



December 20, 2006

Leslie Norwalk
Acting-Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Medicare Program; Hospital Outpatient Prospective Payment System and
CY 2007 Payment Rates; Final Rule with Comment Period**

Dear Ms. Norwalk,

The American College of Radiology (ACR), representing 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists, appreciates this opportunity to comment on the final rule on "Hospital Outpatient Prospective Payment System (HOPPS)" published in the *Federal Register* on November 24, 2006.

Recommendations on How Hospitals Can Better Report Their Costs

The ACR continues to remain concerned that hospitals do not report their costs in a consistent and accurate way nor do they update their charge masters regularly with charges that reflect appropriate relativity. These inconsistencies cause inaccurate payment levels to be set for APCs including many of the newer technologies like CTA, magnetoencephalography (MEG), cardiac CT, and coronary CTA. The ACR understands that CMS requires hospitals to report their costs and charges through the cost report and that CMS believes that this is sufficient specificity to support the use of cost report data for monitoring and payment. However, the ACR believes that requiring hospitals to specify exact components of individual cost centers, charge masters, etc. would provide better data to support the payment levels being set that affect both the hospital outpatient and physician office settings for imaging procedures. The greater accuracy of cost-to-charge ratio (CCR) calculations is vital in order to further refine this prospective payment system which is still somewhat in its development and refinement stages.

The ACR would like to continue to work with CMS to determine how hospitals can further refine their process of reporting costs and updating charge masters in order for CMS to set the most accurate rates possible for imaging.

New Codes for Stereotactic Radiosurgery

The ACR is aware that there are new CPT[®] codes for the services described by the G codes for stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) which will become effective January 1, 2007. These new codes are 77435, 77371-77373.

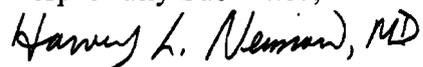
The ACR would like to request that CMS work with the specialty societies to develop appropriate crosswalks from the G codes to CPT[®] codes and the assignment of the new codes to APCs.

This is vitally important to make sure that hospital coders are using the most current codes and reporting costs at the correct levels so that payment rates are consistent in the future.

Conclusion

Thank you for the opportunity to comment on this final rule with comment period. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Pam Kassing at 1-800-227-5463, ext. 4544 or via email at pkassing@acr.org.

Respectfully Submitted,



Harvey L. Neiman, MD, FACR
Executive Director

Cc: Alberta Dwivedi, CMS
Edith Hambrick, MD, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
James Rawson, MD, FACR, Chair, ACR Economics Committee on HOPPS/APC
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December 21, 2006

Leslie Norwalk
Acting Administrator
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Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-FC; Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final Rule; OPPTS: Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals

Dear Ms. Norwalk:

Amgen appreciates the opportunity to comment on CMS's decision to grant pass-through status to Vectibix™ (panitumumab) and assign a temporary Healthcare Common Procedure Coding System (HCPCS) "C" code effective January 1, 2007. This decision was issued in the calendar year (CY) 2007 Medicare hospital outpatient prospective payment system (OPPS) final rule (Final Rule), which the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register on November 24, 2006.¹

As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs" following the agency's convention) for Medicare beneficiaries. For this reason, we strongly support the agency's decision to recognize this important new therapy for transitional pass-through payment. Below, we review the reasons that CMS should finalize this proposal.

CMS should finalize the agency's proposal to award Vectibix™ transitional pass-through status and a temporary product specific "C" code.

Amgen's recently approved biological Vectibix™ is indicated for the treatment of epidermal growth factor (EGF)-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine, oxaliplatin, and/or irinotecan-containing chemotherapy regimens. Vectibix™ is a targeted therapy, which acts on the specific cellular signaling pathway, EGF. Additionally, Vectibix™ is a unique biological and is the only fully human monoclonal antibody treatment designed to directly target tumors by inhibiting their growth.

¹ 71 Fed. Reg. 67959-68008.

Section 1833(t)(6) of the Social Security Act (SSA) provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. Transitional pass-through payments are required for certain "new" drugs and biologicals that were not paid under the OPSS as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPSS payment for the procedures or services associated with the new drug, device, or biological. Under the statute, pass-through payments can be made for a period of at least two years, but not more than three years.

While the "C" code for Vectibix™ appeared in Addendum B of the CY 2007 OPSS Final Rule and will be effective January 1, 2007, the status indicator does not reflect pass-through status. However, CMS states in a letter to Amgen dated November 2, 2006, that the status indicator will be modified, and the specific coding as well as payment instructions regarding Vectibix™ will be announced when the agency issues program instructions implementing the 2007 OPSS update.

