

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
JASHU R. PATEL, M.D. And JACKSON CARDIOLOGY ASSOCIATES, P.C.**

**I. PREAMBLE**

Jashu R. Patel, M.D. (Dr. Patel) and Jackson Cardiology Associates, P.C. (JCA) (hereinafter collectively, Patel-JCA) hereby enter into this Integrity Agreement (IA) 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, program requirements, 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). This IA applies to Patel-JCA, any entity in which Dr. Patel or Patel-JCA has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), at any time during the term of the IA, and to any other Covered Persons of Patel-JCA as defined in Section II.C. Contemporaneously with this IA, Patel-JCA is entering into a Settlement Agreement with the United States.

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

A. This IA shall have a term of three years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. 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 from OIG’s receipt of: (1) Patel-JCA’s final Annual Report; or (2) any additional materials submitted by Patel-JCA pursuant to OIG’s request, whichever is later.

C. The term “Covered Persons” includes:

1. Patel-JCA and all owners, partners, associates, and employees of

Patel-JCA;

2. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Patel-JCA; and

3. all employees of any entity in which Dr. Patel or Patel-JCA has an ownership or control interest (as defined in 42 U.S.C. §1320a-3(a)(3)) at any time during the term of this IA and any contractors, agents, or other persons who provide patient care items or services or who perform billing or coding functions on behalf of such entity.

### **III. INTEGRITY OBLIGATIONS**

Patel-JCA shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Posting of Notice**

Within 90 days after the Effective Date, Patel-JCA shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

#### **B. Independent Cardiology Consultant**

Within 60 days of the Effective Date, Patel-JCA shall engage, and maintain for the term of this IA, an Independent Cardiology Consultant (ICC). The ICC shall be a cardiologist who is certified by the American Board of Internal Medicine in cardiology and shall have expertise in the rules governing submission of claims to Federal health care programs for cardiology items and services. The ICC shall be responsible for utilization review and oversight of quality of care matters at Patel-JCA, including but not limited to performance improvement, quality assessment, patient safety, training, and review of claims submitted to Federal health care programs for cardiology items and services. If Patel-JCA terminates the ICC during the course of the engagement, Patel-JCA must submit a notice explaining its reasons to OIG no later than 30 days after termination and Patel-JCA must engage a new ICC in accordance with this Paragraph III.B.

C. Training and Education

1. *Training.* Patel-JCA and all other Covered Persons shall receive at least three hours of training during the first Reporting Period, including at least one hour of training to be completed within 60 days after the Effective Date. Training may be completed in-person or on-line. These training requirements may be satisfied only by the completion of courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), Patel-JCA's Medicare contractor, or other training courses that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

- a. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives relating to the items or services furnished by Patel-JCA;
- b. the Federal health care program medical record documentation requirements relating to items or services furnished by Patel-JCA;
- c. quality assessment and performance improvement activities; and
- d. management and oversight of cardiac catheterization interventionalist procedures (including angiograms, angioplasties and stents).

New Covered Persons shall receive at least three hours of training within 45 days after becoming a Covered Person. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes the training.

The OIG may, in its discretion, require that Patel-JCA and other Covered Persons complete additional hours of training regarding the topics identified above, or additional

topics, in the second and third years of the IA. The OIG shall provide notice to Patel-JCA of such additional required training at least 180 days prior to the required completion date for such training.

2. *Certification.* Patel-JCA shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received and the date received.

D. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 60 days after the Effective Date, Patel-JCA shall engage an individual or 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. Each IRO must have the qualifications and must be able to meet the other requirements relating to the IRO outlined in Appendix A to this IA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Patel-JCA shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Patel-JCA) related to the reviews.

2. *Claims Review.* The IRO shall conduct a review of Dr. Patel and JCA’s coding, billing, and claims submission to the Federal health care programs and the reimbursement received for procedures performed by Dr. Patel, for each three-month period during the term of this IA (Quarterly Claims Review) and shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

3. *Cardiac Catheterization Procedures Review.* The IRO shall evaluate and analyze the medical necessity and appropriateness of cardiac catheterization procedures performed by Dr. Patel (Quarterly Cardiac Catheterization Procedures Review). In conducting the Quarterly Cardiac Catheterization Procedures Review, the IRO shall consult with the Independent Cardiology Consultant. The IRO shall prepare a Quarterly Cardiac Catheterization Procedures Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Cardiac Catheterization Procedures Review requirement shall begin 30 days after the Effective Date. Each Quarterly Cardiac Catheterization Procedures Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Cardiac Catheterization Procedures Review.

