

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MED-FAST PHARMACY, INC., MED-FAST PHARMACY, L.P, DOUGLAS
KALEUGHER, A JANE K, LLC**

I. PREAMBLE

Med-Fast Pharmacy, Inc.; Med-Fast Pharmacy, L.P., A Jane K, LLC, and Douglas Kaleugher (collectively, “Med-Fast”) 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, Med-Fast Pharmacy, Inc.; Med-Fast Pharmacy, L.P., and Douglas Kaleugher are entering into two Settlement Agreements with the United States.

II. TERM AND SCOPE OF THE CIA

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

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Med-Fast’s final Annual Report or (2) any additional materials submitted by Med-Fast pursuant to OIG’s request, whichever is later.

C. For purposes of this CIA, the term “Covered Persons” includes: (1) all owners, officers, directors, and employees of Med-Fast, and (2) all contractors, subcontractors, agents, and other persons who furnish patient care items or services, who are involved in dispensing prescription drugs or who perform billing or coding functions

on behalf of Med-Fast excluding vendors whose sole connection with Med-Fast is selling or otherwise providing medical supplies or equipment to Med-Fast.

III. CORPORATE INTEGRITY OBLIGATIONS

Med-Fast shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, Med-Fast shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Med-Fast, shall report directly to the Chief Executive Officer of Med-Fast for pharmacy services, 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 Med-Fast. 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; and
- b. monitoring the day-to-day compliance activities engaged in by Med-Fast as well as any reporting obligations created under this CIA.

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

Med-Fast shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Med-Fast shall appoint a Compliance Committee. The Compliance Committee shall, at a Med-Fast CIA

minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Med-Fast's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Owner Certification.* The owner, Douglas Kaleugher, shall, at a minimum, be responsible for the following:

- a. overseeing Med-Fast's compliance program, including but not limited to reviews of the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the documents and other materials reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in his oversight of the compliance program and in support of making the certification below during each Reporting Period; and
- c. for each Reporting Period of the CIA, executing a certification, summarizing his review and oversight of Med-Fast's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the certification shall include the following language:

"I have made a reasonable inquiry into the operations of Med-Fast's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on my inquiry and review, I have concluded that, to the best of my knowledge, Med-Fast has implemented an

effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If Douglas Kaleuger is unable to provide such a conclusion in the certification, he shall include in the certification a written explanation of the reasons why he is unable to provide the conclusion and the steps he is taking to implement an effective Compliance Program at Med-Fast.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Med-Fast employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Med-Fast department is in compliance with applicable Federal health care program requirements and Food and Drug Administration (FDA) requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Financial Officer, and Compliance Officer. For each Reporting Period, each Certifying Employee shall sign a certification that states:

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

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

B. Written Standards

Within 90 days after the Effective Date, Med-Fast shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Med-Fast’s

compliance with Federal health care program requirements and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Med-Fast shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

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

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

C. Training and Education

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

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

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Med-Fast shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined

in Appendix A to this CIA, which is incorporated by reference.

- b. *Retention of Records.* The IRO and Med-Fast shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Med-Fast) related to the reviews.

2. *Claims Review.* The IRO shall review long-term care pharmacy claims submitted by Med-Fast and reimbursed by the Medicare and Medicaid programs to determine whether the prescription drugs furnished by Med-Fast were dispensed according to a valid prescription, whether appropriate documentation of valid prescriptions (including any prescription refills) was maintained, and whether the claims were appropriately submitted and reimbursed (Claims Review). The IRO shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Additional Items Review.* OIG may require that the IRO conduct a review of retail pharmacy claims submitted by Med-Fast and reimbursed by the Medicare and Medicaid programs to determine whether the prescription drugs furnished by Med-Fast were dispensed according to a valid prescription, whether appropriate documentation of valid prescriptions (including any prescription refills) was maintained, and whether the claims were appropriately submitted and reimbursed (Additional Items Review). If the OIG requires an Additional Items Review, then the IRO shall prepare an Additional Items Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

The OIG shall notify Med-Fast of the nature and scope of the Additional Items Review no later than 120 days prior to the end of each Reporting Period. Prior to undertaking the Additional Items Review, the IRO shall submit an audit work plan for approval. The IRO shall conduct the Additional Items Review based on a work plan approved by the OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Med-Fast 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 Med-Fast and the IRO.

