

REIMBURSEMENT GUIDE



PROTECT II CLINICAL TRIAL

PROTECT II: A prospective, multi-center, randomized controlled trial of the Impella 2.5 System versus Intra Aortic Balloon Pump (IABP) in Patients Undergoing Non Emergent High Risk PCI

IDE Number: G050017

**Abiomed Impella® Reimbursement Hotline
Toll Free (877)256-0861
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Current as of October 1, 2007

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Abiomed has made every effort to ensure that the information is suitable and appropriate for describing – and coding – the services rendered in the care and management of patients undergoing procedure. Abiomed has developed this manual as a service to its customers in an effort to facilitate the appropriate and effective use of coding conventions.

INTRODUCTION

Abiomed has developed this guide to assist physicians, and other billing and administrative personnel who are involved in the

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Specifically, this guide was developed to help understand Medicare regulations for investigational devices and claims submission requirements as it relates to Investigational Device Exemption (IDE) clinical trials so that you may inform your Medicare Contractors of the trial and request reimbursement for the trial procedures.

The guide provides the following information:

- Medicare Coverage Policy for IDE Trials
- Coding
- Physician Billing Requirements
- Hospital and Billing Requirements

Topics discussed include coverage, billing for IDE clinical trials, and claims processing issues related to the PROTECT II Clinical Trial. We also strongly suggest that you consult your payer organizations with regard to local coverage and reimbursement policies.

Medicare Coverage Policy for IDE Trials

In November 1995, the Health Care Financing Administration (HCFA)(now the Centers for Medicare & Medicaid Services), which administers the Medicare program, published a rule that permits Part A Fiscal Intermediaries and Part B Carriers to cover a variety of medical devices being studied under Food and Drug Administration (FDA) approved IDE clinical trials. Under this rule, the FDA developed a device categorization to differentiate between novel, first-of-a-kind devices and newer generations of FDA approved/cleared, marketed devices.

FDA Categorization Process

1. Category A – Experimental/Investigational Devices

Definition: An innovative device in Class III for which “absolute risk” for the device type has not been established (i.e., initial questions of safety and effectiveness of that device type have not been resolved, and the FDA is unsure whether the device type can be safe and effective).

2. Category B – Non-experimental/Investigational Devices

Definition: A device believed to be Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective, because other manufacturers have obtained FDA approval for the device type.

Medicare Coverage of Category A & B Devices¹

Medicare coverage differs for Category A and Category B devices.

1. Category A

Medicare excludes Category A devices and related services from Medicare coverage. Category A devices are excluded from coverage because the initial questions of safety and effectiveness are unresolved.

2. Category B

Medicare permits, but does not mandate, coverage of Category B devices. Coverage of the device and related services is dependent upon it meeting all other Medicare coverage requirements contained in the statute, regulations, and instructions issued by CMS, including but not limited to:

- The device must be used in the context of the FDA-approved clinical trial;
- Coverage is limited to beneficiaries meeting the protocol requirements;
- Service must be medically necessary for the particular patient and the amount, duration, and frequency of use or application of the service must be medically appropriate;
- Service must be furnished in a setting appropriate for the patient’s medical needs and condition;

¹ Medicare Coverage of Certain Devices and Related Services, Federal Register/Vol. 60 No.181/September 19, 1995

- The device must be used within the guidelines of established national Medicare policy and, in the absence of national Medicare policy, within the guidelines of local Medicare policy for similar FDA-approved/cleared devices;
- The device must appear on CMS listing of devices eligible for coverage/payment;
- The device and related service must be provided to the patient within the approved period for the investigational device; and
- If a sponsor (manufacturer) violates relevant IDE requirements necessitating FDA's withdrawal of IDE approval, or if the device loses its Category B status, all payment for the device and related services must cease.

The PROTECT II IDE Categorization and Medicare Coverage Eligibility

The Impella 2.5 device utilized in the PROTECT II Clinical Trial: A prospective, multi-center, randomized controlled trial of the Impella 2.5 system versus Intra-Aortic Balloon Pump (IABP) in patients undergoing Non-Emergent High Risk PCI has been classified as a Category B2 IDE device and is therefore eligible for Medicare coverage consideration. Coverage opportunities are limited to designated IDE trial sites for the number of patients specified in the clinical protocol. The hospital and physician must notify the Medicare Fiscal Intermediary and the Medicare Carrier, respectively, of the clinical trial and seek reimbursement for services provided to Medicare beneficiaries enrolled in the trial.

Provider Responsibility for Clinical Trial Notification and Requesting Coverage

Providers that are participating in a clinical trial and anticipate filing Medicare claims must notify the Medicare contractors.

It is the responsibility of the provider participating in the clinical trial to furnish all necessary information concerning the device, the clinical trial, and the participating Medicare beneficiaries that the contractor deems necessary for a coverage determination and claims processing. (Excerpt from Providers Seeking Reimbursement for Investigational Devices, Section 2303.1C, Carrier Transmittal and Section 3151.1C, Intermediary Transmittal, both dates June 28, 1996.)

See Appendix A for sample letters notifying Medicare contractors of provider participation in an IDE clinical trial

Prior to filing a claim, the following information should be furnished by the provider to the Medicare contractor.

- 1) A copy of the FDA IDE approval letter provided to the sponsor or manufacturer of the device;
- 2) The name of the device;
- 3) Action taken to conform to any applicable FDA special controls;
- 4) A narrative description of the device that is sufficient for the Medicare contractor to make a payment determination;
- 5) A statement indicating how the device is similar to and/or different from other comparable products, and
- 6) A copy of the provider's protocol for obtaining informed consent for patients participating in the clinical trial.

In addition, some contractors may request the following:

- Identification of appropriate CPT/HCPCS codes, ICD-9-CM diagnosis codes and anticipated site of service.
- A copy of the clinical trial protocol summary and patient selection criteria.
- A copy of the Institutional Review Board (IRB) approval letter.
- A copy of the manufacturer's letter inviting providers to participate in the study. Include the estimated number of patient's to be enrolled locally in the study and the duration of the study.

Appendix B, Notification of Clinical Trial, contains information specific to the PROTECT II Clinical Trial. This information will be needed to answer #2 through #5. The facility will need to provide a copy of their protocol for obtaining informed consent (#6) to their Medicare Contractor. Appendix C is a copy of the FDA IDE approval letter.

