policies and procedures, at a minimum, meet the requirements of this section.

(b) *Credentialing and recredentialing requirements.* (1) The Agency will establish a uniform credentialing and recredentialing policy that addresses acute, primary, behavioral, substance use disorders, and LTSS providers, as appropriate, and requires Contractor to follow those policies.

(2) Contractor shall follow a documented process for credentialing and recredentialing of network providers.

(c) *Nondiscrimination.* Contractor network provider selection policies and procedures, consistent with 42 C.F.R. § 438.12, shall not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* (1) Contractor may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Social Security Act.

(c) [Reserved]

(e) *State requirements.* Contractor shall comply with any additional requirements established by the State.

§ 438.224 Confidentiality.

Consistent with 42 C.F.R. subpart F of part 431, for medical records and any other health and enrollment information that identifies a particular enrollee, Contractor shall use and disclose such individually identifiable health information in accordance with the privacy requirements in 45 C.F.R. parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

§ 438.228 Grievance and appeal systems.

(a) Contractor shall have in effect a grievance and appeal system that meets the requirements of 42 C.F.R. part 438, subpart F.

(b) The Agency will conduct random reviews of each delegated MCO, PIHP, or PAHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner of grievance and appeal obligations using Agency-approved notice language.

§ 438.230 Subcontractual relationships and delegation.

(a) *Applicability.* The requirements of this section apply to any contract or written arrangement that Contractor has with any subcontractor.

(b) *General rule.*

(1) Notwithstanding any relationship(s) that Contractor may have with any subcontractor, the Contractor shall maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its Contract with the Agency; and

(2) All contracts or written arrangements between the Contractor and any subcontractor must meet the requirements of paragraph (c) of this section.

(c) Each contract or written arrangement described in paragraph (b)(2) of this section must specify that:

(1) If any of the Contractor's activities or obligations under its Contract with the State are delegated to a subcontractor—

(i) The delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement.

(ii) The subcontractor agrees to perform the delegated activities and reporting responsibilities specified in compliance with the Contractor's Contract obligations.

(iii) 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 Agency or the Contractor determine that the subcontractor has not performed satisfactorily.

(2) The subcontractor agrees to comply with all applicable Medicaid laws, regulations, including applicable subregulatory guidance and contract provisions;

(3) The subcontractor agrees that—

(i) The Agency, CMS, the HHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, records, contracts, computer or other electronic systems of the subcontractor, or of the subcontractor's contractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the Contractor's Contract with the Agency.

(ii) The subcontractor will make available, for purposes of an audit, evaluation, or inspection under paragraph (c)(3)(i) of this section, its premises, physical facilities, equipment, books, records, contracts, computer or other electronic systems relating to its Medicaid enrollees.

(iii) The right to audit under paragraph (c)(3)(i) of 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.

(iv) If the Agency, CMS, or the HHS Inspector General determines that there is a reasonable possibility of fraud or similar risk, the Agency, CMS, or the HHS Inspector General may inspect, evaluate, and audit the subcontractor at any time.

§ 438.236 Practice guidelines.

(a) *Basic rule.* Reserved.

(b) *Adoption of practice guidelines.* Contractor shall adopt practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of providers in the particular field.

(2) Consider the needs of the Contractor's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Contractor shall disseminate the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.242 Health information systems.

(a) *General rule.* Contractor shall maintain a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of 42 C.F.R. part 438. The systems must provide information on areas including, but not limited to, utilization, claims, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* Contractor shall comply with the following:

(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 Social Security Act.

(2) Collect data on enrollee and provider characteristics as specified by the Agency, and on all services furnished to enrollees through an encounter data system or other methods as may be specified by the Agency.

(3) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data, including data from network providers the Contractor is compensating on the basis of capitation payments.

(ii) Screening the data for completeness, logic, and consistency.

(iii) 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.

(4) Make all collected data available to the Agency and upon request to CMS.

(c) *Enrollee encounter data.* Contractor shall:

(1) Collect and maintain sufficient enrollee encounter data to identify the provider who delivers any item(s) or service(s) to enrollees.

(2) Submit enrollee encounter data to the Agency at a frequency and level of detail to be specified by CMS and the Agency, based on program administration, oversight, and program integrity needs.

(3) Submit all enrollee encounter data that the Agency is required to report to CMS under 42 C.F.R. § 438.818.

(4) Comply with specifications for submitting encounter data to the Agency in standardized ASC X12N 837 and NCPDP formats, and the ASC X12N 835 format as appropriate.

(d) *State review and validation of encounter data.* The Agency will review and validate that the encounter data collected, maintained, and submitted to the Agency by Contractor meets the requirements of this section. The Agency will have procedures and quality assurance protocols to ensure that enrollee encounter data submitted under paragraph (c) of this section is a complete and accurate representation of the services provided to the enrollees under the contract between the Agency and the Contractor.

Subpart E—Quality Measurement and Improvement; External Quality Review

§ 438.310 Basis, scope, and applicability.

Reserved.

§ 438.320 Definitions.

As used in this subpart—

Access, as it pertains to external quality review, means the timely use of services to achieve optimal outcomes, as evidenced by managed care plans successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under 42 C.F.R. § 438.68 (Network adequacy standards) and 42 C.F.R. § 438.206 (Availability of services).

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)), or their contractors furnish to Medicaid beneficiaries.

External quality review organization means an organization that meets the competence and independence requirements set forth in 42 C.F.R. § 438.354, and performs external quality review, other EQR-related activities as set forth in 42 C.F.R. § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means, and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Health care services means all Medicaid services provided by an MCO, PIHP, or PAHP under contract with the State Medicaid agency in any setting, including but not limited to medical care, behavioral health care, and long-term services and supports.

Outcomes means changes in patient health, functional status, satisfaction or goal achievement that result from health care or supportive services.

Quality, as it pertains to external quality review, means the degree to which an MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) increases the likelihood of desired outcomes of its enrollees through:

(1) Its structural and operational characteristics.

(2) The provision of services that are consistent with current professional, evidenced-based-knowledge.

(3) Interventions for performance improvement.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.330 Quality assessment and performance improvement program.

(a) *General rules.* (1) Contractor shall establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees that includes the elements identified in paragraph (b) of this section.

(2) After consulting with States and other stakeholders and providing public notice and opportunity to comment, CMS may specify performance measures and PIPs, which must be included in the standard measures identified and PIPs required by the Agency in accordance with paragraphs (c) and (d) of this section. The Agency may request an exemption from including the performance measures or PIPs established under paragraph (a)(2) of this section, by submitting a written request to CMS explaining the basis for such request.