E. Risk Assessment and Internal Review Process

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

F. Disclosure Program

Within 90 days after the Effective Date, Med-Fast shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Med-Fast's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Med-Fast shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Med-Fast's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Med-Fast. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure

that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Med-Fast shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

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

- b. Med-Fast shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. Med-Fast shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Med-Fast has actual notice that a Covered Person has become an Ineligible Person, Med-Fast shall remove such Covered Person from responsibility for, or involvement with, Med-Fast's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

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

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Med-Fast shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Med-Fast conducted or brought by a governmental entity or its agents involving an allegation that Med-Fast has committed a

crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Med-Fast also shall provide written notice to OIG within 30 days after the resolution of the matter and a description of the findings and/or results of the investigation or proceeding, if any.

I. Overpayments

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

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

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

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

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

2. *Reporting of Reportable Events.* If Med-Fast determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Med-Fast shall notify

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OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

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

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Med-Fast to identify and quantify any Overpayments; and
- e. a description of Med-Fast'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, Med-Fast shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment.

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

- a. the identity of the Ineligible Person and the job duties performed by that individual;

- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Med-Fast 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.

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Med-Fast to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Med-Fast identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Med-Fast is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

A. Sale or Purchase of a Location or Business

In the event that, after the Effective Date, Med-Fast or Douglas Kaleugher 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 applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, Med-Fast or Douglas Kaleugher wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Med-Fast or Douglas Kaleugher (as applicable) must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. 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.

B. New Employment or Contractual Agreement

At least 30 days prior to Douglas Kaleugher becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by any Federal health care program, Douglas Kaleugher shall notify OIG of his plan to become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of Douglas Kaleugher's responsibilities with respect to such potential employee or contractor. In addition, prior to Douglas Kaleugher becoming an employee or contractor of another party related to the furnishing of items or that may be reimbursed by any Federal health care programs, Douglas Kaleugher shall notify that party of this CIA. That notification shall include a copy of the CIA and a statement indicating the remaining term of the CIA. The CIA shall continue to apply to Douglas Kaleugher following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Med-Fast shall submit a written report to OIG 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. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names and positions of the Certifying Employees required by Section III.A.3;
4. a list of the Policies and Procedures required by Section III.B;
5. the Training Plan required by Section III.C.1;
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; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Med-Fast;
7. a description of the risk assessment and internal review process required by Section III.E;
8. a description of the Disclosure Program required by Section III.F;
9. a description of the Ineligible Persons screening and removal process required by Section III.G;
10. a copy of Med-Fast's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;
11. a description of Med-Fast's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
12. a list of all of Med-Fast's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s); and
13. the certifications required by Section V.C.

B. Annual Reports

Med-Fast shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee and Certifying Employees;
2. the dates of each report made by the Compliance Officer to CEO for pharmacy services (written documentation of such reports shall be made available to OIG upon request);
3. The owner certification required by section III.A.3 of the CIA;
4. a list of any new or revised Policies and Procedures developed during the Reporting Period;
5. a description of any changes to Med-Fast's Training Plan developed pursuant to Section III.C;
6. a complete copy of all reports prepared pursuant to Section III.D and Med-Fast's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
7. a certification from the IRO regarding its professional independence and objectivity with respect to Med-Fast;
8. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;
9. a summary of the following components of the risk assessment and internal review process during the Reporting Period: work plans developed, internal audits performed, corrective action plans developed in response to internal audits, and steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

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

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

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

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

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

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

16. a description of all changes to the most recently provided list of Med-Fast's locations as required by Section V.A.12; and

17. the certifications required by Section V.C.

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

C. Certifications

1. *Certifying Employees.* In each Annual Report, Med-Fast shall include the certifications of Certifying Employees required by Section III.A.3;

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2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include 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, Med-Fast has implemented and is in compliance with all of the requirements of this CIA; and
- 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.

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Med-Fast has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

4. *Douglas Kaleugher.* The Implementation Report and each Annual Report shall include a certification signed by Douglas Kaleugher that:

- a. he has reviewed the CIA in its entirety, understands the requirements described within, and maintains a copy for reference;
- b. to the best of his knowledge, except as described in the report, Med-Fast is in compliance with all the requirements of this CIA;
- c. Med-Fast has policies in place consistent with state law regarding the appropriate disposal and destruction of returned prescription drugs and Med-Fast is acting consistent with those policies and state law; and
- d. he has reviewed the report and has made a reasonable inquiry regarding its content and believes the information is accurate and truthful.

