Submitter : **Mr. Timothy Ravenscroft** **Date: 09/26/2006**

Organization : **Bristol-Myers Squibb Medical Imaging**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-301-Attach-1.PDF

CMS-1321-P-301-Attach-2.PDF

Attach H
301

Timothy Ravenscroft
President
Tel 978.671.8100 Fax 978.436.7521 timothy.ravenscroft@bms.com

Bristol-Myers Squibb Medical Imaging 331 Treble Cove Road North Billerica MA 01862 Tel 800.362.2668 www.bmsmi.com

September 26, 2006

Via FedEx and Electronic Submission to: http://www.cms.hhs.gov/eRulemaking

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B
CMS-1321-P - Comments on Drug Administration and CCI edits

Dear Dr. McClellan:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule updating the Medicare Physician Fee Schedule ("MPFS").[1] A subsidiary of Bristol-Myers Squibb Company (BMS), the global pharmaceutical and related health care products company, BMSMI is one of the leading manufacturers of radiopharmaceuticals and other medical imaging drugs, including DEFINITY®, Vial for Perflutren Lipid Microsphere Injectable Suspension, a medical imaging drug used to enhance and delineate cardiac structures during echocardiography procedures.[2]

In these comments, BMSMI would like to call to your attention a specific issue with respect to payment for the intravenous (IV) administration of echocardiography contrast imaging drugs, like DEFINITY®. As described more fully below, under current coding policies, Medicare is aggregating the payment for the IV injection of the echocardiography contrast imaging drug into the payment for the associated echocardiography procedure. This policy is impractical for two reasons:

1. It ignores the fact that the echocardiography procedure codes do not describe the use of imaging drugs, and
2. There is no evidence that the costs for administration of the imaging drugs are included in the associated echocardiography procedures.

[1] 71 Fed Reg. 48982 (Aug. 22, 2006).

[2] Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

We request, therefore, that CMS remove any coding edits from the Correct Coding Initiative (CCI) that aggregate the IV administration code 90774 "Therapeutic, prophylactic or diagnostic injection (specify substance or drug); Intravenous push, single or initial substance/drug" with the echocardiography procedure codes 93307 and 93308.[3]

Background

Echocardiography procedures are used to evaluate patients with known or suspected cardiac disorders. In most cases, echocardiograms can be interpreted by physicians, and the information can be used in patient management. However, in up to 20-percent of cases[4], unenhanced echocardiograms are suboptimal and repeat studies or additional testing may be required. Echocardiography contrast imaging drugs are FDA-approved intravenously-administered drugs that can enhance images in patients with suboptimal echocardiograms. Clinical studies have shown that echocardiography contrast imaging drugs can salvage up to 58-91-percent of unevaluable images.[5] Published papers have estimated that substantial cost savings can be obtained from use of contrast-enhanced echocardiography in cases with suboptimal unenhanced echocardiograms.[6]

Issue

The American Medical Association (AMA) released new Current Procedural Terminology (CPT) codes effective January 1, 2006, to report IV administration of drugs. In the notes accompanying the new codes, the AMA instructed providers not to use the new codes when an IV injection is an inherent part of a procedure. Administration of contrast in diagnostic imaging is given as an example of when the new codes should not be used because IV injection is considered part of the procedure. This limitation on use of the new codes in diagnostic imaging *generally* makes sense because—outside of echocardiography—there are specific codes for contrast-enhanced diagnostic imaging procedures which differentiate between procedures that do and do not involve IV administration of contrast. **However, this is not the case with echocardiography procedures. Echocardiography procedure codes were developed before echocardiography contrast imaging drugs were approved by the FDA, and the echocardiography procedure codes do not mention use of contrast imaging drugs.**

Consistent with the AMA instruction, CMS's CCI is now aggregating payment under the new IV injection codes into the payment for contrast-enhanced imaging procedures, when performed. Unfortunately, CCI has included echocardiography procedures under this aggregating policy. Although it may be reasonable to aggregate the new IV administration codes when there are specific contrast-enhanced diagnostic imaging procedure codes, there is no justification for aggregating the IV administration of contrast into the payment for echocardiography procedures.

