



GE Healthcare

3000 N. Grandview Blvd.
Waukesha, WI 53188

June 15, 2010

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1498-P
P.O. Box 8011
Baltimore, MD 21244-1850

ATTN: FILE CODE CMS-1498-P

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2011 Rates; Effective Date of Provider Agreements and Supplier Approvals; and Hospital Conditions of Participation for Rehabilitation and Respiratory Care Services Medicaid Program: Accreditation Requirements for Providers of Inpatient Psychiatric Services for Individuals Under Age 21

Dear Ms. Tavenner:

GE Healthcare (GEHC) appreciates this opportunity to comment on the proposed rule with comment period issued by the Centers for Medicare and Medicaid Services (CMS) concerning changes to the Medicare Hospital Inpatient Prospective Payment System for fiscal year 2011 (Federal Register, Vol. 75, No. 85, May 4, 2010) (IPPS Proposed Rule).

GEHC, a \$16 billion unit of General Electric Company that is headquartered in the United Kingdom, has expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement, drug discovery, and biopharmaceuticals manufacturing technologies. GEHC's broad range of products and services enables healthcare providers to offer patients earlier and better diagnosis and treatment of cancer, heart disease, neurological diseases, and other conditions that threaten the quality and length of life. Worldwide, GEHC employs more than 46,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

Overview of Comments

Our comments and recommendations focus on the following issues:

Creation of Standard Cost Centers for Computed Tomography (CT) scanning, Magnetic Resonance Imaging (MRI) and Cardiac Catheterization in the Medicare Cost Report: GEHC believes it is premature to establish new standard cost centers for CT, MR and Cardiac Cath Labs until the payment distortions caused by the RTI dis-aggregation methodology are understood and remedied. This is critically important because the proposed new standard CCRs would not only impact hospital inpatient and outpatient services, but other site of service payment policies that are dependent on credible OPPS rates, such as those pertaining to ambulatory surgery centers and physician facility payments (as required under the Deficit Reduction Act). CMS should provide explicit, unambiguous guidance to hospitals on how to improve allocation of these large capital costs to the radiology cost center. We would also recommend that CMS work with intermediaries to simplify and expedite any requests in this regard, as well as pilot the cost allocation in hospitals before deploying it nationally.

GEHC also recommends that CMS should further analyze the RTI-developed dis-aggregated CCRs methodology by performing specific procedure cost comparisons of low value versus high value diagnostic imaging capital equipment in both the inpatient and outpatient settings to ensure that CCRs reflect the realistic allocation of cost of the capital equipment used in determining procedure cost.

Improved accuracy of Medicare Cost Report data is a laudable goal; however, we believe that it is extremely premature to create separate cost centers for CT, MRI and cardiac catheterization. Since changes to Medicare Cost Report data collection methods are tied to a hospital's cost reporting cycle and also require several months to approve, it is clear that improvements in accuracy will take several years to be realized. Once these new cost reporting practices are in place and the data is shown to be reliable and stable, we recommend that CMS revisit the need to create separate cost centers for MR, CT and cardiac catheterization labs.

Proposed Quality Measures for Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU): GEHC agrees with CMS that a multi-year approach will be helpful to facilities in meeting future reporting requirements and in implementing related quality improvements efforts. GEHC also commends CMS for adopting measures that are NQF-endorsed or listed as an NQF serious reportable event. We also support CMS's interest in use of registry reporting, including its proposal to allow submission of computed measures from registries, especially where use of registries might allow CMS and hospitals to move away from dependence on claims-based data. We also urge that CMS use a broad definition of registry as it has done with the PQRI program.

Electronic Health Record (EHR) Testing of Quality Measures: GEHC agrees that testing of EHR-based measure data will provide invaluable experience and serve as a foundation for establishing the capacity for hospitals to send, and for CMS to receive, data on quality measures via EHRs; however, we have several concerns about CMS's plan for testing eMeasures as proposed under the IPPS Proposed Rule. Electronic capture of quality measurement information (eMeasures) is a core and complex component of an EHR. As such, eMeasures require careful specification, testing, potential re-specification, and phased implementation.

