

**VOLUNTARY TRIBAL COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE CONFEDERATED TRIBES OF THE COLVILLE RESERVATION**

I. PREAMBLE

1. The Confederated Tribes of the Colville Reservation are a federally recognized, sovereign Indian Tribe, with Tribal offices located at Nespelem, Washington, on the Tribes' Reservation (the Tribes and the Reservation, respectively).

2. The Office of Inspector General (OIG) is an agency within the Department of Health and Human Services (HHS) and which has been granted authority and independence under the Inspector General Act of 1978, 5 U.S.C. App., to conduct and supervise audits and investigations of the programs and operations of HHS to prevent and detect fraud and abuse in such programs and operations. The Inspector General Act states that the Inspector General reports to and acts under the general supervision of the Secretary of HHS, but also states that the Secretary cannot prevent or prohibit the Inspector General from initiating, carrying out or completing any audit or investigation.

3. The Health Insurance Portability and Accountability Act authorizes OIG, on behalf of the Secretary of HHS and together with the Department of Justice, to operate the Health Care Fraud and Abuse Control Program to, among other activities, coordinate Federal, state, and local law enforcement efforts relating to health care fraud and abuse; conduct investigations and audits relating to the delivery and payment for health care in the United States; and to facilitate enforcement of federal statutes applicable to health care fraud and abuse. (Social Security Act Sec. 1128C, 42 U.S.C. Sec. 1320a-7c.) The Secretary of HHS has delegated to OIG the authority in Sections 1128 and 1128A, among others, to independently impose civil monetary penalties and exclusions for, among other reasons, the submission of false claims to Federal health care programs. See 53 Fed. Reg. 12993 (April 20, 1988), 42 U.S.C. § 1320a-7a, and 42 C.F.R. § 1003.102.

4. The Secretary has entered a Title I Contract with the Tribes on a government-to-government basis to provide health services to Tribal members and other eligible individuals pursuant to the Indian Self-Determination and Education Assistance

Act, 25 USC § 450aaa, *et seq.* (ISDEAA), in furtherance of the goals of the Indian Health Care Improvement Act (IHCIA), 25 USC § 1601, *et seq.*, and to fulfill the United States' trust and treaty obligations to the Tribes' members.

5. The Tribes are entitled to bill Federal health care programs for services provided to Tribal members and other eligible individuals under their ISDEAA Compact and Annual Funding Agreements with the Secretary, and independently by the IHCIA, 25 USC § 1641. Section 1911 of the Social Security Act requires the Tribes' facilities to meet all the conditions and requirements for Medicaid which are applicable generally to such facilities as a condition of billing for Medicaid services.¹

6. The Tribes are committed to providing quality health and health education services for Tribal members and other eligible individuals on and near the Reservation. The Tribes are equally committed to providing those services in compliance with the statutes, regulations and rules applicable to Federal health care programs and funding.

7. OIG and the Tribes (the Parties) have entered this Voluntary Tribal Compliance Agreement (the Agreement) on a government-to-government basis, in furtherance of their respective obligations and rights under applicable law.

II. TERM AND SCOPE

A. The period of the compliance obligations assumed by the Tribes under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, and XI shall expire no later than 120 days after OIG's receipt of: (1) the Tribes' final annual report; or (2) any additional materials submitted by the Tribes pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" used in the Agreement means –

1. All employees, including management employees, of the Tribes' Health Department and all contractors, subcontractors, agents, and other persons who

¹ The Tribes currently bill Medicaid, but not Medicare.

furnish patient care items or services or who perform billing or coding functions on behalf of the Tribes' Health Department.

2. Notwithstanding the above, this term "Covered Persons" does not include –

- (a) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during a Reporting Period; and
- (b) vendors whose sole connection with the Tribes is selling or otherwise providing medical supplies or equipment to the Tribes.

D. The term "Federal health care program" is used in this Agreement as defined in 42 U.S.C. § 1320a-7b(f).

III. COMPLIANCE AND MEDICAL QUALITY ASSURANCE PROGRAM

A. The OIG has recommended that the Tribes establish and maintain a compliance program that includes the elements described in this section. The Tribes agree with the OIG's recommendation and have established a compliance and medical quality assurance program pursuant to, and subject to the protections of, the Indian Health Care Improvement Act, 25 U.S.C. § 1675.

1. Compliance Officer. As part of the compliance and medical quality assurance program, the Tribes have created a Compliance Officer position in the Health Department. The Tribes shall maintain the Compliance Officer position for the Term and, as the Tribes believe appropriate, for longer.