4. *Validation Review.* In the event OIG has reason to believe that: (a) any Quarterly Claims Review or Quarterly Cardiac Catheterization Procedures Review fails to conform to the requirements of this IA; or (b) the IRO's findings, Quarterly Claims Review, or Quarterly Cardiac Catheterization Procedures Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Quarterly Claims Review or Quarterly Cardiac Catheterization Procedures Review complied with the requirements of the IA and/or the findings, Quarterly Claims Review or Quarterly Cardiac Catheterization Procedures Review results are inaccurate (Validation Review). Patel-JCA shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Patel-JCA's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Patel-JCA in writing of its intent to conduct a Validation Review and the reasons OIG has determined a Validation Review is necessary. Patel-JCA shall have up to 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Quarterly Claims Review or Quarterly Cardiac Catheterization Procedures Review, or to correct the inaccuracy of the Quarterly Claims Review or Quarterly Cardiac Catheterization Procedures Review and/or to propose alternatives to the proposed Validation Review. OIG will attempt in good faith to resolve any Quarterly Claims Review or Quarterly Cardiac Catheterization Procedures Review issues with Patel-JCA prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification.* Prior to performing the first Quarterly Claims Review or Quarterly Cardiac Catheterization Procedures Review, and annually thereafter, the IRO shall provide to Patel-JCA 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 IA.

E. Ineligible Persons

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

a. an “Ineligible Person” shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s System for Award Management (available through the Internet at <http://www.sam.gov>)

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

- a. Patel-JCA shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Covered Persons to disclose whether they are Ineligible Persons.
- b. Patel-JCA shall screen all current Covered Persons against the Exclusion Lists within 30 days after the Effective Date and on a monthly basis thereafter.
- c. Patel-JCA shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

Patel-JCA shall maintain documentation demonstrating that Patel-JCA: (1) has checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) has required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

Nothing in this Section affects the Patel-JCA’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Patel-JCA understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Patel-JCA may be liable for overpayments and/or criminal, civil, and administrative

sanctions for employing or contracting with an excluded person regardless of whether Patel-JCA meets the requirements of Section III.E.

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

4. *Pending Charges and Proposed Exclusions.* If Patel-JCA 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, Patel-JCA 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, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

F. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Patel-JCA shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Patel-JCA conducted or brought by a governmental entity or its agents involving an allegation that Patel-JCA 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. Patel-JCA shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

G. Repayment of Overpayments

1. *Definition of Overpayments.* For purposes of this IA, an "Overpayment" shall mean the amount of money Patel-JCA has received in excess of the amount due and payable under any Federal health care program requirements.

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

#### H. Reportable Events

1. *Definition of Reportable Event.* For purposes of this IA, 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.D.1.a;
- d. the filing of a bankruptcy petition by Patel-JCA; or
- e. a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high risk situations.

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

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

3. *Reportable Events under Section III.H.1.a.* For Reportable Events under Section III.H.1.a, the report to OIG shall be made within 30 days after making the determination that a substantial Overpayment exists, and shall include:

- a. a description of the steps taken by Patel-JCA to identify and quantify the Overpayment;
- b. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated; and
- c. a description of Patel-JCA's actions taken to correct the Reportable Event.

Within 60 days of identification of the Overpayment, Patel-JCA shall send to OIG a copy of the notification and repayment to the payor required by Section III.G.2.

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Patel-JCA's actions taken to correct the Reportable Event; and
- c. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Patel-JCA to identify and quantify the Overpayment.

5. *Reportable Events under Section III.H.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. *Reportable Events under Section III.H.1.e.* For Reportable Events under Section III.H.1.e, the report to the OIG shall include a complete description of the Reportable Event, including the relevant facts, persons involved, legal and Federal health care program authorities implicated, a description of Patel-JCA's actions taken to correct the Reportable Event, and any further steps Patel-JCA plans to take to address the Reportable Event and prevent it from recurring.

I. Third Party Billing

If, prior to the Effective Date or at any time during the term of this IA Patel-JCA contracts with a third party billing company to submit claims to the Federal health care programs on behalf of Patel-JCA, Patel-JCA must certify to OIG that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company.