We commend the agency for its efforts to provide clear and timely guidance on how to code for Vectibix™ in the OPSS setting, ensuring that providers can be confident that their choices for treatment are made independently from any administrative concerns. Towards that end, Amgen looks forward to the agency's forthcoming issuance of program instructions where we expect outstanding issues pertaining to the transitional pass-through status for Vectibix™ to be resolved.

* * * * *

Amgen appreciates this opportunity to provide important information and looks forward to working with you to ensure that Medicare beneficiaries treated in the hospital outpatient setting continue to have access to new and important biological therapies such as Vectibix™. Please contact Sarah Wells Kocsis by phone at (202) 585-9713 or by email at wells@amgen.com to arrange a meeting or if you have any questions regarding our response. Thank you for your attention to this important matter.

Regards,

Joshua J. Ofman, MD, MSHS
Vice President,
Global Coverage and Reimbursement
and Global Health Economics

cc:	Herbert Kuhn, Acting Deputy Administrator, CMS
	Thomas Gustafson, Acting Director, Center for Medicare Management, CMS
	Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, CMS
	Carol Bazell, MD, Medical Officer, Acting Director, Division of Outpatient Care, CMS
	Joan Sanow, Deputy Director, Division of Outpatient Care, CMS
	Edith Hambrick, MD, Hospital and Ambulatory Policy Group, CMS
	Rebecca Kane, Hospital and Ambulatory Policy Group, CMS
	Marjorie Baldo, Division of Outpatient Care, CMS



January 22, 2007

The Honorable Leslie V. Norwalk, Esq.
 Acting Administrator
 Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attention: CMS-1506-FC
 Mail Stop C4-26-05
 7500 Security Boulevard
 Baltimore, MD 21244-1850

RE: Medicare Program; Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final Rule: CMS-1506-FC

Dear Administrator Norwalk:

The American Society for Therapeutic Radiology and Oncology (ASTRO)¹ appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2007 Payment Rates published in the *Federal Register* on November 24, 2006. Our comments focus on: (1) stereotactic radiosurgery (SRS) treatment delivery; (2) breast brachytherapy; and, (3) proposed use of single and multiple procedure claims – CPT[®] code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy*.

1. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, and 0067)

For Calendar Year (CY) 2007, CMS proposed to create several new SRS clinical Ambulatory Payment Classifications (APCs) of different levels to assign the HCPCS codes describing linear accelerator-based SRS treatment (HCPCS codes G0173, G0251, G0339, G0340 and G0243). It was explained by CMS that these assignments would be based on their clinical and hospital resource similarities and differences.

CMS proposed to assign HCPCS codes G0339 and G0173 to the same Level III SRS APC. The HCPCS codes describing subsequent fractions of image-guided, robotic (G0340) and non-image

¹ *ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.*

guided, non-robotic SRS treatments (G0251) would each be assigned to their own clinical APCs. Finally, CMS proposed to continue the assignment of HCPCS code G0243 for multi-source photon (Cobalt 60-based) SRS treatment delivery to clinical APC 0127, renamed Level IV Stereotactic Radiosurgery. A table listing the HCPCS code descriptions and payments is provided below.

HCPCS Code	Short Descriptor	CY 2006 APC	CY 2006 Payment Rate	Proposed CY 2007 APC	Proposed 2007 Payment Rate
G0173	Complete course of non-image guided, non-robotic linear accelerator-based SRS treatment	1528	\$5,250	67	\$4,045
G0251	Fractionated non-image guided, non-robotic linear accelerator-based SRS treatment	1513	\$1,150	65	\$1,381
G0339	Complete course of therapy in one session or first fraction of image-guided, robotic linear accelerator-based SRS	1528	\$5,250	67	\$4,045
G0340	Second through fifth sessions of image-guided, robotic linear accelerator-based SRS treatment	1525	\$3,750	66	\$2,907
G0243	Complete course of multi-source photon SRS	127	\$7,305	127	\$7,305

In our comments on the OPPS proposed rule, we did not oppose these potential APC assignments, although we were concerned by the extent of the payment reductions for some services. At our request, CMS re-checked the cost calculations for all the SRS services using the most current claims data available to determine the payment rates for the final rule. We appreciate the care with which CMS analyzed the available data in setting the final payment rates.

