

**CORPORATE INTEGRITY AGREEMENT BETWEEN THE STATE OF VERMONT  
AND BURLINGTON LABORATORIES, INC. and BURLINGTON LABS, LLC.**

**I. PREAMBLE**

Burlington Laboratories, Inc. and Burlington Labs, LLC, (“Burlington”) hereby enter into this Corporate Integrity Agreement (“CIA”) with the State of Vermont, by and through the Department of Vermont Health Access (“DVHA”), to promote compliance with the statutes, regulations, and written directives of the Vermont Medicaid Program, and all other applicable laws (collectively, “Government Health Care Program Requirements”).

**II. TERM AND SCOPE OF THE CIA**

The period of Burlington’s compliance obligations under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The “Effective Date” shall be the date on which the final signatory 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.”

The scope of this CIA shall include all of Burlington’s activities in providing services and filing claims under the Vermont Medicaid Program, as well as its activities to ensure compliance with Government Health Care Program Requirements. The scope of this CIA includes such actions taken, directed, or caused by a Covered Person. A “Covered Person” includes:

- A. all owners, officers, directors, and employees of Burlington; and
- B. all contractors, subcontractors, agents, and other persons who provide services or who perform billing or coding functions on behalf of Burlington, excluding vendors whose sole connection with Burlington is selling or otherwise providing medical supplies or equipment to Burlington and who do not bill the Vermont Medicaid Program for such medical supplies or equipment.

**III. CORPORATE INTEGRITY OBLIGATIONS**

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

**A. Compliance Officer**

Within 120 days after the Effective Date, Burlington shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible, in coordination with qualified outside counsel, for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Government Health Care Program Requirements. The Compliance Officer shall be a member of senior management of Burlington, shall report directly to the Chief Executive Officer of Burlington and shall make

periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Burlington.

The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Burlington as well as for any reporting obligations created under this CIA. The Compliance Officer is permitted to have other titles and other job duties at Burlington, excepting General Counsel or Chief Financial Officer. However, any noncompliance job responsibilities of the Compliance Officer shall be limited to allow sufficient time for completion of compliance activities and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Burlington shall report to DVHA, in writing, any change 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 CIA, within five business days after the change.

#### **B. Board of Directors Compliance Obligations**

The Burlington Board of Directors ("Board") shall be responsible for the review and oversight of matters related to compliance with Government Health Care Program Requirements and the obligations of this CIA.

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

1. meeting at least quarterly to review and oversee Burlington's Compliance Program, including but not limited to the performance of the Compliance Officer and review of the Compliance Officer's Report;
2. ensuring that Burlington adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and Government Health Care Program Requirements;
3. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Burlington's compliance with Government Health Care Program Requirements and the obligations of this CIA. At minimum, the resolution shall include the following language:

The Board of Directors has made a reasonable inquiry into the operations of Burlington's Compliance Program including the performance of the Compliance Officer and review of the Compliance Officer's report. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Burlington is in compliance with the CIA and Government Health Care Program Requirements."

If the Board is unable to provide such a conclusion in the resolution, the Board 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 Burlington.

4. Burlington shall report to DVHA, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

### **C. Written Standards**

#### **1. Code of Conduct**

Within 120 days after the Effective Date, Burlington shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Burlington shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Burlington's commitment to full compliance with all Government Health Care Program Requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Burlington's requirement that all of its Covered Persons shall be expected to comply with all Government Health Care Program Requirements and with Burlington's own Policies and Procedures;
- c. the requirement that all of Burlington's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Burlington, suspected violations of any Government Health Care Program Requirements or of Burlington's own Policies and Procedures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Burlington's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Burlington shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

## **2. Policies and Procedures**

Within 120 days after the Effective Date, Burlington shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA, and Burlington's compliance with Government Health Care Program Requirements. Within 120 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. Periodically, Burlington shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be distributed to all Covered Persons.

## **3. Compliance Plan**

Within 120 days after the Effective Date, Burlington shall create and implement, with the assistance of qualified outside counsel, a Compliance Plan, which directs and guides the activities that Burlington will undertake to ensure compliance with the statutes, regulations, rules and guidance applicable to Government Health Care Program Requirements. The plan shall include provisions providing for periodic internal audits and random monitoring of claims filed with Vermont Medicaid, a program whereby employees may anonymously report potential violations of Government Health Care Program Requirements to the Compliance Officer without threat of retribution, a description of how Burlington will investigate and respond to reports of potential violations of Government Health Care Program Requirements, and clear disciplinary protocols that will be followed when a Covered Person is found to have violated Government Health Care Program Requirements or any provision of this CIA.