- (a) The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure the Tribes' compliance with the requirements of this Agreement and with Federal health care program requirements.

The Compliance Officer is responsible for monitoring the Tribes' day-to-day compliance activities.

- (b) The Compliance Office shall be a member of the Tribes' senior management. The Compliance Officer will make quarterly reports regarding compliance matters directly to the Colville Business Council Health and Human Services Committee ("the Health Committee"), and is authorized to report directly on any compliance matter to the Health Committee or to the full Colville Business Council at any time the Compliance Office believes appropriate or necessary. Written documentation of the Compliance Officer's reports to the Committee and the Colville Business Council shall be made available to the OIG upon request.
- (c) The Compliance Officer is not, and will not be subordinate to, the Health Director, the Reservation Attorney or the Tribes' Comptroller, nor does the Compliance Officer have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for the Tribes.
- (d) Any noncompliance job responsibilities of the Compliance Officer shall be limited to no more than one-half of the Compliance Officer's time, and must not interfere with the Compliance Officer's ability to perform compliance duties.

2. Compliance Committee. As part of the compliance medical quality assurance program, the Tribes have created a Compliance Committee to serve as the Tribes' compliance committee for, at least, the entire term of the Agreement. The Compliance Committee members are the Compliance Officer, the Health Director, the Deputy Health Director, the Chemical Dependency Clinical Supervisor, the Mental Health Clinical Supervisor, the Health Department's Registered Health Information Technician (RHIT) and the Health Department Billing Supervisor.

- (a) The Compliance Committee will support the Compliance Officer in fulfilling the Compliance Officer's responsibilities, including reporting, analysis of the Tribes' risk areas, monitoring internal and external audits and investigations.

- (b) The Compliance Committee is part of the Tribes “medical quality assurance program” under the Indian Health Care Improvement Act, 25 U.S.C. § 1675.
- (c) The Compliance Committee will be authorized to make recommendations and file reports directly with the Health Director, the Compliance Officer, the Tribal Executive Director, the Health Committee or the Business Council as it deems appropriate in the furtherance of quality health care.
- (d) The Compliance Committee normally meets weekly, and shall meet no less than once monthly. Minutes will be kept of all Compliance Committee meetings, and shall be made available to OIG upon request.

3. Independent Review Organization. As part of the compliance and medical quality assurance program, the Tribes have engaged an accounting firm (“Independent Review Organization” or “IRO”) to perform periodic reviews of the Tribes’ claims submissions. The IRO requirements are outlined in Appendix A.

- (a) *Retention of Records.* The IRO and the Tribes shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and the Tribes related to the reviews.
- (b) *Claims Review.* The IRO shall review the Tribes’ coding, billing, and claims submission to the Medicare and Medicaid programs (“Claims Review”) and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B.
- (c) *Independence and Objectivity Certification.* The IRO shall include in its report(s) to the Tribes a certification that the IRO has evaluated its professional independence and objectivity with respect to the reviews and concluded that it is, in fact, independent and objective.

- (d) *Validation Review.* In the event OIG has reason to believe that (a) the IRO's Claims Review fails to conform to the requirements of Appendix B or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion and expense, conduct its own review to determine whether the Claims Review complied with the requirements of Appendix B or whether results are accurate (Validation Review). OIG will provide the results of its review to the Compliance Committee and the Health Committee.

4. Training and Education. As part of the compliance and medical quality assurance program, the Tribes have initiated a compliance training program for all Department employees and Tribal administrative and management employees who are involved with Federal health care programs.

- (a) *General Training Program.*
 - (i) Within 90 days after the Effective Date, the Tribes shall develop a written plan (Training Plan) that outlines the steps the Tribes will take to ensure that all Covered Persons receive adequate training regarding, at a minimum, the Tribes' Policies and Procedures developed in accordance with section IV below; Federal and State health care billing, coding, and claim submission statutes, regulations, and program requirements; and other matters as necessary to ensure the employees' understanding of, and adherence to, Medicare and Medicaid program requirements and the Tribes' compliance obligations under this Agreement.
 - (ii) The Training Plan shall include information regarding the training topics, the categories of Covered Persons required to attend each training, the length of the training, the schedule for training, and the format of the training. Within 30 days of OIG's receipt of the Tribes' Training Plan, OIG will notify the Tribes of any comments or objections to the Training Plan. Absent

notification by OIG that the Training Plan is unacceptable, the Tribes may implement the Training Plan.

(iii) The Tribes shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

(b) *Business Council Training Program.* The Tribes will provide at least two hours of training during each Reporting Period to Covered Persons who are also the Tribes' Business Council members. This training will address the requirements of this Agreement and the Tribes' Medical and Quality Assurance Program and will focus on the responsibilities of the Business Council and the Tribal Administration to assure compliance with Federal health care program rules.

