consistent in quality with inpatient surgical services.

• To meet the requirements at § 482.51(b)(5), CIHQ modified its standards to require that the operating room register be complete and up-todate.

• To meet the requirements at § 482.51(b)(6), CIHQ modified its standards to address the requirement that an operative report must be written or dictated immediately following surgery and signed by the surgeon.

• To meet the requirements at § 482.56(a)(2), CIHQ modified its standards to include the reference to part 484 of the Code of Federal Regulations.

• To meet the survey process requirements in Appendix A of the SOM, CIHQ revised its policies outlining the survey size and composition to require that every survey will include at least one registered nurse with hospital survey experience.

• To meet the survey process requirements in Appendix Q of the SOM, CIHQ revised its policies to require notification to CMS of an immediate jeopardy situation, the content of the CMS notification, and the appropriate level of citation related to immediate jeopardy findings.

• To meet the requirements found at Section 2728B of the SOM, CIHQ revised its policies to require a more detailed monitoring plan that includes frequency of monitoring, duration of monitoring, sample size and target threshold, as part of a hospital's plan of correction for deficiencies found on survey.

• To meet the requirements found at Section 2005A2 of the SOM, CIHQ revised its policies to require the issuance of an accreditation denial for hospitals initially seeking participation in the Medicare program when the hospital has been found to be noncompliant with a condition of participation. • To meet the requirements at § 498.13 and Section 2008D of the SOM, CIHQ revised its policies to clearly state that the final accreditation decision is based on the final survey report in which the provider meets all requirements or the date, which the provider is found to meet all conditions but has lower level deficiencies and CIHQ has received an acceptable plan of correction.

• To meet the requirements at Section 3012 of the SOM, CIHQ revised its policies to accurately reflect the requirement that follow-up surveys must be conducted within 45 calendar days from the survey end-date of the survey, which the condition level finding was cited.

• To clarify the survey process and to ensure the consistent application of survey activities, CIHQ updated its policies, survey tools and guidance to surveyors related to tracer activities, patient interviews, and staff interviews.

• To eliminate any real or perceived conflict of interest between CIHQ's consulting services through "Accreditation Resource Services" and its accreditation activities, CIHQ updated its plan to ensure that both entities are separated by a firewall and that information is not shared.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that CIHQ's requirements for hospitals meet or exceed our requirements. Therefore, we approve CIHQ as a national accreditation organization for hospitals that request participation in the Medicare program, effective July 26, 2013. through July 26, 2017.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 2, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–18014 Filed 7–25–13; 8:45 am] BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9080-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2013

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS. **ACTION:** Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2013, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	Mitch Bryman	(410) 786-5258
VII Medicare – Approved Carotid Stent Facilities	Lori Ashby	(410) 786-6322
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786-7861
IX Medicare's Active Coverage-Related Guidance Documents	Lori Ashby	(410) 786-6322
X One-time Notices Regarding National Coverage Provisions	Lori Ashby	(410) 786-6322
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIV Medicare-Approved Bariatric Surgery Facilities	Kate Tillman, RN, MAS	(410) 786-9252
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries. health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Revised Format for the Quarterly Issuance Notices

While we are publishing the quarterly notice required by section 1871(c) of the Act, we will no longer republish duplicative information that is available to the public elsewhere. We believe this approach is in alignment with CMS' commitment to the general principles of the President's Executive Order 13563 released January 2011entitled "Improving Regulation and Regulatory Review," which promotes modifying and streamlining an agency's regulatory program to be more effective in achieving regulatory objectives. Section 6 of Executive Order 13563 requires agencies to identify regulations that may be "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand or repeal them in accordance with what has been learned." This approach is also in alignment with the President's Open Government and Transparency Initiative that establishes a system of transparency, public participation, and collaboration.

Therefore, this quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This information is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and "real time" accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at http:// www.cms.gov/manuals.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare— Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: July 19, 2013.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120-01-P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: May 18, 2012 (77 FR 29648), August 17, 2012 (77 FR 49799), November 9, 2012 (77 FR 67368) and May 3, 2013 (78 FR 26038). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2013)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <u>http://cms.gov/manuals</u>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare Claims Processing publication titled Claim Status Category and Claim Status Codes Update use CMS-Pub. 100-04, Transmittal No. 2681.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at <u>www.cms.gov/Manuals</u>.