---

[3] 93307 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete;" 93308 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; follow-up or limited study"

[4] Waggoner AD, Ehler D, Adams D, et al. Guidelines for the cardiac sonographer in the performance of contrast echocardiography: Recommendations of the American Society of Echocardiography Council on cardiac sonography. *J Am Soc Echocardiogr.* 2001;14:417-20.

[5] Package insert for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension (September 2004).

[6] Shaw LJ, Gillam L, Feinstein S, et al. Use of an intravenous contrast agent (Optison™) to enhance echocardiography: efficacy and cost implications. *Am J Man Care.* 1998;4: SP169-SP176.

Echocardiography procedure codes do not describe use of imaging drugs because these drugs are not used in the majority of procedures. Therefore, the practice expense resources involved with the IV administration of contrast imaging drugs are not included among the practice resources for the associated echocardiography procedures.

For example, the resting echocardiography code 93307 ("Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete") includes the following "typical" practice expenses[7].

Clinical labor—59 minutes of a cardiac sonographer's time (pre, intra and post time summed).
Equipment—50 minutes utilization of each of echocardiography ultrasound with 4 transducers, echocardiography ultrasound digital acquisition, desktop computer with monitor, color video printer, stretcher and 18 minutes utilization of each of echocardiography analyzer software and medical grade SVHS VCR video equipment.
Supplies—One each of computer media optical disk (128Mb), electrocardiograph electrode, ultrasound transmission gel, VHS video tape , minimum multi-specialty visit pack, non-sterile sheet drape (40in x 60in) and a sanitizing cloth wipe.

We would understand that the payment for this procedure would be the same whether a particular site with a specific patient used more or less of the resources identified above or used different equipment, supplies or staff than estimated by the RUC/PEAC for the typical case. However, these expenses are totally unrelated to those involved with IV administration of medical imaging drugs, which are used in a minority of echocardiography procedures.

The expenses involved with IV administration of medical imaging drugs are reflected in the practice expense inputs for code 90774.

Clinical labor—41 minutes of a nurse's time (pre, intra and post time summed)
Equipment—32 minutes utilization of an exam table
Supplies—One each of syringe with needle (OSHA compliant), alcohol swab pad, angiocatheter (14g-24g), thermometer probe cover, strip bandage (0.75in x 3in), syringe (10-12ml), syringe-needle (3ml 22-26g), non-sterile gloves, elastic, self-adherent wrap bandage (1in), non-sterile gauze (2in x 2in).

With the exception of the examination table, which contributes minimally to the practice expense inputs of 90774, all of the other expenses associated with 90774 are non-overlapping with the practice expenses for the echocardiography procedure.

In addition, it is important to note that cardiac sonographers are generally not licensed or trained to start IV lines, to administer IV medical imaging drugs or to monitor patients who have received IV drugs. Therefore, nurses, physicians or other licensed and trained technologists must be in attendance—in addition to the cardiac sonographer—to start the IV line, administer the IV contrast imaging drugs and monitor the patient following the administration of these drugs. **These resources are simply not part of the expenses paid for under the echocardiography procedure payment. Separate coding and payment are justified to cover the costs of these substantial resources.**

---

[7] Taken from the practice expense input files for the 2007 MPFS Proposed Rule (inputs are taken from the non-facility amounts; minutes were not reported for equipment, but appear unchanged from the 2006 Final Rule files)(filename: 2007 NPRM Direct Practice Expense Inputs.xls accessed at http://www.cms.hhs.gov August 9, 2006).

By aggregating payment for IV administration of echocardiography contrast imaging drugs into payment for echocardiography procedures, providers will not be compensated for any of the time, skills and supplies required for the IV administration of echocardiography contrast imaging drugs. Without fair reimbursement/payment for these services, providers may avoid use of echo contrast even in suboptimal echocardiography cases where use of contrast may salvage the image and may preclude the need for repeat or additional testing.

Request

We urge CMS to remove any edits from the CCI that aggregate the IV drug injection code(s) 90774 into the codes for the associated echocardiography procedures (93307 and 93308). Deleting the CCI edits should remove financial disincentives limiting appropriate use of echocardiography contrast imaging drugs for medicare beneficiaries to help salvage images when an unenhanced echocardiography image is suboptimal.

We appreciate your consideration of our comments. Please contact Jack Slosky, Ph.D. at jack.slosky@bms.com or at 978-671-8191 if you have any questions about the comments made in this letter.

