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September 2007

MEDICARE INPATIENT HOSPITAL PAYMENTS

CMS Has Used External Data for New Technologies in Certain Instances and Medicare Remains Primary Data Source

GAO-07-46

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Highlights

Highlights of GAO-07-46, a report to congressional committees

Why GAO Did This Study

Under Medicare, hospitals generally receive fixed payments for inpatient stays based on diagnosis-related groups (DRG), a system that classifies stays by patient diagnoses and procedures. The Centers for Medicare & Medicaid Services (CMS) annually uses its own data to reclassify DRGs. CMS also makes add-on payments for stays involving new technologies that meet three eligibility criteria. Stakeholders may submit data that are external to CMS as part of a DRG reclassification request or an add-on payment application. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required GAO to examine whether CMS could improve its use of external data, including using data collected by other government agencies for DRG payments. As discussed with the committees of jurisdiction, GAO examined (1) to what extent CMS has used external data in determining payments for inpatient stays involving new technologies, and (2) to what extent can external data from other government agencies be used by CMS in determining DRG payments for inpatient stays involving new technologies. GAO interviewed officials from CMS and industry stakeholders. GAO interviewed officials from Bureau of Labor Statistics (BLS), Department of Veterans Affairs (VA), Department of Defense (DOD), and Agency for Healthcare Research and Quality (AHRQ) because these agencies may have data useful to CMS. GAO also reviewed regulations and other CMS materials.

To view the full product, including the scope and methodology, click on GAO-07-46. For more information, contact A. Bruce Steinwald at (202) 512-7114 or steinwalda@gao.gov.

What GAO Found

CMS has used external data for two purposes: to inform DRG reclassification and to evaluate new technology add-on payment applications**.** To inform DRG reclassification, CMS accepts the submission of external data that are intended to demonstrate that inpatient stays involving a new technology are costlier on average than the other inpatient stays in the same DRG. CMS uses its data from the Medicare Provider Analysis and Review (MEDPAR) file to validate the external data submitted. Specifically, when external data are submitted for a proposed DRG reclassification for a procedure or new technology, CMS's policy is to find the same or similar evidence in the MEDPAR file. Generally, CMS will not make a reclassification decision for a DRG involving a new technology if the technology is so new that it does not appear in the MEDPAR file. To evaluate new technology add-on payment applications, CMS has generally used external data in conjunction with data from the MEDPAR file to evaluate whether a new technology meets one of the three eligibility criteria, specifically the criterion related to cost.

Data from other government agencies have limitations for CMS's use in setting DRG payments for inpatient stays involving new technologies. This is because when setting DRG payments, CMS generally needs data that are representative of the Medicare population, timely, and complete in that the data include the total charge or other measure of costliness for all services provided during an inpatient stay, including new technologies. The data we identified from other government agencies were either not representative of the Medicare population, were not timelier than data from the MEDPAR file, or were not complete.

Data from the MEDPAR file remain the primary data source for setting DRG payments because they include all charges from paid inpatient claims for inpatient services provided to all Medicare beneficiaries across all hospitals paid under the IPPS. In instances where data from the MEDPAR file have lacked charge information for certain stays involving new technologies, CMS has used external data to inform the DRG reclassification process and to evaluate new technology add-on payment applications. To set DRG payments, CMS needs data that meet criteria of being representative, timely, and complete. Although BLS, VA, DOD, and AHRQ collect data for their own purposes that could potentially be useful to CMS, these data are limited in their utility to set DRG payments because they do not always meet CMS's criteria.

In commenting on a draft of this report, CMS stated that it agreed with GAO's findings.

Contents

Abbreviations

AAMC	Association of American Medical Colleges
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
BBA	Balanced Budget Act of 1997
BIO	Biotechnology Industry Organization
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
BLS	Bureau of Labor Statistics
CMS	Centers for Medicare & Medicaid Services
CPI	Consumer Price Index
DOD	Department of Defense
DOL	Department of Labor
DRG	diagnosis-related groups
FDA	Food and Drug Administration
FSS	federal supply schedule
HCUP	Healthcare Cost and Utilization Project
HHS	Department of Health and Human Services
IPPS	inpatient prospective payment system
MEDPAR	Medicare Provider Analysis and Review
MFC	Most-Favored Customer
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MTF	Military Treatment Facility
PPI	Producer Price Index
TMA	TRICARE Management Activity
VA	Department of Veterans Affairs
X STOP	X STOP Interspinous Process Decompression System

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 26, 2007

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

The Honorable Charles B. Rangel
Chairman
The Honorable Jim McCrery
Ranking Member
Committee on Ways and Means
House of Representatives

At $119.4 billion, spending for hospital inpatient services accounted for more than a third of total Medicare spending in fiscal year 2005. Most of these dollars were spent on care provided to Medicare beneficiaries by the approximately 4,000 acute care hospitals that bill Medicare under its inpatient prospective payment system (IPPS). Under the IPPS, a hospital generally receives a fixed, prospectively determined payment amount for each inpatient stay.[1] Paying prospectively encourages hospitals to operate efficiently, as they retain the difference if the payment for the inpatient stay exceeds the hospital's cost of providing the stay.

Medicare law requires that IPPS payments account for variation in the costs of providing different types of inpatient stays.[2] Consequently, the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that administers Medicare, classifies inpatient stays using a system of diagnosis-related groups (DRG). The number of DRGs changes from year to year. For fiscal year 2007, each inpatient stay billed to Medicare is assigned to one of 538 DRGs based on patient diagnosis and procedures performed. Inpatient stays assigned to the same DRG are expected to have clinical and cost similarities. Hospitals are paid for an inpatient stay based on the assigned

[1]Throughout this report, we use "stay" to represent a patient's hospitalization.

[2]42 U.S.C. § 1395ww(d)(4)(C) (2000).

DRG's weight, which reflects the relative costliness of all inpatient stays assigned to that DRG compared to inpatient stays assigned to all DRGs.[3] DRG classifications and weights are the basis for DRG payments to hospitals. In addition to the DRG-based payment, hospitals may receive a supplemental payment, known as an outlier payment, if the costs of the inpatient stay substantially exceed the DRG-based payment for that stay.