### **D. Training and Education**

#### **1. General Training**

Within 120 days after the Effective Date, Burlington shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Burlington's:

- a. CIA requirements; and
- b. Compliance Program, including the Code of Conduct, Policies and Procedures, and Compliance Plan.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least a one hour of General Training in each subsequent Reporting Period.

#### **2. Specific Training**

Within 120 days after the Effective Date, each Covered Person who has direct responsibility for the submission of claims to Vermont Medicaid and each Covered Person who

directly supervises at least one Covered Person who has direct responsibility for the submission of claims to Vermont Medicaid shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. the Government Health Care Program Requirements regarding the accurate coding and submission of claims;
- b. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- c. applicable reimbursement statutes, regulations, and program requirements and directives;
- d. the legal sanctions for violations of the Government Health Care Program Requirements; and
- e. examples of proper and improper claims submission practices.

New Covered Persons subject to this Specific Training requirement shall receive this training within 30 days after the beginning of their employment or any change in their employment which brings them within the scope of the Specific Training requirement, or within 120 days after the Effective Date, whichever is later. After receiving the initial Specific Training described in this section, each Covered Person subject to this section shall receive at least two hours of Specific Training in each subsequent Reporting Period.

### **3. Laboratory Billing & Coding Training**

Within 120 days after the Effective Date, Burlington shall designate an employee to receive specialized laboratory Billing & Coding training and shall submit a training plan for that designated employee that includes at least 40 hours of training delivered by a reputable medical billing and coding training organization on topics specific to the billing and coding of toxicology laboratory services. The plan may include multiple courses delivered by different training providers and include a mix of live courses and webinars. At least 8 hours of training must be delivered live. DVHA shall approve the plan submitted by Burlington or suggest alternative courses that meet the 40-hour requirement. The designated employee shall complete the approved training plan within 180 days of the approval. If the designated employee shall leave the employment of Burlington, a new employee must be designated and come into compliance within 180 days after the departure of the previous designated employee.

### **4. Certification**

Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. The certifications and training materials shall be made available to DVHA, upon request.

## **5. Qualifications of Trainer**

Persons providing the training shall be knowledgeable about the subject area.

## **6. Update of Training**

Burlington shall review the training annually, and, where appropriate, update the training to reflect changes in Government Health Care Program Requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information.

## **7. Computer-based Training**

Burlington may provide the training required under this CIA through appropriate computer-based training programs. If Burlington chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

## **E. Review Procedures**

### **1. Engagement of Independent Review Organization**

Within 120 days after the Effective Date, Burlington 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. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

### **2. IRO Reviews**

The IRO shall perform the Claims Review, and shall prepare reports, as described in this Section and in Appendix B to this CIA. Annual Reviews will be completed by the IRO by the anniversary date of this CIA for each year the CIA is in effect. The IRO and Burlington shall retain and make available to DVHA, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Burlington) related to the reviews.

### **3. Repayment of Identified Overpayments**

Burlington shall repay within 60 days any Overpayment(s) identified by the IRO. If Burlington disagrees with the IRO's finding of an overpayment it may appeal the finding to the Commissioner, and retains all appellate and adjudication rights it has with regard to that determination under Vermont laws and regulations. This provision does not replace or supersede any duties or responsibilities that Burlington may have pursuant to any state or federal law or regulation regarding the repayment of overpayments discovered in its normal course of business.

#### **4. Validation Review**

In the event DVHA has reason to believe that: (a) Burlington's Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, DVHA may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (Validation Review). Any Validation Review of Reports submitted as part of Burlington's final Annual Report shall be initiated no later than one year after Burlington's final submission (as described in Section II) is received by DVHA. Prior to initiating a Validation Review, DVHA shall notify Burlington of its intent to do so and provide a written explanation of why DVHA believes such a review is necessary. To resolve any concerns raised by DVHA, Burlington may request a meeting with DVHA to: (a) discuss the results of any Claims Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or (c) propose alternatives to the proposed Validation Review. Burlington agrees to provide any additional information as may be requested by DVHA under this Section in an expedited manner. DVHA will attempt in good faith to resolve any Claims Review issues with Burlington prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of DVHA.