Sincerely yours,

T Ravenscroft

Timothy Ravenscroft
President, Bristol-Myers Squibb Medical Imaging

---

cc: American Society of Echocardiography (ASE)
American College of Cardiology (ACC)
Medical Imaging Contrast Agent Association (MICAA)
Jack Slosky, Ph.D., BMSMI

Submitter : **Dr. Pamela Benitez** **Date: 09/26/2006**

Organization : **Dr. Pamela Benitez**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-302-Attach-1.DOC

Attachment 302

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for the opportunity to provide comment on the proposed revisions to the Physician Fee Schedule for 2007 and especially to voice concern regarding the impact these proposed rates will have on breast conservation therapy in those patients diagnosed with breast cancer.

The changes as proposed would have a significant impact on my practice, and particularly on the treatment options I would be able to present to my breast cancer patients. Access to partial breast irradiation which is delivered in the course of 5 days as opposed to whole breast irradiation over 6-7 weeks is an important treatment option for these patients. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy, making this option almost impossible to preserve. As currently planned, CMS is scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below.

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
19296	Placement of a radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application	129.74	89.31	-31%

Once it is determined women are eligible for breast brachytherapy based on strict patient selection criteria, the catheter that delivers this radiation must be surgically implanted. This procedure may take place in the operating room or, in other cases, in the physician's office in the procedure room. Because of the time involved in planning and implanting the catheter, as well as the cost of the device, the proposed RVU reduction will result in this procedure no longer being available as an option for insertion in the physician's office, since the cost of the procedure will exceed the proposed reimbursement. The office is a preferred site of service for some women and this option should be available for them. It replaces the need and expense of performing the procedure in the operating room with all of its added costs. In-office placement provides a significant less-costly setting.

Unfortunately, if the proposed reduction takes place, Medicare patients would incur a greater cost with co-pays and deductibles that would be greater for the procedure if performed in the operating room. More importantly, in-office placement offers these patients, who are often older, an easier experience without the need for an IV, sedation, and the need for a driver to bring them for their procedure which is required if the procedure is done in the operating room.

Performance of this procedure in the hospital will add a greater cost to the Medicare system, as well as impede quick access and scheduling for patients with a confirmed diagnosis of breast cancer. I have much more flexibility scheduling a patient in my office for the procedure than the OR.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I may be willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to breast brachytherapy.

Sincerely,

Pamela R. Benitez, MD

Pamela R. Benitez, MD
Beaumont Cancer Center
3577 West 13 Mile Road
Suite #201
Royal Oak, MI 48073
248-551-8890 (phone)
248-551-8895 (fax)

cc. Senator Debbie Stabenow, Senate Cancer Coaliton
Carolyn Mullen, Deputy Director, Division of Practitioner Services
Helen Pass, MD, FACS, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Mr. Robert Knorr** **Date: 09/26/2006**

Organization : **Tapestry Medical Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

'IDTF Issues' Section L.4 (See Attachment).

CMS-1321-P-303-Attach-1.PDF

Attach A
303

TAPESTRY MEDICAL

1404 Concannon Blvd., Livermore, CA 94550

September 26, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

COMMENT TO: "IDTF Issues"

File Code CMS-1321-P: Comments Related to Proposed Rulemaking re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan:

Tapestry Medical is pleased to provide this comment letter to the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" ("Proposed Rule"). Tapestry Medical is a medical support service organization focused exclusively on providing INR Monitoring products and related services to thousands of Medicare and privately insured patients throughout all 50 United States. We wish to comment specifically on proposed § L ("IDTF Issues") as it relates to the provision of CMS Billing Codes G-0248 and G-0249 under the INR Monitoring Program ("Program") which supports patient self-testing.

The objective of the Program, which was heralded by former CMS Administrator Mr. Thomas Scully as a "lifesaving" service, is to "reduce the risk of strokes and bleeding" for beneficiaries who are able to self-test.[1] In order to ensure that the important objectives of the Program are achieved, we strongly urge CMS to ensure that the Final Rule is unambiguous about the "place of service" for G-0248 and G-0249 services provided from a centralized[2] IDTF facility. **Specifically, we recommend that the Final Rule include a statement, applicable to G-0248 and G-0249 services, which confirms that; "*The location of the IDTF is considered the point of the actual delivery of service (place of service) when the services are provided by an IDTF.***

[1] CMS press release – September 26, 2001.
[2] A "centralized" IDTF facility is the physical location of the principal office of the IDTF that provides G-0248 and G-02499 services. Typically, the facility is the sole location of the IDTF. From this location the IDTF serves Medicare beneficiaries throughout the country.

