

**STATE AGENCY COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LOUISIANA DEPARTMENT OF HEALTH**

I. PREAMBLE

Louisiana Department of Health (LDH) hereby enters into this State Agency Compliance Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this Agreement, LDH is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE AGREEMENT

A. The period of the compliance obligations assumed by LDH under this Agreement shall be three (3) years from the effective date of this Agreement. The “Effective Date” shall be the date on which the final signatory of this Agreement executes this Agreement. 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, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) LDH’s final Annual Report or (2) any additional materials submitted by LDH pursuant to OIG’s request, whichever is later.

C. For purposes of this Agreement, the term “Leadership” includes the following senior employees at LDH: (1) the Secretary; (2) Deputy Secretary; (3) Undersecretary of the State Medicaid Program; (4) Deputy Undersecretary of the State Medicaid Program; (5) State Health Officer; and (6) Director of Medicaid.

D. For purposes of this Agreement, the term “Covered Persons” includes: (1) all members of Leadership, and employees of LDH; and (2) all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of LDH, excluding vendors whose sole

connection with LDH is selling or otherwise providing medical supplies or equipment to LDH.

III. CORPORATE INTEGRITY OBLIGATIONS

LDH shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer, Compliance Committee, Leadership and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, LDH shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the Agreement. The Compliance Officer shall be an employee and a member of senior employee of LDH, shall report directly to the Secretary of LDH, and shall not be, or be subordinate to, the General Counsel or Undersecretary or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for LDH. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Leadership of LDH and shall be authorized to report on such matters to the Leadership at any time. Written documentation of the Compliance Officer's reports to the Leadership shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by LDH as well as any reporting obligations created under this Agreement.

Any non-compliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this Agreement.

LDH shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to

perform the duties necessary to meet the obligations in this Agreement, within five days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, LDH shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other senior employees necessary to meet the requirements of this Agreement (e.g., leadership of relevant departments, such as fiscal, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of LDH's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

LDH shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such a change.

3. *Leadership Compliance Obligations.* The Leadership of LDH shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this Agreement.

The Leadership shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee LDH's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the Agreement, adopting a resolution, signed by each member of the Leadership summarizing its review and oversight of LDH's compliance with Federal health care program requirements and the obligations of this Agreement.

At minimum, the resolution shall include the following language:

“The Leadership has made a reasonable inquiry into the operations of LDH’s Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Leadership has concluded that, to the best of its knowledge, LDH has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the Agreement.”

If the Leadership is unable to provide such a conclusion in the resolution, the Leadership shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at LDH.

LDH shall report to OIG, in writing, any changes in the composition of the Leadership, or any actions or changes that would affect the Leadership’s ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this Agreement for all Covered Persons, certain LDH employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable LDH department is in compliance with applicable Federal health care program requirements and the obligations of this Agreement. These Certifying Employees shall include, at a minimum, the following: members of Leadership and the managers of LDH’s Office of Management and Finance, Bureau of Health Services Financing, and Division of Fiscal Management. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and LDH policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of LDH is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, LDH shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

Within 90 days after the Effective Date, LDH shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this Agreement and LDH's compliance with Federal health care program requirements (Policies and Procedures) Throughout the term of this Agreement, LDH shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), LDH shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, LDH shall develop a written plan (Training Plan) that outlines the steps LDH will take to ensure that all Covered Persons receive at least annual training regarding LDH's Agreement requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. LDH shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Leadership Training.* Within 90 days after the Effective Date, each member of Leadership shall receive at least two hours of training. This training shall address the responsibilities of Leadership with respect to review and oversight of the Compliance Program. Specifically, the training shall address the risks, oversight areas, and strategic approaches to conducting oversight of a state Medicaid agency. This training may be conducted by an outside compliance expert hired by Leadership.

New members of Leadership shall receive the Leadership Training described above within 30 days after becoming a member of Leadership or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* LDH shall make available to OIG, upon request, training materials and records verifying that Covered Persons Leadership have timely received the training required under this section.

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, LDH shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.
- b. *Retention of Records.* The IRO and LDH shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and LDH) related to the reviews.
- c. *Access to Records and Personnel.* LDH shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D and that all records furnished to the IRO are accurate and complete.

2. *Quarterly Medicaid Assistance Expenditures Review.* The IRO shall

review Quarterly Medicaid Assistance Expenditures Review Forms (The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64)) submitted to the Centers for Medicare and Medicaid Services (CMS) by LDH, the Medicaid Program Budget Report (Form CMS-37) and all documentation and materials required to determine the accuracy and appropriateness of expenditures reported by LDH under the Medicaid program pursuant to title XIX of the Social Security Act (the Act), and as applicable, under the Children's Health Insurance Program (CHIP) under Title XXI of the Act, that are allowable in accordance with applicable implementing federal, state, and local statutes, regulations, policies, and the state plan approved by CMS and in effect during the applicable Quarter Ended date under Title XIX of the Act for the Medicaid program, and as applicable, under Title XXI of the Act for the CHIP.