Medicare contractors may request a copy of the IDE protocol upon notification of a providers' participation in a clinical trial. To respond to the Medicare contractor's request, a copy of the protocol or pertinent excerpts of the protocol can be sent to the Medicare contractor. These materials should be marked with the following statement: *"IMPORTANT NOTICE: DOCUMENT CONTAINS PROPRIETARY INFORMATION WHICH MEDICARE CONTRACTOR MAY NOT RELEASE UNDER THE FREEDOM OF INFORMATION ACT."*

Copies of the clinical protocol are available from Abiomed upon request.

Medicare contractors must update their claims edit systems before they can begin to process claims for FDA-approved Category B investigational devices. Ask your Medicare contractor to notify you in writing when the system has been updated to accept IDE trial claims.

To expedite the notification process, you should call your Medicare contractor's Medical Director well in advance prior to submitting any claims to review information regarding the device/procedure and inform them of your plans to file claims. During this call, you may wish to review the pre- and post-operative medical services that you also plan to submit for reimbursement. Medicare contractors reserve the right to deny coverage for any IDE-related service not considered medically necessary for the patient or medically appropriate.

PRIVATE INSURER COVERAGE POLICIES FOR IDE TRIALS

In general, private insurers' contracts exclude coverage of clinical trials and deem devices undergoing clinical trials as investigative. However, some private payers will cover routine patient care costs in clinical trials with limitations. It is always best to check with your payer organizations to determine their policies regarding coverage of routine costs and investigational devices during clinical trials.

CODING

Overview

Codes are necessary for hospitals to report their services/procedures. The following section describes all the coding systems that are used to describe the use of the Impella 2.5 System.

Diagnosis Coding

All claim forms must use ICD-9-CM diagnosis codes to report the patient's condition. The diagnosis codes are used to indicate why the patient was admitted to the hospital. The following diagnosis codes may apply to patients undergoing the Impella 2.5 procedure. If these diagnosis codes are inappropriate for the patient, please use an alternative code.

Diagnosis Codes

ICD-9-CM

<u>Code</u>	<u>Description</u>
410.00	Acute myocardial infarction of anterolateral wall, episode of care unspecified
410.01	Acute myocardial infarction of anterolateral wall, initial episode of care
410.02	Acute myocardial infarction of anterolateral wall, subsequent episode of care
410.10	Acute myocardial infarction of other anterior wall, episode of care unspecified
410.11	Acute myocardial infarction of other anterior wall, initial episode of care
410.12	Acute myocardial infarction of other anterior wall, subsequent episode of care
410.20	Acute myocardial infarction of inferolateral wall, episode of care unspecified
410.21	Acute myocardial infarction of inferolateral wall, initial episode of care
410.22	Acute myocardial infarction of inferolateral wall, subsequent episode of care
410.30	Acute myocardial infarction of inferoposterior wall, episode of care unspecified
410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care
410.32	Acute myocardial infarction of inferoposterior wall, subsequent episode of care
410.40	Acute myocardial infarction of other inferior wall, episode of care unspecified
410.41	Acute myocardial infarction of other inferior wall, initial episode of care
410.42	Acute myocardial infarction of other inferior wall, subsequent episode of care
410.50	Acute myocardial infarction of other lateral wall, episode of care unspecified
410.51	Acute myocardial infarction of other lateral wall, initial episode of care
410.52	Acute myocardial infarction of other lateral wall, subsequent episode of care
410.60	Acute myocardial infarction, true posterior wall infarction, episode of care unspecified
410.61	Acute myocardial infarction, true posterior wall infarction, initial episode of care
410.62	Acute myocardial infarction, true posterior wall infarction, subsequent episode of care
410.70	Acute myocardial infarction, subendocardial infarction, episode of care unspecified
410.71	Acute myocardial infarction, subendocardial infarction, initial episode of care
410.72	Acute myocardial infarction, subendocardial infarction, subsequent episode of care
410.80	Acute myocardial infarction of other specified sites, episode of care unspecified
410.81	Acute myocardial infarction of other specified sites, initial episode of care
410.82	Acute myocardial infarction of other specified sites, subsequent episode of care
410.90	Acute myocardial infarction, unspecified site, episode of care unspecified
410.91	Acute myocardial infarction, unspecified site, initial episode of care
410.92	Acute myocardial infarction, unspecified site, subsequent episode of care
411.1	Intermediate coronary syndrome
411.81	Acute coronary occlusion without myocardial infarction
411.89	Other acute and subacute form of ischemic heart disease

413.0	Angina decubitus
413.9	Other and unspecified angina pectoris
414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft
414.01	Coronary atherosclerosis of native coronary artery
414.02	Coronary atherosclerosis of autologous vein bypass graft
414.03	Coronary atherosclerosis of nonautologous biological bypass graft
414.04	Coronary atherosclerosis of artery bypass graft
414.05	Coronary atherosclerosis of unspecified type of bypass graft
414.07	Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart
414.11	Aneurysm of coronary vessels
414.19	Other aneurysm of heart
414.8	Other specified forms of chronic ischemic heart disease
414.9	Unspecified chronic ischemic heart disease

Providers should select the most appropriate ICD-9-CM diagnosis codes(s) with the highest level of specificity to describe the patient's condition. Effective October 1, 2007, Medicare will implement a payment system based upon a patient's severity of illness, referred to as MS-DRGs (Medicare-Severity DRGs). Accurate documentation of a patient's conditions and accurate coding of primary and secondary diagnostic codes will be vitally important in obtaining accurate reimbursement.

Procedure Codes

Procedure codes indicate the surgical and/or diagnostic procedures performed on the patient. Hospital inpatient claims must report the appropriate ICD-9-CM procedure codes. The ICD-9-CM procedure code that may apply to patients undergoing the Impella 2.5 procedure is:

ICD-9-CM

<u>Code</u>	<u>Description</u>
37.68	Insertion of percutaneous external heart assist device

Revenue Codes

All hospital UB-04 claims forms must include revenue codes. The revenue codes allow the hospital to assign specific accommodation, supplies and ancillary services to specific cost centers. Individual hospitals determine which cost center and revenue codes are applicable. Each supply or service provided during the patient's hospitalization must be associated with a revenue code. Revenue codes are mandatory on Medicare and Medicaid claims and are listed on FL42 of the UB 04 claim form.