B. Ineligible Persons and Entities.

1. Definitions. For purposes of this Agreement:

(a) an "Ineligible Person" shall include an individual or entity who:

(i) is currently excluded, debarred, or suspended from participation in the Federal health care programs or in Federal procurement or nonprocurement programs; or

(ii) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or suspended.

(b) "Exclusion Lists" include:

(i) the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and

- (ii) the General Services Administration's System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. Screening Requirements. The Tribes shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- (a) The Tribes shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- (b) The Tribes shall screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- (c) The Tribes shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, or suspension.

Nothing in this Section III.G affects the Tribes' responsibility to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. The Tribes understand that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that the Tribes may be liable for overpayments and the Government may seek criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether the Tribes meet the requirements of Section III.B.

The Tribes explicitly reserve and do not waive any defenses and rights whatsoever, including administrative and judicial defenses and rights that they may have in the event the OIG asserts such claims.

3. Removal Requirement. If the Tribes have actual notice that a Covered Person has become an Ineligible Person, the Tribes shall remove such Covered Person from responsibility for, or involvement with, the Tribes' business operations related to the Federal health care programs and shall remove such Covered Person from

any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If the Tribes have actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, the Tribes shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

D. Repayment of Overpayments.

1. *Definition of Overpayments.* For purposes of this Agreement, an "overpayment" shall mean the amount of money the Tribes have received in excess of the amount due and payable under any Federal health care program requirement.

2. *Reporting of Overpayments.* If, at any time, the Tribes identify or learn of an overpayment, the Tribes shall repay the overpayment to the appropriate payor (e.g., Medicare or Medicaid contractor) within 60 days after identification of the overpayment and take steps to correct the problem and prevent the overpayment from recurring within 90 days after identification (or such additional time as may be agreed to by the payor). If not yet quantified within 60 days after identification, the Tribes shall notify the payor at the time of its efforts to quantify the overpayment amount and provide a schedule of when such work is expected to be completed. The Tribes should follow the payor's policies regarding the form of notification and the repayment process for any overpayment funds. Any questions regarding the repayment process should be directed to the payor.

IV. POLICIES AND PROCEDURES

A. The Tribes agree to develop and make available to all Covered Persons policies and procedures which include policies and procedures relating to the general obligation of employees to act in compliance with legal and program requirements, the role and responsibilities of the Compliance Officer in Section III.A.1, the role and responsibilities of the Compliance Committee in Section III.A.2, verification of eligibility

under Section III.B, training requirements under III.4, the identification and repayment of overpayments in Section III.D, and any matter the Tribes determine to be necessary to ensure an effective compliance program.

B. The Tribes will make available upon request draft policies and procedures to OIG.

V. ANNUAL PROGRESS MEETINGS AND REPORTS.

A. Within 120 days after the Effective Date, the Tribes and OIG will meet (whether in person or remotely) to review the Tribes' progress in implementing the requirements of this Agreement. The Tribes' representatives should include the compliance officer engaged by the Tribes pursuant to section III.1.A. The discussion will address, at a minimum, the implementation of policies and procedures relating to the engagement of an IRO, screening for Ineligible Persons, and Training and Education. OIG will provide feedback on the Tribes' progress in implementing the requirements of the Agreement and will review with the Tribes matters that should be addressed prior to the submission of the first Annual Report.

B. The Tribes shall annually submit to OIG a report with respect to the Tribes compliance and medical quality assurance program within 60 days of the close of each calendar year during the Term. The Tribes and OIG will meet (whether in person or remotely) after the submission of each Annual Report at a mutually convenient time to review progress under, and satisfaction of the terms of, this Agreement and to identify areas where improvements should be made.

1. Each Annual Report shall include a certification of the Tribes' Health Director (the Director) in the following form:

"I certify that I have been trained on and understand the compliance requirements and responsibilities as they relate to the Tribes' Health Department, an area under my supervision. My job responsibilities include ensuring compliance with regard to the Health Department with all applicable Federal health care program requirements, the Tribes' policies, and the Tribes' obligations under this Agreement. I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described below, the Health Department is in compliance with all applicable Federal health care program requirements and with the

obligations of this Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If the Director is unable to provide such a certification, the Director shall provide to the OIG a written explanation of the reasons why Director is unable to provide the certification.