A major challenge for the IPPS is to maintain a system of DRGs that accounts for the use of new technologies, which can substantially change the costs hospitals incur in providing different types of inpatient stays.[4] For example, a new technology may be clinically advantageous yet so expensive that a hospital's overall cost increases substantially when it provides the technology as part of an inpatient stay. In contrast, the use of an alternative new technology may decrease the overall cost of an inpatient stay—even if the technology is expensive—because it can reduce complications and the length of time patients spend in the hospital. Hospitals consider a range of factors—in addition to payment—before they adopt a new technology, including the extent of its clinical benefit or the needs of their patient populations.

To address changes in the cost of inpatient care, including the use of new technologies, CMS annually revises the DRGs using data that are "internal" to the Medicare program—that is, inpatient claims, which are bills hospitals submit to CMS for inpatient services rendered to Medicare beneficiaries.[5] CMS compiles data from these inpatient claims into an electronic file, known as the Medicare Provider Analysis and Review (MEDPAR) file. The MEDPAR file includes all charges from inpatient claims for inpatient services provided to all Medicare beneficiaries across all hospitals paid under the IPPS. In a process known as DRG reclassification, CMS uses the data from the MEDPAR file to revise the assignment of diagnoses and procedures to particular DRGs to ensure that each DRG continues to represent inpatient stays with cost and clinical

[3]Under the IPPS, payment also includes adjustments for geographic variation in hospital wages, indirect expenses related to medical education, a hospital's caseload of low-income patients, and other factors.

[4]For purposes of this report, "new technology" is defined as a new medical device, drug, or procedure.

[5]CMS also uses hospital cost reports, which are submitted annually to CMS. Cost reports contain each hospital's aggregate information on charges for services and the actual costs of providing those services to all patients, as well as information on total charges and estimates of costs for services provided to Medicare beneficiaries.

similarities. Once inpatient stays assigned to various DRGs have been reclassified, CMS calculates the payment weights for all the DRGs, so that each weight reflects the average expected costliness of inpatient stays that will be assigned to that DRG relative to inpatient stays that will be assigned to all DRGs. Because CMS does not have a direct measure of the actual cost of inpatient stays, it has relied on a proxy measure—the amount hospitals charge Medicare on claims. Until October 1, 2006, CMS had used the average charges of all inpatient stays assigned to each DRG to represent the relative costliness of inpatient stays in that DRG compared to the average charge for all inpatient stays. Effective October 1, 2006, CMS uses the average estimated cost per inpatient stay to measure the relative costliness of each DRG.

The DRG classifications and weights are based on data from inpatient claims for inpatient services provided 2 fiscal years prior.[6] As a result, certain DRG weights do not reflect the cost of the most recent technologies, or those adopted by hospitals in the previous fiscal year. Manufacturers of new technologies have raised concerns that CMS's reliance on data from the MEDPAR file to annually revise the DRG classifications and weights may result in inadequate payments to hospitals for inpatient stays involving the new technologies. Furthermore, they have raised concerns that inadequate payments could jeopardize beneficiary access to these technologies.

To address concerns about the timeliness of data from the MEDPAR file with respect to new technologies, the conference report for the Balanced Budget Act of 1997 (BBA)[7] directed CMS to consider using data that are "external" to the Medicare program—for example, claims data from other payers—when it reclassifies and weights the DRGs,[8] to the extent that doing so is "feasible" and the data are "reliable" and "validated."[9] In response to the BBA conference report, CMS instituted a policy whereby manufacturers and other stakeholders—for example, hospitals—could

[6]For example, payments for fiscal year 2007 are based on data from claims for services provided in fiscal year 2005.

[7]Pub. L. No. 105-33, 111 Stat. 251.

[8]External data can also include, but are not limited to, manufacturer invoices and data from hospital data vendors.

[9]H. R. Rep. No. 105-217, at 734 (1997) (Conf. Rep.). External data are not defined in statute. We define external data as data that are not collected from hospitals by CMS.

submit external data to CMS to help demonstrate that inpatient stays involving a particular new technology are costlier on average than other inpatient stays assigned to the same DRG, and should be assigned to a DRG with a higher payment weight. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required CMS to make additional payments for inpatient stays that, because they involve new technologies that may increase overall costs, would be inadequately paid under DRG-based payments alone.[10] In response to the BIPA provision, CMS implemented "add-on payments" to hospitals for certain expensive new technologies that meet three eligibility criteria for being new, costly, and a substantial clinical improvement over existing technologies. CMS stated that it could use data from external sources to identify technologies that are appropriate for these add-on payments, because those technologies would not be represented in inpatient claims. CMS projected that it would spend approximately $32 million in fiscal year 2007—approximately 0.03 percent of total IPPS spending—on add-on payments.[11]

Manufacturers of new technologies have stated that CMS has not sufficiently used external cost data they may provide on behalf of their products when it reclassifies and weights DRGs or evaluates new technologies for the add-on payments. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), required us to examine whether CMS could improve its use of external data under the IPPS, including whether data collected by other government agencies would be best suited for CMS to use in setting payments for inpatient stays.[12] As discussed with the committees of jurisdiction, we examined (1) to what extent CMS has used external data in determining payments for inpatient stays involving new technologies, and (2) to what extent external data from other government agencies can be used by CMS in determining DRG payments for inpatient stays involving new technologies.

To examine to what extent CMS has used external data in determining payments for inpatient stays involving new technologies, we reviewed IPPS regulations and other CMS materials and interviewed officials from

[10]Pub. L. No. 106-554, app. F, sec. 533(b), § 1886(d)(5)(K)(ii)(III), 114 Stat. 2763, 2763A-548 (codified at 42 U.S.C. § 1395ww(d)(5)(K)(ii)(III) (2000)).

[11]71 Fed. Reg. 47,870, 48,344 (Aug. 18, 2006).

[12]Pub. L. No. 108-173, § 942(c), 117 Stat. 2066, 2422.

CMS and HHS.[13] We interviewed representatives from two hospital associations—the American Hospital Association and the Association of American Medical Colleges—and two associations of technology manufacturers—the Advanced Medical Technology Association and the Biotechnology Industry Organization. Additionally, we interviewed officials from four individual drug and device manufacturers and one hospital that we identified as having submitted external data to CMS.