The following revenue codes will serve as an example only: For hospital billing, revenue code 624 is used when billing for the device in order to identify that the device was used in conjunction with a clinical study. The others are listed as the category, but more specific Revenue Codes exist underneath that category.

Revenue

<u>Code</u>	<u>Description</u>
624	Investigational Device
48X	Cardiology
27X	Medical Supplies

Providers should select the most appropriate revenue codes(s) for the services provided to the patient.

CPT Code Definitions

Physicians' Current Procedural Terminology (CPT), Fourth Edition, is a listing of descriptive terms and identifying codes for reporting medical services and procedures that physicians and other medical professionals perform. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, thereby serving as a means for nationwide communication among physicians, patients, and third parties.

CMS-1500 claims for physician services must contain appropriate CPT codes. In the PROTECT II Clinical Trial, the Impella 2.5 is used in the cath lab in conjunction with a high risk PCI procedure. Codes that may be applicable include:

<u>CPT Code</u>	<u>Description</u>
92982	Percutaneous transluminal coronary balloon angioplasty; single vessel
92980	Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel therapeutic intervention, any method; each additional vessel (List separately in addition to code for primary procedure)
G0290	Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel

CPT codes that may be applicable for the use of the Impella 2.5 are:

<u>CPT Code</u>	<u>Description</u>
93799	Unlisted cardiovascular service or procedure

Modifiers

The following modifier must be reported as it is necessary to indicate that is an investigational device.

<u>Modifier</u>	<u>Description</u>
• QA	Investigational Device Append the QA modifier to the CPT code to reflect a claim for a patient enrolled in a study.

Ultimate responsibility for correct coding lies with the provider of the service. Please contact the payer for their interpretation of the appropriate codes to use for the Impella 2.5 procedure.

CPT-4 codes and nomenclature are Copyright 2007 American Medical Association.

MEDICARE BILLING REQUIREMENTS

Hospital Inpatient Billing Requirements

The Centers for Medicare & Medicaid Services (CMS) has developed specific coding instruction for instructions for filing hospital and physician IDE-related claims for medically necessary and appropriate services.

This section outlines coding guidelines for hospital claims. Please note that the FDA-approved protocol has requirements for pre-procedure and post-procedure medical services. Providers need to understand how to code correctly for the various services rendered and should be billed according to the service performed in conjunction with your standard billing and coding guidelines. Please note that this guide is limited to the reporting and billing of the Impella 2.5 procedure only.

Facilities should report hospital-related services approved under the PROTECT II Clinical Trial using the UB-04 claim form. The table below summarizes the instructions for completing the UB-04 (CMS 1450) claim form. We strongly recommend that IDE participating sites contact their local Medical Fiscal Intermediary prior to submitting hospital claims for the device and related-services to verify the codes and their billing policies.

Note: Coding of additional diagnoses and procedure codes is dependent on the documentation in the patient's medical record. Accurate documentation is essential to proper coding.

Hospital <u>INPATIENT</u> Coding Guidelines Using the UB-04 (CMS 1450) Hardcopy Claim Form		
Claim Form Field	Code	Instructions
Field 4 (Type of Bill)	11x	Enter "11x" in this field. This indicates to Medicare that it is an inpatient stay.
Field 42 (Revenue Code)	624	Enter revenue code "624" in this field. This identifies it as an IDE device.
Field 43 (Revenue Description)	FDA IDE number: G050017	Enter FDA IDE #G050017 in this field Note: Medicare does not require the description of the IDE: however, it may be required by other payers.
Field 67 (Primary Diagnosis)	ICD-9-CM diagnosis codes will vary by patient's condition. Please refer to coding section for complete descriptions.	Document appropriate primary ICD-9-CM diagnosis code in this field. The diagnosis codes listed on the claim form must be consistent with those in the IDE trial indications to be eligible for Medicare reimbursement.

Field 80 (Principal Procedure)	ICD-9-CM procedure codes are dependent on the documentation. Appropriate code for patients enrolled in the IDE trial may include: <ul style="list-style-type: none"> • 37.68 	Document appropriate procedure code in this field. The ICD-9-CM procedure code listed on the claim must be consistent with those in the IDE trial indications.
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The study identifier and IDE number must be identified on the CMS 1450 (UB-04). Because existing codes may be used to bill for services performed under the clinical study, the IDE number, along with the appropriate clinical study modifiers, are key to identifying claims for the clinical study. Submitting codes without the IDE number and appropriate modifier may result in lost payment and/or penalties.

Physician Billing Requirements

Medicare also has developed specific coding instructions for filing physician IDE-related claims. Physicians file claims using the CMS 1500 form to their Medicare Part B Carriers, regardless of where the service was performed.

The table below summarizes instructions for completing a physician claim form (CMS 1500). We strongly recommend that IDE investigators contact their local Medicare Carrier prior to submitting physician claims for the clinical trial and related services to verify specific billing and claims submission.

CMS 1500 Physician Claim Form		
Claim Form Field	Code	Instructions
Field 21 (Primary Diagnosis)	ICD-9-CM diagnosis codes will vary by patient's condition. Please refer to coding section for complete descriptions	Document appropriate primary diagnosis code in this field. The ICD-9-CM diagnosis codes listed on the claim must be consistent with those in the IDE trial indications.
Field 23	FDA IDE number: G050017	Enter FDA IDE # G050017 in this field. Note: Medicare does not require the description of the IDE; however, it may be required by other payers.

Field 24D (CPT Code)	<ul style="list-style-type: none"> CPT codes(s) will vary based on the services rendered. CPT coding is dependent upon the documentation in the patient's medical record. Typical CPT code may include: 93799 Unlisted cardiovascular service or procedure 	<p>Document the appropriate CPT codes in Section D of Field 24.</p> <p>If other additional separate procedures are performed, each procedure should be listed separately.</p>
Field 24D (QA Modifier)	QA	Enter "QA" in the Modifier column, next to the CPT code. The modifier "QA" indicates an investigational device.
Enclosure (Optional)	FDA approval letter for IDE clinical trial	Regulations request that providers include a copy of the FDA approval letter for an IDE clinical trial to substantiate their claim for payment, although this is not mandatory.