#### **5. Independence and Objectivity Certification**

The IRO shall include in its report(s) to Burlington a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, and that it has concluded that it is, in fact, independent and objective.

#### **F. Reportable Events**

##### **1. Definition of Reportable Event**

For purposes of this CIA, a "Reportable Event" means anything that involves:

- a. the discovery of a substantial Overpayment;
- b. any ongoing investigation, legal proceeding, or administrative recoupment proceeding, known to Burlington, conducted or brought by a governmental entity or its agents involving an allegation that Burlington has committed a crime, has engaged in fraudulent activities, has submitted false claims, or has failed to return overpayments;
- c. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any government health care program for which penalties or exclusion may be authorized;
- d. the employment of or contracting with a person or entity who is ineligible to participate in government healthcare programs; or

- e. any change in ownership or control of Burlington or the filing of any bankruptcy petition or other legal proceedings involving Burlington which would impact its ability to fulfill its obligations under its Provider Agreements or this CIA.

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

## **2. Reporting of Reportable Events.**

If Burlington determines (after a reasonable opportunity to conduct an appropriate review or investigation) through any means that there is a Reportable Event, Burlington shall notify DVHA, in writing, within 30 days, excepting Reportable Events under Section III.F.1.a, after making the determination that the Reportable Event exists.

### **3. Reportable Events under Section III.F.1.a**

For Reportable Events under Section III.F.1.a, the report to DVHA shall be made within 60 days of discovery of the overpayment, and shall include:

- a. description of the steps taken by Burlington to identify and quantify the Overpayment;
- b. a complete description of the overpayment and the circumstances leading to the occurrence of the overpayment, including the relevant facts, persons involved, and legal and government health care program authorities implicated;
- c. a description of Burlington's actions taken to correct the overpayment; and
- d. any further action Burlington plans to take to address the overpayment and prevent it from recurring.

### **4. Reportable Events under Section III.F.1.b and c.**

For Reportable Events under Section III.I.1.b and c, the report to DVHA shall include:

- a. a complete description of the event or allegations including the relevant facts, persons involved, and legal and government health care program authorities implicated;
- b. the identity of the investigating or prosecuting agency;
- c. the forum where any proceedings are pending;
- d. the status of such investigation or legal proceeding;
- e. a description of Burlington's actions taken to correct the Reportable Event;
- f. any further steps Burlington plans to take to address the Reportable Event and prevent it from recurring; and

- g. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Burlington to identify and quantify the Overpayment;

Burlington shall also provide written notice to DVHA within 30 days after the resolution of the matter, and shall provide DVHA with a description of the findings and/or results of the investigation or proceedings, if any.

**5. Reportable Events under Section III.F.1.d.**

For Reportable Events under Section III.I.1.d, the report to the DVHA shall include:

- a. the identity of the ineligible person or entity;
- b. the position or function for which the person or entity was employed or contracted, including a description of the job duties in that position or function;
- c. the dates of the person or entity's employment or contractual relationship;
- d. a description Burlington's screening process for employees or contractors including any background checks that were completed by Burlington before and/or during the person or entity's employment or contract;
- e. a description of how the conduct was discovered, including a description of any flaw or breakdown in the screening process that led to the employment or contracting with the ineligible individual;
- f. a description of Burlington's actions taken to correct the Reportable Event; and
- g. any further steps Burlington plans to take to address the Reportable Event and prevent it from recurring.

**6. Reportable Events under Section III.F.1.e.**

For Reportable Events under Section III.I.1.e, the report to the DVHA shall include documentation of the change in ownership or control, the bankruptcy filing, or the filed legal action that is the subject of the Reportable Event and a description of any anticipated impacts on Burlington's ability to perform its obligations under its Provider Agreements or this CIA.