To examine to what extent external data from other government agencies can be used by CMS in determining DRG payments for inpatient stays involving new technologies, we reviewed IPPS regulations and other CMS materials and interviewed officials from CMS and HHS. In addition, we interviewed officials from the Bureau of Labor Statistics (BLS) in the Department of Labor (DOL) because BLS collects price information for new technologies. We also interviewed officials from the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the Agency for Healthcare Research and Quality (AHRQ) in HHS because we identified these agencies as having inpatient stay information, including cost or charge data, that they collect for their own purposes that could be useful to Medicare. We conducted our work from December 2004 through January 2006 and from August 2006 through August 2007 in accordance with generally accepted government auditing standards.

Results in Brief

CMS has used external data for two purposes: to inform DRG reclassification and to evaluate new technology add-on payment applications. To inform DRG reclassification, CMS accepts the submission of external data that are intended to demonstrate that inpatient stays involving a new technology are costlier on average than the other inpatient stays in the same DRG. CMS uses data from the MEDPAR file to validate the external data submitted. Specifically, when external data are submitted for a proposed DRG reclassification for a procedure or new technology, CMS's policy is to find the same or similar evidence in the MEDPAR file. Generally, CMS will not make a reclassification decision for a DRG involving a new technology if the technology is so new that it does not appear in the MEDPAR file. To evaluate new technology add-on payment applications, CMS has generally used external data in

[13]We did not examine or evaluate the add-on payment application process, CMS's policy for accepting external data, or the adequacy of the add-on and outlier payments made to hospitals.

conjunction with data from the MEDPAR file to evaluate whether a new technology meets one of the three eligibility criteria, specifically the criterion related to cost.

Data from other government agencies have limitations for CMS's setting DRG payments for inpatient stays involving new technologies. This is because, when setting DRG payments, CMS generally needs data that are representative of the Medicare population, timely, and complete in that the data include the total charge or other measure of costliness for all services provided during an inpatient stay, including new technologies. The data we identified from BLS, VA, DOD, and AHRQ were either not representative of the Medicare population, were no timelier than data from the MEDPAR file, or were not complete.

Data from the MEDPAR file remain the primary data source for setting DRG payments because they include all charges from inpatient claims for inpatient services provided to all Medicare beneficiaries across all hospitals paid under the IPPS. CMS needs these data to determine payment for each DRG relative to other DRGs. In instances where data from the MEDPAR file have lacked charge information for certain stays involving new technologies, CMS has used external data to inform the DRG reclassification process and to evaluate new technology add-on payment applications. To set DRG payments, CMS needs data that meet criteria of being representative, timely, and complete. Although BLS, VA, DOD, and AHRQ collect data for their own purposes that could potentially be useful to CMS, these data are limited in their utility to set DRG payments because they do not always meet CMS's criteria.

In commenting on a draft of this report, CMS stated that it agreed with our findings and reiterated its commitment to using external data when appropriate. DOD offered no comments on the draft of this report. VA agreed with the facts as they pertain to the department. We also sent a draft to DOL. DOL did not provide comments. Industry association reviewers agreed with our findings but said that we should have discussed CMS's use of data from sources other than the federal government. As we discussed in the draft report, CMS has used external data from sources other than the federal government including manufacturer data to inform DRG reclassification and evaluate new technology add-on applications.

Background

Under the IPPS, hospitals are not paid separately for each item or service they provide. Rather, payment is based on the DRG to which the entire inpatient stay is assigned. Each of the 538 DRGs has a classification, that

is, an assigned combination of any of the approximately 17,000 diagnoses and procedures codes. When codes for these diagnoses and/or procedures appear together on a claim,[14] the inpatient stay is assigned to the appropriate DRG and paid accordingly.[15] In addition, CMS determines if the inpatient stay is eligible for an outlier payment beyond the DRG payment.[16] Hospitals can receive outlier payments for individual inpatient stays determined to be extremely costly if a hospital can demonstrate that the estimated cost of an individual inpatient stay exceeds a cost threshold established by CMS.

CMS Annually Revises DRG Classifications and Payment Weights

Medicare law requires CMS to revise the DRG classifications and payment weights at least annually to reflect changes in treatment patterns, new medical services and technologies, and other factors that may change the relative costliness of an inpatient stay.[17] To accomplish this, CMS assembles a MEDPAR file from inpatient claims for a fiscal year, so that the file contains one record for each inpatient stay provided during that year. A MEDPAR record includes the admission and discharge dates, patient and hospital identifiers, and codes that identify the diagnosis and the procedures delivered during the inpatient stay. The record also contains the hospital's total charge for the inpatient stay. The total charge represents the charges for all services—including any new technology, drugs, or supplies—provided during the inpatient stay. The total payment to the hospital is also included in the MEDPAR record. MEDPAR records do not indicate the hospital's actual cost for the inpatient stay or the cost of individual procedures, which are not recorded on claims by hospitals.

[14]Hospitals bill procedures and diagnoses with codes provided by *The International Classification of Diseases, 9th Revision, Clinical Modification* Hyattsville, Md.: Centers for Disease Control and Prevention, National Center for Health Statistics (Jan. 11, 2007).

[15]For example, a claim with a diagnosis code for heart failure and a procedure code for the implantation of a pacemaker would be assigned to DRG 115, "Permanent Cardiac Pacemaker Implant with Acute Myocardial Infarction, Heart Failure, or Shock." CMS would then multiply the weight for DRG 115 by a base payment amount, or the amount that Medicare would pay for an average unit of service if no other payment adjustments applied, to determine the hospital's base payment amount for the stay. The higher the DRG weight the more costly the stays assigned to that DRG are estimated to be and the higher the payment.

[16]For example, in fiscal year 2007, a hospital receives an outlier payment if its estimated cost for a stay is at least $24,485 more than its DRG payment for that stay. The actual amount of the outlier payment will equal 80 percent of the difference between the two amounts.

[17]42 U.S.C. § 1395ww(d)(4)(C) (2000).