Transmittal Number	Manual/Subject/Publication Number
	Medicare General Information (CMS-Pub. 100-01)
00	None
	Medicare Benefit Policy (CMS-Pub. 100-02)
170	Updates to Medicare Coverage of Hepatitis B Vaccine and its Administration and Medicare Coverage of the Annual Wellness Visit (AWV) Providing Personalized Prevention Plan Services (PPPS) Antigens Immunizations Annual Wellness Visit (AWV) Providing Personalized Prevention Plan Services (PPPS) Routine Services and Appliances
171	Implementation of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Definitions Relating to ESRD Renal Dialysis Items and Services Composite Rate Items and Services Drugs and Biologicals

Bad Debts Reserved Composite Rate Tests for Hemodialysis, IPD, CCPD, and Hemofiltration Composite Rate Tests for CAPD Brief History of ESRD Composite Payment Rates for Outpatient Maintenance Dialysis Medicare National Coverage Determination (CMS-Pub. 100-03) 153 Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds Blood-Derived Products for Chronic Non-Healing Wounds Docular Photodynamic Therapy (OPT) Photodynamic Therapy Ocular Photodynamic Therapy (OPT) Photosensitive Drugs Verteporfin Medicare Claims Processing (CMS-Pub. 100-04) 2680 Data Reporting on Home Health Prospective Payment System (HH PPS) Claims HIH PPS Claims Input/Output Record Layout 2681 Claim Status Category and Claim Status Codes Update 2682 Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Drogram (CBP) - July 2013		
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	Tax Identification Numbers of Foreign Owning and Managing Entities and Individuals
459	Tax Identification Numbers of Foreign Owning and Managing Entities and
459	Tax Identification Numbers of Foreign Owning and Managing Entities and Individuals Clarify the definition of customized durable medical equipment (DME) item:

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CWF) Informational Unsolicited Respon visit billed by the same physician or phy
rs. n Procedure Coding System (HCPCS) C
dical Equipment rd - Operating Rules for code usage in R
CARC 23 - Analysis and Design
nt Operating Rules
rd - Phase I
VMS for implementing system changes f
ence, not posted to Internet/ Intranet due
n Procedure Coding System (HCPCS) C dical Equipment
ence, not posted to Internet/ Intranet due
ence not posted to Internet/Intranet due t etion
for CMS Standard Edit/Audit/Reason C Ruling 1455-R (Medicare Program; Par
CWF) Informational Unsolicited Respon

	Due d'es Terret'en Te Connedt'en
	Practice Location Information Movement of Providers and Suppliers into the High Level
462	Reconsideration Requests Update to Chapter 15 of the Program Integrity Manual (PIM)
462	Model Letter Revisions
00	e Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09) None
	care End Stage Renal Disease Network Organizations (CMS Pub 100-14)
00	None
00	Medicare Managed Care (CMS-Pub. 100-16)
111	Chapter 9, Employer/Union-Sponsored Group Health Plans
111	Adding MSP Validity Indicator to the CWF to MBD Feed Working Aged
112	Adjustment
113	Chapter 12, Effect of Change of Ownership
115	Entire Chapter
114	Risk Adjustment
114	Entire Chapter
	Medicare Business Partners Systems Security (CMS-Pub, 100-17)
00	None
	Demonstrations (CMS-Pub. 100-19)
00	None
	One Time Notification (CMS-Pub. 100-20)
1205	Incentive Payment Related to Prior Authorization for Power Mobility Devices
1	(PMD).
1207	Direct Mailing to Referral Agents about the DMEPOS Competitive Bidding
	Program Round 2 and National Mail-Order for Diabetic Testing Supplies
1208	Use of Q6 Modifier for Locum Tenens by Providing Performing Provider
	NPT "FOR ANALYSIS ONLY"
1209	Recovery of Annual Wellness Visit (AWV) Overpayments
1210	Implementing the Recompetition Award for the Jurisdiction C Durable
	Medical Equipment (DME) Medicare Administrative Contractor (MAC)
	Workload
1211	Modification to Change Request (CR)7254
1212	MCS Prepayment Review Report
1213	Updating the Shared Systems and Common Working File (CWF) to no
	Longer Create Veteran Affairs (VA) "I" records in the Medicare Secondary
	Payer (MSP) Auxiliary File
1214	Medicare System Update to Include Line Level National Provider Identifier
	(NPI) Sanction Editing on Critical Access Hospital (CAH) Method II
	Outpatient Claims
1215	VMS Prepayment Review Report
1216	Applying Multiple Procedure Payment Reductions to Therapy Cap Amounts
	for Critical Access Hospital Claims
1217	CWF Editing for Vaccines Furnished at Hospice
1218	American Recovery and Reinvestment Act of 2009 Electronic Health Record
	(EHR) Incentive : New Critical Access Hospital Banking Information File
	Transfer for Eligible Professional Payment
1219	National Competitive Bidding Program (CBP): Instructions for Processing
	CBP Oxygen and Capped Rental Item Claims with the Start of the Round One

