CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BIOTEK REMEDYS, INC., AZBDBR, LLC, D/B/A AVASA RX PHARMACY,VALUSTAR PHARMACY AND CHAITANYA GADDE

I. PREAMBLE

BioTek reMEDys, Inc., and its subsidiaries AZBDBR, LLC d/b/a Avasa Rx Pharmacy and Valustar Pharmacy, along with their owner Chaitanya Gadde (collectively "BioTek") hereby enter into this Corporate Integrity Agreement (CIA) 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 CIA, BioTek is entering into a Settlement Agreement with the United States.

In consideration of the obligations of BioTek in the September, 2023 Settlement Agreement (Agreement) with the United States and in this CIA, the OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs against BioTek under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct as defined in the Agreement, except that the OIG expressly reserves all rights to comply with any statutory obligations to exclude BioTek from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion).

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The "Effective Date" of this CIA shall be the signature date of the final signatory to this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG's receipt of: (1) BioTek's final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and BioTek complies with the decision.

C. Definitions.

1. "Arrangements" means:

a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value and is between BioTek and (i) any actual or potential source of health care business or referrals to BioTek or (ii) any actual or potential recipient of health care business or referrals from BioTek; and

b. every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between BioTek and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to BioTek for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

i. "Source of health care business or referrals" means any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

ii. "Recipient of health care business or referrals" means any individual or entity (a) to whom BioTek refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom BioTek purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service, for which payment may be made in whole or in part by a Federal health care program.

2. "Certifying Covered Persons" means the following: all members of senior management and the leaders of all business units, divisions or departments with operations that relate to Federal health care programs, including, at a minimum, the Chief Executive Officer, President, CPA, Chief Operating Officer, Implementation Project Manager, Clinical and Operational Support Nurse, Vice President of Revenue Cycle Management, Director of Compliance, Senior Director of Operations, Sales Manager, and Pharmacist In Charge.

3. "Covered Persons" means: (a) all owners who are natural persons, officers, board members, and employees of BioTek; (b) all contractors who furnish patient care items or services or perform billing or coding functions on behalf of BioTek, excluding vendors whose sole connection with BioTek is selling or otherwise providing medical supplies or equipment to Biotek.

4. "Disclosure Program" means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual's chain of command any potential violations of criminal, civil, or administrative law related to the Federal health care programs or any issues or questions associated with BioTek's policies, conduct, practices, or procedures.

5. "Exclusion Lists" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and state Medicaid program exclusion lists that are publicly available.

6. "Ineligible Person" means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

7. "Overpayment" means any funds that BioTek receives or retains under any Federal health care program to which BioTek, after applicable reconciliation, is not entitled under such Federal health care program.

8. "Reportable Event" means: (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 criminal penalties or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by BioTek.

9. "Reporting Period" means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.

10. "Training Plan" means a written plan that outlines the steps BioTek will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding BioTek's CIA requirements and compliance program and the applicable Federal health care program requirements, including the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) and 42 U.S.C. § 1395nn (the Stark Law).

11. "Transition Plan" means a plan to address whether and how BioTek's compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA's term.

III. COMPLIANCE PROGRAM REQUIREMENTS

BioTek shall establish and maintain a compliance program that includes the following elements:

A. Compliance Officer, Compliance Committee, Board Oversight, and Management Certifications.

1. *Compliance Officer*. Within 90 days after the Effective Date, BioTek shall appoint a Compliance Officer who is an employee and a member of senior management of BioTek. The Compliance Officer shall report directly to the Chief Executive Officer of BioTek and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for BioTek. The Compliance Officer shall be authorized to report to the Board of Directors of BioTek (Board) regarding compliance matters at any time. 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 CIA and with Federal health care program requirements;

b. making at least quarterly reports regarding compliance matters to the Board;

c. monitoring the day-to-day compliance activities engaged in by BioTek; and

d. all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

BioTek shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, BioTek shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.J below. The Compliance Committee shall meet at least quarterly.