As a result, G-0248 and G-0249 services must be billed to the carrier with jurisdiction for the location of the IDTF."

My personal involvement in the growing field of INR Monitoring pre-dates Medicare's National Coverage Decision in 2001. In my former capacity, as the business unit head of a major healthcare company, I had the opportunity to work with leaders from several major medical societies[3] and individual stroke prevention experts to provide CMS medical staff with a comprehensive recommendation for assessing the medical necessity of self-testing for patients on anticoagulation therapy. CMS elected to pay for the Program as Diagnostic Services rather than Durable Medical Equipment (DME) despite the fact that G-0248 requires the provision of capital equipment and G-0249 involves the provision ancillary testing supplies. At the time, we understood that CMS made this benefit selection for two principle reasons; 1) to recognize the value-added service of documenting and reporting beneficiary-generated INR test results to the treating physician and, 2) to prevent the type of fraud and abuse inherent in other self-testing benefits covered as DME. This alternative benefit structure involves a substantial amount of financial and business risk for the service provider. In order to support self-testing, providers must first ensure that each beneficiary is equipped with a dedicated INR monitor that they have been trained to use.

At the time, physicians indicated that they were unlikely to directly provide G-0248 and G-0249 services because they are not in the business of purchasing expensive home-use equipment for use by their patients. In order to ensure practical access to the Program, we developed a recommendation that I presented to senior CMS employees (including CMM Deputy Director Thomas A. Gustafson, PhD) which requested that CMS permit IDTFs to provide G-0248 and G-0249 services. Our recommendation, which was based on input provided by physician-experts, medical societies and former senior CMS employees, sought to ensure that these unique services could be provided as efficiently as possible under the benefit category selected by CMS. We reasoned that IDTFs are better equipped than physicians to manage the large upfront investments in INR monitoring equipment. Furthermore, IDTFs are better structured to handle the ongoing provision of testing supplies to beneficiaries, particularly those who traveled at any time during their lifelong treatment period. The August 2002 issue of CAP TODAY (http://www.cap.org) highlights just some of the concerns expressed by the American College of Cardiology and others if IDTFs were prevented from providing this unique support service. Fortunately, CMS accepted our recommendation in March 2003 and confirmed that IDTFs could provide G-0248 and G-0249 services under the Physician Fee Schedule.

More recently, as CEO of Tapestry Medical, I had the opportunity to discuss and debate some procedural nuances related to Program with our local Medicare carrier, National Heritage

[3] American College of Cardiology, Anticoagulation Forum, American Academy of Neurology, and Society of Thoracic Surgeons

Insurance Company (NHIC) and staff from CMS Central Office. The critical question in the debate was – *What is the appropriate place of service when INR Monitoring support services are provided from a centralized IDTF office?* The implication of this question was whether G-0248 and G-0249 could be provided on a national basis from an efficient central office rather than requiring IDTFs to establish separate facilities in all 50 Medicare jurisdictions. With the guidance of my advisor, former NHIC Medical Director, Gerald N. Rogan, M.D., and other former, senior CMS employees, we considered the implications of this question on quality of care, administrative efficiency, patient access, and program safeguards. We recommended that the "place of service" for G-0248 and G-0249 services, when provided by a centralized IDTF should be the location of the IDTF and not the beneficiary's residence. We explained that designating the beneficiary's residence as the place of service would significantly compromise the intent of the Program by dramatically increasing the cost and complexity of providing these services while at the same time making it more difficult for CMS/OIG to monitor quality and compliance of the few IDTFs which provide G-0248 and G-0249 services.

Our recommendation is the best solution to help CMS meet its goal to prevent fraud and abuse. The Office of the Inspector General OEI-03-00-00091[4] documents duplicate Medicare payments by individual carriers. The report recommends CMS "... *implement corrective edits or* ***related measures*** *within carrier and Common Working File claims processing systems to detect and prevent payments for duplicate services billed to the same carrier.*" This OIG/OEI recommendation is best accomplished for G-0248 and G-0249 by confirming that all services may be provided from a central IDTF office and billed to a single carrier.