CMS uses data from the MEDPAR file to revise the DRGs for the coming fiscal year. It revises the DRGs in a two-step process: reclassification of DRGs and calculation of DRG payment weights. First, CMS incorporates new codes into the IPPS that represent new diagnoses or procedures by assigning them to the same DRGs as existing codes for clinically similar diagnoses or procedures.[18] Using data from the MEDPAR file, CMS may reclassify the DRG assignment of inpatient stays with a particular procedure or diagnosis code if it determines the inpatient stays are more similar in their clinical characteristics and costliness to a DRG other than the DRG to which those stays were previously assigned.[19] CMS will create a new DRG if it determines that the inpatient stays involving newly identified diagnoses and procedures cannot be described by any of the existing DRGs.[20] The classification of most DRGs does not change from year to year.[21]

The second step in revising the DRGs involves calculating weights across all DRGs, so that the DRGs reflect the expected relative differences in costliness of inpatient stays for the upcoming fiscal year. Prior to fiscal year 2007, CMS annually derived each DRG's weight by dividing the average charge per inpatient stay for that DRG by the average charge per inpatient stay across all DRGs for a fiscal year. Effective fiscal year 2007, CMS uses charge data from the MEDPAR file and hospitals' cost-to-charge ratios from Medicare cost reports to estimate the costs per inpatient stay. CMS then uses these average estimated costs to measure the relative costliness of inpatient stays that will be assigned to each DRG.

[18]Codes for new procedures and diagnoses are assigned by CMS and the National Center for Health Care Statistics, respectively, in a process that is separate from the DRG reclassification process. New codes are assigned for procedures and diagnoses that are deemed so different from existing procedures and diagnoses that they warrant their own unique identifiers.

[19]CMS makes a clinical determination to reclassify a DRG based on input from the public as well as its own clinical staff. CMS evaluates costliness by comparing the average charge for inpatient stays with the particular code—as calculated using data from the MEDPAR file—to the average charges for all stays assigned to the current and proposed DRGs, respectively.

[20]For fiscal year 2008, CMS has proposed to refine the classification of and expand the number of DRGs from 538 to 745 to better reflect severity of illness and the cost of treating Medicare beneficiaries. 72 Fed. Reg. 24,680, 24,687 (May 3, 2007).

[21]For fiscal year 2007, for example, CMS added 20 new DRGs, made changes to the classifications of approximately 32 existing DRGs, and deleted 8 DRGs. See 71 Fed. Reg. 47,870, 47,879 (Aug. 18, 2006).

In reclassifying and weighting DRGs, CMS generally requires that the data meet three criteria: (1) the data must be representative of the Medicare population; (2) the data must be timely—that is, they should be the most recent data available; and (3) the data must be complete—meaning that CMS needs total charges or other measure of costliness for all services provided during an inpatient stay. Charge data collected at the inpatient-stay level allow CMS to appropriately measure relative costliness across the DRGs.

DRG Classifications and Payment Weights for Any Given Fiscal Year Are Based on Inpatient Claims Data That Do Not Reflect the Cost of the Most Recent Technologies

The DRG classifications and payment weights for any given fiscal year are based on data from the MEDPAR file for inpatient services provided 2 fiscal years prior, and therefore, do not reflect the cost of the most recently used technologies. For example, during the summer of 2006, when CMS was finalizing the DRGs for fiscal year 2007, the most recent data pertained to inpatient services provided through the end of fiscal year 2005, and did not reflect the cost of technologies first adopted by hospitals in fiscal year 2006.

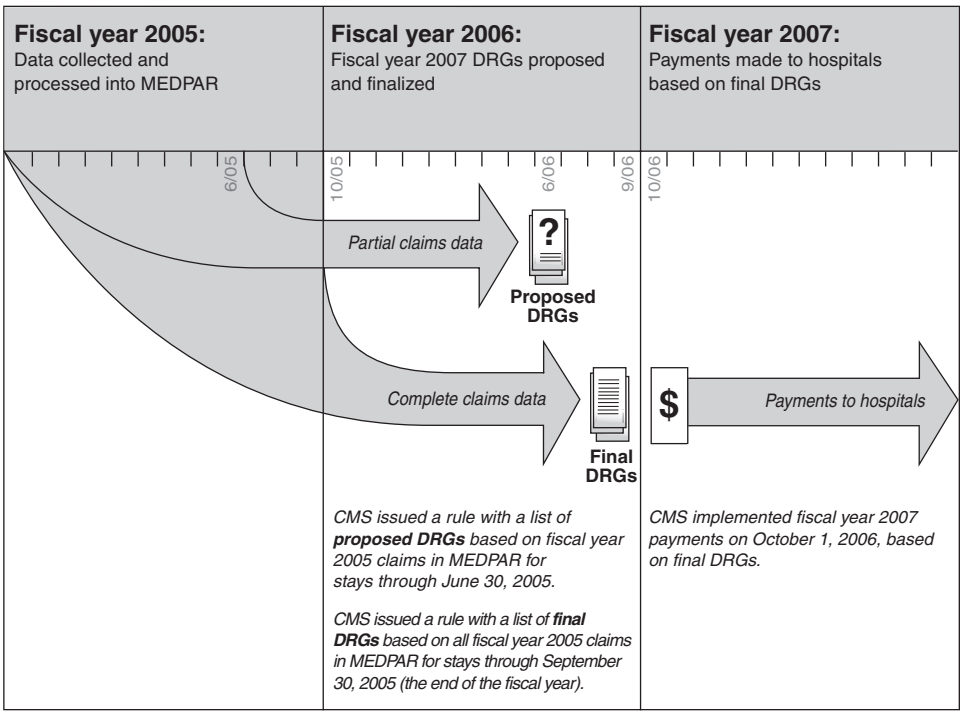
The time lag in the data that are used to set DRG classifications and weights is primarily due to two factors in combination: the time it takes to annually finalize the DRGs, and the time it takes for CMS to process each inpatient claim into a MEDPAR record. First, Medicare law requires that DRG classifications and weights be revised annually and published in the *Federal Register* on or before the August 1 before each fiscal year.[22] Fiscal years begin October 1 and end the following September 30. In order to obtain public input, CMS generally publishes its proposed DRGs for the coming fiscal year in the *Federal Register* each April and accepts comments for 60 days before publishing the final DRGs by August.

The second factor that affects the incorporation of the cost of new technologies into the MEDPAR file involves the time it takes for CMS to process each inpatient claim into a MEDPAR record. Before a record for an inpatient stay can be added to the MEDPAR file, the hospital must submit the claim, a private contractor must process and pay the claim, and CMS must create a MEDPAR record using information on the claim. It takes about 6 months from the time of the inpatient stay to the time the MEDPAR record for that inpatient stay is created. In addition, the MEDPAR record may not be added to the MEDPAR file until as much as

[22]42 U.S.C. § 1395ww(d)(6) (2000).