Note:

- CMS 1500 form the IDE number should be entered in Field 23
- EMC-NSF IDE number is DAO, Field 14
- ANSI 837 IDE number should be contained in position 180
- REF G1 segment with REF01 set to G1 and REF02

CPT-4 codes and nomenclature of Copyright 2007 American Medical Association.

The study identifier and IDE number must be identified on the CMS 1500. Because existing codes may be used to bill for services performed under the clinical study, the IDE number, along with the appropriate clinical study modifiers, are key to identifying claims for the clinical study. Submitting codes without the IDE number and appropriate modifier may result in lost payment and/or penalties. For more information, contact

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APPENDIX A

Sample letter of hospital's notification of Investigation Device Exemption (IDE) clinical trial to Medicare Part A Fiscal Intermediary

[Date]

[Name of Medical Director]

[Title]

[Medicare Part A fiscal intermediary]

[Street Address]

[City, State, Zip Code]

Dear Sir or Madam:

The *[insert hospital name and Medicare Provider Number]* is a site that is participating in the clinical study titled PROTECT II: A Prospective, Multi-center, Randomized Controlled Trial of the Impella 2.5 System Versus Intra-Aortic Balloon Pump (IABP) in Patients Undergoing High Risk PCI. This clinical trial carries the IDE number G050017 and it has been designated by CMS as a Category B clinical study. The anticipated start date of the trial is September 2007. The sponsor of this trial is Abiomed, Inc. headquartered in Danvers, MA. Attached are details about the device and a copy of the protocol for obtaining informed consent for patients in the trial. The product and services related to usage of the product may be considered for reimbursement.

We would like to verify Medicare coverage for the Medicare beneficiaries participating in the clinical trial. In anticipation of a positive coverage determination and to expedite claims processing, we would appreciate your responses to the following:

- Information and date of when your edit system be ready to accept claims for services related to this trial
- Information regarding any special submission instructions for claims for clinical trials, i.e. should claims be addressed to a specific claims examiner?
- Information regarding any specific coding requirements for services related to clinical trials

I look forward to your reply. If you have any questions, please feel free to contact me an XXX-XXX-XXXX

Sincerely,

Sample letter of physician's notification of Investigation Device Exemption (IDE) clinical trial to Medicare Part B Carrier

[Date]

[Name of Medical Director]

[Title]

[Medicare Part B Carrier]

[Street Address]

[City, State, Zip Code]

Dear Sir or Madam:

I am writing to request consideration of Medicare coverage and associated payment for the physician services (including device) for Impella 2.5 in PROTECT II: A Prospective, Multi-center, Randomized Controlled Trial of the Impella 2.5 System Versus Intra-Aortic Balloon Pump (IABP) in Patients Undergoing High Risk PCI.

The FDA is allowing the Impella 2.5 System to be used in an investigational trial. In its consideration, the FDA assigned a Category B designation. As such, this device is eligible for consideration of coverage and reimbursement by Medicare.

The objective of this clinical trial is to evaluate the performance of the Impella 2.5 System in High Risk PCI patients in comparison to the IABP.

To assist in your review and consideration I have enclosed the following materials:

- Copy of FDA letter with IDE approval
- Description of the device
- Overview of clinical study

The clinical protocol allows me to perform the procedure on (number of patients allowed by the study protocol) patients from my clinical practice. I have identified approximately (number of Medicare patients) Medicare beneficiaries who may benefit from this therapy. I plan to provide these services at (hospital name). If more than (approximate number of Medicare patients) qualify for the procedure under the trial protocol, I will contact you.

If you have any questions or need additional information, please call me at (phone number). If I have not heard from you, I will follow-up with you in approximately ten days to discuss this therapy in further detail and determine your openness to considering coverage and payment.

Sincerely,

_____, MD

Enclosures

APPENDIX B

Notification of Clinical Trial

This contains proprietary information that is exempt from release under the Freedom of Information Act.

Study Title: PROTECT II: A Prospective, Multi-center, Randomized Controlled Trial of the Impella 2.5 System Versus Intra-Aortic Balloon Pump (IABP) in Patients Undergoing High Risk PCI

1. Copy of the FDA IDE approval letter to the manufacturer is attached. (See Appendix C)
2. The name of the device:
 - Impella 2.5 System
 - IDE # G050017
 - Reimbursement Category B2

3. Action taken to conform to any applicable FDA special controls:

There are no special controls relative to an IDE study. There are very specific requirements as to what needs to be included in an IDE application as outlined in 21 CFR 812. Abiomed prepared their IDE application for the Impella 2.5 System in conformance with these requirements and filed them in an IDE application. The IDE application received conditional approval on August 22, 2007.

4. A narrative description of the device sufficient to make a payment determination:

The Impella 2.5 System is intended to provide circulatory support for patients undergoing high risk PCI procedures and to prevent hemodynamic collapse during the time of pump operation. The System can operate for up to 5 days should the patient require additional hemodynamic support.

At present, stenting is the current standard of care for the treatment of ischemic coronary disease. The use of adjunct circulatory support devices, such as IABP, during high risk coronary stenting procedures is an accepted procedure and has been associated with improved outcomes and reduces intra-procedural adverse events.

Patients receiving treatment with the Impella 2.5 System may experience the added benefit of improved coronary perfusion during the PCI procedure because of improved intracoronary blood flow rates. In addition, the System may lead to faster improvement of left ventricular function by providing superior unloading of the ventricle and prove to be superior to treatment provided by the IABP.

5. A statement indicating how the device is similar to and/or different from other comparable products:

Impella 2.5 System

The Impella 2.5 System is a minimally invasive percutaneous catheter that actively unloads the left ventricle by drawing blood from the left ventricle and propelling it into the ascending aorta. Unloading the left ventricle allows the heart to rest and recover by:

- Actively unloading the left ventricle
- Reducing myocardial workload and oxygen consumption
- Increasing cardiac output, coronary and end-organ perfusion

The 9F/12F system is inserted via a sheath into the femoral artery and passed over a 0.014" guidewire into the left ventricle through the aortic valve. The system pumps up to 2.5 liters of blood per minute from the left ventricle and can be used for up to 5 days of support. It is anticipated that the procedure will be performed in a cardiac cath laboratory by an interventional cardiologist.