(3) Reserved.

(b) *Basic elements of quality assessment and performance improvement programs.* The comprehensive quality assessment and performance improvement program described in paragraph (a) of this section will include at least the following elements:

(1) Performance improvement projects in accordance with paragraph (d) of this section.

(2) Collection and submission of performance measurement data in accordance with paragraph (c) of this section.

(3) Mechanisms to detect both underutilization and overutilization of services.

(4) Mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the Agency in the quality strategy under 42 C.F.R. § 438.340.

(5) Reserved.

(c) *Performance measurement.* The Agency will—

(1)(i) Identify standard performance measures, including those performance measures that may be specified by CMS under paragraph (a)(2) of this section, relating to the performance of MCOs, PIHPs, and PAHPs.

(ii) Reserved.

(2) Require that Contractor annually—

(i) Measure and report to the Agency on its performance, using the standard measures required by the Agency in paragraph (c)(1) of this section;

(ii) Submit to the Agency data, specified by the Agency, which enables the Agency to calculate the Contractor's performance using the standard measures identified by the Agency under paragraph (c)(1) of this section; or

(iii) Perform a combination of the activities described in paragraphs (c)(2)(i) and (ii) of this section.

(d) *Performance improvement projects.* (1) Contractor shall conduct performance improvement projects, including any performance improvement projects required by CMS in accordance with paragraph (a)(2) of this section, that focus on both clinical and nonclinical areas.

(2) Each performance improvement project will be designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction, and must include the following elements:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of interventions to achieve improvement in the access to and quality of care.

(iii) Evaluation of the effectiveness of the interventions based on the performance measures in paragraph (d)(2)(i) of this section.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(3) Contractor shall report the status and results of each project conducted per paragraph (d)(1) of this section to the Agency as requested, but not less than once per year.

(4) Reserved.

(e) *Program review by the State.* Reserved.

§ 438.332 State review of the accreditation status of MCOs, PIHPs, and PAHPs.

(a) Contractor shall inform the Agency whether it has been accredited by a private independent accrediting entity.

(b) If Contractor has received accreditation by a private independent accrediting entity, Contractor shall authorize the private independent accrediting entity to provide the Agency a copy of its most recent accreditation review, including:

(1) Accreditation status, survey type, and level (as applicable);

(2) Accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings; and

(3) Expiration date of the accreditation.

(c) The Agency will—

(1) Make the accreditation status for each contracted MCO, PIHP, and PAHP available on the Web site required under 42 C.F.R. § 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

(2) Update this information at least annually.

§ 438.334 Medicaid managed care quality rating system.

(a) *General rule.* The Agency will—

(1) Adopt the Medicaid managed care quality rating system developed by CMS in accordance with paragraph (b) of this section; or

(2) Adopt an alternative Medicaid managed care quality rating system in accordance with paragraph (c) of this section.

(3) Implement such Medicaid managed care quality rating system within 3 years of the date of a final notice published in the FEDERAL REGISTER.

(b) *Quality rating system.* CMS, in consultation with States and other stakeholders and after providing public notice and opportunity to comment, will identify performance measures and a methodology for a Medicaid managed care quality rating system that aligns with the summary indicators of the qualified health plan quality rating system developed per 45 C.F.R. § 156.1120.

(c) *Alternative quality rating system.* (1) The Agency may submit a request to CMS for approval to use an alternative Medicaid managed care quality rating system that utilizes different performance measures or applies a different methodology from that described in paragraph (b) of this section provided that—

(i) The ratings generated by the alternative Medicaid managed care quality rating system yield information regarding MCO, PIHP, and PAHP performance which is substantially comparable to that yielded by the Medicaid managed care quality rating system described in paragraph (b) of this section; and,

(ii) The Agency receives CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

(2) Prior to submitting a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS, the State must—

(i) Obtain input from the State's Medical Care Advisory Committee established under 42 C.F.R. § 431.12; and

(ii) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(3) The Agency will document in the request to CMS the public comment process utilized by the Agency including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must document any policy revisions or modifications made in response to the comments and rationale for comments not accepted.

(d) *Quality ratings.* Each year, the Agency will collect data from each MCO, PIHP, and PAHP with which it contracts and issue an annual quality rating for each MCO, PIHP, and PAHP based on the data collected, using the Medicaid managed care quality rating system adopted under this section.

(e) *Availability of information.* The Agency will prominently display the quality rating given by the Agency to each MCO, PIHP, or PAHP under paragraph (d) of this section on the Web site required under §438.10(c)(3) in a manner that complies with the standards in 42 C.F.R. § 438.10(d).

§ 438.340 Managed care State quality strategy.

(a) *General rule.* The Agency will draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, PAHP or PCCM entity.

(b) *Elements of the Agency quality strategy.* At a minimum, the Agency's quality strategy will include the following:

(1) The Agency-defined network adequacy and availability of services standards for MCOs, PIHPs, and PAHPs required by 42 C.F.R. §§ 438.68 and 438.206 and examples of evidence-based clinical practice guidelines the Agency requires in accordance with 42 C.F.R. § 438.236.

(2) The Agency's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, and PAHP.

(3) A description of—

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, and PAHP with which the Agency contracts, including but not limited to, the performance measures reported in accordance with 42 C.F.R. § 438.330(c). The Agency will identify which quality measures and performance outcomes the Agency will publish at least annually on the Web site required under 42 C.F.R. § 438.10(c)(3); and

(ii) The performance improvement projects to be implemented in accordance with 42 C.F.R. § 438.330(d), including a description of any interventions the Agency proposes to improve access, quality, or timeliness of care for beneficiaries enrolled in an MCO, PIHP, or PAHP.

(4) Arrangements for annual, external independent reviews, in accordance with 42 C.F.R. § 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, PAHP, and PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) contract.

(5) A description of the Agency's transition of care policy required under 42 C.F.R. § 438.62(b)(3).

(6) The Agency's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. The Agency will identify this demographic information for each Medicaid enrollee and provide it to the MCO, PIHP or PAHP at the time of enrollment. For purposes of this paragraph (b)(6), "disability status" means whether the individual qualified for Medicaid on the basis of a disability.

(7) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of 42 C.F.R. part 438 subpart I.