GEHC recommends that CMS not implement use of eMeasures under RHQDAPU until these measures and related methods of transmission have been thoroughly tested. We are also concerned that CMS proposes to begin testing of ED, Stroke, and VTE measures as early as summer of 2011, which is well into the projected first stage of HITECH meaningful use, when such measures will be required for hospital reporting as a condition of meaningful use. We urge that CMS expedite its development and testing of eMeasures, moving up the projected test to no later than year end CY2010. Quality measurement specialists and vendors will need time to create valid, reliable and field-tested e-measures for deployment in hospital EHRs. We also strongly recommend that CMS harmonize reporting of eMeasures under RHQDAPU with reporting requirements under “meaningful use.”

International Classification of Diseases, Tenth Revision, Diagnosis (ICD-10) and Procedure Coding System (ICD-10 PCS) Implementation Timeline: GEHC agrees with CMS that there is a need to give the provider, payer, and vendor community time to prepare for the implementation of ICD-10 and the accompanying system and product updates. We also agree that this code freeze should include allowances to continue code assignments for new technologies and new diseases, and commend CMS for including this provision.

Detailed Comments

Creation of Standard Cost Centers for CT scanning, MRI and Cardiac Catheterization in the Medicare Cost Report:

CMS is proposing to adopt standard cost centers specific to CT, MRI and cardiac catheterization on the Medicare Cost Report Form CMS 2552-10. The draft version of CMS 2552-10 released by CMS on April 30, 2010 already includes these new standard cost centers. Although CMS acknowledges that it does not know the impact of these changes on cost-to-charge ratios (CCRs) for these services, it believes that they are merited because these services constitute significant payment under both the inpatient and outpatient hospital prospective payment systems. CMS notes that once the data become available (three years after revised Medicare Cost Reports are implemented), it would analyze the data and determine whether or not it is appropriate to create distinct CCRs from these cost centers for the relative weight calculations for inpatient and outpatient hospital prospective payment systems.

Currently, hospitals have two options for treating the capital costs of large, fixed pieces of equipment such as CT and MRI equipment. They may treat them as building fixtures and allocate them across all departments, usually on a per-square-foot basis. Alternatively, they may choose to treat them as moveable equipment and allocate them directly to the departments where they are used. An analysis of Medicare cost report data by Direct Research, LLC suggests that a large number of hospitals either allocate CT and MRI equipment costs as building fixtures, allocate them in separate cost centers, or in some cases do not allocate them at all.¹ The study also estimates that Medicare Cost Reports are missing approximately 63 percent of CT and 55 percent of MRI capital costs (based on a comparison of cost report data to industry average equipment purchases in the three year period 2006-2008).

The Direct Research analysis also suggests that while many hospitals have separate CT and MR cost centers, they do not allocate capital costs to those cost centers on the Medicare Cost Report, and this calls into question the accuracy of the rest of the cost reporting for these centers. These findings raise concerns regarding the analysis and proposal by RTI to split the inpatient PPS radiology cost

¹ Direct Research LLC. Capital Costs for MR and CT. June 1, 2010

center. In their 2008 final report, RTI estimated (among other things) the effects of splitting CT and MR services out of the general radiology CCR.² Based on their analysis of cost report and charge data, RTI found the following:³

- Original pooled CCR for radiology: 0.178
- New CT CCR 0.066
- New MRI CCR 0.138
- New all-other-radiology CCR 0.277

Implementing such changes system-wide would reduce payment rates for CT and MR while increasing payments for other types of radiology services. Estimated costs for CT would be about one-third of their current level. The CT CCR, in particular, seems implausibly low. It is less than half the CCR of any other service category studied by RTI.

Further, the payments implied by the RTI-estimated CT CCR appear to lack face validity. For example, if the current OPSS payments are adjusted approximately based on the changes in the CCRs, we find that CMS would pay roughly the same amount for a routine chest x-ray as it would for CT of the chest (Table 1).⁴

| CPT | | APC | Current OPSS rate (2010 final rule, Addendum B) | Ratio, disaggregate CCR to aggregate CCR (from RTI) | Approx. rate using RTI CCRs |
|-------|-------------------|------|---|---|-----------------------------|
| 71010 | Chest x-ray | 0260 | \$44.90 | 1.56 | \$69.87 |
| 71250 | Ct thorax w/o dye | 0332 | \$195.07 | 0.37 | \$72.33 |

Source: Analysis of CMS 2010 OPSS rule addendum B, June 2008 RTI charge compression final report.