Patel-JCA also shall obtain (as applicable) a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens its prospective and current employees against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's System for Award Management; and (iii) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in Patel-JCA's Implementation Report and each Annual Report required by Section V below.

#### **IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT**

A. Change or Closure of Location. In the event that, after the Effective Date, Patel-JCA changes locations or closes a location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Patel-JCA shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Location or Business. In the event that, after the Effective Date, Patel-JCA purchases or establishes a new location or business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Patel-JCA shall notify OIG at least 30 days prior to such purchase or the operation of the new location or business. This notification shall include the address of the new location or business, phone number, fax number, Medicare and state Medicaid program provider identification number and/or supplier number, and the name and address of each Medicare and state Medicaid program contractor to which Patel-JCA currently submits claims. Each new location or business and all Covered Persons at each new location or business shall be subject to the applicable requirements of this IA, unless otherwise determined and agreed to in writing by OIG.

C. Sale of Location or Business. In the event that, after the Effective Date, Patel-JCA proposes to sell any or all of its locations or businesses that are subject to this IA, Patel-JCA shall notify OIG at least 30 days prior to the proposed sale. This notification shall include a description of the location or business to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This IA shall be binding on the purchaser of such location or business, unless otherwise determined and agreed to in writing by OIG.

D. New Employment or Contractual Arrangement. At least 30 days prior to Patel-JCA becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Patel-JCA shall notify OIG of its plan to become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of Patel-JCA's responsibilities with respect to such potential employer or contractor. In addition, prior to Patel-JCA becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Patel-JCA shall notify that party of this IA. This notification shall include

a copy of the IA and a statement indicating the remaining term of the IA. The IA shall continue to apply to Patel-JCA following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

**V. IMPLEMENTATION REPORT, IRO REPORTS AND ANNUAL REPORTS**

A. Implementation Report. Within 90 days after the Effective Date, Patel-JCA shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. a copy of the notice Patel-JCA posted in its office as required by Section III.A, a description of where the notice is posted, and the date the notice was posted;
2. the following information regarding the one hour of training required by Section III.C to be completed within 60 days of the Effective Date: a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program.

A copy of all training materials shall be made available to OIG upon request.

3. the following information regarding each IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this IA; (d) a summary and description of any and all current and prior engagements and agreements between Patel-JCA and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Patel-JCA;

4. the following information regarding the Independent Cardiology Consultant: (a) identity, address, and phone number; (b) a copy of the engagement letter, including a description of duties under the consulting agreement; (c) information to demonstrate that the Independent Cardiology Consultant has the expertise in utilization review and oversight of quality of care matters, and in the rules governing submission of

claims to Federal health care programs for cardiology items and services; (d) a summary and description of any and all current and prior engagements and agreements between Patel-JCA and the Independent Cardiology Consultant; and (e) a certification from the Independent Cardiology Consultant regarding his/her professional independence and objectivity with respect to Patel-JCA;

5. a copy of the documentation demonstrating that Patel-JCA has screened all Covered Persons against the Exclusion Lists, as required by section III.E, within 30 days of the Effective Date;

6. a copy of any certifications from Patel-JCA and the third party billing company required by Section III.I (if applicable);

7. a list of all of Patel-JCA's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare and state Medicaid program provider identification number(s), and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which Patel-JCA currently submits claims; and

8. a certification by Patel-JCA that: (a) it has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Patel-JCA is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. IRO Reports. Within 60 days following the end of each three-month period during the term of this IA, Patel-JCA shall provide to OIG a copy of: (1) the Quarterly Claims Review Report; and (2) the Quarterly Cardiac Catheterization Procedures Review Report prepared by the IRO(s) for each Quarterly Claims Review and each Quarterly Cardiac Catheterization Procedures Review performed. Each Quarterly Claims Review Report and each Quarterly Cardiac Catheterization Procedures Review Report shall include the information specified in Appendix B to this IA.

C. Annual Reports. Patel-JCA shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Patel-JCA's compliance activities for each of the three Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. a description of any changes to the notice required by Section III.A, and the reason for such changes, along with a copy of the revised notice;
2. the following information regarding the additional two hours of training required by Section III.C during the first reporting period (and any additional hours of training required for the second and third reporting periods): a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program;

A copy of all training materials shall be made available to OIG upon request.