2. Each Annual Report shall also include:
 - (a) the name and contact information of the Compliance Officer;
 - (b) a copy of the Tribes’ policies and procedures, prepared in accordance with Section IV (for subsequent years, only policies which have changed since the prior year need be submitted);
 - (c) a syllabus or other training material describing, summarizing, or demonstrating the substance of the General Training and Business Council Training provided in accordance with Section III.A.4;
 - (d) a confirmation that all Department employees and Tribal administrative and management employees who are involved with Federal health care programs have received the required training and a copy of the policies and procedures (or an explanation as to why not);
 - (e) any material changes to the Tribes’ compliance and medical quality assurance program during the previous calendar year;
 - (f) the dates of each report made by the Compliance Officer to the Colville Business Council and the Health Committee (written documentation of such reports shall be made available upon request);
 - (g) a report of the aggregate overpayments, if any, that have been returned to any Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures

established by the payor do not need to be included in the report;

- (h) a summary describing any audits conducted during the previous calendar year by any Federal health care programs and the Tribes' response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

C. Designation of Information

The Tribes shall clearly identify any portions of the reports that it believes are trade secrets, or information that is commercial, financial, privileged or confidential and potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a. The Tribes shall make their best efforts to refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA or the Privacy Act.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

A. Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this Agreement shall be submitted to the following:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

The Tribes:

Casey Moore Compliance Officer

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Health Department
Confederated Tribes of the Colville Reservation
PO Box 150
Nespelem, WA 99155-0150
Telephone: 509.634.2611

B. Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. The Parties may request an electronic copy of each notification or report required by this Agreement in searchable portable document format (pdf), in addition to a paper copy.

VII. INSPECTION, AUDIT, AND REVIEW RIGHTS

OIG may exercise any rights it has by statute, regulation or contract to examine or request copies of the Tribes' books, records, and other documents and supporting materials or conduct on-site reviews of any of the Tribes' locations for the purpose of verifying and evaluating: (a) the Tribes' compliance with the terms of this Agreement; and (b) the Tribes' compliance with the requirements of any Federal health care programs.

VII. DOCUMENT AND RECORD RETENTION

The Tribes shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs for six years (or longer if otherwise required by law) from the Effective Date.

VIII. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify the Tribes prior to any release by the Secretary of information submitted by the Tribes pursuant to its obligations under this Agreement and identified upon submission by the Tribes as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, the Tribes shall have the rights set forth at 45 C.F.R. § 5.65(d).

IX. BREACH OF AGREEMENT

A. The Tribes acknowledge their obligation to comply with laws, regulations, and requirements applicable to providers of services under Federal health care programs and will act in good faith to implement the terms of this Agreement as a means to ensure future compliance.

B. OIG acknowledges the special relationship the Tribes have with the Federal government as well as the historical and financial circumstances that affect the demand for health care services from the Tribes' Health Department.

C. Accordingly, the Tribes and OIG will work together in good faith to resolve any disagreements regarding the Tribes' implementation of the terms of this Agreement.

D. However, in the event that a matter which OIG deems to constitute a material breach of the Agreement cannot be resolved, OIG may unilaterally terminate the Agreement. OIG will provide 30 days' notice before doing so. In such circumstances, it would remain within OIG's authority to address its concerns through other means authorized by statute, including (as appropriate based on the facts giving rise to the dispute) the initiation of audits or investigations, referral to the Department of Justice, referral for possible administrative resolution, and/or reporting to Congress.

XI. EFFECTIVE DATE

The Tribes and the Secretary agree as follows:

A. This Agreement shall become effective on the date the final signature is obtained below;

B. This Agreement constitutes the complete expression of intent between the Parties and may not be amended except by written consent of the Parties;

C. The undersigned signatories represent and warrant that they are authorized to execute this Agreement in their respective official capacities.

D. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same document, and may be exchanged by facsimile or electronic media.

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**ON BEHALF OF THE CONFEDERATED TRIBES OF
THE COLVILLE RESERVATION**

/Michael Marchand/

MICHAEL MARCHAND

Chairman

Colville Business Council

O/b/o The Confederated Tribes of the Colville Reservation

12/15/2016

DATE

/Richard Monkman/

RICHARD D. MONKMAN

Counsel for

The Confederated Tribes of the Colville Reservation

Sonosky, Chambers, Sachse, Miller & Munson LLP

302 Gold Street, Suite 201

Juneau, Alaska 99801

11/30/16

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Lisa M. Re/
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

01/06/17
DATE

/Melinda V. Golub/
MELINDA GOLUB
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

January 9, 2017
DATE

/Amitava Mazumdar/
AMITAVA MAZUMDAR
Deputy Branch Chief
Office of Inspector General
U. S. Department of Health and Human Services

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DATE

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ANDREA L. TREESE BERLIN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

January 9, 2017
DATE

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APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required in Paragraph III.A.3 of this agreement.