TandemHeart PVAD®

The TandemHeart PVAD® System by CardiacAssist, Inc. is commercially approved in the U.S. for hemodynamic support for up to 6 hours. The Transseptal Cannula system is inserted into the femoral vein, passed into the right atrium and used to access and dilate the septum to allow placement of a 21F Cannula into the left atrium. Blood is pumped from the left atrium via an external pump and delivered back into the body by a 17F catheter placed in the femoral artery. The TandemHeart system can pump up to 4 liters of blood flow per minute from the left atrium and can be used for up to 6 hours. In smaller patients, two 12F femoral artery access sites have been required to achieve 4L/minute blood flow.

System Comparison

Both systems actively unload the heart, although the means of access differentiates these two systems. The TandemHeart's transseptal placement and two or three access sites (femoral vein and femoral artery) makes this system more complicated to use than the Impella 2.5 System, which utilizes a standard percutaneous femoral artery approach for access (the same procedure for a LV Gram). The standard percutaneous femoral artery approach eliminates the risks associated with transseptal catheter placement and multiple access sites.

6. The protocol for obtaining informed consent for patients participating in the clinical trial is attached. (Provider to attach copy of their protocol.)

APPENDIX C



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

COPY

Karim Benali, M.D.
Chief Medical Officer
Abiomed, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

AUG 22 2007

Re: G050017/S11
IMPELLA® RECOVER® LP 2.5 System
Dated: July 20, 2007
Received: July 23, 2007
CMS Category: B2
Annual Report Due: May 24, 2008

Dear Dr. Benali:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing a pivotal study of your device in patients undergoing high-risk percutaneous coronary intervention (PCI), randomized to intra-aortic balloon pump (IABP). Your supplement is conditionally approved, and you may implement that change at institutions in accordance with the investigational site waiver granted below. Your investigation is limited to 150 institutions and 654 subjects.

Since FDA believes this change affects the rights, safety or welfare of the subjects, you must also obtain institutional review board (IRB) approval before implementing this change in your investigation (21 CFR 812.35(a)).

This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies:

APPENDIX D

Medicare Part A Directory

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
Blue Cross Blue Shield of Georgia	J. Ronald Hunt, M.D.	6501 Veterans Pkwy. Building 3 Columbus, GA 31909	706-571-5153 706-571-5431 - fax	ron.hunt@bcbsga.com www.georgiamedicare.com	GEORGIA
Blue Cross Blue Shield of Tennessee	Daniel J. Duvall, M.D.	801 Pine St., Bldg C-6 Chatanooga, TN 37402	423-763-3038 423-209-4890 (fax)	Dan_Duvall@bcbst.com www.riverbendgba.com	NEW JERSEY TENNESSEE
Cahaba Government Benefits Administrators (GBA)	Greg McKinney, M.D., MBA	P.O. Box 13384 Birmingham, AL 35202	205-220-4894 205-220-4708 (fax)	gmckinney@bcbsal.org www.cahabagba.com	ALABAMA
Cooperativa De Seguros De Vida (COSVI)	Manuel Pubillones, M.D.	P.O. Box 363428 San Juan, PR 00936-3428 Overnight: Americo - Miranda Ave. #400 San Juan, PR 00936	787-758-2205 787-756-8199 (fax)	MPubillones@cosvi.com www.cosvi.com/medicare	PUERTO RICO U.S. VIRGIN ISLANDS
First Coast Service Options, Inc.	James J. Corcoran, Jr., M.D., MPH	532 Riverside Avenue, 20T Jacksonville, FL 32202	904-791-6195 904-791-6115 (fax)	James.Corcoran@fcso.com www.floridamedicare.com	FLORIDA
First Coast Service Options, Inc.	Eugene Winter, M.D.	532 Riverside Avenue, 20T Jacksonville, FL 32202	904-791-8182 904-791-6115 (fax)	Eugene.Winter@fcso.com www.floridamedicare.com	FLORIDA
Highmark Medicare Services	Clifford Amend, M.D.	1946 Greenspring Drive Timonium, MD 21093	410-605-2544 410-528-7028 (fax)	Clifford.Amend@carefirst.com www.marylandmedicare.com	MARYLAND WASHINGTON DC
Highmark Medicare Services	Mandy Garber, MD, FACP	120 Fifth Avenue Place, Ste P5101 Pittsburgh, PA 15222	412-544-1964 412-544-1971 (fax)	www.highmarkservices.com	PENNSYLVANIA
Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
Mutual of Omaha Medicare Division	Ellen Evans, M.D.	Mutual of Omaha Plaza P.O. Box 1602 (zip 68101) Omaha, NE 68175	402-351-2585 402-351-5931 (fax)	ellen.evans@mutualofomaha.com www.mutualmedicare.com	ALL STATES EXCEPT CO, IA, KS, MO, NE, NM, NY, TX
National Government Services (f.k.a. Adminastar Federal, Inc)	Richard Baer, M.D.	225 N. Michigan Ave. 22nd FL Mailpoint AFCH-85 Chicago, IL 60601	312-297-4527 312-297-4592 (fax)	richard.baer@anthem.com www.astar-federal.com/anthem/affiliates/adminastar/index	ILLINOIS INDIANA KENTUCKY OHIO
National Government Services (f.k.a. United Government Services)	James W. Cope, M.D.	401 W. Michigan Street Milwaukee, WI 53203 Mailing: P.O. Box 2019 Milwaukee, WI 53201-2019	414-226-6080 414-226-2850 (fax)	james.cope@ugswlp.com www.ugsmedicare.com	MICHIGAN VIRGINIA WEST VIRGINIA WISCONSIN
National Government Services (f.k.a. United Government Services)	Arthur Lurvey, MD	5151 Camino Ruiz, Building G Camarillo, CA 93012 PO Box 9140 Oxnard, CA 93031-9140	805-367-1048 805-367-1115 (fax)	arthur.lurvey@ugswlp.com www.ugsmedicare.com	AMERICAN SOMOA CALIFORNIA GUAM HAWAII NO. MARIANA ISLANDS
National Government Services	Gary Weaver, M.D., FACP	110 Free Street Portland, ME 04104	207-822-7000 207-822-8843 (fax)	Gary.Weaver@anthem.com www.empiremedicare.com	CONNECTIC UT DELAWARE MASSACHUS ETTS NEW YORK
National Government Services	Gary Weaver, M.D., FACP	3000 Goffs Falls Road Manchester, NH 03111-0001	425-670-4760 425-670-4270 (fax)	Gary.Weaver@anthem.com www.ahpnhmedicare.com	NEW HAMPSHIRE VERMONT
National Government Services	Gary Weaver, M.D., FACP	Medicare Medical Review 2 Gannett Drive South Portland, ME 04106-6911	207-822-7000 207-822-8843 (fax)	Gary.Weaver@anthem.com www.ahsmedicare.com	MAINE MASSACHUS ETTS