The debate concluded when we received a letter from Dr. Gustafson on February 21, 2006 in which he confirmed that the *"service occurs at the location of the IDTF"* and affirmed our position that *"the location of the IDTF is considered the place of service and the training (G-0248) and associated supplies (G-0249) must be billed to the carrier with the jurisdiction for the location of the IDTF."* In order to prevent further confusion on the matter, we would like this position affirmatively stated in the Final Rule using the language we proposed earlier (at the end of paragraph 2) in this comment letter to you.

After spending well over a year seeking clarification from CMS on the "place of service" issue, we are concerned that the language in § L.4. of the Proposed Rule will create further ambiguity for G-0248 and G-0249 provided by IDTFs. The example cited in § L.4. says *"...when an IDTF performs a diagnostic test at a beneficiary's residence...we believe that the information is gathered at the collection point from the beneficiary, and this is the place of service."* Tapestry Medical and its expert advisors do not believe that this example applies to G-0248 and G-0249 services for a number of reasons including;

[4] http://oig.hhs.gov/oei/reports/oei-03-00-00091.pdf#search=%22OEI-03-00-00091%22

1. **The services are not in fact *diagnostic tests*.** Although formally classified by CMS as Type of Service (TOS) 5: Diagnostic Laboratory, G-0248 and G-0249 are support services to enable the beneficiary to self-test. The self-test allows the patient's physician to obtain the same information that would have to be obtained from a CLIA-certified diagnostic clinical laboratory. In fact, G-0248 and G-0249 are the only services provided by IDTFs that are not diagnostic tests.
2. **The IDTF does not *perform* a test.** The beneficiary self-tests. The IDTF supports the quality of the self-testing and information transfer to the treating physician.
3. **The testing performed by the beneficiary is not necessarily *at the beneficairy's residence.*** The beneficiary could in fact be anywhere in the country when the self-test is performed. The IDTF cannot assure Medicare of the beneficiary location when self-testing is done. For some beneficiaries, the IDTF would periodically file an erroneous claim if the location of the self-test is deemed to be "beneficiary residence." Moreover, the self-test is not the Medicare benefit. Medicare is not paying the beneficiary to self-test. The IDTF is not testing the beneficiary. Since G-0248 and G-0249 are support services, the location that the patient self-tests is irrelevant to the provision of activities paid for under G-0248 and G-0249.
4. **CMS has never described a diagnostic test as an *information gathering service*.** Even if CMS adopted this proposed new definition and applied it to G-0248 and G-0249, the "gathering" activity is performed by the IDTF from a central office not in the beneficiary's residence. CMS states in the preamble to the proposed rule that *we believe the information is gathered at the collection point from the beneficiary and this is the place of service.*[5] For G-0248 and G-0249, we believe the "collection point" is the IDTF central office, because this is where the information is collected by an approved Medicare provider. The beneficiary is not a Medicare provider, so self-test information "collected" by the beneficiary is not a Medicare service for which payment is made. Medicare makes payment for collection of information by the IDTF. The IDTF is located at its central office, not wherever the beneficiary happens to be when self-testing.
5. The final rule proposes to state: *When an IDTF performs a diagnostic test at the beneficiary's residence, the beneficiary's residence is the Place of Service.* In principal, we have no problem with this requirement, so long as CMS understands that G-0248 and G-0249 are not diagnostic tests and therefore this rule would not apply to these two services. We recommend CMS clarify this point for G-0248 and G-0249 so all stakeholders understand the rule as it applies to these unique IDTF services.

We believe that the interests of beneficiaries, their treating physicians, service providers and CMS are best served by ensuring that the Final Rule includes a statement that ensures that new and existing beneficiaries requiring G-0248 and G-0249 services can continue to be serviced by centralized IDTFs. Furthermore, we believe that any language in the Final Rule that would

[5] CMS-1321-p Page 49062

specifically prevent, or may be erroneously interpreted by carriers to prevent, a centralized IDTF from providing these unique support services would:

1. make it more difficult for CMS/OIG to monitor compliance of IDTFs,
2. create unnecessary complexities for all stakeholders, and
3. undermine the quality of care enabled by this "lifesaving" therapy.