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to LDH a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this Agreement. The IRO's certification shall include a summary of all current and prior engagements between LDH and the IRO.

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, LDH shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with LDH's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall require compliance, legal, and members of Leadership, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. LDH shall maintain the risk assessment and internal review process for the term of the Agreement.

F. Disclosure Program

Within 90 days after the Effective Date, LDH shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated

with LDH's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. LDH shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of LDH's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by LDH. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, LDH shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

1. *Definitions.* For purposes of this Agreement:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; 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.

b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

a. LDH shall screen all prospective Covered Persons against the Exclusion List 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. LDH shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.

c. LDH shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects LDH’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. LDH understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that LDH may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether LDH meets the requirements of Section III.G.

3. *Removal Requirement.* If LDH has actual notice that a Covered Person has become an Ineligible Person, LDH shall remove such Covered Person from responsibility for, or involvement with, LDH’s business operations related to the Federal health care program(s) from which such Covered Person has been excluded 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 any Federal health care

program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If LDH has 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, LDH 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.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, LDH shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to LDH conducted or brought by a governmental entity or its agents involving an allegation that LDH has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. LDH also shall provide written notice to OIG within 30 days after the resolution of the matter and a description of the findings and/or results of the investigation or proceeding, if any.

I. Overpayments

1. *Definition of Overpayment.* An "Overpayment" means any funds that LDH receives or retains under any Federal health care program to which LDH, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, LDH shall develop and implement written policies and procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this Agreement, a "Reportable Event" means anything that involves:

- a. a substantial Overpayment;

- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If LDH determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, LDH shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a. and III.J.1.b.* For Reportable Events under Section III.J.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by LDH to identify and quantify any Overpayments; and
- e. a description of LDH's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, LDH shall repay the Overpayment, in accordance with the

requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that LDH completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

V. **IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report

Within 120 days after the Effective Date, LDH shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the members of Leadership who are responsible for satisfying the Leadership compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees, and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4.;
5. a list of the Policies and Procedures required by Section III.B.;
6. the Training Plan required by Section III.C.1 and a description of the Leadership training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
7. the following information regarding the IRO(s): (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 Appendix A to this Agreement; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to LDH;
8. a description of the risk assessment and internal review process required by Section III.E.;
9. a description of the Disclosure Program required by Section III.F.;
10. a description of the Ineligible Persons screening and removal process required by Section III.G.;
11. a copy of LDH's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I.;
12. a description of LDH's organizational structure;
13. a list of all of LDH's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s); and
14. the certifications required by Section V.C.

B. Annual Reports

LDH shall submit to OIG a report on its compliance with the Agreement requirements for each of the three Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the members of Leadership members who are responsible for satisfying the Leadership compliance obligations, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Leadership and Certifying Employees; and any changes to the written process for completing Management Certifications under Section III.A.4;
2. the dates of each report made by the Compliance Officer to the Leadership (written documentation of such reports shall be made available to OIG upon request);
3. the Leadership resolution required by Section III.A.3 and a description of the documents and other materials reviewed by Leadership, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
4. a list of any new or revised Policies and Procedures developed during the Reporting Period;
5. a description of any changes to LDH's Training Plan developed pursuant to Section III.C, and a summary of any Leadership training provided during the Reporting Period;
6. a complete copy of all reports prepared pursuant to Section III.D and LDH's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
7. a certification from the IRO regarding its professional independence and objectivity with respect to LDH;
8. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;
9. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

10. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

11. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

13. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

14. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

15. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and LDH's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

16. a description of all changes to the most recently provided list of LDH's locations as required by Section V.A.13;

17. a description of any changes to LDH's organizational structure; and

18. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees.* In each Annual Report, LDH shall include the certifications of Certifying Employees required by Section III.A.4;

2. *Compliance Officer and Secretary.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Secretary that:

- a. to the best of his or her knowledge, except as otherwise described in the report, LDH has implemented and is in compliance with all of the requirements of this Agreement;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he or she understands that the certification is being provided to and relied upon by the United States

3. *Undersecretary.* The first Annual Report shall include a certification by the Undersecretary that, to the best of his or her knowledge, LDH has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

LDH shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. LDH shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and

reports required under this Agreement shall be submitted to the following entities:

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

LDH:

