

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
Center for Medicare Management  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850



**Application for New Medical Services and Technologies Seeking to Qualify for  
Add-On Payments Under the Hospital Inpatient Prospective Payment System  
for Federal Fiscal Year (FY) 2011**

Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. To qualify for additional payments under this provision; a new technology must represent a substantial clinical improvement; data reflecting the cost of new technology must not yet be available in the data used to recalibrate the diagnosis-related groups (DRGs); and the DRG payment rate otherwise applicable to the new technology would be inadequate (see 42 CFR 412.87 (b)).

**DEADLINE**

Submit a complete application (see required information below) showing substantial clinical improvement and significant sample of charge data – **No later than November 20, 2009**

Complete database – **No later than December 31, 2009**

An application is considered complete when all of the information requested below has been submitted and when questions related to such information have been answered by the applicant.

**REQUIRED INFORMATION**

Applications must include the following information (may be entered directly onto this form). CMS may request other information in order to evaluate specific requests. Note that a separate application is required for each distinct item included in a request. For example, if an applicant requests add-on payments for two unique technologies or services, a separate application is required for each technology or service.

1. A completed tracking form. (A tracking form may be downloaded at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).)
2. Name, address, and telephone number of primary contact for the application.
3. Trade/brand name of the new technology.
4. Describe the technology fully in general terminology. (What is it? What does it do? How is it used? Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new medical services and technologies.)

**Note: Data provided in this application or in the tracking form may become subject to disclosure. If you are providing data or information that is proprietary or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act, please mark this information as such. CMS will attempt, to the extent allowed by Federal law, to keep this information protected from public view.**

## **Newness Criterion**

**Note:** To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs). Additional information on substantial similarity can be found in the FY 2006 Final Rule (70 FR 47351 through 47352) and in the FY 2010 Final Rule (74 FR 43813 through 43814).

1. Date of Food and Drug Administration (FDA) pre-market approval (or expected approval) for the technology or service. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. List the name and phone number of a contact at the FDA who is knowledgeable about the pre-market approval request for the new technology listed above.
2. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation and documentation of any delay (i.e. manufacturing issues, shelf life concerns or other reasons).
3. If the technology is a drug, was/is your FDA application considered under priority review? Refer to <http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm> for more details.
4. If the technology is a device, is there an investigational device exemption (IDE) number from the FDA assigned to the device? If yes, please provide this code. Refer to <http://www.fda.gov/cdrh/devadvice/ide/index.shtml> for more details. What class (I, II, or III) was/is assigned to the device? Refer to <http://www.fda.gov/cdrh/devadvice/313.html> for more details.
5. Does the service or technology have an existing International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code or is an application pending? Refer to [http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01\\_overview.asp#TopOfPage](http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage) for more details. We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment.
6. Has the service or technology received a Healthcare Common Procedure Coding System (HCPCS) code? If yes, when was it approved? What is the code? Refer to [http://www.cms.hhs.gov/MedHCPCSGenInfo/01\\_Overview.asp#TopOfPage](http://www.cms.hhs.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage) for more information.

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7. Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. Refer to [http://www.cms.hhs.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp#TopOfPage](http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage) for more information.

### **Cost Criterion**

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by MS-DRG. The most recent version of Table 10 can be downloaded at: <http://www.cms.hhs.gov/AcuteInpatientPPS/10FR/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1227460&intNumPerPage=10>.

### **Charge Information**

8. What is the (anticipated) average standardized charge per case involving this new technology? (**Note:** Please refer to Technical Appendix A for an explanation of how to standardize charges.)
9. Please describe the type of data used to calculate the average standardized charge? (i.e. number of cases [Medicare or non-Medicare], number of providers, time period from which data was collected).
  - a. What DRGs are affected by this new technology? Note: For applicants with cases prior to October 1, 2007 that use the CMS- DRGs instead of the MS- DRGs, please download the crosswalk of CMS- DRGs to MS- DRGs at <http://www.cms.hhs.gov/acuteinpatientpps/downloads/CrosswalkCMSDRGtoMSDRG.zip>. Applicants should list both CMS and MS- DRGs for this question. **NOTE:** Technologies that map to multiple DRGs should view Technical Appendix B as an example of how to case weight data for the cost criterion.
  - b. What is the anticipated volume of this technology for FY 2010 (by DRG)? Please describe how you arrived at this estimate.
10. Please provide all data used to calculate charges and standardized charges per case involving the new technology (in electronic format).

### **Cost Information**

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11. What is the (current and/or anticipated) cost of the technology to the hospital, per patient?
12. Please provide a breakdown of how the cost of the technology is calculated (e.g. for drugs, the average dosage or number of units per patient (ml/kg/hr); for devices, a breakdown of the cost of all of the new technology components used per patient, clearly showing which components are the “new” ones).