**IV. IMPLEMENTATION AND ANNUAL REPORTS**

**A. Implementation Report**

Within 180 days after the Effective Date, Burlington shall submit a written report to DVHA summarizing the status of its implementation of the requirements of this CIA (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. a copy of Burlington's Code of Conduct required by Section III.B.1;
3. a summary of all Policies and Procedures required by Section III.B;
4. the total number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions;
5. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the total number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.
6. 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 CIA; (d) a summary and description of any and all current and prior engagements and agreements between Burlington and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Burlington;
7. a description of Burlington's corporate structure, and
8. the certifications required by Section IV.B.

**B. Annual Reports.**

Burlington shall submit to DVHA annually a report with respect to the status of, and findings regarding, Burlington's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes;
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions;
4. the following information regarding each type of training required by Section III.Ca

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.
5. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter;
  6. Burlington's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;
  7. a summary and description of any and all current and prior engagements and agreements between Burlington and the IRO (if different from what was submitted as part of the Implementation Report);
  8. a certification from the IRO regarding its professional independence and objectivity with respect to Burlington;
  9. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
  10. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. 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;
  11. the certifications required by Sections III.E.5 and IV.C.

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

### **C. Certifications**

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

1. to the best of his or her knowledge, except as otherwise described in the report, Burlington is in compliance with all of the requirements of this CIA; and

2. 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.

## **V. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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

DVHA:  
Department of Vermont Health Access  
Attn: General Counsel  
NOB 1 South  
280 State Drive  
Waterbury, Vermont 05671

Unless otherwise specified, all notifications and reports required by this CIA 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. Upon request by DVHA, Burlington may be required to provide DVHA with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

## **VI. DVHA INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights DVHA may have by statute, regulation, or contract, DVHA or its duly authorized representative(s) may examine or request copies of Burlington's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Burlington's locations for the purpose of verifying and evaluating:

(a) Burlington's compliance with the terms of this CIA; (b) Burlington's compliance with the requirements of the Vermont Medicaid Program; and (c) the propriety of claims for any services for which the total claims for such services by Burlington exceed 115% of the baseline volume established by Burlington's claims over the previous twelve months for such services.

The documentation described above shall be made available by Burlington to DVHA or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, DVHA or its duly authorized representative(s) may interview any of Burlington's employees, contractors, or agents 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 DVHA. Burlington shall assist DVHA or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon DVHA's request.

## **VII. DOCUMENT AND RECORD RETENTION**

Burlington shall maintain for inspection all documents and records relating to reimbursement from the Vermont Medicaid Program and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

## **VIII. DISCLOSURES**

DVHA shall make a reasonable effort to notify Burlington upon a request for and prior to any release by DVHA of information submitted by Burlington pursuant to its obligations under this CIA and identified upon submission by Burlington as trade secrets, or information that is commercial or financial and privileged or confidential, under the Vermont Public Records Law (1 V.S.A. §§310-320). With respect to such releases, Burlington shall have any rights set forth by Vermont Law.

## **IX. BREACH AND DEFAULT PROVISIONS**

Burlington is expected to fully and timely comply with all of its CIA obligations.

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations.**

As a contractual remedy, Burlington and DVHA hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Burlington fails to establish and implement any of the following obligations as described in Section III:

1. appointment of a Compliance Officer;
2. a written Code of Conduct;
3. written Policies and Procedures;
4. written Compliance Plan
5. training required by Section III.D;
6. reporting of Reportable Events.

A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Burlington fails to engage and use an IRO, as required in Section III.E, Appendix A, and Appendix B.

A Stipulated Penalty of \$500 (which shall begin to accrue on the day after the date the obligation became due) for each day Burlington fails to submit the Implementation Report or any Annual Reports to DVHA in accordance with the requirements of Section IV by the deadlines for submission.

A Stipulated Penalty of \$500 (which shall begin to accrue on the day after the date the obligation became due) for each day Burlington fails to submit any Claims Review Report in accordance with the requirements of Section III.E and Appendix B.

A Stipulated Penalty of \$1,000 for each day Burlington fails to grant access as required in Section VI. (This Stipulated Penalty shall begin to accrue on the date Burlington fails to grant access.)

A Stipulated Penalty of \$1,000 for each false certification submitted by or on behalf of Burlington as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the DVHA), or otherwise required by this CIA.