Virginia L. Brandt, CPA, CRFAC, CFE, AHFI
Compliance Officer
Office of the Secretary, Louisiana Department of Health
Bienville Building, Office 583
628 North 4th Street
Baton Rouge, LA 70802
Phone: (225) 219-3454
Fax: (225) 342-2065

Unless otherwise specified, all notifications and reports required by this Agreement may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, LDH may be required to provide OIG with an electronic copy of each notification or report required by this Agreement in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy LDH's books, records, and other documents and supporting materials, and conduct on-site reviews of any of LDH's locations, for the purpose of verifying and evaluating: (a) LDH's compliance with the terms of this Agreement and (b) LDH's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by LDH to OIG or its duly

authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of LDH's Leadership, employees, and contractors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. LDH shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. LDH's Leadership, employees, and contractors may elect to be interviewed with or without a representative of LDH present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify LDH prior to any release by OIG of information submitted by LDH pursuant to its obligations under this Agreement and identified upon submission by LDH as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, LDH shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH OF AGREEMENT

A. LDH acknowledges its obligation to comply with laws, regulations, and requirements applicable to state Medicaid agencies and providers of services under Federal health care programs, and shall act in good faith to implement the terms of this Agreement as a means to ensure future compliance.

B. LDH and OIG shall work together in good faith to resolve any disagreements regarding LDH's implementation of and compliance with the terms of this Agreement. 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 prior to such termination. In the event of termination, it would remain within OIG's authority and discretion 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 OIG audits or investigations, referral of matters to the

Department of Justice, referral of matters for possible administrative resolution, and/or reporting of matters to Congress.

XI. EFFECTIVE AND BINDING AGREEMENT

LDH and OIG agree as follows:

A. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement.

B. This Agreement constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this Agreement.

C. All requirements and remedies set forth in this Agreement are in addition to and do not affect (1) LDH's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

D. The undersigned LDH signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

E. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

ON BEHALF OF LDH

/Rebekah Gee/
REBEKAH E. GEE, MD, MPH
Secretary
Louisiana Department of Health

10/29/19
DATE

/Stephen Russo/
STEPHEN RUSSO, ESQ.
Counsel
Louisiana Department of Health

10/29/2019
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

1. LDH 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 30 days after OIG receives the information identified in Section V.A.6 of the CIA or any additional information submitted by LDH in response to a request by OIG, whichever is later, OIG will notify LDH if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, LDH may continue to engage the IRO.

2. If LDH engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, LDH shall submit the information identified in Section V.A.6 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by LDH at the request of OIG, whichever is later, OIG will notify LDH if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, LDH may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Quarterly Medicaid Assistance Expenditures Review who have expertise in the Medicaid program requirements applicable to the accounting, documentation and reporting of expenditures by state Medicaid programs pursuant to title XIX of the Social Security Act (the Act), and as applicable, under the Children's Health Insurance Program (CHIP) under Title XXI of the Act, that are allowable in accordance with applicable implementing federal, state, and local statutes, regulations, policies, and the state plan approved by the Centers for Medicare and Medicaid Services (CMS); and

2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Quarterly Medicaid Assistance Expenditures Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicaid program statutes, regulations, and other applicable guidance in making assessments in the Quarterly Medicaid Assistance Expenditures Review;
3. request clarification from CMS if in doubt of the application of a particular Medicaid program policy or regulation;
4. respond to all OIG inquires 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 the CIA.

D. LDH Responsibilities

LDH shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the Quarterly Medicaid Assistance Expenditures Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *LDH and IRO.* If LDH terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, LDH must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. LDH 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 shall notify LDH in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. LDH shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by LDH regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify LDH in writing that LDH shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. LDH must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require LDH to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

QUARTERLY MEDICAID ASSISTANCE EXPENDITURES REVIEW

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

1. *Definitions*. For the purposes of the Quarterly Medicaid Assistance Expenditures Review, the following definitions shall be used:

- a. Overstatement: Any amount consisting of enhanced Federal share reimbursement to which LDH has improperly received, as determined by the IRO in connection with the Quarterly Medicaid Assistance Expenditures Review performed under this Appendix B.
- b. Quarterly Medicaid Assistance Expenditures Review Forms: The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64) filed by LDH of its quarterly Medicaid assistance expenditures, and the Medicaid Program Budget Report (Form CMS-37) of the LDH.
- c. Population: The Population shall be defined as all Quarterly Medicaid Assistance Expenditures Forms (CMS-64s) filed during the 12-month period covered by the Claims Review.