(8) A description of how the Agency will assess the performance and quality outcomes achieved by each PCCM entity described in 42 C.F.R. § 438.310(c)(2).

(9) The mechanisms implemented by the Agency to comply with 42 C.F.R. § 438.208(c)(1) (relating to the identification of persons who need long-term services and supports or persons with special health care needs).

(10) The information required under 42 C.F.R. § 438.360(c) (relating to nonduplication of EQR activities); and

(11) The Agency's definition of a "significant change" for the purposes of paragraph (c)(3)(ii) of this section.

(c) *Development, evaluation, and revision.* In drafting or revising its quality strategy, the Agency will:

(1) Make the strategy available for public comment before submitting the strategy to CMS for review, including:

(i) Obtaining input from the Medical Care Advisory Committee (established by 42 C.F.R. § 431.12), beneficiaries, and other stakeholders.

(ii) If the Agency enrolls Indians in the MCO, PIHP, or PAHP, consulting with Tribes in accordance with the State's Tribal consultation policy.

(2) Review and update the quality strategy as needed, but no less than once every 3 years.

(i) This review must include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years.

(ii) The Agency will make the results of the review available on the Web site required under 42 C.F.R. § 438.10(c)(3).

(iii) Updates to the quality strategy must take into consideration the recommendations provided pursuant to 42 C.F.R. § 438.364(a)(4).

(3) Submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback prior to adopting it in final.

(ii) A copy of the revised strategy whenever significant changes, as defined in the State's quality strategy per paragraph (b)(11) of this section, are made to the document, or whenever significant changes occur within the State's Medicaid program.

(d) *Availability.* The Agency will make the final quality strategy available on the Web site required under 42 C.F.R. § 438.10(c)(3).

§4§ 438.350 External quality review.

The Agency will ensure that—

(a) Except as provided in 42 C.F.R. § 438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, PAHP or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)).

(b) The EQRO has sufficient information to use in performing the review.

(c) The information used to carry out the review must be obtained from the EQR-related activities described in 42 C.F.R. § 438.358 or, if applicable, from a Medicare or private accreditation review as described in 42 C.F.R. § 438.360.

(d) For each EQR-related activity, the information gathered for use in the EQR must include the elements described in 42 C.F.R. § 438.364(a)(1)(i) through (iv).

(e) The information provided to the EQRO in accordance with paragraph (b) of this section is obtained through methods consistent with the protocols established by the Secretary in accordance with 42 C.F.R. § 438.352.

(f) The results of the reviews are made available as specified in 42 C.F.R. § 438.364.

§4§ 438.352 External quality review protocols.

The Secretary, in coordination with the National Governor's Association, must develop protocols for the external quality reviews required under this subpart. Each protocol issued by the Secretary must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

§ 438.354 Qualifications of external quality review organizations.

(a) *General rule.* The Agency will ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid beneficiaries, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors must be independent from the State Medicaid agency and from the MCOs, PIHPs, PAHPs, or PCCM entities (described in 42 C.F.R. § 438.310(c)(2)) that they review. To qualify as "independent"—

(1) If a State agency, department, university, or other State entity:

(i) May not have Medicaid purchasing or managed care licensing authority; and

(ii) Must be governed by a Board or similar body the majority of whose members are not government employees.

(2) An EQRO may not:

(i) Review any MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)), or a competitor operating in the State, over which the EQRO exerts control or which exerts control over the EQRO (as used in this paragraph, "control" has the meaning given the term in 48 C.F.R. § 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and

(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid beneficiaries;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) services, except for the related activities specified in 42 C.F.R. § 438.358;

(iv) Review any MCO, PIHP, PAHP or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) for which it is conducting or has conducted an accreditation review within the previous 3 years; or

(v) Have a present, or known future, direct or indirect financial relationship with an MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) that it will review as an EQRO.

§4§ 438.356 State contract options for external quality review.

(a) The Agency—

(1) Will contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities.

(2) May contract with additional EQROs or other entities to conduct EQR-related activities as set forth in 42 C.F.R. § 438.358.

(b) Each EQRO must meet the competence requirements as specified in 42 C.F.R. § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in 42 C.F.R. § 438.354(c).

(e) For each contract with an EQRO described in paragraph (a) of this section, the State must follow an open, competitive procurement process that is in accordance with State law and regulations. In addition, the State must comply with 45 C.F.R. part 75 as it applies to State procurement of Medicaid services.

§4§ 438.358 Activities related to external quality review.

(a) *General rule.* (1) The Agency, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)), or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(2) The data obtained from the mandatory and optional EQR-related activities in this section will be used for the annual EQR in 42 C.F.R. § 438.350 and must include, at a minimum, the elements in §438.364(a)(i) through (iv).

(b) *Mandatory activities.* (1) For each MCO, PIHP, or PAHP the following EQR-related activities will be performed:

(i) Validation of performance improvement projects required in accordance with 42 C.F.R. § 438.330(b)(1) that were underway during the preceding 12 months.

(ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with 42 C.F.R. § 438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the Agency during the preceding 12 months.

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in 42 C.F.R. part 438, subpart D and the quality assessment and performance improvement requirements described in 42 C.F.R. § 438.330.

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months to comply with requirements set forth in 42 C.F.R. § 438.68 and, if the Agency enrolls Indians in the MCO, PIHP, or PAHP, 42 C.F.R. § 438.14(b)(1).

(2) For each PCCM entity (described in 42 C.F.R. § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section will be performed.

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in 42 C.F.R. § 438.310(c)(2)), the following activities may be performed by using information derived during the preceding 12 months:

(1) Validation of encounter data reported by an MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)).

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) and validated by an EQRO in accordance with (b)(2) of this section.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) and validated by an EQRO in accordance with (b)(1) of this section.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with 42 C.F.R. § 438.334.

(d) *Technical assistance.* The EQRO may, at the Agency's direction, provide technical guidance to groups of MCOs, PIHPs, PAHPs, or PCCM entities (described in 42 C.F.R. § 438.310(c)(2)) to assist them in conducting activities related to the mandatory and optional activities described in this section that provide information for the EQR and the resulting EQR technical report.

§4§ 438.360 Nonduplication of mandatory activities with Medicare or accreditation review.