Also in our OPPS proposed rule comments, we noted that new CPT[®] codes for the services described by the above mentioned HCPCS codes, had been successfully presented to the American Medical Association's (AMA) CPT Editorial Panel and RVS Update Committee (RUC), and would become effective January 1, 2007. Furthermore, we requested the opportunity to work with CMS to ensure an appropriate transition to the new CPT codes, including their assignment to APCs with payment rates consistent with the resource costs required to provide the services.

We were pleased to note that in the OPPS final rule, CMS deleted HCPCS code G0243 and crosswalked the existing cost data to new CPT code 77371; *Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of*

1 session; multi-source Cobalt 60 based. However, we were disappointed that CMS did not delete the other HCPCS codes for SRS. ASTRO feels that the new AMA approved CPT® codes fully describe the services' and the process of care for stereotactic radiation therapy, and therefore should replace the existing HCPCS codes. The following table lists the appropriate crosswalk between the existing HCPCS codes and the new CPT codes:

Current HCPCS Code	HCPCS Code Description	New CPT® Code	2007 CPT® Code Description
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session	77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of 1 session; linear accelerator based
G0251	Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed 5 fractions
G0339	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed 5 fractions
G0340	Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed 5 fractions
G0243	Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, all lesions	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of 1 session; multi-source Cobalt 60 based

We recognize that it is too late for changes to be made for the 2007 OPPS. However, we believe that changes in 2008 will be essential since the co-existence of HCPCS codes and CPT codes

that describe the same services is extremely problematic for hospitals, as well as for payers, since not all payers recognize Medicare's temporary HCPCS codes.

We ask that CMS consider our recommendation to replace the temporary HCPCS codes with the permanent CPT[®] codes in 2008, and invite CMS to work with ASTRO to ensure an appropriate transition to the new CPT codes and in drafting a billing clarification directive to ensure that providers understand the new coding schema. Additionally, if CMS has any questions or concerns, we ask that they be brought to our attention prior to the development of the 2008 OPSS proposed rule. Finally, we recommend that the proposed rule for 2008 specifically recommend the elimination of the HCPCS codes for SRS and propose their replacement with the new CPT codes for SRS that are described above.

2. Breast Brachytherapy

For CY 2007, CMS proposed to reassign CPT code 19296; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy*, from New Technology APC 1524 (New Technology Level XIV— (\$3000-\$3500)) to clinical APC 0030 (Level III Breast Surgery) with a proposed median cost of \$2,516.94. CMS also proposed to reassign CPT code 19297; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy*, from New Technology APC 1523 (New Technology Level XXIII—(\$2500– \$3000)) to clinical APC 0029 (Level II Breast Surgery), with a proposed median cost of \$1,738.75.

After full consideration of the comments submitted by ASTRO and others, CMS decided to assign both services to clinical APC 0648 with an APC title of “Level IV Breast Surgery” and a final median cost of \$3,130.45. We greatly appreciate this decision which will help to ensure continued access to this important breast cancer treatment option.

3. Proposed Use of Single and Multiple Procedure Claims: CPT[®] Code 77421

We support the methodological changes to increase the number of single bills which could be used to calculate the relative weights. These changes include refinement of the policy for determining which HCPCS codes could be bypassed for purposes of creating single bills from multiple bills. In the proposed rule, CMS requests comments on the list of codes that the agency is proposing to add to the existing bypass list for creation of “pseudo” singles for CY 2007.

The current bypass list includes CPT code 76950; *Ultrasonic guidance for placement of radiation therapy fields*. CMS proposed to add the following radiation oncology guidance CPT codes to the list for CY 2007:

- 76370; *Computed tomography guidance for placement of radiation therapy fields*
- 76965; *Ultrasonic guidance for interstitial radioelement application.*

ASTRO supported the proposed inclusion of CPT[®] codes 76370 and 76965 on the bypass list and appreciate their being added to the bypass list in the final rule. We also recommended the addition of CPT code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy*.

For reasons that are not clear, CMS decided against our recommendation although this addition would have made the bypass list inclusive of all the guidance codes used in radiation oncology and would increase the number of “single claims” eligible for use in OPPS rate-setting, especially for image-guided radiation therapy (IGRT). We CMS to reconsider its decision and add CPT code 77421 to the bypass list when the median costs for radiation oncology APCs are calculated for the CY 2008 OPPS.