Without a clarifying statement in the Final Rule, or a specific instruction to the carriers, we are concerned the carrier will force us to enter a protracted dispute with our local carrier based on whether or not the Final Rule governs G-0248 and G-0249. We wish to avoid this dispute because our business will be impaired. Such a dispute will deplete the resources of our small company, endanger our service, and impair the hundreds of beneficiaries we serve.

In theory, the only possible reason to require an IDTF to be located in every State of residence of its beneficiaries is to assure the auxiliary person who performs the training service under G-0248 is properly licensed in that State, when the training portion of the G-0248 service is performed at the beneficiary's residence. Normally, licensure assurance is a bona fide carrier function best accomplished by the local carrier. However, for the G-0248 service no license is required. The FDA approval of home self-testing devices does not require licensed medical people to train patients in the use of these CLIA-waived home-use devices. CMS rules require the supervising physician to; 1) certify that the trainer is qualified to train beneficiaries and, 2) provide ongoing general supervision. Some IDTFs, including ours, prefer to use medical personnel, such as nurses to provide the training, but State licensure is in fact not required. Therefore, the local carrier has no bona fide role to oversee the license qualifications and compliance of the auxiliary persons who provide G-0248. A single carrier can assure CMS that G-0248 will be properly supplied throughout the country.

Our conclusion is based on the following information regarding the two codes billable by IDTF under the Program; G-0248 for the one-time initiation of services, and G-0249 for the ongoing provision of testing supplies and related support services:

- **G-0249** includes the provision of test materials and the collection and reporting of test results back to the beneficiary's treating physician. IDTF technicians provide test materials to beneficiaries (wherever they are currently located) by mailing the required items from a central office. IDTF technicians also gather, document and report INR test results to the beneficiary's treating physician using a software system located in the IDTF's central office. IDTFs do not bill their local carrier until and unless the test results have been reported to the beneficiary's treating physician. All IDTF activities operate under the general supervision of the IDTF's supervising physician. All of these functions are performed most efficiently and effectively from a central office.

  The "provision of", "collection of", and "reporting of" are all activities performed by the IDTF at the central office. None of these aforementioned G-0249 steps are performed at the

beneficiary's residence. Beneficiaries may self-test in any number of locations other than the beneficiary's residence, including the trainer's place of business or the beneficiary's temporary residences while traveling or on vacation. Therefore, we see no reason why the "place of service" for G-0249 services could be anything other than the location of the IDTF.

- **G-0248** is a multi-part service involving several steps, some of which can be performed efficiently and effectively from a central office and other steps which can be performed either in the beneficiary's residence, another beneficiary location, or from an IDTF's central office. In order to initiate anticoagulation management services IDTF's are required to provide an expensive (> $2,000), dedicated INR monitor, testing supplies, and educational materials to each eligible beneficiary and document the patient's ability to obtain a blood sample and perform testing. While some IDTF's elect to perform all aspects of the G-0248 function from telephone call center in a central office, Tapestry Medical elects to use trained healthcare professionals (operating under the direction and supervision of a board-certified cardiologist) to demonstrate the INR system in the patient's residence. Tapestry Medical has elected to use this approach (even though its costs us significantly more) because it represents a higher level of patient care than the telephonic approach used by other IDTFs. If our policy of providing the demonstration portion of this service face-to-face would result in the "place of service" being designated as the "beneficiary's residence" then my company would (reluctantly) be forced to reconsider adopting the inferior telephonic approach.

  All other requisite aspects of the G-0248 services (provision of equipment, supplies and materials) are performed at our central office. Typically, the IDTF provides the equipment described under G-0249 with the training described under G-0248. Since the two services are linked it is most efficient and reasonable to deem both services are provided at the central IDTF office and not the beneficiary's residence.

When considering whether to add a statement to § L.4. in the Final Rule which would confirm or deny an IDTF's ability to provide G-0248 and G-0249 services from a central office, CMS should consider:

1. the impact of this decision on CMS/OIG's ability to monitor compliance of IDTFs,
2. whether complexities are increased or decreased for all stakeholders, and
3. the impact on quality of care and broader CMS/OIG objectives.