(a) *General rule.* Consistent with guidance issued by the Secretary under 42 C.F.R. § 438.352, to avoid duplication the Agency may use information from a Medicare or private accreditation review of an MCO, PIHP, or PAHP to provide information for the annual EQR (described in 42 C.F.R. § 438.350) instead of conducting one or more of the EQR activities described in 42 C.F.R. § 438.358(b)(1)(i) through (iii) (relating to the validation of performance improvement projects, validation of performance measures, and compliance review) if the following conditions are met:

(1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in 42 C.F.R. § 422.158;

(2) The Medicare or private accreditation review standards are comparable to standards established through the EQR protocols (42 C.F.R. § 438.352) for the EQR activities described in 42 C.F.R. § 438.358(b)(1)(i) through (iii); and

(3) The MCO, PIHP, or PAHP provides to the Agency all the reports, findings, and other results of the Medicare or private accreditation review activities applicable to the standards for the EQR activities.

(b) *External quality review report.* If the Agency uses information from a Medicare or private accreditation review in accordance with paragraph (a) of this section, the Agency will ensure that all such information is furnished to the EQRO for analysis and inclusion in the report described in 42 C.F.R. § 438.364(a).

(c) *Quality strategy.* The Agency will identify in its quality strategy under 42 C.F.R. § 438.340 the EQR activities for which it has exercised the option described in this section, and explain the rationale for the Agency's determination that the Medicare review or private accreditation activity is comparable to such EQR activities, consistent with paragraph (a)(2) of this section.

§4§ 438.362 Exemption from external quality review.

(a) *Basis for exemption.* The Agency may exempt an MCO from EQR if the following conditions are met:

(1) The MCO has a current Medicare contract under part C of Title XVIII or under section 1876 of the Social Security Act, and a current Medicaid contract under section 1903(m) of the Social Security Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO has been subject to EQR under this part, and found to be performing acceptably for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries.

(b) *Information on exempted MCOs.* When the Agency exercises this option, the Agency will obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the Agency will obtain from each MCO that it exempts from EQR the most recent Medicare review findings reported on the MCO including—

(i) All data, correspondence, information, and findings pertaining to the MCO's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities.

(ii) All measures of the MCO's performance.

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for Medicare Advantage Organization deeming.* (i) If an exempted MCO has been reviewed by a private accrediting organization, the SAgency will require the MCO to provide the Agency with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under 42 C.F.R. part 422 subpart D.

(B) To deem compliance with Medicare requirements, as provided in 42 C.F.R. § 422.156.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

§4§ 438.364 External quality review results.

(a) *Information that must be produced.* The Agency will ensure that the EQR results in an annual detailed technical report that summarizes findings on access and quality of care, including:

(1) A description of the manner in which the data from all activities conducted in accordance with 42 C.F.R. § 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 C.F.R. § 438.310(c)(2)).

(2) For each EQR-related activity conducted in accordance with 42 C.F.R. § 438.358:

(i) Objectives;

(ii) Technical methods of data collection and analysis;

(iii) Description of data obtained, including validated performance measurement data for each activity conducted in accordance with 42 C.F.R. § 438.358(b)(1)(i) and (ii); and

(iv) Conclusions drawn from the data.

(3) An assessment of each MCO's, PIHP's, PAHP's, or PCCM entity's (described in 42 C.F.R. § 438.310(c)(2)) strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) including how the Agency can target goals and objectives in the quality strategy, under 42 C.F.R. § 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(5) Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities (described in 42 C.F.R. § 438.310(c)(2)), consistent with guidance included in the EQR protocols issued in accordance with 42 C.F.R. § 438.352(e).

(6) An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)) has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Revision.* The Agency will not substantively revise the content of the final EQR technical report without evidence of error or omission.

(c) *Availability of information.* (1) The Agency will contract with a qualified EQRO to produce and submit to the Agency an annual EQR technical report in accordance with paragraph (a) of this section. The Agency will finalize the annual technical report by April 30th of each year.

(2) The Agency will—

(i) Post the most recent copy of the annual EQR technical report on the Web site required under 42 C.F.R. § 438.10(c)(3) by April 30th of each year.

(ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, PAHP, or PCCM entity (described in 42 C.F.R. § 438.310(c)(2)), beneficiary advocacy groups, and members of the general public.

(3) The Agency will make the information specified in paragraph (a) of this section available in alternative formats for persons with disabilities, when requested.

(d) *Safeguarding patient identity.* The information released under paragraph (b) of this section may not disclose the identity or other protected health information of any patient.

§ 438.370 Federal financial participation (FFP).

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and the EQR-related activities set forth in 42 C.F.R. § 438.358 performed on MCOs and conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO, and for EQR (including the production of EQR results) and EQR-related activities performed by an EQRO on entities other than MCOs.

(c) Prior to claiming FFP at the 75 percent rate in accordance with paragraph (a) of this section, the Agency will submit each EQRO contract to CMS for review and approval.

Subpart F—Grievance and Appeal System

§ 438.400 Statutory basis, definitions, and applicability.

(a) *Statutory basis.* Reserved

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Adverse benefit determination means, in the case of an MCO, PIHP, or PAHP, any of the following:

(1) The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit.

(2) The reduction, suspension, or termination of a previously authorized service.

(3) The denial, in whole or in part, of payment for a service.

(4) The failure to provide services in a timely manner, as defined by the Agency.

(5) The failure of Contractor to act within the timeframes provided in 42 C.F.R. § 438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals.

(6) For a resident of a rural area with only one MCO, the denial of an enrollee's request to exercise his or her right, under 42 C.F.R. § 438.52(b)(2)(ii), to obtain services outside the network.

(7) The denial of an enrollee's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other enrollee financial liabilities.

Appeal means a review by Contractor of an adverse benefit determination.

Grievance means an expression of dissatisfaction about any matter other than an adverse benefit determination. Grievances may include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights regardless of whether remedial action is requested. Grievance includes an enrollee's right to dispute an extension of time proposed by the Contractor to make an authorization decision.

Grievance and appeal system means the processes the Contractor implements to handle appeals of an adverse benefit determination and grievances, as well as the processes to collect and track information about them.

State fair hearing means the process set forth in 42 C.F.R. subpart E of part 431.

(c) *Applicability.* Reserved.

§ 438.402 General requirements.

(a) *The grievance and appeal system.* Contractor have a grievance and appeal system in place for enrollees.

(b) *Level of appeals.* Contractor may have only one level of appeal for enrollees.

(c) *Filing requirements*—(1) *Authority to file.* (i) An enrollee may file a grievance and request an appeal with the Contractor. An enrollee may request a State fair hearing after receiving notice under 42 C.F.R. § 438.408 that the adverse benefit determination is upheld.