1220	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End
	Updates for October 2013
1221	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1222	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1223	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1224	Phase III ERA Enrollment Operating Rules
1225	Reporting of Principal and Interest when returning previously recouped
	money – Analysis
1226	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1227	Update to the Common Working File (CWF) Qualifying Stay Edit for Skilled
1227	Nursing Facility (SNF) and Swing Bed (SB) Providers
1228	Debts Referred to Treasury through the Healthcare Integrated General Ledger
1220	Accounting System (HIGLAS)
1229	Issued to a specific audience, not posted to Internet/Intranet due to
1229	
1220	Confidentiality of Instruction
1230	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
1231	Common Working File (CWF) Informational Unsolicited Response (IUR) or
	Reject for a new patient visit billed by the same physician or physician group
	within the past three years.
1232	New Healthcare Common Procedure Coding System (HCPCS) Codes for Customized Durable Medical Equipment
1233	Standardizing the standard - Operating Rules for code usage in Remittance
1200	Advice
1234	MSP Claims and use of CARC 23 - Analysis and Design
1234	Phase III ERA Enrollment Operating Rules
1236	Standardizing the Standard - Phase I
1237	Analysis and Design of VMS for implementing system changes for handling Bankrupt Suppliers
1238	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1239	New Healthcare Common Procedure Coding System (HCPCS) Codes for
1209	Customized Durable Medical Equipment
1240	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity
1270	of Instruction
1241	Issued to a Specific audience not posted to Internet/Intranet due to
1241	Confidentiality of Instruction
1242	Change in Creation Date for CMS Standard Edit/Audit/Reason Code Reports
1243	Implementation of CMS Ruling 1455-R (Medicare Program; Part B Billing in
1.4.10	Hospitals)
1244	Common Working File (CWF) Informational Unsolicited Response (IUR) or
1244	Reject for a new patient visit billed by the same physician or physician group
1244	

Recompete

	Jurisdiction 12) Part A/Part B Medicare Administrative Contractor (A/B MAC) Workload
1246	Implementation of the Award for the Jurisdiction K (JK) Part A and Part B Medicare Administrative Contractor (A/B MAC) to National Government Services
1247	Implementation of CMS Ruling 1455-R (Medicare Program; Part B Billing in Hospitals)
1248	Multi Carrier System (MCS) Modifications to Liability Assignment Regarding Therapy Cap Claim Denials

Addendum II: Regulation Documents Published in the Federal Register (April through June 2013)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at <u>www.gpo.gov/fdsys</u>. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through <u>GPO Access</u>. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <u>http://www.gpoaccess.gov/fr/index.html</u>. The following website <u>http://www.archives.gov/federal-register/</u> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: <u>http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-</u>20130PU.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at

http://www.cms.gov/Rulings/CMSR/list.asp#TopOfPage. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2013)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we list only the specific updates that have occurred in the 3-month period. This information is available at: www.cms.gov/medicare-coveragedatabase/. For questions or additional information, contact Wanda Belle (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
TAVR Mandatory Clinical Trail Number	NCD20.32	TN2689	05/03/2013	07/1/2013
OPT with Verteporfin for Macular Degeneration	NCD80.3.1	TN155	06/14/2013	04/03/2013
Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds	NCD270.3	TN154	06/10//2013	08/02/2012

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2013)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered

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by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
G130054	Juvederm Volbella XC	04/03/2013
G130056	Sensor Optimization of CRT Response (SOCR) Study	04/03/2013
G130055	Neuroport Array and Neuroport System	04/04/2013
G120243	Abdominal Compression Elastic Support (ACES)	04/11/2013
G120053	Perceval S Heart Valve	04/12/2013
G130007	Model 9005 Lutonix DCB	04/18/2013
G130068	Ulthera System	04/19/2013
G120172	Mguard Prime Micronet Covered Coronary Stent System	04/19/2013
G120266	Angel Catheter	04/19/2013
G130012	9.4 Tesla 80 CM MR Scanner	04/24/2013
G130069	Pantaprazole 13C Breath Test (PTZ-BT)	04/24/2013
G120275	Enlightn Renal Denervation System	04/25/2013
G130073	NRAS Q61 Mutation test	04/26/2013
G130078	Gel-One	04/26/2013
G130077	Brava Systems	04/26/2013
G130084	EPI-Sense-AF Guided Coagulation System with Visitrax	05/03/2013
G130087	Gastric Emptying Breath Test (GEBT)	05/08/2013
G130082	Cortical Recording and Stimulation Array System	05/10/2013
G130048	MECTA 5000Q Feast Drive	05/15/2013
G120160	Direct Flow Medical Trans Catheter Aortic Valve System	05/15/2013
G120254	VORTX RX	05/22/2013
G130046	Magnamosis Magnetic Compression Anastomosis Device	05/23/2013
G130093	Veni RF Plus Endovenous Ablation System	05/24/2013
G130095	Lap-Band & MetFormin	05/28/2013
G130094	Dermaveil	05/29/2013
G130097	Multimodality Image-Guided (MIMIG) System	05/30/2013
G130081	Intuitive Surgical Da Vinci Single-Site Instruments And	05/31/2013
	Accessories	
G120300	GE Datex-Ohmeda AISYS With Smartflow	05/31/2013
G130099	Exablate 2000 MRGHIFU System	06/04/2013
G130141	Cook Cervical Ripening Balloon	06/04/2013
G120263	Portico Transcatheter Aortic Valve Implant	06/05/2013
G120235	Entrainment Based Mechanical Ventilation	06/06/2013
G130108	Rezum Generator, Rezum Delivery Device, Rezum Accessory	06/06/2013

	Pack	
G130100	Neural Prosthetic System 2 (NPS2)	06/12/2013
G130111	Axialif System	06/14/2013
G110072	Perclot Polysacharide Hemostatis System	06/14/2013
G130110	Essure System For Permanent Birth Control	06/14/2013
G130113	Integrated Bracanalysis	06/14/2013
G130024	Perfusion-Induced Systemic-Hyperthermia (PISH)	06/18/2013
G070038	Aethlon GNA Hemopurifier	06/20/2013
G120015	Croma Eyefill Viscoelastic Device	06/20/2013
G130105	Medtronic Application Card For Spinal Cord Stimulation Model 8870	06/20/2013
G130120	Gore Tag Thoracic Branch Endoprosthesis	06/21/2013
G130080	PantoPrazole-C Breath Test (PTZ-BT)	06/27/2013
G130130	DAKO MET 2 Pharmdx Kit	06/27/2013
G130123	Tristan 621 Biomagnetometer	06/28/2013
G130126	Medtronic Symplicity Renal Denervation System	06/29/2013

Addendum VI: Approval Numbers for Collections of Information (April through June 2013)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact Mitch Bryman (410-786-5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2013)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Lori Ashby (410-786-6322).