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
MAC-Jurisdiction 3 Noridian Administrative Services, LLC*	Bernice Hecker, M.D.	901 40th Street South, Suite 1 Fargo, ND 58103 <i>*Different PO Boxes for each state: AZ-6730, MT-6732, ND-6709, SD- 6733, UT-67254, WY-6734</i> PO Box **** Fargo, ND 5810	253-437-5442 253-437-5300 (fax)	bernice.hecker@noridian.com www.noridianmedicare.com	ARIZONA MONTANA NORTH DAKOTA SOUTH DAKOTA UTAH WYOMING
Noridian Administrative Services, LLC	Bernice Hecker, M.D.	901 40th Street South, Suite 1 Fargo, ND 58103 PO Box 6726 Fargo, ND 58108	253-437-5442 253-437-5300 (fax)	bernice.hecker@noridian.com www.noridianmedicare.com	IDAHO OREGON
Noridian Administrative Services, LLC	Bernice Hecker, M.D.	901 40th Street South, Suite 1 Fargo, ND 58103 PO Box 6720 Fargo, ND 58108	253-437-5442 253-437-5300 (fax)	bernice.hecker@noridian.com www.noridianmedicare.com	ALASKA WASHINGTON
Noridian Administrative Services, LLC	Bernice Hecker, M.D.	901 40th Street South, Suite 1 Fargo, ND 58103 PO Box 6714 Fargo, ND 58108	253-437-5442 253-437-5300 (fax)	bernice.hecker@noridian.com www.noridianmedicare.com	MINNESOTA
Palmetto Government Benefits Administrators (GBA)	Stacey Brennan, MD	Medicare Intermediary Part A Office 800 South Duke Street P.O. Box 3824 Durham, NC 27702	919-687-7178 919-687-7951 (fax)	stacey.brennan@palmettogba .com www.palmettogba.com	NORTH CAROLINA
Palmetto Government Benefits Administrators (GBA)	Harry Feliciano, M.D.	2300 Springdale Drive BUILDING ONE Camden, South Carolina 29020 or P.O. Box 7004 Mail Code AG-300 Camden, South Carolina 29020	803-788-0222 ext. 35007 803-935-0199	harry.feliciano@PalmettoGBA. com www.PalmettoGBA.com	SOUTH CAROLINA
Pinnacle Business Solutions, Inc.	Mayo Gilson, M.D.	701 NW 63rd St., Suite 300 Oklahoma City, OK 73116	405-841-6755 405-848-0131 (fax)	mdgilson@arkbluecross.com www.rimedicare.org	RHODE ISLAND
Pinnacle Business Solutions, Inc.	Sidney Hayes, M.D.	601 Gaines Street Little Rock, AR 72201	501-918-7423 501-918-7424	sphayes@arkbluecross.com www.arkmedicare.com	ARKANSAS

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
MAC-Jurisdiction 4 TrailBlazer Health Enterprises, LLC*	*No New Medical Directors have been named. (Charles Haley, M.D., Trailblazer)	Headquarters: P.O. Box 660156 Dallas, Texas 75266-0156 STREET ADDRESS: 901 South Central Expressway Richardson, Texas 75080	469-372-0992 469-372-2649 (fax)	charles.haley@trailblazerh ealth.com www.trailblazerhealth.com	COLORADO NEW MEXICO OKLAHOMA TEXAS
Trispan Health Services	Barry Whites, M.D., FCCP, MSHA	1064 Flynt Drive Mailstop: AX2MC6 Flowood, MS 39232 P.O. Box 23046 Jackson, MS 39225-3046			LOUISIANA MISSOURI MISSISSIPPI
MAC-Jurisdiction 5 Wisconsin Physician Services (WPS)*	*No New Medical Directors have been named. (David, Borel,MD, Sidney Hayes, MD, Patrick Price, MD - formerly BCBS of KS. John Olds, M.D. formerly Cahaba)	Headquarters: 208 E. Olin Avenue PO Box 8190 Madison, WI 53713	888-915-4001 800-236- 1448 608-223-3626 (fax)	david.borel@bcbsks.com Patrick.Price@bcbsks.com jolds@cahabagba.com	IOWA KANSAS MISSOURI NEBRASKA

*MAC 4 – Awarded on 8/2/07 & fully operational no later than spring 2008. New Medical Directors have not been named.

*MAC 5 – Awarded 9/5/07 & fully operational no later than 9/9/08. New Medical Directors have not been named.

Medicare Part B Directory

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
Cahaba Government Benefits Administrators (GBA)	Fred Robertson, M.D.	P.O. Box 13384 450 Riverchase Parkway East Birmingham, AL 35202	205-220-4921 205-220-4708 (fax)	almedicare@bcbsal.org froberson@bcbsal.org www.almedicare.com	ALABAMA
Cahaba Government Benefits Administrators (GBA)	Charles Whigham, M.D.	12052 Middleground Road Suite A P.O. Box 3018 Savannah, GA 31402-3018	912-921-3081 912-921-4990 - fax	cwhigham@bcbsal.com www.gamedicare.com	GEORGIA
Cahaba Government Benefits Administrators (GBA)	James E. Strong, M.D.	775 Woodland Pkwy. Ridgeland, MS 39157	601-977-5744 601-977-5536 (fax)	jstrong@cahabagba.com www.cahabagba.com	MISSISSIPPI
CIGNA Medicare Administration	Boyd K. Honeycutt, M.D., MBA, FACP	Attn: Medical Review 4135 Mendenhall Oaks Pkwy High Point, NC 27265	336-821-4511 336-821-4594 (fax)	Boyd.Honeycutt@cigna.com www.cignamedicare.com	NORTH CAROLINA
CIGNA Medicare Administration	Gary Oakes, M.D	Attn: Medical Review Two Vantage Way Nashville, TN 37228	615-782-4565 615-782-4480 (fax)	gary.oakes@cigna.com www.cignamedicare.com	IDAHO
CIGNA Medicare Administration	Boyd K. Honeycutt, M.D., MBA, FACP	Attn: Medical Review 4135 Mendenhall Oaks Pkwy High Point, NC 27265	336-821-4511 336-821-4594 (fax)	Boyd.Honeycutt@cigna.com www.cignamedicare.com	IDAHO
CIGNA Medicare Administration	Gary Oakes, M.D	Attn: Medical Review Two Vantage Way Nashville, TN 37228	615-782-4565 615-782-4480 (fax)	gary.oakes@cigna.com www.cignamedicare.com	TENNESSEE
First Coast Service Options, Inc.	Neil Sandler, M.D.	321 Research Parkway P.O. Box 9000 Meriden, CT 06450-5410	203-634-5410 203-634-5484 (fax)	neil.sandler@fcso.com www.connecticutmedicare.com	CONNECTICUT