(A) *Deemed exhaustion of appeals processes.* If Contractor fails to adhere to the notice and timing requirements in 42 C.F.R. § 438.408, the enrollee is deemed to have exhausted the Contractor's appeals process. The enrollee may initiate a State fair hearing.

(B) *External medical review.* The Agency may offer and arrange for an external medical review if the following conditions are met.

(*1*) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(*2*) The review must be independent of both the State and Contractor.

(*3*) The review must be offered without any cost to the enrollee.

(*4*) The review must not extend any of the timeframes specified in 42 C.F.R. § 438.408 and must not disrupt the continuation of benefits in 42 C.F.R. § 438.420.

(ii) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of an enrollee. When the term "enrollee" is used throughout 42 C.F.R. part 438, subpart F, it includes providers and authorized representatives consistent with this paragraph, with the exception that providers cannot request continuation of benefits as specified in 42 C.F.R. § 438.420(b)(5). The Agency will not grant a state fair hearing to address payment disputes between the Contractor and the provider, and a provider is not considered an "enrollee" for such appeal purposes.

(2) *Timing*—(i) *Grievance.* An enrollee may file a grievance with the Contractor at any time.

(ii) *Appeal.* Following receipt of a notification of an adverse benefit determination by Contractor, an enrollee has 60 calendar days from the date on the adverse benefit determination notice in which to file a request for an appeal to the managed care plan.

(3) *Procedures*—(i) *Grievance.* The enrollee may file a grievance either orally or in writing with the Contractor.

(ii) *Appeal.* The enrollee may request an appeal either orally or in writing. Further, unless the enrollee requests an expedited resolution, an oral appeal must be followed by a written, signed appeal.

§ 438.404 Timely and adequate notice of adverse benefit determination.

(a) *Notice.* The Contractor must give enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below and in 42 C.F.R. § 438.10.

(b) *Content of notice.* The notice must explain the following:

(1) The adverse benefit determination the Contractor has made or intends to make.

(2) 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.

(3) The enrollee's right to request an appeal of the Contractor's adverse benefit determination, including information on exhausting the Contractor's one level of appeal described at 42 C.F.R. § 438.402(b) and the right to request a State fair hearing consistent with 42 C.F.R. § 438.402(c).

(4) The procedures for exercising the rights specified in this paragraph (b).

(5) The circumstances under which an appeal process can be expedited and how to request it.

(6) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances, consistent with state policy, under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The Contractor must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in 42 C.F.R. §§ 431.211, 431.213, and 431.214.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in 42 C.F.R. § 438.210(d)(1).

(4) If the Contractor meets the criteria set forth for extending the timeframe for standard service authorization decisions consistent with 42 C.F.R. § 438.210(d)(1)(ii), it must—

(i) 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; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in 42 C.F.R. § 438.210(d) (which constitutes a denial and is thus an adverse benefit determination), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in 42 C.F.R. § 438.210(d)(2).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, Contractor must give enrollees any 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.

(b) *Special requirements.* Contractor's process for handling enrollee grievances and appeals of adverse benefit determinations must:

(1) Acknowledge receipt of each grievance and appeal.

(2) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) Who, if deciding any of the following, are individuals who have the appropriate clinical expertise, as determined by the Agency, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(iii) Who take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination.

(3) Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(4) Provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments. Contractor shall inform the enrollee of the limited time available for this sufficiently in advance of the resolution timeframe for appeals as specified in 42 C.F.R. § 438.408(b) and (c) in the case of expedited resolution.

(5) Provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by Contractor (or at the direction of the Contractor) 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 as specified in 42 C.F.R. § 438.408(b) and (c).

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* Contractor shall resolve each grievance and appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within Agency-established timeframes that may not exceed the timeframes specified in this section.

(b) *Specific timeframes*—(1) *Standard resolution of grievances.* For standard resolution of a grievance and notice to the affected parties, the timeframe is established by the Agency but may not exceed 90 calendar days from the day the Contractor receives the grievance.

(2) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, Contractor shall resolve appeals within 30 calendar days from the day the Contractor receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) *Expedited resolution of appeals.* For expedited resolution of an appeal and notice to affected parties, Contractor shall resolve the appeal within 72 hours after the Contractor receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes.* (1) Contractor may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) Contractor shows (to the satisfaction of the Agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the Contractor extends the timeframes not at the request of the enrollee, it must complete all of the following:

(i) Make reasonable efforts to give the enrollee prompt oral notice of the delay.

(ii) 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.

(iii) Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(3) *Deemed exhaustion of appeals processes.* If Contractor that fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the Contractor's appeals process. The enrollee may initiate a State fair hearing.

(d) *Format of notice*—(1) *Grievances.* The Agency will establish the method that Contractor 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 C.F.R. § 438.10.

(2) *Appeals.* (i) For all appeals, Contractor shall provide written notice of resolution in a format and language that, at a minimum, meet the standards described at 42 C.F.R. § 438.10.

(ii) For notice of an expedited resolution, the Contractor must also make reasonable efforts to provide oral notice.

(e) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The results of the resolution process and the date it was completed.

(2) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State fair hearing, and how to do so.

(ii) The right to request and receive benefits while the hearing is pending, and how to make the request.

(iii) That the enrollee may, consistent with state policy, be held liable for the cost of those benefits if the hearing decision upholds the Contractor's adverse benefit determination.

(f) *Requirements for State fair hearings*—(1) *Availability.* An enrollee may request a State fair hearing only after receiving notice that the Contractor is upholding the adverse benefit determination.

(i) *Deemed exhaustion of appeals processes.* If Contractor fails to adhere to the notice and timing requirements in 42 C.F.R. § 438.408, the enrollee is deemed to have exhausted the Contractor's appeals process. The enrollee may initiate a State fair hearing.

(ii) *External medical review.* The Agency may offer and arrange for an external medical review if the following conditions are met.

(A) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(B) The review must be independent of both the Agency and Contractor.

(C) The review must be offered without any cost to the enrollee.

(D) The review must not extend any of the timeframes specified in 42 C.F.R. § 438.408 and must not disrupt the continuation of benefits in 42 C.F.R. § 438.420.

(2) *State fair hearing.* The enrollee must request a State fair hearing no later than 120 calendar days from the date of the Contractor's notice of resolution.

(3) *Parties.* The parties to the State fair hearing include the Contractor, as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

§ 438.410 Expedited resolution of appeals.