Facility	Provider Number	Effective Date	State
The following facilities are new l			1
Northside Hospital Atlanta	1457396079	04/25/2013	GA
1000 Johnson Ferry Road, NE	1.010500075	0.1.2012010	
Atlanta, GA 30342			
Memorial Hospital	1447206438	04/25/2013	FL
3625 University Boulevard South	1117200150	01/20/2010	12
Jacksonville, FL 32216			
Saint Mary's Regional Medical Center	1801152566	04/25/2013	NV
235 West Sixth Street	1001152500	0 11 201 201 0	
Reno, NV 89503			
Good Samaritan Regional Health Center	441221	04/25/2013	IL
1 Good Samaritan Way	441221	04/2012015	112
Mt. Vernon, IL 62864			
Wayne Memorial Hospital	1750353462	04/25/2013	NC
2700 Wayne Memorial Drive	1750555402	04/23/2013	INC
Goldsboro, NC 27534			
Lowell General Hospital	220063	05/17/2013	MA
295 Varnum Avenue	220005	03/17/2013	MA
Lowell, MA 01854			
ARH Regional Medical Center	180002	05/17/2013	KY
100 Medical Center Drive	100002	05/17/2015	
Hazard, KY 41701			
Providence Holy Cross Medical Center	1477587632	05/17/2013	CA
15031 Rinaldi Street	14/7507052	05/17/2015	
P.O. Box 9600			
Mission Hills, CA 91346			
Memorial Hospital at Gulfport	1639401318	06/05/2013	MS
4500 13 th Street	1057401518	00/05/2015	IVIS
Gulfport, MS 39501			
Kaiser Foundation Hospital Redwood City	050541	06/05/2013	CA
1150 Veterans Boulevard	050541	00/05/2015	
901 Marshall Building 3 rd Floor			
Redwood City, CA 94063			
University of South Alabama Medical Center	010087	06/26/2013	AL
2451 Fillingim Street	010087	00/20/2015	AL
Mobile, AL 36617			
Editorial changes (shown in bold) were m	ada ta tha faciliti	v listed below	
Wake Forest Baptist Medical Center	340047	06/27/2005	NC
Medical Center Boulevard	540047	00/2/12005	INC
Winston-Salem, NC 27157			
Sherman Health	140030	11/18/2005	IL
1425 North Randall Road	140030	11/10/2003	
Elgin, IL 60123			
Ligin, iL 00125	L	<u> </u>	

Addendum VIII: American College of Cardiology's National Cardiovascular Data

Registry Sites (April through June 2013) Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filt erByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at <u>www.ncdr.com/webncdr/common</u>

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: <u>www.ncdr.com/webncdr/common</u>. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	City	State
The following facilities are new	listings for this quarter.	
Verdugo Hills Hospital	Glendale	CA
Forest Hills Hospital	Forest Hills	NY
Spring Valley Hospital	Las Vegas	NV
The Hospital at Westlake Medical Center	Austin	TX
Carondelet St Mary's Hospital	Tueson	AZ
Soin Medical Center	Beavercreek	OH
Gulf Breeze Hospital	Gulf Breeze	FL
Florida Hospital Heartland	Sebring	FL
Saint Mary's Health Center	Jefferson City	MO
Women and Children's Hospital	Lake Charles	LA
Palms West Hospital	Loxahatchee	FL
Children's Medical Center of Dallas	Dallas	TX
Sumner Regional Medical Center	Gallatin	TN
Waccamaw Community Hospital	Murrells Inlet	SC
Delnor Hospital	Geneva	IL
Newman Regional Health	Emporia	KS
Health Alliance Hospital	Leominster	MA
Mercy Western Hills	Cincinnati	OH
The following facility is termi	nated as of this quarter.	
Greene Memorial Hospital	Xenia	OH

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2013)

There are no CMS coverage-related guidance documents published in the April through June 2013 quarter. To obtain the document, visit the CMS coverage website at <u>http://www.cms.gov/medicare-coveragedatabase/details/medicare-coverage-document-details.aspx?MCDId=23</u>. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2013)

There were no special one-time notices regarding national coverage provisions published in the April through June 2013 quarter. This information is available at <u>www.cms.hhs.gov/coverage</u>. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum XI: National Oncologic PET Registry (NOPR)

(April through June 2013)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no updates to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the January through March 2013 quarter. This information is available at

http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564)

New Facility	Provider Number	Effective Date	State
University Radiology Associates, LLP 550 Harrison Street Suite #100; Telephone: 315-464-2226	38874A	05/15/2013	NY
Syracuse, NY 13202			
Editorial changes (shown in bold) were ma	de to the faciliti	es listed below.	
Old name: Medcenter One	1538245634	07/24/2013	ND
New name: Sanford Health Bismarck			
300 North 7 th Street			
Bismarck, ND 58506-5525			
Old name: Hackensack Medical and Molecular	1306944657	01/29/2010	NJ
Imaging			
New name: American Imaging			
155 State Street			
Hackensack, NJ 07601			

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2013)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the

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Only the first two types are in the list. There were no additions to the listing of facilities for lung volume reduction surgery published in the April through June 2013 quarter. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2013)

Addendum XIV includes a listing of Medicare-approved facilities society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. greater than or equal to 35, have at least one co-morbidity related to obesity certified by the American College of Surgeons (ACS) as a Level 1 Bariatric

For the purposes of this quarterly notice, we list only the specific updates to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery and have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Kate Tillman, RN, MAS (410-786-9252).