Conclusion

Thank you for this opportunity to comment on the CY 2007 OPPS final rule. We look forward to continued dialogues with CMS officials. Should you have any questions or require further discussion regarding the items addressed in this comment letter, please contact Trisha Crishock, MSW, Director of ASTRO’s Health Policy Department at (703) 502-1550.

Respectfully,



Laura Thevenot
ASTRO, Chief Executive Officer

Cc: Terrence Kay
Ken Simon, M.D.
Edith Hambrick, M.D.
Carolyn Mullen
Alberta Dwivedi
Michael Steinberg, M.D.
Louis Potters, M.D.
Timothy Williams, M.D.
David Beyer, M.D.
Thomas Eichler, M.D.
Trisha Crishock, MSW



CHRISTIANA CARE
HEALTH SYSTEM

Helen F. Graham Cancer Center

4
Comment #624-2

October 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of (\$1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of (\$833.32). These proposed revisions would result in a reduction in payment averaging (\$2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."¹ Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."²

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum³. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

¹ Federal Register, November 30, 2001, page 59865.

² Federal Register, November 30, 2001, page 59866.

³ CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of \$1,125, which did not reflect the consistent use and cost of resources for each treatment.⁴ As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife[®]) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that *“any SRS code changes would be premature without cost data to support a code restructuring”*. (CMS-1506-P, page 156).

⁴ Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173, . . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is *whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.*

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that *CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.*

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition's assertions that:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife[®] (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at \$6,203.27 per unit. For non-CyberKnife centers, the average cost is \$3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. *Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.*

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that *it is a "mature technology [with] stable median costs"* (CMS-1506-P, p 157). This would be an accurate

reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPDS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

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In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

	# centers operating Jan 1st	New centers treating during year	% of centers in first year
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Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPDS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

Further, the CY 2004 Identifiable Data Set Hospital OPDS file for code G0339 for example, consists of only 486 claims with cost data ranging from \$3,479.65 (non-robotic SRS centers) to \$6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated, however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge.*** We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

- ▶ No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.
- ▶ CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

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October 4, 2006

Electronic Submission

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of (\$1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of (\$833.32). These proposed revisions would result in a reduction in payment averaging (\$2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPSS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review.

The success of image-guided robotic stereotactic radiosurgery technology, thus far, has been very positive and well accepted by patients with various tumors. However, we believe we will soon be able to successfully treat many other types of cancers using this technology if reimbursement is

reasonable and institutions can afford to make this technology available to their patients. Dramatic reductions in Medicare rates will deter use of this therapy and will delay advances in a very promising, less invasive and effective method of cancer treatment.

It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology. Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge.*** We join the many stakeholders who urge you to look at external data in making your classification decisions.

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Sincerely,

Karen Grogan, RN, MSOM, OCN
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Tel: (828)213-5030

CMS-1321-P-634

OPPS

Submitter : Mrs. Karen Grogan

Date: 10/09/2006

Organization : Mission Hospitals

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-634-Attach-1.RTF



Community Foundation
Of Northwest Indiana, Inc.

Community Hospital
St. Catherine Hospital
St. Mary Medical Center

October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

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We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."¹ Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."²

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum³. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery,

¹ Federal Register, November 30, 2001, page 59865.

² Federal Register, November 30, 2001, page 59866.

³ CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

fractionated treatment, per session, maximum 5 sessions per course of treatment.”). This code only became effective July 1, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of \$1,125, which did not reflect the consistent use and cost of resources for each treatment.⁴ As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife[®]) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

⁴ Federal Register November 30, 2001, page 59868

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that *“any SRS code changes would be premature without cost data to support a code restructuring”*. (CMS-1506-P, page 156).

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel’s recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is *whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved*.

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that *CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC*.

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition’s assertions that:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife[®] (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these

centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

2. By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year. Our institution did begin CyberKnife operation until May 2005.

Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration and specifically they do not have two years of claims from our facility.

3. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPSS file raises serious questions about the reliability of the claims as reported.

The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPSS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at \$6,203.27 per unit. For non-CyberKnife centers, the average cost is \$3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

4. In addition, the 2004 Identifiable Data Set Hospital OPSS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPSS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPSS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. *Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPSS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPSS file for G0339 and G340 together.*

The CY 2004 Identifiable Data Set Hospital OPSS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the

high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPSS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that *it is a “mature technology [with] stable median costs”* (CMS-1506-P, p 157). This would be an accurate reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPSS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the “common working file”.

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Sincerely,

Milton Triana, Administrator
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Hobart, IN 46342
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