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
First Coast Service Options, Inc.	Eugene Winter, M.D.	532 Riverside Avenue P.O. Box 2078 Jacksonville, FL 32231	904-791-8182 904-791-8006 (fax)	Eugene.Winter@fcso.com www.floridamedicare.com	FLORIDA
Group Health Incorporated (NY)	Joseph G. Presto, M.D.	25 Broadway, 13th Floor New York, NY 10004	646-458-6671 616-458-6763 (fax)	presto@ghimedicare.com www.ghimedicare.com	NEW YORK
HealthNow of Upstate New York	Edward Cox, M.D.	Upstate Medicare Div., Part B 33 Lewis Road P.O. Box 5200 Binghamton, NY 13902-5236	607-766-6217 607-766-6452 (fax)	emcox@nycpic.com www.umd.nycpic.com	UPSTATE NEW YORK
Highmark Medicare Services	Andrew Bloschichak, M.D., M.B.A.	1800 Center Street, 1A-L4 Camp Hill, PA 17089	717-760-9516 717-612-4978 (fax)	andrew.bloschichak@highmarkservices.com www.hgsa.com	PENNSYLVANIA
National Government Services (f.k.a. adminastar)	Carolyn Cunningham, M.D.	8115 Knue Road, AF10 Indianapolis, IN 46250	317-841-4607 317-841-4600 (fax)	Carolyn.Cunningham@Anthem.com www.astar-federal.com/anthem/affiliates/adminastar/index	INDIANA KENTUCKY
National Government Services (f.k.a. empire)	Salvatore M. Moffa, M.D.	300 E. Park Drive Harrisburg, PA 17111	717-565-3616 717-565-3432 - fax	salvatore.moffa@empireblue.com www.empiremedicare.com	NEW JERSEY
National Government Services (f.k.a. empire)	Eileen M. Moynihan, M.D.	1333 Brunswick Avenue Lawrenceville, N.J. 08096	609-826-5678 609-826-5699 (fax)	eileen.moynihan@empireblue.com www.empiremedicare.com	NEW JERSEY
National Government Services (f.k.a. empire)	Paul Deutsch, M.D.	2651 Strang Boulevard Yorktown Heights, NY 10598	914-248-3214 914-248-2766 (fax)	pdeutsch@empirebcbs.com www.empiremedicare.com	NEW YORK

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
National Government Services (f.k.a. empire)	Norbert Rainford, M.D.	2651 Strang Boulevard Yorktown Heights, NY 10598	914-248-2725 914-248-2766 (fax)	nrainford@empirebcbs.com www.empiremedicare.com	NEW YORK
National Heritage Insurance Company	Craig Haug, M.D.	75 Sgt. William Terry Drive Hingham, MA 02043	781-741-3122 781-741-3211 (fax)	www.medicarenhic.com	MAINE MASSACHUSETTS NEW HAMPSHIRE VERMONT
National Heritage Insurance Company	Bruce Quinn, M.D.	402 Otterson Drive Chico, CA 95928	530-896-7123 530-896-7162 (fax)	bruce.quinn@eds.com www.medicarenhic.com	CALIFORNIA
National Heritage Insurance Company	Bruce Quinn, M.D.	1055 W. 7th Street, Fifth Floor Los Angeles, CA 90017	213-593-6801 213-593-5921 (fax)	bruce.quinn@eds.com www.medicarenhic.com	CALIFORNIA
MAC - Jurisdiction 3 Noridian Administrative Services, LLC*	William (Bill) J. Mangold, Jr., M.D., J.D.	901 40th St. S, Suite 1 Fargo, ND 58103	602-749-2506 602-749-2550 (fax)	william.mangold@noridian.com www.noridianmedicare.com	ARIZONA MONTANA UTAH
MAC - Jurisdiction 3 Noridian Administrative Services, LLC*	Robert F. Szczys, M.D.	901 40th St. S, Suite 1 Fargo, ND 58103	701-277-5204 701-277-6558 (fax)	robert.szczys@noridian.com www.noridianmedicare.com	WYOMING
MAC - Jurisdiction 3 Noridian Administrative Services, LLC*	George Waldmann, M.D.	901 40th St. S, Suite 1 Fargo, ND 58103	503-977-1205 503-977-1201 (fax)	george.waldmann@noridian.com www.noridian.com	NORTH DAKOTA SOUTH DAKOTA
Noridian Administrative Services, LLC	William (Bill) J. Mangold, Jr., M.D., J.D.	901 40th St. S, Suite 1 Fargo, ND 58103	602-749-2506 602-749-2550 (fax)	william.mangold@noridian.com www.noridianmedicare.com	NEVADA
Noridian Administrative Services, LLC	Robert F. Szczys, M.D.	901 40th St. S, Suite 1 Fargo, ND 58103	701-277-5204 701-277-6558 (fax)	robert.szczys@noridian.com www.noridianmedicare.com	WYOMING