Facility	Provider Number	Date Approved	State
The following facilities :	are new listings for this qu	arter.	
MedStar Washington Hospital Center 110 Irving Street NW Washington, DC 20010 Kenneth Alexander (202) 877-3152	1548378235	02/20/2013	DC
Crouse Hospital 736 Irvine Avenue	1033107743	03/19/2013	NY

(410-786-7861).

questions or additional information, contact Marie Casey, BSN, MPH

that meet minimum standards for facilities modeled in part on professional We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

facilities that meet our standards in the 3-month period. This information is http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact Marie Casey, BSN, MPH

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Memorial Hermann Hospital 6411 Fannin Street	450068	04/10/2013	TX
Houston TX 77030			
Editorial changes (shown in bold) were made to the facilities listed below.			
From: University Hospital	360003	01/11/2012	OH
To: University Cincinnati Medical			
Center			
234 Goodman Street			
Cincinnati, OH 45219			

clinical indication of destination therapy. We determined that VADs used

as destination therapy are reasonable and necessary only if performed in

infrastructure to ensure optimal patient outcomes. We established facility

standards and an application process. All facilities were required to meet

For the purposes of this quarterly notice, we are providing only the

facilities that have been determined to have the experience and

our standards in order to receive coverage for VADs implanted as

specific updates that have occurred to the list of Medicare-approved

destination therapy.

available at

(410-786-7861).

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2013)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

• National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);

• Credentialed by the Joint Commission (formerly, the Joint Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and

• Medicare approved for lung transplants.

	1	r · · · · · · · · · · · · · · · · · · ·	
Syracuse, NY			
(315) 470-7111; ASMBS			
Crittenton Hospital Medical Center (CHMC)	1437176203	04/11/2013	MI
1101 W. University Drive			
Rochester, MI 48307			
Moe Gamal (248) 643-4646			
Cooper University Hospital	310014	04/30/2013	NJ
1 Cooper Plaza			
Camden, NJ 08103			
ASMBS			
Herrin Hospital	1528158573	04/02/2013	IL
201 S 14 th Street			
Herrin, IL 62948			
ASMBS			
Memorial Hospital of Florida LP	100206	08/30/2011	FL
12901 Swann Avenue			
Tampa, FL 33609-4056			
ASMBS; (813) 342-1429			
Editorial changes (shown in bold) we			· · · · · ·
St. Vincent's Medical Center	1639124134	05/18/2010	IN
13500 North Meridian Street			
Carmel, IN 46032			
Ted Eads (317) 582-7737			
Boston Medical Center	220031/1346218294	12/19/2012	MA
732 Harrison Avenue, 2 nd Floor			
Boston, MA 02118			
Melody Route (617) 414-6833			
The Ohio State University Hospital	360085	01/01/2010	OH
410 W. 10 th Avenue			
Columbus, OH 43210			
Etene Terrell (614) 293-3504			
Bradley Needleman (614) 293-3504			
University of Alabama at Birmingham	1154435824	12/08/2012	AL
Hospital			
1813 6th Avenue South, MEB 300, zip 3293			
Birmingham, AL 35294-0016			
Deborah Thedford (205) 996-6984			
St. Vincent's Medical Center	1134117575	12/14/20012	FL
1 Shircliff Way			
Jacksonville, FL 32204			
Katherine Jewell (904) 308-3664			
Penrose- St. Francis Health Services	060031	02/24/2006	CO
2222 North Nevada Avenue			
Colorado Springs, CO 80907			
ASMBS (719) 776-5359			
The Methodist Hospital	450358	03/23/2013	TX
6565 Fannin, NB1-001			
Houston, TX 77030			
Marietta Schmid (713) 441-5970			
Carolinas Medical Center Mercy	1497792550	04/01/2013	NC

2608 E 7 th Street			
Charlotte, NC 28204			
Constance Simms (704) 446-4075			
William Beaumont Hospital- Royal Oak	230130/1689653305	04/21/2013	MI
3601 West Thirteen Mile Road			
Royal Oak, MI 48073-6769			
Elizabeth Gates (248) 551-9705			
The following facility was r	emoved as of this quar	ter.	
Meriter Hospital (NPI#)	520089	12/15/2006	WI
202 South Park Street			
Madison, WI 53715			
ASMBS (608) 890-9996			L

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2013)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the April through June 2013 quarter.