Based on our evaluation of this issue over the past two years, our expert advisors have concluded:

1. **CMS/OIG IDTF compliance monitoring will be made more difficult if the place of service for G-0248 and G-0249 services is the beneficiary's residence.** The OIG report cited in the Proposed Rule (A-03-03-00002) identifies a concern expressed by CMS about its inability to require the large number of IDTFs, particularly those performing fewer than 100 services. If IDTFs are prevented from providing G-0248 and G-0249 services from a central office, then

they would be required to establish offices in all 50 jurisdictions. There are currently, at least three known IDTFs servicing patients on a national basis from a centralized office. If all three IDTFs chose to continue to provide this service, it would result in an additional 147 IDTFs (i.e. 3 companies times 49 new IDTF offices) that would have to be enrolled and monitored by CMS. Furthermore, because the current number of G-0248 and G-0249 services would be dispersed amongst 150 total IDTFs, it would increase the number of IDTFs providing fewer than 100 services. If CMS is already unable to monitor IDTF compliance, why would it deliberately enact rule changes that might increase the total number of IDTFs in the United States?

Furthermore, Section 4 of the CMS 855B application requires IDTFs to register all practice locations for the services it performs. If each beneficiary's residence was considered the place of service for either G-0248 or G-0249, then each of the 150 new IDTFs locations would also need to identify thousands of additional practice locations (i.e. each and every beneficiary residence). This list of new practice locations would change frequently whenever a beneficiary moves to temporary residence while traveling or on vacation. CMS guidelines require that each of these practice locations be subject to a site inspection by the local carrier. If CMS is already unable to monitor IDTF compliance why would it deliberately want to increase by thousands the total practice locations that it would have to inspect?

2. **Administrative complexities for all stakeholders (including CMS) will increase dramatically.** If the place of service for G-0248 and G-0249 services is required to be the beneficiary's residence, then beneficiaries could only be serviced by an IDTF in the jurisdiction in which they happen to be located at the time they are receiving the service. Consider the very realistic example of a beneficiary who first receives his monitor and demonstration (G-0248) in New York from an IDTF registered in New York. The monitor has been purchased by the New York-based IDTF and furnished to the beneficiary for exclusive use by the beneficiary. IDTFs are only willing to furnish this equipment to beneficiaries with the expectation that they will recover the cost of the equipment through ongoing G-0249 charges. The New York-based IDTF could only legitimately charge for G-0249 services when the beneficiary is located in their New York residence.

When this same beneficiary travels to Arizona for six months, he would need to re-register with a new Arizona-based IDTF in order for the "place of service" to accurately reflect his temporary residence. It would also require the Arizona-based IDTF to purchase and furnish an entirely new monitor for the beneficiary's use while they are temporarily residing in Arizona. Before furnishing the beneficiary with a new monitor the IDTF would need a new physician order from the beneficiary's primary treating physician either in New York or Arizona. Of course, the Arizona-based IDTF would be unable to bill CMS for the new monitor and demonstration because G-0248 can only be billed once in a beneficiary's lifetime. Presumably this same exercise would be repeated every time the patient traveled and self-tested in a new and different location. When traveling outside the country or on a cruise ship where would the actual place of

service be? These are just a few examples of how incredibly complex this benefit would become for all stakeholders if CMS confirms that the place of service is "collection point from the beneficiary's residence".

3. Access to Quality Care will be significantly compromised if the place of service for G-0248 and G-0249 services is the beneficiary's residence. One of the principal benefits of the Program is that it enables physicians to monitor their patient's condition regardless of where they are located. Beneficiaries who travel from one state to another during the course of the year would have to be serviced by a unique IDTF in every state they visit. As a result, historical INR values would be lost as the beneficiary is serviced by different IDTFs during the course of the year. Quality of care is enhanced if a single IDTF is permitted to follow a beneficiary throughout the treatment period regardless of whether the beneficiary changes residences during the treatment. This is because accurate prescribing of anti-coagulants requires the physician to understand the beneficiary's dosing history over several months.

Summary:
Documentation of reporting beneficiary-generated INR test results are enhanced by adopting our recommendation. Program safeguards are enhanced by adopting our recommendation. Proper training of trainers is assured by the supervising physician. Licensure requirements of auxiliary personnel who train beneficiaries are irrelevant. CMS should understand the G-0248 and G-0249 are not diagnostic tests even though they are listed as TOS 5.