(a) *General rule.* Contractor shall establish and maintain an expedited review process for appeals, when the Contractor 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.

(b) *Punitive action.* The Contractor shall ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

(c) *Action following denial of a request for expedited resolution.* If the Contractor denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution in accordance with 42 C.F.R. § 438.408(b)(2).

(2) Follow the requirements in 42 C.F.R. § 438.408(c)(2).

§ 438.414 Information about the grievance and appeal system to providers and subcontractors.

The Contractor shall provide information specified in 42 C.F.R. § 438.10(g)(2)(xi) about the grievance and appeal system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping requirements.

(a) Contractor shall maintain records of grievances and appeals, and the Agency will review the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(b) The record of each grievance or appeal must contain, at a minimum, all of the following information:

(1) A general description of the reason for the appeal or grievance.

(2) The date received.

(3) The date of each review or, if applicable, review meeting.

(4) Resolution at each level of the appeal or grievance, if applicable.

(5) Date of resolution at each level, if applicable.

(6) Name of the covered person for whom the appeal or grievance was filed.

(c) The record must be accurately maintained in a manner accessible to the Agency and available upon request to CMS.

§ 438.420 Continuation of benefits while the Contractor appeal and the State fair hearing are pending.

(a) *Definition.* As used in this section—

Timely files means files for continuation of benefits on or before the later of the following:

(i) Within 10 calendar days of the Contractor sending the notice of adverse benefit determination.

(ii) The intended effective date of the Contractor's proposed adverse benefit determination.

(b) *Continuation of benefits.* Contractor shall continue the enrollee's benefits if all of the following occur:

(1) The enrollee files the request for an appeal timely in accordance with 42 C.F.R. § 438.402(c)(1)(ii) and (c)(2)(ii);

(2) The appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the Contractor continues or reinstates the enrollee's benefits while the appeal or state fair hearing is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal or request for state fair hearing.

(2) The enrollee fails to request a state fair hearing and continuation of benefits within 10 calendar days after the Contractor sends the notice of an adverse resolution to the enrollee's appeal under 42 C.F.R. § 438.408(d)(2).

(3) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Enrollee responsibility for services furnished while the appeal or state fair hearing is pending.* If the final resolution of the appeal or state fair hearing is adverse to the enrollee, that is, upholds the Contractor's adverse benefit determination, the Contractor may, consistent with the Agency's usual policy on recoveries under 42 C.F.R. § 431.230(b) and as specified in the Contractor's Contract, recover the cost of services furnished to the enrollee while the appeal and state fair hearing was pending, to the extent that they were furnished solely because of the requirements of this section.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the Contractor, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the Contractor 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.

(b) *Services furnished while the appeal is pending.* If the Contractor, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the Contractor will pay for those services, in accordance with Agency policy and regulations.

Subpart G [Reserved]

Subpart H—Additional Program Integrity Safeguards

§ 438.600 Statutory basis, basic rule, and applicability.

(a) *Reserved.* Reserved.

§ 438.602 State responsibilities.

(a) *Monitoring contractor compliance.* Consistent with 42 C.F.R. § 438.66, the Agency will monitor the Contractor's compliance, as applicable, with 42 C.F.R. §§ 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808.

(b) *Screening and enrollment and revalidation of providers.* (1) The Agency will screen and enroll, and periodically revalidate, all network providers of Contractor, in accordance with the requirements of 42 C.F.R. part 455, subparts B and E. This provision does not require the network provider to render services to FFS beneficiaries.

(2) Contractor may execute network provider agreements pending the outcome of the process in paragraph (b)(1) of this section of up to 120 days, but must terminate a network provider immediately upon notification from the Agency that the network provider cannot be enrolled, or the expiration of one 120 day period without enrollment of the provider, and notify affected enrollees.

(c) *Ownership and control information.* The Agency will review the ownership and control disclosures submitted by the Contractor, and any subcontractors as required in 42 C.F.R. § 438.608(c).

(d) *Federal database checks.* Consistent with the requirements at 42 C.F.R. § 455.436, the Agency will confirm the identity and determine the exclusion status of the Contractor, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the Contractor through routine checks of Federal databases. This includes the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the System for Award Management (SAM), and any other databases as the Agency or Secretary may prescribe. These databases must be consulted upon contracting and no less frequently than monthly thereafter. If the Agency finds a party that is excluded, it will promptly notify the Contractor and take action consistent with 42 C.F.R. § 438.610(c).

(e) *Periodic audits.* The Agency will periodically, but no less frequently than once every 3 years, conduct, or contract 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, Contractor.

(f) *Whistleblowers.* The Agency will receive and investigate information from whistleblowers relating to the integrity of the Contractor, subcontractors, or network providers receiving Federal funds under 42 C.F.R. part 438.

(g) *Transparency.* The State will post on its Web site, as required in 42 C.F.R. § 438.10(c)(3), the following documents and reports:

(1) The Contractor's Contract.

(2) The data at 42 C.F.R. § 438.604(a)(5).

(3) The name and title of individuals included in 42 C.F.R. § 438.604(a)(6).

(4) The results of any audits under paragraph (e) of this section.

(h) *Contracting integrity.* The Agency has in place conflict of interest safeguards described in 42 C.F.R. § 438.58 and will comply with the requirement described in section 1902(a)(4)(C) of the Social Security Act applicable to contracting officers, employees, or independent contractors.

(i) *Entities located outside of the U.S.* Contractor shall not be located outside of the United States, and no claims paid by Contractor to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. will be considered in the development of actuarially sound capitation rates.

§ 438.604 Data, information, and documentation that must be submitted.

(a) *Specified data, information, and documentation.* Contractor shall submit to the Agency the following data:

(1) Encounter data in the form and manner described in 42 C.F.R. § 438.818.

(2) Data on the basis of which the Agency certifies the actuarial soundness of capitation rates to Contractor under 42 C.F.R. § 438.3, including base data described in 42 C.F.R. § 438.5(c) that is generated by the Contractor.

(3) Data on the basis of which the Agency determines the compliance of the Contractor with the medical loss ratio requirement described in 42 C.F.R. § 438.8.

(4) Data on the basis of which the Agency determines that the Contractor has made adequate provision against the risk of insolvency as required under 42 C.F.R. § 438.116.

(5) Documentation described in 42 C.F.R. § 438.207(b) on which the Agency bases its certification that the Contractor has complied with the Agency's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in 42 C.F.R. § 438.206.