BioTek shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. *Board Oversight.* The Board shall be responsible for the review and oversight of BioTek's compliance with Federal health care program requirements and the

requirements of this CIA. The Board must include at least one independent (e.g, non-owner, non-employee, and non-executive) member.

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

a. meeting at least quarterly to review and oversee BioTek'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 materials it reviewed and 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 CIA, adopting a resolution approved by each member of the Board regarding its review and oversight of BioTek's compliance with Federal health care program requirements and the requirements of this CIA.

At minimum, the resolution shall include the following language:

> "The Board has made a reasonable inquiry into the operations of BioTek's compliance program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, BioTek has implemented an effective compliance program to meet Federal health care program requirements and the requirements of BioTek's Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services."

If the Board is unable to adopt such a resolution, the Board shall provide a written explanation of the reasons why it is unable to adopt the resolution and the steps the Board is taking to implement an effective compliance program at BioTek.

BioTek shall report to OIG, in writing, any changes in the membership of the Board, within 15 business days after such a change.

4. *Management Certifications.* The Certifying Covered Persons shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable BioTek division or department is in compliance with applicable Federal health care program requirements and the requirements of this CIA. For each Reporting Period, each Certifying Covered Person shall certify as follows:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of division or department], an area under my supervision. My job responsibilities include ensuring [insert name of

division or department]'s compliance with all applicable Federal health care program requirements, requirements of the Corporate Integrity Agreement, and BioTek's policies and procedures. To the best of my knowledge, the [insert name of division or department] is in compliance with all applicable Federal health care program requirements and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Covered Person is unable to provide this certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, BioTek shall develop and implement a written process for Certifying Covered Persons 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 Covered Person making the required certification).

B. Written Standards. Within 90 days after the Effective Date, BioTek shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of BioTek's compliance program, including the compliance program requirements outlined in this CIA; (2) BioTek's compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute and the Stark Law, and the regulations and other guidance documents related to these statutes; (3) a written review and approval process for Arrangements, the purpose of which is to ensure that all Arrangements do not violate the Anti-Kickback Statute and the Stark Law; and (4) the identification, quantification, and repayment of Overpayments. BioTek shall enforce its Policies and Procedures and make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures as necessary. 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, BioTek shall develop a Training Plan that includes the following information: (a) training topics: (b) categories of Covered Persons required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.

2. *Board Training*. Within 90 days after the Effective Date, members of the Board shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity and shall include a discussion of the OIG's guidance on board member responsibilities. Each member of the Board also shall receive the training described in Section III.C.1.

New members of the Board shall receive the training described in this Section III.C.2 within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board training at least annually and update the Board training as necessary.

3. *Training Records*. BioTek shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, BioTek shall engage an entity (the "Independent Review Organization" or "IRO") that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.D.

b. *Retention of Records*. The IRO and BioTek shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and BioTek related to the reviews described in this Section III.D.

c. *Access to Records and Personnel.* BioTek 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. *Claims Review.* The IRO shall review claims submitted by BioTek and reimbursed by the Medicare program, to determine whether the items furnished were dispensed according to a valid prescription, whether the claims submitted by BioTek are consistent with the underlying prescription documentation maintained by BioTek, and whether BioTek maintained appropriate documentation of a valid prescription for each item dispensed (including any refills), any prior authorization required by the payor was obtained in accordance with payor requirements, all cost-sharing amounts were collected

or appropriately waived, and that the claims were correctly billed and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to BioTek 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 CIA. The IRO's certification shall include a summary of all current and prior engagements between BioTek and the IRO.

E. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, BioTek shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with BioTek'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 and the Anti-Kickback Statute and Stark Law risks associated with Arrangements. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require BioTek to: (1) identify and prioritize risks, (2) develop work plans or audit plans (as appropriate) related to the identified risk areas, (3) implement the work plans and audit plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

F. Disclosure Program. Within 90 days after the Effective Date, BioTek shall establish a Disclosure Program. BioTek shall appropriately publicize the existence of the Disclosure Program (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to use of the Disclosure Program and BioTek shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that appropriate follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received (whether anonymous or not), (2) the date the disclosure was received, (3) the individual or department responsible for reviewing the disclosure, (4) the status of the review, (5) any corrective action taken in response to the review, and (6) the date the disclosure was resolved.