3 months later, since the MEDPAR file is updated quarterly—in December, March, June, and September. This means that MEDPAR records are not available to CMS until 6 to 9 months after the inpatient stay has occurred. (See fig. 1.)

Figure 1: Process by Which CMS Used the MEDPAR File to Propose and Finalize DRGs for Fiscal Year 2007 DRG Payments



Source: GAO analysis of CMS's fiscal year 2007 proposed and final rules.

Add-on Payments for New Technologies Can Supplement DRG Payments

Because DRG payments for a given fiscal year are based on claims for inpatient services provided 2 fiscal years prior, Medicare can provide hospitals with add-on payments, in addition to the DRG-based payments, for inpatient stays involving certain new technologies. CMS designates technologies for add-on payments if they meet specified criteria for being new, costly, and a substantial clinical improvement over existing technologies. CMS considers a technology new if no more than 2 to 3 years have passed between the date when the technology was first introduced

on the market, as identified by CMS, and the payment year.[23] At the end of this period, CMS assumes the costs for the technology to be fully reflected in the most recent MEDPAR file and supplemental add-on payments are no longer necessary. CMS considers a new technology costly if the average amount charged by hospitals for all inpatient stays involving the technology exceeds a charge threshold or a predetermined amount.[24] CMS considers a new technology a substantial clinical improvement over existing technologies if the technology has one or more unique clinical advantages—for example, the technology diagnoses a medical condition in a patient population where that condition was previously undetectable.

Every year, CMS accepts applications from technology manufacturers, hospitals, and other stakeholders, in which they present evidence that certain technologies meet the criteria for add-on payments in the coming fiscal year. When CMS publishes its final DRG classifications and weights, it summarizes each application, and explains why the particular technology was approved or rejected for add-on payments. For fiscal year 2007, CMS approved one new application and continued add-on payments for two technologies approved for fiscal year 2006.[25] As a result, hospitals receive an add-on payment, in addition to a DRG payment, when they submit a claim to Medicare that includes the code for a procedure involving one of those three technologies. The amount of the add-on payment is determined on a claim-by-claim basis; the hospital receives up to half the estimated cost of the technology, depending on the amount by

[23]BIPA required that CMS collect cost data on a new technology for a 2 to 3 year period and that a new technology be eligible for add-on payments during that period. Pub. L. No. 106-554, app. F, sec. 533(b), § 1886(d)(5)(K)(ii)(III),114 Stat. 2763, 2763A-548 (codified at 42 U.S.C. § 1395ww(d)(5)(K)(ii)(III) (2000)). CMS established that the beginning of the 2 to 3 years would be the date it determines that the technology became available on the market. 69 Fed. Reg. 28,196, 28,237 (May 18, 2004).

[24]Specifically, the charge for the inpatient stay involving the new technology must exceed the lower of two thresholds: (1) 75 percent of the base payment amount adjusted to reflect charges, or (2) 75 percent of a standard deviation beyond the average charge of all stays that fall within the DRGs to which the new technology is assigned. 42 U.S.C. § 1395ww(d)(5)(K)(ii)(I) (2000 & Supp. III 2003).

[25]Specifically, CMS approved the new technology application for the X-STOP Interspinous Process Decompression System and continued add-on payments for the Endovascular Graft Repair of the Thoracic Aorta and Restore ® Rechargeable Implantable Neurostimulator.

which the total cost of the inpatient stay is estimated by CMS to exceed the DRG-based payment.[26]

CMS Has Used External Data to Inform DRG Reclassification and to Evaluate New Technology Add-on Payment Applications

CMS has used external data for two purposes: to inform DRG reclassification and to evaluate new technology add-on payment applications. To inform DRG reclassification, CMS accepts the submission of external data that are intended to demonstrate that inpatient stays involving a new technology are costlier on average than the other inpatient stays in the same DRG. CMS uses data from the MEDPAR file to validate the external data submitted. Generally, CMS will not make a reclassification decision for a DRG involving a new technology if the technology is so new that it does not appear in the MEDPAR file. To evaluate new technology add-on payment applications, CMS has generally used external data in conjunction with data from the MEDPAR file to evaluate whether a new technology meets one of three eligibility criteria, specifically, the criterion related to cost.

CMS Has Used External Data to Inform the DRG Reclassification Process on Inpatient Stays Involving New Technologies

CMS officials told us they have used external data to inform the DRG reclassification process. External data are submitted by stakeholders as part of a request to reclassify—from one DRG to another—certain procedure codes involving particular new technologies. Although CMS will accept the submission of external data, it has used data from the MEDPAR file to validate the external data submitted.[27] Specifically, when external data are submitted for a proposed DRG reclassification for a procedure or new technology, CMS's policy is to find the same or similar evidence in the MEDPAR file. CMS encourages stakeholders to submit their external data for DRG reclassification purposes by the December before the issuance of the proposed rule the following April.

[26]To calculate the amount of the add-on payment, CMS converts the charges billed for the inpatient stay to an estimated cost using the hospital's cost-to-charge ratio. If the total estimated cost for the inpatient stay is higher than the DRG-based payment, then the add-on payment is 50 percent of the difference, up to half of the estimated cost of the new technology.

[27]CMS was directed by the conference report accompanying the BBA to only use external data it can validate. H.R. Rep. No. 105-217, at 734 (1997) (Conf. Rep.).

Although there is no formal application process to request a DRG reclassification, CMS explained its policy for accepting external data submissions in its July 30, 1999, notice of final rulemaking.[28,29] It stated that external data submissions must be sufficiently detailed—include applicable hospital and beneficiary identifiers, procedure and diagnosis codes, admission and discharge dates, and total charges for each inpatient stay involving the codes—so that CMS can validate whether the same, or similar, inpatient stays appear in the MEDPAR file. CMS also requires that the external data submitted comprise a complete set, or representative sample, of cases involving the technology. CMS will not reclassify a procedure code from one DRG to another based on the external data submission alone. As a result, CMS generally will not make a DRG reclassification involving a technology that is so new it does not yet appear in the MEDPAR file.[30]

CMS Has Used External Data to Evaluate Applications for New Technology Add-on Payments

CMS has used external data to evaluate applications for new technology add-on payments to better recognize the cost of technologies that are clinically beneficial yet would not be fully reflected in the MEDPAR file. CMS designates technologies for add-on payments if they meet specified criteria for being new, costly, and a substantial clinical improvement over existing technologies. CMS's use of external data is limited to its evaluation of the cost criterion. CMS has generally used external data and data from the MEDPAR file to evaluate whether a new technology that is being considered for an add-on payment meets the criterion for being considered costly.[31]

[28]CMS maintains a list of DRG issues raised throughout the year by manufacturers, providers, and the general public. It reviews these requests with its staff and analyzes external data if those data were submitted. CMS does not address each and every DRG reclassification request it receives throughout the year in its proposed or final rules for the upcoming year, nor does it track how many times external data were submitted with those reclassification requests.