(6) Information on ownership and control described in 42 C.F.R. § 455.104 from Contractor, and subcontractors as governed by 42 C.F.R. § 438.230.

(7) The annual report of overpayment recoveries as required in 42 C.F.R. § 438.608(d)(3).

(b) *Additional data, documentation, or information.* In addition to the data, documentation, or information specified in paragraph (a) of this section, Contractor shall submit any other data, documentation, or information relating to the performance of the entity's obligations under 42 C.F.R. part 438 required by the Agency or the Secretary.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data, documentation, or information specified in 42 C.F.R. § 438.604, the Agency requires that the data, documentation or information the Contractor submits to the Agency be certified by either the Contractor's Chief Executive Officer; Chief Financial Officer; or an individual who reports directly to the Chief Executive Officer or Chief Financial Officer with delegated authority to sign for the Chief Executive Officer or Chief Financial Officer so that the Chief Executive Officer or Chief Financial Officer is ultimately responsible for the certification.

(b) *Content of certification.* The certification provided by the individual in paragraph (a) of this section must attest that, based on best information, knowledge, and belief, the data, documentation, and information specified in 42 C.F.R. § 438.604 is accurate, complete, and truthful.

(c) *Timing of certification.* Contractor shall submit the certification concurrently with the submission of the data, documentation, or information required in 42 C.F.R. § 438.604(a) and (b).

§ 438.608 Program integrity requirements under the contract.

(a) *Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse.* Contractor, or subcontractor to the extent that the subcontractor is delegated responsibility by the Contractor for coverage of services and payment of claims under this Contract, shall 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:

(1) A compliance program that includes, at a minimum, all of the following elements:

(i) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the Contract, and all applicable Federal and State requirements.

(ii) 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.

(iii) The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the Contract.

(iv) 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.

(v) Effective lines of communication between the compliance officer and the organization's employees.

(vi) Enforcement of standards through well-publicized disciplinary guidelines.

(vii) 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.

(2) Provision for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the Agency.

(3) Provision for prompt notification to the Agency when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including all of the following:

(i) Changes in the enrollee's residence;

(ii) The death of an enrollee.

(4) Provision for notification to the Agency 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 Contractor.

(5) 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.

(6) If Contractor receives 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 Social Security Act, including information about rights of employees to be protected as whistleblowers.

(7) Provision for the prompt referral of any potential fraud, waste, or abuse that the Contractor identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit.

(8) Provision for the Contractor's suspension of payments to a network provider for which the Agency determines there is a credible allegation of fraud in accordance with 42 C.F.R. § 455.23.

(b) *Provider screening and enrollment requirements.* Contractor shall ensure that all network providers are enrolled with the Agency as Medicaid providers consistent with the provider disclosure, screening and enrollment requirements of 42 C.F.R. part 455, subparts B and E. This provision does not require the network provider to render services to FFS beneficiaries.

(c) *Disclosures.* Contractor, and any subcontractors, shall:

(1) Provide written disclosure of any prohibited affiliation under 42 C.F.R. § 438.610.

(2) Provide written disclosures of information on ownership and control required under 42 C.F.R. § 455.104.

(3) Report to the Agency within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the Contract.

(d) *Treatment of recoveries made by the Contractor of overpayments to providers.* (1) Reporting and Retention of Overpayments.

(i) Contractor may retain overpayments attributable to claims paid by the Contractor.

(ii) Te State will transmit recovery of an overpayment attributable to claims paid by Contractor or or efore the 60th day following receipt of the overpayment.

(iii) If the Contractor recovers overpayments attributable to claims paid by the Agency, the Contractor shall:

I. Return the overpayment to the Agency on or before the 60th day following receipt of the overpayment by the payment method designated by the Agency.

II. Provide documentation identifying the provider from whom the recovery was made, the dates of service for the claims recovered, a description why the claims were recovered, and an explanation of the Contractor's process resulting in recovering the overpayment.

(iv) This provision does not apply to any amount of a recovery to be retained under False Claims Act cases or through other investigations.

(2) Contractor shall have a mechanism for a network provider to report to the Contractor when it has received an overpayment, to return the overpayment to the Contractor within 60 calendar days after the date on which the overpayment was identified, and to notify the Contractor in writing of the reason for the overpayment.

(3) Contractor shall report annually to the State on their recoveries of overpayments.

(4) The Agency will use the results of the information and documentation collected in paragraph (d)(1) of this section and the report in paragraph (d)(3) of this section for setting actuarially sound capitation rates for Contractor consistent with the requirements in 42 C.F.R. § 438.4.

§ 438.610 Prohibited affiliations.

(a) Contractor may not knowingly have a relationship of the type described in paragraph (c) of this section with the following:

(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.

(2) An individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation at 48 C.F.R. § 2.101, of a person described in paragraph (a)(1) of this section.

(b) Contractor 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 Social Security Act.

(c) The relationships described in paragraph (a) of this section, are as follows:

(1) A director, officer, or partner of the Contractor.

(2) A subcontractor of the Contractor, as governed by 42 C.F.R. § 438.230.

(3) A person with beneficial ownership of 5 percent or more of the Contractor equity.

(4) A network provider or person with an employment, consulting or other arrangement with the Contractor for the provision of items and services that are significant and material to the Contractor's obligations under its Contract with the State.

(d) If Contractor is not in compliance with paragraphs (a) and (b) of this section, the Agency:

(1) Will notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the Contractor unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the Contractor unless the Secretary provides to the Agency and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliations.

(4) Nothing in this section 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.

(e) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (d)(2) or (3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) – (d) *Reserved (not applicable to PAHPs).*

§ 438.702 Types of intermediate sanctions.

(a) Reserved.

(b) The Agency retains authority to impose sanctions under State statutes or State regulations that address areas of noncompliance specified in 42 C.F.R. § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties.

(a) *Reserved.*

§ 438.706 Special rules for temporary management.

(a) *Reserved.*

§ 438.708 Termination of an MCO, PCCM or PCCM entity contract.

Reserved.

§ 438.710 Notice of sanction and pre-termination hearing.

(a) *Reserved.*

§ 438.722 Disenrollment during termination hearing process.

Reserved.

§ 438.724 Notice to CMS.

(a) The Agency will give CMS written notice whenever it imposes or lifts a sanction for one of the violations listed in 42 C.F.R. § 438.700, to the extent such sanction is permissible under State statute or regulation.