A Stipulated Penalty of \$1,000 for each day Burlington fails to comply fully and adequately with any obligation of this CIA. DVHA shall provide notice to Burlington stating the specific grounds for its determination that Burlington has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Burlington shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 15 days after Burlington receives this notice from DVHA of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which DVHA has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

#### **B. Timely Written Requests for Extensions.**

Burlington may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if DVHA grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Burlington fails to meet the revised deadline set by DVHA. Notwithstanding any other provision in this Section, if DVHA denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Burlington receives DVHA's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by DVHA at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

## **C. Payment of Stipulated Penalties**

### **1. Demand Letter.**

Upon a finding that Burlington has failed to comply with any of the obligations described in Section IX.A and after determining that Stipulated Penalties are appropriate, DVHA shall notify Burlington of: (a) Burlington's failure to comply; and (b) DVHA's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

### **2. Response to Demand Letter.**

Within 10 days after the receipt of the Demand Letter, Burlington shall either: (a) cure the breach to DVHA's satisfaction and pay the applicable Stipulated Penalties or (b) exercise its right of appeal pursuant to the procedures set forth in Medicaid Covered Service Rule 7106.6 to dispute DVHA's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section IX.E. In the event Burlington elects to request a hearing pursuant to Rule 7106.6, the Stipulated Penalties shall continue to accrue until Burlington cures, to DVHA's satisfaction, the alleged breach in dispute regardless of any language in Rule 7106.6 to the contrary. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section IX.D.

### **3. Form of Payment.**

Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by DVHA in the Demand Letter.

### **4. Independence from Material Breach Determination.**

Except as set forth in Section IX.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for DVHA's decision that Burlington has materially breached this CIA, which decision shall be made at DVHA's discretion and shall be governed by the provisions in Section X.D, below.

## **D. Exclusion for Material Breach of this CIA.**

### **1. Definition of Material Breach**

A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section IX.A;
- b. a failure by Burlington to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.F;

- c. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, and Appendix B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

## **2. Notice of Material Breach and Intent to Exclude**

The parties agree that a material breach of this CIA by Burlington constitutes an independent basis for Burlington's exclusion from participation in the Vermont Medicaid Program. Upon a determination by DVHA that Burlington has materially breached this CIA and that exclusion is the appropriate remedy, DVHA shall notify Burlington of: (a) Burlington's material breach; and (b) DVHA's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

## **3. Opportunity to Cure**

Burlington shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to DVHA's satisfaction that:

- a. Burlington is in compliance with the obligations of the CIA cited by DVHA as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Burlington has begun to take action to cure the material breach; (ii) Burlington is pursuing such action with due diligence; and (iii) Burlington has provided to DVHA a reasonable timetable for curing the material breach.

## **4. Exclusion Letter**

If, at the conclusion of the 30-day period, Burlington fails to satisfy the requirements of Section IX.D.3, DVHA may exclude Burlington from participation in the Vermont Medicaid Program. DVHA shall notify Burlington in writing of its determination to exclude Burlington. (This letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section IX.E, below, and Medicaid Covered Service Rule 7106.6, the exclusion shall go into effect 30 days after the date of Burlington's receipt of the Exclusion Letter. Pursuant to federal laws and regulations, the exclusion may have national effect and apply to other government healthcare programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Burlington may apply for reinstatement by submitting a written request for reinstatement in accordance applicable regulations.

## **E. Dispute Resolution**

### **1. Review Rights.**

Upon DVHA's delivery to Burlington of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Burlington shall be afforded certain review rights comparable to the ones that are provided in Medicaid Covered Service Rule 7106.6 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, DVHA's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by the Secretary of the Agency of Human Services or a hearing officer appointed by the Secretary. In the event that Burlington decides to appeal the Secretary's final decision, such appeal shall proceed pursuant to 3 V.S.A. § 815.

### **2. Stipulated Penalties Review**

The only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Burlington was in full and timely compliance with the obligations of this CIA for which DVHA demands payment; and (b) the period of noncompliance. Burlington shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. DVHA shall not have the right to a judicial appeal from an adverse decision related to Stipulated Penalties. If the Secretary or Hearing Officer agrees with DVHA with regard to a finding of a breach of this CIA and orders Burlington to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the Secretary or Hearing Officer issues such a decision unless Burlington requests a judicial review of the decision. If the Secretary or Hearing Officer decision is properly appealed to the courts and the court upholds the determination of DVHA, the Stipulated Penalties shall become due and payable 20 days after the court issues its decision.