D. Designation of Information

Med-Fast 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. Med-Fast shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

Med-Fast:

Lisa Brosky
2003 Sheffield Road
Aliquippa, PA 15001
Telephone: 724-378-5325
Facsimile: 724-857-4567

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

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

VIII. DOCUMENT AND RECORD RETENTION

Med-Fast 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 Med-Fast prior to any release by OIG of information submitted by Med-Fast pursuant to its obligations under this CIA and identified upon submission by Med-Fast as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Med-Fast shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Med-Fast 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, Med-Fast and OIG 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.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Med-Fast fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the management certification obligations;
- d. written Policies and Procedures;
- e. training and education of Covered Persons;
- f. a risk assessment and internal review process;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. policies and procedures regarding the repayment of Overpayments; and
- k. reporting of Reportable Events.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Med-Fast fails to engage and use an IRO, as required by Section III.D, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Med-Fast fails to submit a complete Implementation Report, Annual Report or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Med-Fast fails to submit any Claims Review Report or Additional Items Review Report in accordance with the requirements of Section III.D and Appendix B or fails to repay any Overpayment identified by the IRO, as required by Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Med-Fast fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Med-Fast fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Med-Fast as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Med-Fast fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Med-Fast stating the specific grounds for its determination that Med-Fast has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Med-Fast shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Med-Fast receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions

Med-Fast 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 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 Med-Fast fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, 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 days after Med-Fast 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 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 Med-Fast has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Med-Fast of: (a) Med-Fast's failure to comply; and (b) OIG'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, Med-Fast shall either: (a) cure the breach to OIG's satisfaction and 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. In the event Med-Fast elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Med-Fast cures, to OIG's satisfaction, the alleged breach in dispute. 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 X.D.

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.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Med-Fast has materially breached this CIA, which decision shall be made at OIG'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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Med-Fast to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Med-Fast constitutes an independent basis for Med-Fast'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 per material breach. Upon a determination by OIG that Med-Fast has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Med-Fast of: (a) Med-Fast's material breach; and (b) OIG'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.* Med-Fast shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Med-Fast has begun to take action to cure the material breach; (ii) Med-Fast is pursuing such action with due diligence; and (iii) Med-Fast has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Med-Fast fails to satisfy the requirements of Section X.D.3, OIG may exclude Med-Fast from participation in the Federal health care programs. OIG shall notify Med-Fast in writing of its determination to exclude Med-Fast. (This letter shall be referred to as the Med-Fast CIA

“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 Med-Fast’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Med-Fast 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 delivery to Med-Fast 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, Med-Fast 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 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. 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 HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. 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 Med-Fast was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Med-Fast shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Med-Fast to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Med-Fast requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 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 Med-Fast was in material breach of this CIA and, if so, whether:

- a. Med-Fast cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Med-Fast's receipt of the Notice of Material Breach: (i) Med-Fast had begun to take action to cure the material breach; (ii) Med-Fast pursued such action with due diligence; and (iii) Med-Fast provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Med-Fast, only after a DAB decision in favor of OIG. Med-Fast's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Med-Fast upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Med-Fast may request review of the ALJ decision by the DAB. 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. Med-Fast 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 Med-Fast, Med-Fast 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. Consequently, 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.

XI. EFFECTIVE AND BINDING AGREEMENT

Med-Fast and OIG agree as follows:

- A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- C. OIG may agree to a suspension of Med-Fast's obligations under this CIA based on a certification by Med-Fast that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Med-Fast is relieved of its CIA obligations, Med-Fast shall be required to notify OIG in writing at least 30 days in advance if Med-Fast plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.
- D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Med-Fast'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.
- E. The undersigned Med-Fast signatory represents and warrants that he is 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.
- F. 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 MED-FAST PHARMACY, INC.

/Douglas Kaleugher/

Douglas Kaleugher
Chief Executive Officer

/David A. Strassburger/

David A Strassburger,
Counsel for Med-Fast Pharmacy, Inc.

9-6-17
DATE

9-7-17
DATE



ON BEHALF OF MED-FAST PHARMACY LP

/Douglas Kaleugher/

~~Douglas Kaleugher~~
~~Chief Executive Officer~~
/David A. Strassburger/

9-6-17
DATE

David A Strassburger,
Counsel for Med-Fast Pharmacy, Inc.

9-7-17
DATE


A JANE/K, LLC
/Douglas Kaleugher/

~~Douglas Kaleugher~~
~~Chief Executive Officer~~
/David A. Strassburger/

David A Strassburger,
Counsel for Med-Fast Pharmacy, Inc.

9-6-17

DATE

9-7-17

DATE

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

/Lisa M. Re/

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

9/11/17
DATE

/Christina K. McGarvey/

CHRISTINA K. MCGARVEY
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

9/14/17
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Med-Fast shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.6 of the CIA or any additional information submitted by Med-Fast in response to a request by OIG, whichever is later, OIG will notify Med-Fast if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Med-Fast may continue to engage the IRO.