[29]64 Fed. Reg. 41,490, 41,499-504.

[30]CMS has made one reclassification decision for a medical technology—drug-eluting stents—that had not yet received Food and Drug Administration (FDA) approval, and therefore, did not appear in the MEDPAR file. CMS explained that it took this action because of the potential for drug-eluting stents to significantly impact the treatment of coronary blockages, and the expectation that hospitals would rapidly adopt the technology upon FDA approval. 67 Fed. Reg. 49,983, 50,004 (Aug. 1, 2002).

[31]CMS outlined the new technology add-on application process in its September 7, 2001, final rule. 66 Fed. Reg. 46,902, 46,916.

As of fiscal year 2007, according to our review of CMS regulations and our interviews with CMS officials, CMS has received few applications for add-on payments—a total of 25, which is an average of about 5 per year since fiscal year 2002. All but two applications were submitted by device and drug manufacturers. When CMS receives an application for a new technology add-on payment, it first evaluates whether the technology meets the criterion of being new before it evaluates the technology under the cost and clinical improvement criteria. The majority of new technology add-on payment applications have been rejected because the technology failed to meet the newness criterion. For these applications, CMS did not have to review any information related to the cost and clinical improvement criteria, including external data related to the cost criterion. Of the 25 applications received, CMS evaluated 14 under the cost criterion. Of these 14 technologies, CMS approved 7 for new technology add-on payments.

When CMS evaluates new technologies under the cost criterion, it uses external data in conjunction with data from the MEDPAR file to determine whether the technology meets the cost criterion.[32] Table 1 illustrates three hypothetical scenarios in which CMS, during fiscal year 2007, could use external data in conjunction with data from the fiscal year 2006 MEDPAR file in determining if a new technology is eligible for add-on payments for fiscal year 2008 under the cost criterion.

[32]For example, in explaining the fiscal year 2007 final rule, CMS summarized the application for the X STOP Interspinous Process Decompression System (X STOP). The device manufacturer provided CMS with data from clinical trials demonstrating that the total costs of inpatient stays involving X STOP met the cost criterion. CMS verified the standardized charge for the stays in the MEDPAR file. 71 Fed. Reg. 47,870, 48,003 (Aug. 18, 2006).

Table 1: Three Hypothetical Scenarios in Which CMS, during Fiscal Year 2007, Could Determine Eligibility under the Cost Criterion for Fiscal Year 2008 Add-on Payments

Scenario	Does the fiscal year 2006 MEDPAR file contain data on stays involving the new technology?	Is the charge for the new technology included in the total charge in the fiscal year 2006 MEDPAR file for each stay involving the technology?	What data does the applicant[a] submit to CMS to demonstrate that the new technology meets the charge threshold[b] established by CMS for the cost criterion?	How does CMS use data from the fiscal year 2006 MEDPAR file to verify that the new technology meets the charge threshold established by CMS for the cost criterion?
The new technology became available on the U.S. market in 2006, was adopted by a few hospitals by the end of that year, and was provided by those hospitals to Medicare beneficiaries.	Yes	Yes	The applicant submits an analysis comparing the average charge of the stays involving the new technology based on data from the fiscal year 2006 MEDPAR file to the charge threshold.	CMS conducts its own analysis using data from the fiscal year 2006 MEDPAR file to validate the accuracy of the applicant's analysis.
The new technology was not available on the U.S. market until 2007. However, in 2006 it was provided to Medicare beneficiaries by a few U.S. hospitals that received the technology at no charge for use in clinical trials.	Yes	No[c]	Using external data, the applicant estimates what U.S. hospitals would have charged for the technology on average in 2006. The applicant then submits an analysis comparing the average charge of inpatient stays involving the new technology in 2006 based on data from the fiscal year 2006 MEDPAR file to the charge threshold.	CMS evaluates the reasonableness of the applicant's estimated hospital charges for the technology. If CMS determines the estimates are reasonable, it verifies the accuracy of the applicant's analysis of data using the fiscal year 2006 MEDPAR file.

Scenario	Does the fiscal year 2006 MEDPAR file contain data on stays involving the new technology?	Is the charge for the new technology included in the total charge in the fiscal year 2006 MEDPAR file for each stay involving the technology?	What data does the applicant[a] submit to CMS to demonstrate that the new technology meets the charge threshold[b] established by CMS for the cost criterion?	How does CMS use data from the fiscal year 2006 MEDPAR file to verify that the new technology meets the charge threshold established by CMS for the cost criterion?
The technology was not available on the U.S. market until 2007. Although it was provided to patients in 2006 in clinical trials, the trials were conducted in Europe and the patients were not Medicare beneficiaries.	No	Not applicable	The applicant submits external data from U.S. hospitals from 2007—for example, copies of bills from hospitals that provided the technology to Medicare beneficiaries during inpatient stays. The applicant compares the average charge calculated for these stays, which includes charges for the new technology, to the charge threshold.	CMS verifies the accuracy of the applicant's external data analysis using data from the fiscal year 2006 MEDPAR file. For example, CMS could locate stays in the fiscal year 2006 MEDPAR file that likely would have involved the technology had it been available to U.S. hospitals. CMS would calculate an average charge for those stays, add the estimated charge for the new technology, and subtract the estimated charge for the technology it may be replacing to arrive at a total estimated charge for those stays had they involved the new technology.

Source: GAO based on CMS regulations and interviews with CMS officials.

[a]"Applicant" refers to a manufacturer, hospital, or other stakeholder. Although hospitals receive the add-on payment, almost all applicants for new technology add-on payments have been technology manufacturers.

[b]Specifically, the charge for the inpatient stay involving the new technology must exceed the lower of two thresholds: (1) 75 percent of the base payment amount adjusted to reflect charges, or (2) 75 percent of a standard deviation beyond the average charge of all stays that fall within the DRG to which the new technology is assigned. 42 U.S.C. § 1395ww(d)(5)(K)(ii)(I) (2000 & Supp. III 2003).