### **3. Exclusion Review**

The only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Burlington was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Burlington had begun to take action to cure the material breach within that period; (ii) Burlington has pursued and is pursuing such action with due diligence; and (iii) Burlington provided to DVHA within that period a reasonable timetable for curing the material breach and Burlington has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after the Secretary or Hearing Officer issues a decision favorable to DVHA, or, if the Secretary or Hearing Officer rules for Burlington, only after a judicial decision in favor of DVHA. If the Secretary or

Hearing Officer sustains the determination of DVHA and determines that exclusion is authorized, such exclusion shall take effect 20 days after the Secretary or Hearing Officer issues such a decision, notwithstanding that Burlington may request review of the Secretary or Hearing Officer decision by the courts, unless the court issues a stay order preventing the effect of the exclusion. If the court finds in favor of DVHA after a Secretary or Hearing Officer decision adverse to DVHA, the exclusion shall take effect 20 days after the court decision. If the court finds in favor of Burlington, Burlington shall be reinstated effective on the date of the original exclusion.

#### **X. EFFECTIVE AND BINDING AGREEMENT**

Burlington and DVHA agree as follows:

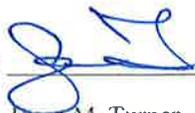
- A. This CIA shall be binding on the successors, assigns, and transferees of Burlington.
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- D. DVHA may agree to a suspension of Burlington's obligations under this CIA based on a certification by Burlington that it is no longer providing health care items or services that will be billed to the Vermont Medicaid Program and that it does not have any ownership or control interest in any entity that bills the Vermont Medicaid program. If Burlington is relieved of its CIA obligations, Burlington will be required to notify DVHA in writing at least 30 days in advance if Burlington plans to resume providing health care items or services that are billed to the Vermont Medicaid program or to obtain an ownership or control interest in any entity that bills the Vermont Medicaid program. At such time, DVHA shall evaluate whether the CIA will be reactivated or modified.
- E. The undersigned Burlington signatories represent and warrant that they are authorized to execute this CIA. The undersigned DVHA and Attorney General's Office signatories represents that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.
- F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

IN WITNESS WHEREOF, the parties have executed this Agreement ~~as of the 26<sup>th</sup> day of~~  
~~September, 2016.~~

STATE OF VERMONT

William H. Sorrell

VERMONT ATTORNEY GENERAL

BY:  \_\_\_\_\_ *October 19, 2016*  
Jason M. Turner

Assistant Attorney General

Director, Medicaid Fraud & Residential Abuse  
Unit

BURLINGTON LABS, LLC

By:  \_\_\_\_\_  
Michael Casarico, CEO

BURLINGTON LABORATORIES, INC.

By:  \_\_\_\_\_  
Michael Casarico, CEO

## **APPENDIX A INDEPENDENT REVIEW ORGANIZATION**

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

### **I. IRO Engagement**

Burlington shall engage an IRO that possesses the qualifications set forth in Paragraph II, below, to perform the responsibilities in Paragraph III, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph IV. Within 30 days after DVHA receives the information identified in Section IV.A(f) of the CIA or any additional information submitted by Burlington in response to a request by DVHA, whichever is later, DVHA will notify Burlington if the IRO is unacceptable. Absent notification from DVHA that the IRO is unacceptable, Burlington may continue to engage the IRO.

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

### **II. IRO Qualifications**

The IRO shall:

- A. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of laboratory services and in the general requirements of the Vermont Medicaid Program;
- B. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;
- C. 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
- D. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

### **III. IRO Responsibilities**

The IRO shall:

- A. perform each Claims Review in accordance with the specific requirements of the CIA;

- B. follow all applicable Vermont Medicaid rules and reimbursement guidance in making assessments in the Claims Review;
- C. if in doubt of the application of a particular Medicaid policy or regulation, request clarification from the appropriate division of DVHA;
- D. respond to all DVHA inquires in a prompt, objective, and factual manner; and
- E. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

#### **IV. IRO Independence and Objectivity**

The IRO must perform the Claims Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Burlington.