A. IRO Engagement

1. The Tribes shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 90 days of the Effective Date of this agreement, The Tribes will provide the OIG with the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in this Appendix ; (d) a summary and description of any and all current and prior engagements and agreements between The Tribes and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to The Tribes. Within 60 days after OIG receives the information described in this paragraph or any additional information submitted by The Tribes in response to a request by OIG, whichever is later, OIG will notify The Tribes if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, The Tribes may continue to engage the IRO.

2. If The Tribes engage a new IRO during the term of this agreement, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, The Tribes shall submit the information identified in Paragraph A.1 of this Appendix to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by The Tribes at the request of OIG, whichever is later, OIG will notify The Tribes if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, The Tribes may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

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1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of Medicare and Medicaid and in the general requirements of the Federal health care program(s) from which The Tribes seek reimbursement;
2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;
3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements); and
4. have sufficient staff and resources to conduct the reviews required by the Voluntary Tribal Compliance Agreement on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review in accordance with the specific requirements of this agreement;
2. follow all applicable Medicare and Medicaid rules and reimbursement guidelines in making assessments in the Claims Review;
3. if in doubt of the application of a particular Medicare or Medicaid policy or regulation, request clarification from the appropriate authority (e.g., Medicare contractor);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to this agreement.

D. IRO Independence and Objectivity

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The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO.* If The Tribes terminate their IRO or if the IRO withdraws from the engagement during the term of this agreement, The Tribes must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. The Tribes must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require The Tribes to engage a new IRO in accordance with Paragraph A of this Appendix. The Tribes must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring The Tribes to engage a new IRO, OIG shall notify The Tribes of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, The Tribes may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with The Tribes prior to requiring The Tribes to terminate the IRO. However, the final determination as to whether or not to require The Tribes to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

1. *Definitions.* For the purposes of the Claims Review, the following definitions shall be used:

- (a) Overpayment: The amount of money The Tribes have received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.
- (b) Paid Claim: A claim submitted by The Tribes and for which The Tribes have received reimbursement from the Medicaid program.²
- (c) Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
- (d) Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

² It is the OIG's understanding that, currently, The Tribes do not submit claims to the Medicare program. However, in the event that The Tribes begin to submit claims to the Medicare program, this definition will automatically expand to include Medicare claims.

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Discovery Sample).³ The Paid Claims shall be reviewed based on the supporting documentation available at The Tribes' office or under The Tribes' control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, The Tribes should, as appropriate, further analyze any errors identified in the Discovery Sample. The Tribes recognize that OIG or another HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority, may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at The Tribes or under The Tribes' control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from

³ If The Tribes begin to bill Medicare, the IRO shall randomly select and review a sample of 200 Paid Claims (Discovery Sample). The Paid Claims reviewed shall be comprised of two strata (Strata) as follows: 100 Medicare Paid Claims and 100 Medicaid Paid Claims. Each Strata shall be reviewed separately.

The Tribes to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

4. *Systems Review.* If The Tribes' Discovery Sample identifies an Error Rate of 5% or greater, The Tribes' IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- (a) a review of The Tribes' billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);
- (b) for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements*

- (a) Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and The Tribes shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from The Tribes after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report

describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

- (b) Paid Claims without Supporting Documentation. Any Paid Claim for which The Tribes cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by The Tribes for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- (c) Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments.* The Tribes shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. The Tribes shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology*

- (a) Claims Review Population. A description of the Population subject to the Claims Review.
- (b) Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

- (c) Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- (d) Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- (e) Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation*

- (a) A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- (b) A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.
- (c) A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings*

- (a) Narrative Results
 - (i) A description of The Tribes’ billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - (ii) A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns

noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

- (b) Quantitative Results
- (i) Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by The Tribes (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
 - (ii) Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to The Tribes.
 - (iii) Total dollar amount of all Overpayments in the Discovery Sample and the Full Sample (if applicable).
 - (iv) Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample.
 - (v) Error Rate in the Discovery Sample and the Full Sample.
 - (vi) A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
 - (vii) If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.

- (c) Recommendations. The IRO's report shall include any recommendations for improvements to The Tribes' billing and coding system based on the findings of the Claims Review.

4. *Systems Review Findings.* The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

- (a) the strengths and weaknesses in The Tribes' billing systems and processes;
- (b) the strengths and weaknesses in The Tribes' coding systems and processes; and
- (c) possible improvements to The Tribes' billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.