This information is available on our website at <u>www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage</u>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564). [FR Doc. 2013–17967 Filed 7–25–13; 8:45 am] BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services National HIV Program: Enhanced HIV/AIDS Screening and Engagement in Care

Announcement Type: New. Funding Announcement Number: HHS–2013–IHS–OCPS–HIV–0001. Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: August 26, 2013.

Review Date: August 29, 2013. Earliest Anticipated Start Date: September 15, 2013.

Signed Tribal Resolutions Due Date: August 26, 2013.

Proof of Non-Profit Status Due Date: August 26, 2013.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for Enhanced HIV/AIDS Screening and Engagement in Care. This program is funded by the Office of the Secretary (OS), Department of Health and Human Services (HHS). Funding for the HIV/AIDS award will be provided by OS via an Intra-Departmental Delegation of Authority dated 07/17/13 to IHS to permit obligation of funding appropriated by the Department of Defense, Military Construction and Veterans Affairs, and **Full-Year Continuing Appropriations** Act, 2013, Public Law 113-6. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The IHS Office of Clinical and Preventive Services (OCPS), National Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome (HIV/AIDS) Program serves as the primary source for national education, policy development, budget development, and allocation for clinical, preventive, and public health HIV/AIDS programs for the IHS, Area Offices, and Service Units. It provides leadership in articulating the clinical, preventive, and public health needs of American Indian/ Alaska Native (AI/AN) communities and developing, managing, and administering program functions related to HIV/AIDS.

Purpose

The purpose of this cooperative agreement is to meet community needs for the enhancement of HIV/AIDS testing activities and the provision of HIV/AIDS-related services among AI/ AN people. Such programs are necessary to reduce the incidence of HIV/AIDS and improve quality of life for People Living with HIV/AIDS (PLWHA). The main goals are to: increase the number of AI/AN with awareness of his/her HIV status; and, improve engagement and retention in care among PLWHA. Awardee activities will seek to: increase access to HIV related services, reduce stigma, make HIV testing routine, and improve engagement in care. Emphasis should be placed on increasing routine HIV screening for adults as per 2006 Centers for Disease Control and Prevention (CDC) guidelines, provide pre- and posttest counseling (when indicated), and developing or deploying strategies for engaging PLWHA in appropriate, culturally responsive HIV-related care.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year 2013 is approximately \$320,000. Individual award amounts are anticipated to be between \$60,000 and \$90,000. All competing and continuation awards issued under this announcement are subject to the availability of funds. In the absence of funding, the IHS is under no obligation to make any awards selected for funding under this announcement.

Anticipated Number of Awards

Approximately four awards will be issued under this program announcement. OS and IHS will concur on the final decision as to who will receive awards.

Project Period

The project period will be for five years and will run consecutively from September 1, 2013 to August 31, 2018.

Cooperative Agreement

In the Department of Health and Human Services (HHS), a cooperative agreement is administered under the same policies as a grant. The funding agency (OS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both the funding agency and the grantee. OS, through IHS, will be responsible for activities listed under section A and the awardee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

Provide funded organizations with ongoing consultation and technical assistance to plan, implement, and evaluate each component of the comprehensive program as described under Grantee Cooperative Agreement Award Activities below. Consultation and technical assistance will include, but not be limited to, the following areas:

(1) Interpretation of current scientific literature related to epidemiology, statistics, surveillance, Healthy People 2020 Objectives, and other HIV disease control activities;

(2) Design and implementation of program components (including, but not limited to, program implementation methods, surveillance, epidemiologic analysis, outbreak investigation, development of programmatic evaluation, development of disease control programs, and coordination of activities);

(3) Implementation of program management best practices;

(4) Conduct site visits to assess program progress and provide programmatic technical assistance as travel funds allow; and

(5) Coordination of these activities with all IHS HIV activities on a national basis.

B. Grantee Cooperative Agreement Award Activities

• Assist AI/AN communities and Tribal organizations in increasing the number of AI/ANs with awareness of their HIV status. The grantee will assist and facilitate reporting of HIV diagnoses to local and State public health authorities in the region as required by applicable law.

• Test at least one previously untested (not tested in the prior five years) patient for every \$75.00 in cooperative agreement funds received, inclusive of all ancillary and indirect costs.

• Collaborate with national IHS programs by providing standardized, anonymous HIV surveillance data on a quarterly basis, and in identifying and documenting best practices for implementing routine HIV testing.