By contrast, Medicare’s 2010 physician proposed rule practice expense data estimate that the CT scan takes more than three times as long (34 technologist minutes versus 11 for the routine chest x-ray), and that the CT equipment costs about 10 times as much (Table 2). Nearly equal payment for these two services is not plausible, given the significant differences in time and equipment costs involved.

| CPT | | APC | Technologist Time | Room Capital Cost |
|-------|-------------------|------|-------------------|------------------------------------|
| 71010 | Chest x-ray | 0260 | 11 minutes | \$127,000 (routine radiology room) |
| 71250 | Ct thorax w/o dye | 0332 | 34 minutes | \$1,280,000 (CT room) |

Source: CMS 2010 physician proposed rule practice expense input files.

² Dalton K, S Freeman, A Bragg, Refining Cost to Charge Ratios for Calculating APC and MS-DRG Relative Payment Weights, RTI Incorporated, Research Triangle Park, NC, July 2008, page 34. Available at http://www.rti.org/reports/cms/HHSM-500-2005-0291/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf

³ Direct Research’s analysis of the cost report data shows roughly the same CCRs, despite the fact that the RTI analysis includes some modest impacts from re-assignment of non-standard cost report lines based on a text description (available only within HCRIS, not available from the downloadable cost report files).

⁴ This is only approximate because CMS calculates these rates in a complex fashion, based on median cost of “single procedure” bills, and because some hospitals’ costs are already being calculated using a separate CT cost center CCR. Nevertheless, this calculation illustrates the approximate magnitude of the change that would occur from using a separate CT CCR throughout.

The conclusion is that adoption of the RTI dis-aggregated CCRs for CT, MR and Cath Labs would likely create significant distortions in payment – to – cost ratios for individual services, and a root-cause analysis should be performed to determine if the variability in the allocation process, the statistical methods used for allocating capital, or other factors are the cause of such distortions. At a minimum, additional CCR dis-aggregation modeling should include a sensitivity analysis comparing OPPS rates for low capital value and high capital value assets similar to the example provided by Direct Research’s analysis, to ensure that the final CCR values allocate costs in a manner that matches actual operational practice.

Clearly, improving the accuracy of Medicare Cost Reporting for imaging services will require that hospitals change how they report and allocate large capital costs for imaging equipment. With the exception of creating new worksheet line items for CT, MRI and cardiac catheterization cost centers, the draft Medicare Cost Report form 2552-10 does not provide any mandatory reporting guidance to hospitals on how to improve the accuracy of the cost allocation of these items, such as reporting imaging equipment as moveable equipment, or using dollar value as the most appropriate statistical basis for allocation of these costs. In fact, instructions for the 2552-10 indicate that unless there is a change in ownership, the hospital must continue the same cost finding methods for capital costs. In any other circumstance, if a hospital wants to change its cost finding method for the direct assignment of capital costs, it must make a written request to the intermediary prior to the cost reporting period and must provide justification why the change will result in more accurate and appropriate cost finding.⁵

Additionally, the revised Medicare Cost Report 2552-10 continues to recommend a simplified cost allocation methodology where movable equipment is allocated on a square footage basis.⁶ This is contrary to the recommendation made by CMS in the IPPS Proposed Rule where it states that accuracy would be improved when dollar value is used as the statistical basis for allocation of these types of costs.⁷ As noted above, if the hospital wants to change the order of allocation and/or allocation statistics, it must make a written request to the intermediary 90 days prior to the end of the applicable reporting period. The hospital must demonstrate that the change more accurately allocates the costs, and must include all supporting documentation and a thorough explanation of why the alternative approach should be used. Until the change is approved, the hospital must maintain both sets of statistics. The intermediary has 60 days to make a decision. Given this involved and lengthy process, one would not expect many hospitals to request modifications to their Medicare Cost Report methods.