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
Noridian Administrative Services, LLC	George Waldmann, M.D.	901 40th St. S, Suite 1 Fargo, ND 58103	503-977-1205 503-977-1201 (fax)	george.waldmann@noridian.com www.noridian.com	OREGON
Noridian Administrative Services, LLC	Richard Whitten, MD	901 40th St. S, Suite 1 Fargo, ND 58103	808-522-1570 808-522-1577 (fax)	dick.whitten@noridian.com www.noridianmedicare.com	HAWAII
Noridian Administrative Services, LLC	Richard Whitten, M.D.	901 40th St. S, Suite 1 Fargo, ND 58103	253-437-5402 253-437-5300 (fax)	dick.whitten@noridian.com www.noridianmedicare.com	ALASKA WASHINGTON
Palmetto Government Benefits Administrators (GBA)	Elaine Jeter, M.D..	2300 Springdale Drive BUILDING ONE Camden, South Carolina 29020 or P.O. Box 100190 Mailstop AG-300 Columbia, SC 29203	803-763-5059 or 803-735-1034 803-935-0199 (fax)	elaine.jeter@PalmettoGBA.com www.PalmettoGBA.com	SOUTH CAROLINA
Palmetto Government Benefits Administrators (GBA)	Robert R. Kamps, M.D.	3400 Southpark Place, Suite F Grove City, OH 43123-4846	614-277-6424 614-277-6204 (fax)	robert.kamps@palmettogba.com www.palmettogba.com	OHIO WEST VIRGINIA
Palmetto Government Benefits Administrators (GBA)	Robert Ludwig, M.D.	3400 South Park Place Grove City, OH 43123	614-277-6427 614-277-6204 (fax)	robert.ludwig@palmettogba.com www.palmettogba.com	OHIO WEST VIRGINIA
Pinnacle Business Solutions, Inc.	Mayo Gilson, M.D.	701 NW 63rd Street, Suite 300 Oklahoma City, OK 73116	405-841-6755 405-848-0131(fax)	mdgilson@arkbluecross.com www.oknmmedicare.com	RHODE ISLAND
Pinnacle Business Solutions, Inc.	Sidney P. Hayes, M.D.	601 Gaines Street Little Rock, AR 72201	501-918-7423 501-918-7424	sphayes@arkbluecross.com www.arkmedicare.com	ARKANSAS
Pinnacle Business Solutions, Inc.	Lynn Hickman, M.D.	8687 United Plaza Blvd., Bldg. 9 Baton Rouge, LA 70809-9501 or P.O. Box 98501 Baton Rouge, LA 70884-9501	225-231-2114 225-231-2277 (fax)	lehickman@arkbluecross.com www.lamedicare.com	LOUISIANA

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
TrailBlazer Health Enterprises, LLC	Mitchell Burken, M.D.	Timonium II 1954 Greenspring Drive Timonium, MD 21093	410-683-2610 410-683-2939 (fax)	mitchell.burken@trailblazerhealth.com www.trailblazerhealth.com	DELAWARE MARYLAND VIRGINIA WASHINGTON D.C.
TrailBlazer Health Enterprises, LLC	Laurence Clark, M.D.	Timonium II 1954 Greenspring Drive Timonium, MD 21093	410-683-2611 410-683-2939 (fax)	laurence.clark@trailblazerhealth.com www.trailblazerhealth.com	DELAWARE MARYLAND WASHINGTON DC
MAC - Jurisdiction 4 TrailBlazer Health Enterprises, LLC*	*No new Medical Directors have been named. Charles Haley, M.D., Debra Patterson, MD, Mayo Gilson, M.D., Lynn Hickman, M.D., Robert F. Szczyz, M.D	Headquarters: P.O. Box 660156 Dallas, Texas 75266-0156 STREET ADDRESS: 901 South Central Expressway Richardson, Texas 75080	469-372-0992 469-372-2649 (fax)	Charles.Haley@trailblazerhealth.com; Debra.Patterson@trailblazerhealth.com; mdgilson@arkbluecross.com; lehickman@arkbluecross.com www.trailblazerhealth.com, robert.szczyz@noridian.com	COLORADO NEW MEXICO OKLAHOMA TEXAS
Triple-S Inc.	Gonzalo Gonzalez-LiBoy, M.D., FACP	1441 Franklin D. Roosevelt Ave.4th Floor Puerto Rico 00936-1937 P.O. Box 363628 San Juan, Puerto Rico 00936-3628	787-749-4144 787-749-4092 (fax)	gvg1035@pol.net www.TripleS-med.org	PUERTO RICO VIRGIN ISLANDS
MAC-Jurisdiction 5 Wisconsin Physician Services (WPS)*	*No New Medical Directors have been named. Patrick Price, M.D., David Borel, MD, Sidney P. Hayes, M.D	Headquarters: 208 E. Olin Avenue PO Box 8190 Madison, WI 53713	888-915-4001 800-236-1448 608-223-3626 (fax)	david.borel@bcbsks.com Patrick.Price@bcbsks.com jolds@cahabagba.com	IOWA KANSAS MISSOURI NEBRASKA
WPS	Stephen Boren, M.D.	111 East Wacker Drive Chicago, IL 60611	312-228-6254 312-228-6280 (fax)	stephen.boren@wpsic.com www.wpsic.com	ILLINOIS
WPS	Stephen Boren, M.D.	111 East Wacker Drive Chicago, IL 60611	312-228-6254 312-228-6280 (fax)	stephen.boren@wpsic.com www.wpsic.com	ILLINOIS

Contractor	Director Names	Street Address	Phone/Fax	Email/Website	State
WPS	Stephen Boren, M.D. *interim basis	8120 Penn Avenue South, Suite 200 Bloomington, MN 55431	952-885-2832 952-885-2980 (fax)	stephen.boren@wpsic.com www.wpsic.com	MINNESOTA
WPS	Kenneth L. Bussan, M.D.	1601 Engel Street P.O. Box 1787 Madison, WI 53713	608-301-2604 608-301-2625 (fax)	kenneth.bussan@wpsic.com www.wpsic.com	WISCONSIN
WPS	Michael Rosenberg, M.D.	28300 Northwestern Hwy. Suite 200 Southfield, MI 48075	248-395-7702 248-395-7903 (fax)	michael.rosenbe@wpsic.com www.wpsic.com	MICHIGAN

*MAC 4 – Awarded on 8/2/07 & fully operational no later than spring 2008. New Medical Directors have not been named.

*MAC 5 – Awarded 9/5/07 & fully operational no later than 9/9/08. New Medical Directors have not been named.