3. a certification from each IRO regarding its professional independence and objectivity with respect to Patel-JCA;
4. a certification from the ICC regarding its professional independence and objectivity with respect to Patel-JCA;
5. a copy of the documentation demonstrating that Patel-JCA screened all prospective and current Covered Persons against the Exclusion Lists, as required by section III.E;
6. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.F. 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;
7. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;
8. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts

shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

9. a copy of any certifications from Patel-JCA and the third party billing company required by Section III.I (if applicable);

10. a description of all changes to the most recently provided list of Patel-JCA's locations (including addresses) as required by Section V.A.7; and

11. a certification signed by Patel-JCA that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, Patel-JCA is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

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.

D. Designation of Information. Patel-JCA 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. Patel-JCA 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 IA 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, SW  
Washington, DC 20201  
Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

**Patel-JCA Compliance Contact:**

Jashu R. Patel, M.D.  
205 Page Avenue  
Jackson, MI 49201  
Telephone: (517) 787-3577  
Facsimile: (517) 787-4280

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

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Patel-JCA's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Patel-JCA's locations for the purpose of verifying and evaluating: (a) Patel-JCA's compliance with the terms of this IA; and (b) Patel-JCA's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Patel-JCA to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview Patel-JCA and any of Patel-JCA's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Patel-JCA shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Patel-

JCA's employees may elect to be interviewed with or without a representative of Patel-JCA present.

## **VIII. DOCUMENT AND RECORD RETENTION**

Patel-JCA shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for four 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 Patel-JCA prior to any release by OIG of information submitted by Patel-JCA pursuant to its obligations under this IA and identified upon submission by Patel-JCA as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Patel-JCA shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

Patel-JCA is expected to fully and timely comply with all of its IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Patel-JCA and OIG hereby agree that failure to comply with certain obligations set forth in this IA (unless a timely written request for an extension has been submitted and approved in accordance with Section B below) 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 \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Patel-JCA fails to:
  - a. establish and/or post a notice in accordance with the requirements of Section III.A;
  - b. complete the training required for Patel-JCA and Covered Persons and maintain training certifications, in accordance with the requirements of Section III.C;

- c. engage and use an IRO (or IROs) in accordance with the requirements of Section III.D, Appendix A, and Appendix B;
- d. engage and use an ICC in accordance with the requirements of Section III.B;
- e. screen Covered Persons in accordance with the requirements of Section III.E; or require Covered Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.E; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.E;
- f. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.F;
- g. repay any Overpayments in accordance with Section III.G;
- h. report a Reportable Event in accordance with Section III.H.;  
or
- i. provide to OIG the certifications required by Section III.I relating to any third party biller engaged by Patel-JCA during the term of the IA.

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Patel-JCA fails to submit to OIG by the deadlines for submission the Implementation Report or Annual Reports, in accordance with the requirements of Section V, the Quarterly Claims Review Report, or the Quarterly Cardiac Catheterization Procedures Review Report.

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

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Patel-JCA as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

5. A Stipulated Penalty of \$1,000 for each day Patel-JCA fails to comply fully and adequately with any obligation of this IA. OIG shall provide notice to Patel-JCA stating the specific grounds for its determination that Patel-JCA has failed to comply fully and adequately with the IA obligation(s) at issue and steps the Patel-JCA shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date Patel-JCA 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 1-4 of this Section.

B. Timely Written Requests for Extensions. Patel-JCA 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 IA. 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 Patel-JCA 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 business days after Patel-JCA 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.* Upon a finding that Patel-JCA 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 Patel-JCA of: (a) Patel-JCA's failure to comply; and (b) OIG's intent to exercise 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 of the receipt of the Demand Letter, Patel-JCA shall either: (a) cure the breach to OIG's satisfaction and pay

the applicable Stipulated Penalties; or (b) send in writing to OIG a request for 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 Patel-JCA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Patel-JCA 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 IA 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 Patel-JCA has materially breached this IA, 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 IA.