G. Ineligible Persons.

1. *Screening Requirements.* BioTek shall:

a. screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons;

b. screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter; and

c. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement*. If BioTek has actual notice that a Covered Person has become an Ineligible Person, BioTek 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 for 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). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and BioTek may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether BioTek meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. BioTek shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that BioTek has committed a crime or has engaged in fraudulent activities, within 30 days of BioTek receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within 30 days after resolution of the matter, BioTek shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. BioTek shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Substantial Overpayment.* 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. the Federal health care programs affected by the Reportable Event;

c. a description of the steps taken by BioTek to identify and quantify the Overpayment; and

d. a description of BioTek's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, BioTek shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance, and provide OIG with documentation of the repayment.

2. *Probable Violation of Law.* 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;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the steps taken by BioTek to identify and quantify any Overpayments; and

e. a description of BioTek'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, BioTek shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance, and provide OIG with documentation of the repayment.

3. *Ineligible Person.* 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 Lists screening that BioTek 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.

4. *Bankruptcy.* The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

5. *Reportable Events Involving the Stark Law*. Any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by BioTek to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if BioTek identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then BioTek is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP, but shall provide OIG with a copy of the repayment documentation.

J. Transition Plan. Prior to the end of the fourth Reporting Period, BioTek shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be implemented following the end of the CIA's term. A copy of BioTek's approved Transition Plan shall be included in BioTek's fourth Annual Report.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, BioTek proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. BioTek shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit, or location.

If BioTek wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, BioTek must notify OIG in writing at

least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, BioTek shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3;

4. the names and positions of the Certifying Covered Persons required by Section III.A.4 and a copy of the written process for Certifying Covered Persons to follow in order to complete the certification 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 Board 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 CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to BioTek that includes a summary of all current and prior engagements between BioTek and the IRO;

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 description of BioTek's corporate structure, including identification of any parent and sister companies, subsidiaries, or individual owners and their respective lines of business;

12. a list of all of BioTek's locations (including 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

13. a certification by the Compliance Officer and Chief Executive Officer that:

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

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.

B. Annual Reports. BioTek shall submit to OIG a written report (Annual Report) for each of the five Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, or Certifying Covered Persons;

2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

4. the Board resolution required by Section III.A.3 and a description of the materials reviewed by the Board and any additional steps taken in its oversight of the compliance program and in support of making the resolution;

5. a description of any changes to the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;

6. the certifications of Certifying Covered Persons required by Section III.A.4;

7. a list of any new or revised Policies and Procedures required by Section III.B. developed during the Reporting Period;

8. a description of any changes to the Training Plan required by Section III.C, and a summary of all training furnished to Covered Persons and Board members during the Reporting Period;

9. a complete copy of all reports prepared pursuant to Section III.D and BioTek's response to the reports, along with corrective action plan(s) related to any issues raised by the report, and documentation of BioTek's refund of the Estimated Overpayment (as defined in Appendix B to this CIA);

10. a certification from the IRO regarding its professional independence and objectivity with respect to BioTek, including a summary of all current and prior engagements between BioTek and the IRO;

11. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;

12. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (c) internal audits performed, (d) corrective action plans developed in response to internal audits, and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

13. 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. The complete disclosure log shall be made available to OIG upon request;

14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;

15. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;

17. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.J;

18. 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 BioTek's response and corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

19. a description of all changes to the most recently provided list of BioTek's locations (including addresses) as required by Section V.A.12;

20. a description of any changes to BioTek's corporate structure, including any parent and sister companies, subsidiaries, individual owners and their respective lines of business; and

21. a certification by the Compliance Officer and Chief Executive Officer that:

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

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.