[c]Data from the MEDPAR file may not include charges for a new technology if patients were in a clinical trial and the technology was provided to hospitals at no charge.

Data from Other Government Agencies Have Limitations for Setting DRG Payments for Inpatient Stays Involving New Technologies

Data collected and used by other government agencies have limitations for CMS's use in setting DRG payments for inpatient stays involving new technologies. This is because, when setting DRG payments, CMS generally needs data that are representative of the Medicare population, timely, and complete in that the data include the total charge or other measure of costliness for all services provided during an inpatient stay, including new technologies. The data we identified from BLS, VA, DOD, and AHRQ were either not representative of the Medicare population, were no timelier than data from the MEDPAR file, or were not complete.

BLS collects monthly selling prices for samples of products from three industries that may have data relevant to CMS because these data include price information for new technologies: medical instruments, pharmaceuticals, and biological products.[33] These data, collected from manufacturers, are used to publish the Producer Price Index (PPI), which tracks the inflation of prices by producers of goods and services at the national level.[34] Because BLS cannot obtain pricing for every medical instrument and pharmaceutical and biological product sold, it employs a sampling methodology to track prices. Using probability statistics, BLS selects a sample of products whose price changes over time will be representative of the price changes characteristic of the medical instrument and pharmaceutical and biological product industries. Generally, BLS selects a new sample of products per industry every 7-8 years.[35] The monthly selling prices collected include prices for transactions between manufacturers and hospitals, wholesalers, group purchasing organizations, or other customers.

BLS data have a number of limitations that would affect CMS's use in setting DRG payments. Because the selling prices reflect transactions between manufacturers and a variety of purchasers such as group purchasing organizations as well as hospitals, not all of these prices are directly relevant for setting DRG payments. To set payments, CMS needs data that reflect hospitals serving Medicare beneficiaries. In addition, since BLS relies on a sample of products from each industry, and the

[33]BLS collects data on approximately 800 industries.

[34]BLS collects data for other purposes, including the Consumer Price Index (CPI), which tracks the price of goods purchased by consumers. BLS also collects data on the total reimbursement to hospitals and other medical facilities for providing a sample of medical procedures.

[35]For pharmaceuticals, BLS augments its sample continuously to reflect new products.

sample is generally updated on average every 7-8 years, it is unlikely that BLS will have price data for a new technology that CMS does not already have, or cannot obtain from a manufacturer. Finally, the BLS data lack information needed by CMS on the costliness of inpatient stays involving the technology relative to other inpatient stays; instead, they only include price data for the technology alone.

Two types of VA data, price data from the federal supply schedule (FSS) and data on inpatient stays at VA hospitals, also have limitations that would affect CMS's use in setting DRG payments. VA collects data from drug and device manufacturers on the prices manufacturers charge their Most-Favored Customers (MFC).[36] These data are used to negotiate prices on the FSS, which is a schedule of prices for products used by federal agencies. Prices on the FSS are awarded at equal to or better than the prices manufacturers charge their MFCs. Because all federal agencies and programs may access FSS price information on the Internet, CMS already has access to these prices. Similar to BLS data, FSS data are not complete for CMS's purposes because they lack information on the costliness of inpatient stays involving the technology relative to other inpatient stays.

VA also collects data on inpatient stays at its medical centers.[37] These data are complete for CMS's purposes in that they include all services provided during inpatient stays and their associated costs, including the cost of any new technologies. However, there are still limitations for CMS's use of these data in setting DRG payments. First, the costs of providing care at VA medical centers may not be representative of the costs of providing care at hospitals that provide care to Medicare beneficiaries. VA is a provider of services and, as such, VA has the authority to purchase new technologies at discounted rates through various federal purchasing options, such as the FSS. Medicare, on the other hand, is a payer—not a provider—of services and does not purchase drugs and devices for hospitals. Therefore, Medicare does not negotiate discounts on behalf of hospitals providing services to Medicare beneficiaries. Furthermore, VA inpatient stay data are no timelier than MEDPAR data for determining payments to hospitals. For example, VA's allocation of funding to its medical centers for fiscal year 2007 is based on data spanning fiscal years

[36]MFC is generally the customer that receives the best discount or has the best price arrangement on a given item.

[37]Although medical care to eligible veterans is provided by the VA, some care is provided through arrangements with affiliated academic medical centers and other contractors.

2003 through 2005.[38] Medicare used fiscal year 2005 data to develop fiscal year 2007 DRG payments.

DOD data also have limitations for CMS's use in setting DRG payments. DOD health care delivery consists of two integrated systems: the direct care system delivered by DOD hospitals, known as Military Treatment Facilities (MTF), and the civilian system. The latter is coordinated by the TRICARE Management Activity (TMA), which contracts with managed care organizations to deliver care, including inpatient services. Data from the DOD direct care system would not meet CMS's criterion for completeness for two reasons. First, DOD collects overall cost data at the facility level rather than the inpatient-stay level. CMS needs charge or cost data at the inpatient stay level to set DRG payments. Second, while DOD uses cost and pricing data from a variety of sources when purchasing medical products, such as drugs and devices for its MTFs, these data alone are not appropriate for CMS's use in setting DRG payments because CMS needs information on the costliness of inpatient stays involving the technology relative to other inpatient stays.

Data from the DOD civilian system also have limitations for CMS's use in setting DRG payments. TMA pays for inpatient stays using a DRG-based payment system that is modeled on the Medicare IPPS.[39] Although TMA's data would be complete for CMS's purposes in that the data include total charges for all services provided during an inpatient stay, they would not meet CMS's criterion for representativeness. According to DOD, its population tends to be younger and healthier and, therefore, not comparable to the Medicare population.[40]

AHRQ collects claims data from nearly all nongovernmental acute care hospitals in 38 states and these data represent approximately 90 percent of inpatient stays in the United States. AHRQ partners with state organizations, which collect claims data directly from hospitals; these data are then submitted to AHRQ. According to AHRQ, these data, which are available to researchers through the Healthcare Cost and Utilization

[38]VA's fiscal year 2007 budget for its medical centers and other medical services was based on actuarial projections of expected enrollees and patients for fiscal year 2007.