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

- a. a failure by Patel-JCA to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.G;
- b. a repeated or flagrant violation of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A;
- 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, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by Patel-JCA constitutes an independent basis for Patel-JCA's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Patel-JCA has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify Patel-JCA of: (a) Patel-JCA'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.* Patel-JCA shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Patel-JCA fails to satisfy the requirements of Section X.D.3, OIG may exclude Patel-JCA from participation in the Federal health care programs. OIG shall notify Patel-JCA in writing of its determination to exclude Patel-JCA. (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 Patel-JCA'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, Patel-JCA 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 Patel-JCA of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the

resolution of disputes arising under this IA, Patel-JCA 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 IA. 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 the 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.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this IA shall be: (a) whether Patel-JCA was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Patel-JCA 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 IA and orders Patel-JCA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Patel-JCA 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be:

- a. whether Patel-JCA was in material breach of this IA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) Patel-JCA had begun to take action to cure the material breach within that

period; (ii) Patel-JCA has pursued and is pursuing such action with due diligence; and (iii) Patel-JCA provided to OIG within that period a reasonable timetable for curing the material breach and Patel-JCA has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Patel-JCA, only after a DAB decision in favor of OIG. Patel-JCA's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Patel-JCA 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 Patel-JCA 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. Patel-JCA 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 Patel-JCA, Patel-JCA shall be reinstated effective 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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Patel-JCA and OIG agree as follows:

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

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

C. OIG may agree to a suspension of Patel-JCA's obligations under this IA based on a certification by Patel-JCA that it is no longer providing health care items or services that will be billed to any Federal health care programs and it does not have any ownership or control interest in any entity that bills any Federal health care program. If Patel-JCA is relieved of its IA obligations, Patel-JCA shall be required to notify OIG in

writing at least 30 days in advance if Patel-JCA 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, the OIG shall evaluate whether the IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to, and do not affect (1) Patel-JCA'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 program requirements.

E. The undersigned Patel-JCA signatory represents and warrants that it is authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

F. This IA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same IA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this IA.

**ON BEHALF OF JASHU R. PATEL, M.D. AND JACKSON CARDIOLOGY ASSOCIATES, P.C.**

/Jashu R. Patel, M.D./

5/9/13

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Jashu R. Patel, M.D.  
Jackson Cardiology Associates

\_\_\_\_\_  
Date

/Douglas Mullkoff/

5/9/13

\_\_\_\_\_  
Douglas Mullkoff  
Counsel for Patel-JCA

\_\_\_\_\_  
Date

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

/Robert K. DeConti/

6/3/13

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ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

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DATE

/Henry E. Green/

6/4/2013

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HENRY E. GREEN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

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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 IA.

#### A. IRO Engagement

1. Patel-JCA shall engage an IRO (or IROs) that possess(es) the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO(s) shall conduct the reviews 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.3 of the IA or any additional information submitted by Patel-JCA in response to a request by OIG, whichever is later, OIG will notify Patel-JCA if the IRO(s) are unacceptable. Absent notification from OIG that the IRO(s) are unacceptable, Patel-JCA may continue to engage the IRO(s).

2. If Patel-JCA engages a new IRO during the term of the IA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Patel-JCA shall submit the information identified in Section V.A.3 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, or any additional information submitted by Patel-JCA at the request of OIG, whichever is later, OIG will notify Patel-JCA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Patel-JCA may continue to engage the IRO.

#### B. IRO Qualifications

The IRO(s) shall:

1. assign to conduct the Claims Review individuals who have expertise in the billing, coding, claims submission, and other Federal health care program requirements relating to claims submitted by or on behalf of Dr. Patel or JCA for cardiology items and services provided by Dr. Patel;

2. assign to conduct the Cardiac Catheterization Procedures Review

individuals who are certified by the American Board of Internal Medicine in Cardiology, have expertise in interventional cardiology and in the billing, coding, claims submission, and other Federal health care program reimbursement requirements for cardiology services;

3. assign to design and select the Claims Review and the Cardiac Catheterization Procedures Review samples individuals who are knowledgeable about the appropriate statistical sampling techniques;

4. assign to conduct the coding review portions of the Claims Review individuals who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements); and

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

C. IRO Responsibilities

The IRO(s) shall:

1. perform each Claims Review and each Cardiac Catheterization Procedures Review in accordance with the specific requirements of the IA;

2. follow all applicable Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review and the Cardiac Catheterization Procedures Review;

3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the IA.

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

1. *Patel-JCA and IRO.* If Patel-JCA terminates an IRO or an IRO withdraws from the engagement during the term of the IA, Patel-JCA must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Patel-JCA must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of an IRO.