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. Designation of Information. BioTek 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. BioTek 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

All notifications and reports required under this CIA shall be submitted using the following contact information:

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
Email Address: officeofcounsel@oig.hhs.gov

BioTek:

Compliance Officer
BioTek Remedys, Inc.
2 Penns Way, #404
New Castle, DE 19720
Telephone: 877.246.9104
Email Address: jfiggs@biotekrx.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify BioTek in writing of any changes to the OIG contact information listed above. BioTek shall notify OIG in writing within two business days of any changes to the BioTek contact information listed above.

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 BioTek's books, records, and other documents and supporting materials, and conduct on-site reviews of any of BioTek's locations, for the purpose of evaluating: (a) BioTek's compliance with the requirements of this CIA and (b) BioTek's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by BioTek to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of BioTek's owners, employees, contractors, and Board members 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. BioTek shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. BioTek's owners, employees, contractors, and Board members may elect to be interviewed with or without a representative of BioTek present.

VIII. DOCUMENT AND RECORD RETENTION

BioTek shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA 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 BioTek prior to any release by OIG of information submitted by BioTek pursuant to this CIA and identified upon submission by BioTek as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, BioTek shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.A;

2. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.B;

3. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.C;

4. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.D;

5. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.E;

6. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.F;

7. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.G;

8. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.H;

9. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.I;

10. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section III.J;

11. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section IV;

12. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section V;

13. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section VII;

14. A Stipulated Penalty of up to $2,500 for each day BioTek fails to comply with Section VIII; or

15. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of BioTek under this CIA.

B. Timely Written Requests for Extensions. BioTek 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. If OIG 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 BioTek fails to meet the revised deadline set by OIG. If OIG 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 BioTek receives OIG'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 OIG 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*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify BioTek of: (a) BioTek's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, BioTek shall either: (a) pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E.

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

D. Exclusion for Material Breach.

1. *Definition of Material Breach*. A material breach of this CIA means:

a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;

b. failure to comply with Section III.A.1;

c. failure to comply with Section III.D;

d. failure to comply with Section III.I;

e. failure to comply with Section V;

f. failure to respond to a Demand Letter in accordance with Section X.C;

g. a false statement or false certification made to OIG by or on behalf of BioTek under this CIA;

h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering BioTek to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or

i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by BioTek constitutes an independent basis for BioTek's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that BioTek has materially breached this CIA, OIG shall notify BioTek of: (a) BioTek's material breach and (b) OIG's intent to exclude BioTek. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. BioTek shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify BioTek in writing of its determination to exclude BioTek. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by BioTek, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, BioTek may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights*. Upon OIG's issuing a Demand Letter or Exclusion Letter to BioTek, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, BioTek shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether BioTek was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. BioTek shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that BioTek has breached this CIA and orders BioTek to pay Stipulated Penalties, BioTek must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless BioTek properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, BioTek must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether BioTek was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of

OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. BioTek shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of BioTek, BioTek shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and BioTek agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

BioTek and OIG agree as follows:

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

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) BioTek'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.

C. The undersigned BioTek signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

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

/Lisa Re/ 2023.09.28

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

DATE

/Sandra Jean Sands/ September 29, 2023

SANDRA JEAN SANDS
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

DATE

ON BEHALF OF BIOTEK

ON BEHALF OF CHAITANYA GADDE

___/Chaitanya Gadde/_____ ___09/29/2023_____
CHAITANYA GADDE DATE
An Individual

ON BEHALF OF BIOTEK REMEDYS INC

___/Chaitanya Gadde/_____ ___09/29/2023_____
CHAITANYA GADDE DATE
Chief Executive Officer

ON BEHALF OF AZBDBR LLC d/b/a AVASA RX PHARMACY

___/Chaitanya Gadde/_____ ___09/29/2023_____
CHAITANYA GADDE DATE
Chief Executive Officer

ON BEHALF OF VALUSTAR PHARMACY LLC

___/Chaitanya Gadde/_____ ___09/29/2023_____
CHAITANYA GADDE DATE
Chief Executive Officer