(b) The notice will adhere to all of the following requirements:

(1) Be given no later than 30 days after the Agency imposes or lifts a sanction.

(2) Specify the Contractor, the kind of sanction, and the reason for the Agency's decision to impose or lift a sanction.

§ 438.726 State plan requirement.

(a) *Reserved.*

§ 438.730 Sanction by CMS: Special rules for MCOs.

Reserved.

Subpart J—Conditions for Federal Financial Participation (FFP)

§ 438.802 Basic requirements.

Reserved.

§ 438.806 Prior approval.

Reserved.

§ 438.808 Exclusion of entities.

(a) *General rule.* Federal financial participation is not available to fund this Contract if Contractor includes any of the following entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Social Security Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in 42 C.F.R. § 431.55(h)(3), either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Social Security Act or an individual described in 42 C.F.R. § 438.610(a) and (b).

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity described in 42 C.F.R. § 438.610(a) and (b).

(ii) Any individual or entity that would provide those services through an individual or entity described in 42 C.F.R. § 438.610(a) and (b).

§ 438.810 Expenditures for enrollment broker services.

Reserved.

§ 438.812 Costs under risk and nonrisk contracts.

Reserved.

§ 438.816 Expenditures for the beneficiary support system for enrollees using LTSS.

Reserved.

§ 438.818 Enrollee encounter data.

(a) Contractor shall provide encounter data of Contractor's enrollees in a form and in a timeframe to meet all CMS requirements imposed on the Agency.

(1) Enrollee encounter data reports must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security and privacy standards and be submitted in the format required by the Medicaid Statistical Information System or format required by any successor system to the Medicaid Statistical Information System.

(2) The Agency will ensure that enrollee encounter data is validated for accuracy and completeness as required under 42 C.F.R. § 438.242 before submitting data to CMS. The Agency will also validate that the data submitted to CMS is a complete and accurate representation of the information submitted to the Agency by the Contractor.

(3) The Agency will cooperate with CMS to fully comply with all encounter data reporting requirements of the Medicaid Statistical Information System or any successor system.

(b) CMS will assess a Agency's submission to determine if it complies with current criteria for accuracy and completeness.

(c) If, after being notified of compliance issues under paragraph (b) of this section the Agency is unable to make a data submission compliant, CMS will take appropriate steps to defer and/or disallow FFP on all or part of Contractor's Contract in a manner based on the enrollee and specific service type of the noncompliant data. Any deferral and/or disallowance of FFP will be effectuated utilizing the processes specified in 42 C.F.R. §§ 430.40 and 430.42. Contractor shall within 60 days of such deferral or disallowance refund the deferred or disallowed FFP sum to the Agency.

Subpart K—Parity in Mental Health and Substance Use Disorder Benefits

§ 438.900 Meaning of terms.

For purposes of this subpart, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a MCO, PIHP, or PAHP.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a MCO, PIHP, or PAHP.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits are benefits defined in section 1905(r) of the Social Security Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined by the Agency and in accordance with applicable Federal and State law, but do not include mental health or substance use disorder benefits. Any condition defined by the State as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines). Medical/surgical benefits include long term care services.

Mental health benefits means benefits for items or services for mental health conditions, as defined by the Agency and in accordance with applicable Federal and State law. Any condition defined by the Agency as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines). Mental health benefits include long term care services.

Substance use disorder benefits means benefits for items or services for substance use disorders, as defined by the Agency and in accordance with applicable Federal and State law. Any disorder defined by the Agency as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines). Substance use disorder benefits include long term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (*See* 42 C.F.R. § 438.910(d)(2) for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

§ 438.905 Parity requirements for aggregate lifetime and annual dollar limits.

Reserved (not applicable to a dental-only PAHP).

§ 438.910 Parity requirements for financial requirements and treatment limitations.

Reserved (not applicable to a dental-only PAHP).

§ 438.915 Availability of information.

(a) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations, made by a MCO or by a PIHP or PAHP providing services to an MCO enrollee, for mental health or substance use disorder

benefits must be made available by the MCO, PIHP, or PAHP administrator to any enrollee, potential enrollee, or contracting provider upon request. MCOs, PIHPs, and PAHPs operating in compliance with 42 C.F.R. § 438.236(c) will be deemed compliant with the requirements in this paragraph (a).

(b) *Reason for any denial.* The reason for any denial by a MCO, PIHP, or PAHP of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available by the MCO, PIHP, or PAHP administrator to the enrollee.

(c) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (a) and (b) of this section is not determinative of compliance with any other provision of applicable Federal or State law.

§ 438.920 Applicability.

(a) *MCOs, PIHPs, and PAHPs.* The requirements of this subpart apply to each MCO, PIHP, and PAHP offering services to enrollees of a MCO, in States covering medical/surgical and mental health or substance use disorder services under the State plan. These requirements regarding coverage for services that must be provided to enrollees of an MCO apply regardless of the delivery system of the medical/surgical, mental health, or substance use disorder services under the State plan.

(b) *State responsibilities.* (1) In any instance where the full scope of medical/surgical and mental health and substance use disorder services are not provided through the MCO, the Agency will review the mental health and substance use disorder and medical/surgical benefits provided through the MCO, PIHP, PAHP, and fee-for service (FFS) coverage to ensure the full scope of services available to all enrollees of the MCO complies with the requirements in this subpart. The Agency will provide documentation of compliance with requirements in this subpart to the general public and post this information on the State Medicaid Web site by October 2, 2018. Such documentation must be updated prior to any change in MCO, PIHP, PAHP or FFS State plan benefits.

(2) The State must ensure that all services are delivered to the enrollees of the MCO in compliance with this subpart.

(c) *Scope.* This subpart does not—

(1) Require a MCO, PIHP, or PAHP to provide any mental health benefits or substance use disorder benefits beyond what is specified in its contract, and the provision of benefits by a MCO, PIHP, or PAHP for one or more mental health conditions or substance use disorders does not require the MCO, PIHP or PAHP to provide benefits for any other mental health condition or substance use disorder;

(2) Require a MCO, PIHP, or PAHP that provides coverage for mental health or substance use disorder benefits only to the extent required under 1905(a)(4)(D) of the Social Security Act to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(3) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the Medicaid MCO, PIHP, or PAHP contract except as specifically provided in 42 C.F.R. §§ 438.905 and 438.910.

§ 438.930 Compliance dates.

The parties to this Contract will comply with the requirements of this subpart no later than October 2, 2018.