GEHC believes it is premature to establish new standard cost centers for CT, MR and Cardiac Cath Labs until the payment distortions caused by the RTI dis-aggregation methodology are understood and remedied. This is critically important because the proposed new standard CCRs would not only impact hospital inpatient and outpatient services, but other site of service payment policies that are dependent on credible OPPS rates, such as those pertaining to ambulatory surgery centers, and physician facility services (as required under the Deficit Reduction Act).

Further, CMS should provide explicit, unambiguous guidance to hospitals on how to improve allocation of these large capital costs to the radiology cost center. This guidance would instruct hospitals to allocate the capital costs of imaging equipment (regardless of departmental location or site of use) directly to the radiology cost center or alternatively to the non-standard MR- or

⁵ Instructions to Medicare Cost Report 2552-10. Section 4013. p 40-89.

⁶ Instructions to Medicare Cost Report 2552-10. Section 4020. p. 40-116

⁷ Federal Register. Vol. 75(85). May 4, 2010 (IPPS Proposed Rule). p 23879.

CT-cost centers (if a hospital chooses to use these non-standard options). In rare circumstances where allocation across multiple imaging cost centers is appropriate, hospitals should make these allocations on the basis of dollar value. We would also recommend that CMS work with intermediaries to simplify and expedite any requests in this regard, as well as pilot the cost allocation in hospitals before deploying it nationally.

GEHC also recommends that CMS should further analyze the RTI-developed dis-aggregated CCRs methodology by performing specific procedure cost comparisons of low value versus high value diagnostic imaging capital equipment in both the inpatient and outpatient settings to ensure that CCRs reflect the realistic allocation of cost of the capital equipment used in determining procedure cost. We encourage CMS to use hospitals that have already created separate MR and CT cost centers to evaluate what factors create cost distortions and how those cost distortions can be eliminated.

Improved accuracy of Medicare Cost Report data is a laudable goal; however, we believe that it is extremely premature to create separate cost centers for CT, MRI and cardiac catheterization. Without first validating the separate CCR assignments for CT, MR and Cath Labs compared to other radiology equipment used in inpatient and outpatient settings, followed by making improvements in the accuracy of large capital equipment cost allocations in the Medicare Cost Report, the data generated by these new cost centers will be not only be meaningless, they will negatively impact other payment policies that use payment rates based on the distorted costs. Since changes to Medicare Cost Report data collection methods are tied to a hospital's cost reporting cycle and also require several months to approve, it is clear that improvements in accuracy will take several years to be realized. Once these new cost reporting practices are in place and the data is shown to be reliable and stable, we recommend that CMS revisit the need to create separate cost centers for MR, CT and cardiac catheterization labs.

Proposed Quality Measures for Reporting Hospital Quality Data for Annual Update (RHQDAPU):

In this FY 2011 rulemaking cycle, CMS is proposing an expansion to the RHQDAPU program that will take place over three payment years. That is, CMS is proposing to add measures not only for the FY 2012 payment determination, but also for FY 2013 and FY 2014 payment years. **GEHC agrees with CMS that this multi-year approach will be helpful to facilities in meeting future reporting requirements and in implementing related quality improvements efforts.**

GEHC also commends CMS for adopting measures that are NQF-endorsed or listed as an NQF serious reportable event. We believe that this consensus-based approach provides an important opportunity for expert and public review of each measure. Most measures have complex definitions, which require careful consideration with respect to their importance, scientific acceptability, usability by potential stakeholders, and feasibility of data collection. As CMS transitions to value-based purchasing, the role of quality measures in determining provider reimbursement will only increase -- increasing the importance of using a consensus-based approach.

For FY 2013 payment determination and onwards, CMS is proposing new registry-based measures. Specifically, CMS is proposing that hospitals choose one of the following four proposed measure topics and report the data to a qualified registry: (1) Implantable Cardioverter Defibrillator (ICD) Complications; (2) Cardiac Surgery; (3) Stroke; or (4) Nursing-Sensitive Care. CMS proposes that hospitals direct these registries to both calculate the measure results for the hospital and release those results (along with the numerator/denominator information and exclusion information) to CMS for the RHQDAPU program. Hospitals would begin submitting data to the qualified registry for

discharges on or after January 1, 2011. **GEHC supports CMS's interest in use of registry reporting, including its proposal to allow submission of computed measures from registries, especially where use of registries might allow CMS and hospitals to move away from dependence on claims-based data.. We also urge that CMS use a broad definition of registry as it has done with the PQRI program.**