### **Clinical Improvement Criterion**

13. Describe in detail how the new service or technology represents a substantial clinical improvement over existing services or technologies. Additional information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823).
14. Describe relevant clinical trial(s), including dates and findings.
15. Provide a list and copies of published peer-reviewed articles relevant to the new service or technology.

### **WHERE TO SEND APPLICATIONS**

Mail **ten (10)** copies of each completed application to the following address:

Inpatient PPS New Medical Services and Technologies  
Division of Acute Care  
Mailstop C4-08-06  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Additionally, please email an electronic version of the application and tracking form to [NewTech@cms.hhs.gov](mailto:NewTech@cms.hhs.gov). Applicants should also try and email all relevant supporting documentation electronically. Those documents that are too large or cannot be sent electronically should be sent via mail.

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## **Technical Appendix A**

### **Standardizing Charges**

We standardize charges in order to compare charges equally amongst all hospitals. Standardized charges are charges per case minus the wage index, indirect medical education (IME) and disproportionate share hospital (DSH). The formula below explains how to calculate standardized charges per case.

In order to standardize charges you must obtain hospital specific operating cost-to-charge ratio (CCR), capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA.

**Note:** Use all values (DSH, IME etc...) from the fiscal year that corresponds to the year that the claim(s) is/are being submitted from including the Labor and Non Labor share percentage. Also, different labor and non labor percentages may apply for hospitals with a wage index over or under 1 depending on the fiscal year.

### **Formulae to Standardize Charges:**

#### **Capital Charges**

**The formula to calculate the Capital Standardized Charge is below.**

1. Capital Standardized Charge =  $\left( \left( \left( \left( \text{Capital CCR} / (\text{Capital CCR} + \text{Operating CCR}) \right) * \text{Covered Charges} \right) / (1 + \text{Capital IME} + \text{Capital DSH}) \right) / \text{GAF} \right) / (1 + (0.3152 * (\text{COLA} - 1)))$

#### **Operating Charges**

**The formula to calculate the operating standardized charge is a two step process; first you must calculate the Adjusted Operating Charge (AOC) then use the calculated AOC to compute the Operating Standardized Charge.**

2. Adjusted Operating Charge (AOC) =  $\left( (\text{Operating CCR} / (\text{Capital CCR} + \text{Operating CCR})) * \text{Covered Charges} \right) / (1 + \text{Operating IME} + \text{Operating DSH})$

If wage index greater than 1:

- i) Operating Standardized Charge =  $\left( (\text{AOC} * \text{Labor Share \%}) / \text{wage index} \right) + \left( (\text{AOC} * \text{Non Labor Share \%}) / \text{COLA} \right)$

If wage index less than 1:

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ii) Operating Standardized Charge =  $((AOC * .62) / \text{wage index}) + ((AOC * .38) / \text{COLA})$

### **Total Standardized Charges**

**The formula to calculate Total Standardized Charges is below**

3) Standardize Charges = Capital Standardize Charges + Operating Standardized Charges

#### Definition Key

-The Labor share percentages and Non Labor share percentages can be obtained from Table 1A of the annual IPPS final rule.

-COLA is always equal to 1, except for hospitals in Alaska and Hawaii.

-Operating CCR, capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA values by provider can be obtained by downloading the Public Use Files at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage> or  
<http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage>

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## **Technical Appendix B**

### **Example of How to Submit and Case Weight Data for Cost Criterion**

As explained above, applicants must meet a “cost threshold”. The applicant submits data to CMS verifying that the average charge per case exceeds the MS-DRG threshold published in Table 10 of the IPPS final rule. If the technology is across multiple MS-DRGs then the case-weighted average standardized charge per case must exceed the case-weighted threshold by MS-DRG. Applicants can submit a sample of data demonstrating they meet the cost criteria using multiple source(s) such as: MedPAR, Clinical Trial Claims Data, External (non MedPAR) data; Premier, other non Medicare claims databases, actual claims the manufacturer collects from hospitals.

Below is an example of a technology that maps to more than one DRG. The threshold and average standardized charge per case are weighted based on the percentage of cases that maps to each MS-DRG.

<b>MS-DRG</b>	<b>Cases</b>	<b>Case Weighted Amount</b>	<b>Table 10 Threshold</b>	<b>Table 10 Case Weighted Threshold</b>	<b>Stdz. Charges</b>	<b>Stdz. Charges Case Weighted Amount</b>
220	20	40.0%	\$93,832	\$37,533	\$110,000	\$44,000
221	30	60.0%	\$81,272	\$48,763	\$90,000	\$54,000
<b>Total</b>	<b>50</b>	<b>100%</b>	<b>\$175,104</b>	<b>\$86,296</b>	<b>\$200,000</b>	<b>\$98,000</b>

Because the average case-weighted standardized charge per case of \$98,000 exceeds the case weighted MS-DRG threshold of \$86,296, the technology would meet the cost criterion.

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