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review and any Additional Items Review who have expertise in the Medicare Part D, state Medicaid program and state Board of Pharmacy requirements applicable to the dispensing of and billing for prescription drugs;

2. assign individuals to design and select the Claims Review and any Additional Items Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the Claims Review and any Additional Items Review who have expertise in pharmacy billing for prescription drugs; and

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

C. IRO Responsibilities

The IRO shall:

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

D. IRO Independence and Objectivity

The IRO must perform the Claims Review and any Additional Items Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Med-Fast and IRO.* If Med-Fast terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Med-Fast must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Med-Fast must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Med-Fast in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Med-Fast shall have 30 days

from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Med-Fast regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Med-Fast in writing that Med-Fast shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Med-Fast must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Med-Fast to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW AND ADDITIONAL ITEMS REVIEW

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

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

- a. **Overpayment:** The amount of money Med-Fast has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. **Paid Claim:** A claim for a prescription drug furnished by Med-Fast's long-term care pharmacy and submitted by Med-Fast and for which Med-Fast has received reimbursement from the Medicare program or a state Medicaid program.
- c. **Population:** The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

2. **Claims Review Sample.** The IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample). The Paid Claims shall be reviewed by the IRO based on the supporting documentation available at Med-Fast or under Med-Fast's control and applicable Medicare and state Medicaid program requirements and applicable State Board of Pharmacy requirements to determine whether each prescription drug was dispensed according to a valid prescription, whether documentation of the prescription (including any prescription refills) is maintained, and whether the claim was correctly submitted and reimbursed. For each Paid Claim reviewed, the IRO should verify that Med-Fast maintained documentation of: (1) the prescription or order for the drug dispensed; (2) the delivery of the drug; and (3) any required steps to initiate a prescription refill. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid 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 Paid Claim.

3. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample and Med-Fast shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from Med-Fast after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Med-Fast cannot produce documentation shall be considered an error and the total reimbursement received by Med-Fast for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected 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 Claims Review Sample).

4. *Repayment of Identified Overpayments.* Med-Fast shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) (the "CMS overpayment rule"). If Med-Fast determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Med-Fast shall repay that amount at the mean point estimate as calculated by the IRO. Med-Fast shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from Med-Fast to the

appropriate Medicare or state Medicaid program contractor for appropriate follow up by the payor.

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

1. *Claims Review Methodology.*

- a. Claims Review Population. A description of the Population subject to the Claims Review.
- b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
- c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation relied upon by the IRO when performing the Claims Review (e.g., physician orders (including drug prescriptions), State pharmacy laws or regulations regarding the dispensing and handling of prescription drugs, any applicable local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.

2. *Statistical Sampling Documentation.*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- b. A description or identification of the statistical sampling software package used by the IRO.

3. *Claims Review Findings.*

a. Narrative Results.

- i. A description of Med-Fast's billing system, including the identification, by position description, of the personnel involved in billing.
- ii. A description of controls in place at Med-Fast to ensure that all prescription drugs billed to Medicare or a state Medicaid program are dispensed and billed in accordance with a valid prescription, that documentation of the prescription (including any refills) is maintained, and that the claims are correctly submitted and reimbursed.
- iii. 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 Claims Review Sample.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that Paid Claims submitted by Med-Fast (Submitted Claim) differed from what should have been submitted (Correct Claim) and in which such difference resulted in an Overpayment to Med-Fast.
- ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not supported by a valid prescription (original or refill) and in which such errors resulted in an Overpayment to Med-Fast.
- iii. Total dollar amount of all Overpayments in the Claims Review Sample.
- iv. Total dollar amount of Paid Claims included in the Claims Review Sample.
- v. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the

Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.

- vi. An estimate of the actual Overpayment in the Population at the mean point estimate.
- vii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, national drug code submitted, quantity prescribed, quantity dispensed, quantity billed, amount reimbursed by payor, correct amount to be reimbursed (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

- c. **Recommendations.** The IRO's report shall include any recommendations for improvements to Med-Fast's billing system or to Med-Fast's controls for ensuring that all prescription drugs billed to Medicare or a state Medicaid program are dispensed in accordance with a valid prescription, whether documentation of the prescription (including any prescription refills) is maintained, and whether the claim was correctly submitted and reimbursed, based on the findings of the Claims Review.

4. ***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.

C. **Additional Items Review.** If the OIG requires an Additional Items Review, then the IRO shall prepare an Additional Items Review Report for each Additional Items Review performed. The Additional Items Review Report shall include the information regarding the Additional Items Review methodology, statistical sampling documentation, findings and credentials required by Section B.1-B.4 of this Appendix B.