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

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

## APPENDIX B

### CLAIMS AND CARDIAC CATHETERIZATION PROCEDURES REVIEWS

#### A. Claims Review.

The IRO shall conduct a review of the coding, billing, and claims submission to the Federal health care programs by or on behalf of Dr. Patel or JCA's, and the reimbursement received for cardiology items and services provided by Dr. Patel, for each three-month period during the term of this IA (Quarterly Claims Review) and prepare a report for each Quarterly Claims Review performed. The first three-month period shall begin 30 days following the Effective Date of this IA.

1. *Definitions.* For the purposes of this Appendix B, the following definitions shall be used:

- a. Overpayment: The amount of money Dr. Patel or JCA has received for cardiology items and services provided by Dr. Patel in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.
- b. Paid Claim: A claim submitted by or on behalf of Dr. Patel or JCA for cardiology items and services provided by Dr. Patel for which Dr. Patel or JCA has received reimbursement from the Medicare, Medicaid, or any Federal health care program.
- c. Population: The Population shall be defined as all Paid Claims during the three-month period covered by the Quarterly Claims Review.
- d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all

underpayments identified in the sample from all gross  
Overpayments identified in the sample.

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

2. *Quarterly Claims Sample.* Within 15 days following the end of each three-month period during the term of this IA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of Patel-JCA during the preceding three-month period (Quarterly Claims Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at <https://oig.hhs.gov/compliance/rat-stats/index.asp>. Patel-JCA shall provide the IRO with a list of all Patel-JCA's Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Population that will be subject to review by the IRO. The randomly selected 30 Paid Claims will be reviewed by the IRO based on the supporting documentation available at Patel-JCA's office or under Patel-JCA's control and applicable billing and coding regulations and guidance to determine whether each claim was correctly coded, submitted, and reimbursed. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section C below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Additional Steps if Error Rate is 5% or Greater.* If the Error Rate (as defined above) for any Quarterly Claims Review performed is 5% or greater, the IRO will estimate the actual Overpayment in the Population for that three-month period by identifying the point estimate. To identify the point estimate, the IRO shall extrapolate the Error Rate as determined in the Quarterly Claims Sample to the Population for the applicable Quarterly Claims Review. Patel-JCA shall be required to repay the point estimate of the extrapolated Overpayment in accordance with Section E, below. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Sample (and any related workpapers) to the appropriate Federal health care program payor for appropriate follow-up by that payor. The Quarterly Claims Review Report prepared by the IRO shall

indicate the extrapolated Overpayment amount and the methodology used by the IRO to determine the extrapolated Overpayment amount.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology*.
  - a. Claims Review Population. A description of the Population subject to the Quarterly Claims Review.
  - b. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Quarterly Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare contractor manual or bulletins (including issue and date), other policies, regulations, or directives).
  - c. Review Protocol. A narrative description of how the Quarterly Claims Review was conducted and what was evaluated.
  - d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of each Quarterly Claims Sample and Patel-JCA shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from Patel-JCA after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly 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 Quarterly Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation.* A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings.*

a. Narrative Results.

i. For the first Quarterly Claims Review Report only, a description of Patel-JCA's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing. Subsequent Quarterly Claims Review Reports should describe any significant changes to Patel-JCA's billing and coding system or, if no significant changes were made, state that the billing and coding systems remain the same as described in the prior Quarterly Claims Review Report.

ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Patel-JCA (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Patel-

JCA.

- iii. Total dollar amount of all Overpayments in the sample.
  - iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.
  - v. Error Rate in the sample.
  - vi. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Dr. Patel and JCA's billing and coding system based on the findings of the Quarterly Claims Review.
  - d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

C. Other Requirements. The following requirements apply to any Quarterly Claims Review performed pursuant to this Appendix B.

1. *Paid Claims without Supporting Documentation*. Any Paid Claim for which Patel-JCA cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Patel-JCA for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

2. *Use of First Samples Drawn.* For the purposes of all samples discussed in this Appendix, the Paid Claims selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the sample).

D. Repayment of Identified Overpayments. Patel-JCA shall repay within 60 days any Overpayment(s) identified in each Quarterly Claims Sample (including any extrapolated amounts identified in accordance with Section A.3 of this Appendix), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Patel-JCA shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

E. Cardiac Catheterization Procedures Review.

The IRO shall conduct a review of cardiac catheterization procedures performed by Dr. Patel, for each three-month period during the term of this IA (Quarterly Cardiac Catheterization Procedures Review). In conducting the Quarterly Cardiac Catheterization Procedures Reviews, the IRO shall consult with the Independent Cardiology Consultant. The IRO shall prepare a report for each Quarterly Cardiac Catheterization Review performed. The first three-month period shall begin 30 days following the Effective Date of this IA.