EHR Testing of Quality Measures:

In this proposed rule, CMS continues to encourage hospitals to adopt and use EHRs that conform to the certification criteria that will be defined by the Office of the National Coordinator for Health Information Technology (ONC). Also, CMS reiterates its intention to report quality measures using EHRs and notes that the electronic specifications and interoperability standards for EHR-based collection and transmission of the data elements for the ED Throughput, Stroke, and Venous Thromboembolism (VTE) measures have been finalized by the Health Information Technology Standards Panel (HITSP) and are available for review and testing at <http://www.HITSP.org>. CMS hopes to move forward with testing CMS's technical ability to accept data from EHRs for the ED, Stroke, and VTE measures as early as summer of 2011. Importantly, CMS notes that testing of these measures does not imply that they will be adopted for future use under RHQDAPU.

GEHC understands that the provisions in this proposed rule do not implement any aspects of the Health Information Technology for Economic and Clinical Health (HITECH) Act provision of the American Recovery and Reinvestment Act (ARRA). Implementation of HITECH is being done through separate rulemaking; including the Notice of Proposed Rule Making (NPRM) titled "Medicare and Medicaid Programs; Electronic Health Record (EHR) Incentive Program," [CMS-0033-P] which was issued on January 13, 2010. In CMS-0033-P, CMS proposed definitions of "meaningful use" of certified EHR technology that would occur in three stages – with 23 specific EHR and health information exchange (HIE) objectives, or requirements, that must be met by hospitals to be considered "meaningful users" of certified EHRs and receive incentive payments in Stage 1.

GEHC agrees that testing of EHR-based measure data will provide invaluable experience and serve as a foundation for establishing the capacity for hospitals to send, and for CMS to receive, data on quality measures via EHRs; however, we have concerns about CMS's plan for testing eMeasures as proposed under the IPPS Proposed Rule. Electronic capture of quality measurement information (eMeasures) is a core and complex component of an EHR. As such, eMeasures require careful specification, testing, potential re-specification, and phased implementation.

GEHC recommends that CMS not implement use of eMeasures under RHQDAPU until these measures and related methods of transmission have been thoroughly tested. We are also concerned that CMS proposes to begin testing of ED, Stroke, and VTE measures as early as summer of 2011, which is well into the projected first stage of HITECH meaningful use, when such measures will be required for hospital reporting as a condition of meaningful use. We urge that CMS expedite its development and testing of eMeasures, moving up the projected test to no later than year end CY2010. Quality measurement specialists and vendors will need time to create valid, reliable and field-tested e-measures for deployment in hospital EHRs. We also strongly recommend that CMS harmonize reporting of eMeasures under RHQDAPU with reporting requirements under "meaningful use."

ICD-10 Implementation Timeline:

The International Classification of Diseases, 10th Revision (ICD-10) coding system applicable to hospital inpatient services will be implemented on October 1, 2013. CMS is soliciting comments on whether a code freeze is needed to help with adoption of health IT, given other priorities such as achievement of EHR meaningful use. The proposed code freeze is to have the last regular, annual update to both ICD-9-CM and ICD-10 be made on October 1, 2011. On October 1, 2012, there would be only limited code updates to both the ICD-9-CM and ICD-10 coding systems to capture new technologies and diseases. On October 1, 2013, there would be only limited code updates to ICD-10 to capture new technologies and diagnoses. Any other issues raised would be considered for implementation in ICD 10 on October 1, 2014, a year after ICD-10 is implemented.

GEHC agrees with CMS that there is a need to give the provider, payer, and vendor community time to prepare for the implementation of ICD-10 and the accompanying system and product updates. We also agree that this code freeze should include allowances to continue code assignments for new technologies and new diseases, and commend CMS for including this provision.

GEHC very much appreciates the opportunity to submit comments on these important issues. If you have any questions on our comments, please do not hesitate to contact me at hubert.zettel@ge.com.

Sincerely,

A handwritten signature in black ink that reads "Hugh Zettel". The signature is written in a cursive, flowing style.

Hugh Zettel
Strategic Reimbursement Executive