#### **V. IRO Removal/Termination**

##### **A. Provider and IRO**

If Burlington terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Burlington must submit a notice explaining its reasons for termination or the reason for withdrawal to DVHA no later than 30 days after termination or withdrawal. Burlington must engage a new IRO in accordance with Paragraph I of this Appendix within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

##### **B. DVHA Removal of IRO.**

In the event DVHA has reason to believe that the IRO does not possess the qualifications described in Paragraph II, is not independent and/or objective as set forth in Paragraph IV, or has failed to carry out its responsibilities as described in Paragraph III, DVHA may, at its sole discretion, require Burlington to engage a new IRO in accordance with Paragraph I of this Appendix. Burlington must engage a new IRO within 60 days of termination of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier. Prior to requiring Burlington to engage a new IRO, DVHA shall notify Burlington of its intent to do so and provide a written explanation of why DVHA believes such a step is necessary. To resolve any concerns raised by DVHA, Burlington may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. DVHA will attempt in good faith to resolve any differences regarding the IRO with Burlington prior to requiring Burlington to terminate the IRO. However, the final determination as to whether or not to require Burlington to engage a new IRO shall be made at the sole discretion of DVHA.

## **APPENDIX B CLAIMS REVIEW**

### **I. Definitions.**

For the purposes of the Claims Review, the following definitions shall be used:

- A. **Overpayment:** The amount of money Burlington has received in excess of the amount due and payable under any Vermont Medicaid program requirements.
- B. **Paid Claim:** A claim submitted by Burlington and for which Burlington has received reimbursement from the Medicare program.
- 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 gross underpayments identified in the sample from all gross Overpayments identified in the sample. 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.

### **II. 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.

#### **A. Discovery Sample.**

The IRO shall randomly select and review a sample of 50 Paid Claims from the Reporting Period (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Burlington's office or under Burlington's 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, Burlington should, as appropriate, further analyze any errors identified in the Discovery Sample. Burlington recognizes that DVHA, 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.)

### **B. 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 Full Sample shall be designed to:

1. estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and
2. conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines.

The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Burlington or under Burlington's 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. DVHA, in its sole discretion, may use the findings of the Full Sample (and any related workpapers) received from Burlington in any manner appropriate under the rules of the Vermont Medicaid Program, and may share this information with any federal authority who oversees or participates in the Vermont Medicaid Program.

### **C. Systems Review.**

If the Full Sample indicates an Error Rate of 5% or greater, the IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

1. a review of Burlington's billing and coding systems and processes relating to claims submitted to Vermont Medicaid program (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);
2. 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.

## **D. Other Requirements**

### **1. Supporting Documentation.**

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 Burlington 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 Burlington after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Documentation), the IRO shall identify in the Claims Review Report the Supplemental Documentation, the date the Supplemental Documentation was accepted, and the relative weight the IRO gave to the Supplemental Documentation in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Documentation was accepted and the IRO's reasons for accepting the Supplemental Documentation.

### **2. Paid Claims without Supporting Documentation.**

Any Paid Claim for which Burlington cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Burlington for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

### **3. 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).

## **III. Claims Review Report.**

The IRO shall complete 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).

### **A. Claims Review Methodology**

1. Claims Review Population. A description of the Population subject to the Claims Review.
2. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
3. 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), Vermont Medicaid Program Manuals, Vermont Medicaid banner pages or guidance CMS program memoranda (including title and issuance number), Medicare carrier, intermediary, or Medicare Administrative Contractor manual or bulletins (including issue and date), other policies, regulations, or directives).

4. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
5. Supplemental Documentation. A description of any Supplemental Documentation as required by II.D.1 above.

#### **B. Statistical Sampling Documentation**

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

#### **C. Claims Review Findings**

1. Narrative Results
  - a. A description of Burlington's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
  - b. 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).
2. Quantitative Results
  - a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Burlington (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
  - b. 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 Burlington.
  - c. Total dollar amount of all Overpayments in the sample.

- d. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.
- e. Error Rate in the sample.
- f. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: 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.

#### **D. Recommendations**

The IRO's report shall include any recommendations for improvements to Burlington's billing and coding system based on the findings of the Claims Review.

#### **E. Systems Review**

The IRO shall prepare a report based on the Systems Review (Systems Review Report) that shall include the IRO's observations, findings, and recommendations regarding:

1. the strengths and weaknesses in Burlington's billing systems and processes;
2. the strengths and weaknesses in Burlington's coding systems and processes; and
3. possible improvements to Burlington's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

#### **F. 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.

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