[39]71 Fed. Reg. 60,112 (Oct. 12, 2006). DOD noted that the vast majority of DOD's DRGs are the same as CMS's DRGs; however, DOD has additional DRGs for neonatal cases and age-defined mental health and substance abuse diagnoses.

[40]52 Fed. Reg. 32,992, 32,998 (Sept. 1, 1987).

Project (HCUP) claims database, are representative of the Medicare population overall.[41] The data from the HCUP database are also complete in that they include charge, diagnosis, and procedure information from Medicare as well as private payers. Although data from the HCUP database would meet CMS's criteria for being representative of the Medicare population and are complete, these data are less timely than data from the MEDPAR file. AHRQ data lag between 15-18 months, so, for example, if CMS were to use data from the HCUP database to set payments for fiscal year 2007, the latest available data from AHRQ would include inpatient services for calendar year 2004, while the latest available data from the MEDPAR file would include inpatient services from fiscal year 2005.

Concluding Observations

Data from the MEDPAR file remain the primary data source for setting DRG payments because they include all charges from inpatient claims for inpatient services provided to all Medicare beneficiaries across all hospitals paid under the IPPS. CMS needs these data to determine payment for each DRG relative to other DRGs. In instances where data from the MEDPAR file have lacked charge information for certain stays involving new technologies, CMS has used external data to inform the DRG reclassification process and to evaluate new technology add-on payment applications. To set DRG payments, CMS needs data that meet criteria of being representative, timely, and complete. Although BLS, VA, DOD, and AHRQ collect data for their own purposes that could potentially be useful to CMS, these data are limited in their utility to set DRG payments because they do not always meet CMS's criteria.

Agency and Other External Comments

In commenting on a draft of this report, CMS stated that it agreed with our findings and reiterated its commitment to using external data when appropriate. (See app. I.) DOD said it had no comments on the draft of this report. (See app. II.) We received comments from VA via email. The department agreed with the facts as they pertain to VA. We also sent a draft of this report to DOL. DOL did not provide comments. Representatives from American Hospital Association (AHA), Association of American Medical Colleges (AAMC), and the Biotechnology Industry Organization (BIO) provided oral comments on a draft of this report. They said they agreed with our findings related to the use of external data by CMS.

[41]Researchers must sign a data use agreement with AHRQ to access HCUP data.

With regard to our finding that data from other government agencies have limitations for CMS's use in setting DRG payments, both AAMC and BIO said we should have discussed CMS's use of data from sources other than the federal government. As we discussed in the draft report, CMS has used external data from sources other than the federal government including manufacturer data to inform DRG reclassification and evaluate new technology add-on applications.

AAMC said it was concerned that we only examined how CMS used the external data and did not conduct an evaluation of CMS's policy for using external data. However, as discussed in the draft report, an examination of CMS's policy for accepting external data was not within the scope of the report.

In addition, CMS, AAMC and AHA offered technical comments on the draft of this report, which we incorporated as appropriate.

We are sending a copy of this report to the Administrator of CMS and interested congressional committees. We will also provide copies to others on request. The report is available online at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions, please contact me at (202) 512-7114 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

A. Bruce Steinwald
Director, Health Care

Appendix I: Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Deputy Administrator
Baltimore, MD 21244-1850

JUL 2 7 2007

TO: A. Bruce Steinwald
Director, Health Care
Government Accountability Office

FROM: Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office's Draft Report: "MEDICARE INPATIENT HOSPITAL PAYMENTS: CMS Has Used External Data for New Technologies in Certain Instances and Medicare Remains Primary Data Source" (GAO-07-46)

Thank you for the opportunity to review and comment on the Government Accountability Office's (GAO) draft report entitled, "MEDICARE INPATIENT HOSPITAL PAYMENTS: CMS Has Used External Data for New Technologies in Certain Instances and Medicare Remains Primary Data Source." We appreciate GAO's efforts to examine whether the Centers for Medicare & Medicaid Services (CMS) could improve our use of external data with respect to new technologies in informing diagnosis-related group (DRG) reclassification and evaluating new technology add-on applications for technologies used in hospitals paid under the inpatient prospective payment system (IPPS). CMS agrees with GAO's findings which suggest that we utilize external data, "to inform DRG reclassification and to evaluate new technology add-on payment applications" to the extent possible considering limitations of external data (including other government agencies' data). We are pleased that GAO's report acknowledges that data CMS uses for purposes of DRG reclassification and new technology add-on payment application evaluation needs to be "representative of the Medicare population, timely, and complete" and we agree with that assessment.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required GAO to examine whether CMS could improve its use of external data, including using data collected by other government agencies for DRG payments. The GAO report acknowledges the limitations in using such data and generally reinforces our approach for using external data for DRG reclassification and new technology add-on application evaluation. The GAO report did not suggest any alternatives for our use of external data. We agree that there are currently no good alternatives for us to use external data to a greater extent than we presently do. However, we remain committed to using external data when appropriate in the new technology add-on payment application evaluation process. By using the best data available, we are better able to ensure that Medicare beneficiaries will continue to have access to innovative new technologies that might otherwise be too expensive to be used in the inpatient hospital setting

Once again, thank you for your analysis of this issue and the opportunity to review and comment on your report.

Appendix II: Comments from the Department of Defense

HEALTH AFFAIRS

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

JUL 23 2007

Mr. A. Bruce Steinwald
Director, Health Care
U.S. Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Mr. Steinwald:

This is the Department of Defense (DoD) response to the GAO Draft Report, GAO-07-46, "MEDICARE INPATIENT HOSPITAL PAYMENTS: CMS Has Used External Data for New Technologies in Certain Instances and Medicare Remains Primary Data Source."

Thank you for the opportunity to review and provide comments on the GAO Draft Report. I have no comments to offer.

My points of contact are Lt Col Jeanne Yoder (Functional) at (703) 681-3492 ext. 4068 and Mr. Gunther Zimmerman (Audit Liaison) at (703) 681-3492 ext. 4065.

Sincerely,

Stephen L. Jones, DHA
Principal Deputy Assistant Secretary

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

A. Bruce Steinwald, (202) 512-7114 or steinwalda@gao.gov

Acknowledgments

In addition to the contact above, Maria Martino, Assistant Director; Melanie Anne Egorin; Yorick F. Uzes; and Craig Winslow made key contributions to this report.

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