*Definitions.* For the purposes of the Cardiac Catheterization Procedures Review, the following definitions shall be used:

- a. Cardiac Catheterization Procedure. Cardiac procedures (including catheterization, angiographies, ultrasounds, stents, angioplasties) performed by Dr. Patel.
- b. Population. For each Reporting Period, the Population shall be defined as all Cardiac Catheterization Procedures performed by Dr. Patel for which Dr. Patel or JCA has received reimbursement from Medicare, Medicaid, or other Federal health care programs during the three-month period covered by the Quarterly Cardiac Catheterization Review.

F. *Quarterly Cardiac Catheterization Procedures Sample.* Within 15 days

following the end of each three-month period during the term of this IA, the IRO shall randomly select a sample of 30 Cardiac Catheterization Procedures performed by Dr. Patel during the preceding three-month period (Quarterly Cardiac Catheterization Procedures Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at <https://oig.hhs.gov/compliance/rat-stats/index.asp>. Patel-JCA shall provide the IRO with a list of all Patel-JCA's Paid Claims for the three-month period covered by the Quarterly Cardiac Catheterization Procedures Sample. The IRO should number each Cardiac Catheterization Procedure in the Population sequentially prior to generating the random numbers used to select the Quarterly Cardiac Catheterization Procedures Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Cardiac Catheterization Procedures in the Population that will be subject to review by the IRO. The randomly selected 30 Cardiac Catheterization Procedures will be reviewed by the IRO based on the supporting documentation available at Patel-JCA's office or under Patel-JCA's control and applicable billing and coding regulations and guidance to determine whether each procedure was medically necessary or appropriate, based on established practice guidelines and generally accepted standards of medical practice as described by the American College of Cardiology. The IRO shall prepare a written report of its findings from the Quarterly Cardiac Catheterization Procedures Sample, as described in Section G below (Quarterly Cardiac Catheterization Procedures Review Report). The Quarterly Cardiac Catheterization Procedures Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Cardiac Catheterization Procedures Review.

G. Cardiac Catheterization Procedures Review Report. The following information shall be included in the Cardiac Catheterization Procedures Review for each Sample.

1. *Cardiac Catheterization Procedures Review Methodology*.
  - a. Sampling Unit. A description of the Cardiac Catheterization Procedures as that term is defined above.
  - b. Cardiac Catheterization Procedures Review Population. A description of the Population subject to the Catheterization Review.

- c. Cardiac Catheterization Review Objective. A clear statement of the objective intended to be achieved by the Cardiac Catheterization Procedures Review.
- d. Sampling Frame. A description of the sampling frame, which is the totality of Cardiac Catheterization Procedures from which the Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances the sampling frame will be identical to the Population.
- e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Cardiac Catheterization Procedures Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- f. Review Protocol. A narrative description of how the Cardiac Catheterization Procedures Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

- a. The number of Cardiac Catheterization Procedures appraised in the Sample.
- b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- c. A description or identification of the statistical sampling software package used to select the Sample.

3. *Cardiac Catheterization Procedures Review Findings.*

- a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Cardiac Catheterization Procedures Review, including the results of the Sample.
  - b. Total number of instances in which the IRO determined that the Cardiac Catheterization Procedures was not medically necessary or appropriate, based on established practice guidelines and generally accepted standards of medical practice as described by the American College of Cardiology.
  - c. A spreadsheet of the Cardiac Catheterization Procedures Review results that includes the following information for each Cardiac Catheterization Procedure appraised: type of Cardiac Catheterization Procedure performed, whether the Procedure was medically necessary and appropriate, beneficiary name, beneficiary health insurance claim number, date of service, procedure code submitted, Federal health care program billed, and amount reimbursed.
4. *Systems Review.* Observations, findings, and recommendations on possible improvements to Dr. Patel's Cardiac Catheterization Procedures and process(es).
  5. *Credential.* The names and credential of the individuals who designed the statistical sampling procedures and the review methodology utilized for the Cardiac Catheterization Procedures Review.