2. *Quarterly Medicaid Assistance Expenditures Review*. The IRO shall randomly select Quarterly Medicaid Assistance Expenditures Review Forms from the Population for review. In addition, the IRO shall select for review all Quarterly Medicaid Assistance Expenditures Forms from the Population for all quarters prior to and after any change in the Federal medical assistance percentage (FMAP) for the State of Louisiana. The selected Quarterly Medicaid Assistance Expenditures Review Forms shall be reviewed based on the supporting documentation available at LDH's office or under LDH's control and applicable Medicaid program requirements to determine whether: (a) the CMS-64 only includes expenditures under the Medicaid program and, as applicable, under the CHIP, that are allowable in accordance with applicable implementing federal, state, and local statutes, regulations, policies and the state plan approved by CMS and in effect during the Quarter Ended (as identified on the CMS-64); (b) the expenditures included in the CMS-64 are based on LDH's account of actual recorded expenditures and are not based on estimates; (c) the required amount of state and/or local funds were available and used to match the state's allowable expenditures included in the CMS-64 and such state and/or local funds were in accordance with all applicable federal requirements for the non-federal share match of expenditures; and (d) Federal matching

funds were not claimed on the CMS-64 to match any expenditure under any Medicaid and/or CHIP state plan amendment that was submitted after January 2, 2001, and that has not been approved by CMS effective for the Quarter Ended indicated on the CMS-64. For each Quarterly Medicaid Assistance Expenditures Form that result in an Overstatement, the IRO shall review the system(s) and process(es) that generated the Quarterly Medicaid Assistance Expenditures Forms and identify any problems or weaknesses that may have resulted in the identified Overstatement. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Quarterly Medicaid Assistance Expenditures Forms.

3. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Quarterly Medicaid Assistance Expenditures Forms and LDH shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Quarterly Medicaid Assistance Expenditures Forms. If the IRO accepts any supplemental documentation or materials from LDH after the IRO has completed its initial review of the Quarterly Medicaid Assistance Expenditures Review (Supplemental Materials), the IRO shall identify in the Quarterly Medicaid Assistance Expenditures 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 Quarterly Medicaid Assistance Expenditures Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

4. *Repayment of Identified Overpayments.* LDH shall repay to CMS within 60 days the Overstatement(s) identified by the IRO in the Quarterly Medicaid Assistance Expenditures Review Report. LDH shall make available to OIG all documentation that reflects the refund of the Overstatement(s) to CMS. OIG, in its sole discretion, may refer the findings of the Quarterly Medicaid Assistance Expenditures Review (and any related work papers) received from LDH to CMS for appropriate follow up.

B. Quarterly Medicaid Assistance Expenditures Review Report. The IRO shall prepare a Quarterly Medicaid Assistance Expenditures Review Report as described in this Appendix for each Quarterly Medicaid Assistance Expenditures Review performed. The following information shall be included in the Quarterly Medicaid Assistance Expenditures Review Report.

1. *Quarterly Medicaid Assistance Expenditures Review Methodology.*
 - a. Quarterly Medicaid Assistance Expenditures Review Population. A statement of the Population subject to the Quarterly Medicaid Assistance Expenditures Review.
 - b. Quarterly Medicaid Assistance Expenditures Review Objective. A clear statement of the objective intended to be achieved by the Quarterly Medicaid Assistance Expenditures Review.
 - c. Source of Data. A description of the underlying source documentation (e.g., invoices, cost reports, eligibility records, etc) relied upon by the IRO when performing the Quarterly Medicaid Assistance Expenditures Review as well as the applicable statutes, regulations guidance, policies, or directives relied on by the IRO.
 - d. Review Protocol. A narrative description of how the Quarterly Medicaid Assistance Expenditures Review was conducted and what was evaluated.
 - e. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.
2. *Quarterly Medicaid Assistance Expenditures Review Findings.*
 - a. Narrative Results.
 - i. A description of LDH's expenditures accounting, calculation, documentation, and reporting system(s), including the identification, by position description, of the personnel involved in expenditures accounting, calculation, documentation, and reporting.
 - ii. A description of controls in place at LDH to ensure that the amounts reported on the Quarterly Medicaid Assistance Expenditures Form are actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the Quarterly Medicaid Assistance Expenditures Form is filed.
 - iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Quarterly Medicaid Assistance Expenditures Review.

- b. Quantitative Results.
 - i. Total dollar amount of any Overstatement in the Quarterly Medicaid Assistance Expenditures Review.
 - ii. Total dollar amount of actual quarterly expenses reported on the Quarterly Medicaid Assistance Expenditures Form subject to the Quarterly Medicaid Assistance Expenditures Review.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to LDH's expenditure accounting, calculation, documentation and reporting systems or to LDH's controls for ensuring that all amounts reported on the Quarterly Medicaid Assistance Expenditures Forms are actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the Quarterly Medicaid Assistance Expenditures Forms is filed, based on the findings of the Quarterly Medicaid Assistance Expenditures Review.

3. *Credentials.* The names and credentials of the individuals who performed the Quarterly Medicaid Assistance Expenditures Review.