In commenting on the "IDTF Issues" section (L) of the Proposed Rule, I want to also express my strong support for the provisions in sections L.1-3,which are intended to formalize IDTF quality, performance and supervision standards of IDTFs in general. As a legitimate member of a provider class (IDTF) that unfortunately has a poor history with CMS, I support CMS' efforts to reduce fraud and abuse, and to improve the quality of those services (such as G-0248 and G-0249 services) which can be best provided by IDTFs. I anticipate that the adoption of these proposed standards and our recommendation will improve the image of the IDTFs in general and reduce fraud and abuse.

With regard to § L.4, I am very concerned that the language in the Proposed Rule is ambiguous and could cause confusion amongst carriers and IDTF providers as to the actual place of service for G-0248 and G-0249. In order to ensure that the intentions expressed by Dr. Gustafson are memorialized in the Final Rule, we propose that CMS include the following language to § L.4. as it relates to G-0248 and G-0249. ***"The location of the IDTF is considered the point of the actual delivery of service (place of service) when the services are provided by an IDTF. As a result, G-0248 and G-0249 must be billed to the carrier with jurisdiction for the location of the IDTF."***

TAPESTRY MEDICAL

1404 Concannon Blvd., Livermore, CA 94550

On behalf of the hundreds of beneficiaries and physicians that we service, I sincerely appreciate CMS continued effort to ensure that access to this lifesaving benefit remains unimpeded by potentially restrictive provisions which would add no value for CMS.

Sincerely,

Robert J. Knorr
Chief Executive Officer

Submitter : Dr. James Lesser **Date:** 09/27/2006

Organization : American Rheumatology Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

These comments refer to the Coverage of Bone Mass Measurement (BMM) Tests. I am a board certified Rheumatologist. I provide bone mineral density (DXA) scans in my office for my patients. I perform less than one scan per day.

I am against the proposed changes with regard to BMM tests on Medicare patients. DXA scans are the only reliable way to diagnose Osteoporosis, a disease that is present in 30-40% of my Medicare patients. Osteoporosis increases the chance of hip or back fractures without trauma significantly.

DXA was recently added by CMS as preventative service. The proposed cuts go against your own initiative to increase the utilization of this service, and decrease the impact of CMS' own "Healthy People 2010" initiative. The proposed decreased reimbursement will result in less of my patients being screened for Osteoporosis. The resulting increased fractures will result in hospitilizations and far greater expense then the screening for this highly treatable disease.

I agree with decreasing the requirements for steroid dosage to 5.0 mg. of Prednisone per day (from 7.5mg).

Evaluating and treating patients who have, or are likely to develop Osteoporosis is complicated. Yesterday, for example I evaulated a new patient with Rheumatoid Arthritis. Afterwords, I took a history using 20 criteria to determine if she was at risk for Osteoporosis. I sent her to have her DXA scan, and I found Osteoporosis. I had to review the DXA machine's data report which quantifies how serious the disease is. I then had to counsel my patient for 20 minutes about the serious nature of her disease. I had to discuss 8 available treatments with their respective side effects and advantages. She chose a treatment requiring daily injection, called "Forteo." My nursing staff then had to teach her how to give herself the injections. The whole visit from beginning of the DXA scan to leaving my office took 1 hour.

The assumptions used to re-calculate the MPFS are inaccurate. The new methodology should be be a policy based on trial and error. The data used to calculate bone densitometry (i.e. pencil beam vs. fan beam) was inaccurate, since the majority of DXA systems sold are fan beam.

My DXA equipment is not ustilized 50% of the time as CMS assumed, but rather 5% of the time.

Thank you.

James Lesser, M.D.

Submitter : **Dr. Kenneth Miller** **Date: 09/27/2006**

Organization : **Arthritis Associates of CT/NY, LLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

September 25, 2006

Department of Health and Human Services
Attention: CMS-1502-P

To Whom It May Concern:

I am writing this letter as the President of the Connecticut Rheumatology Association to address my concerns regarding document CMS-1321-P. The proposed reassessment of changes will have a great impact on the ability of rheumatologists to care for their patients.

Specifically, the proposed cuts in DXA payments will essentially shut down in-office DXA, since most of us do not utilize our machine at the level that it would be economically feasible to continue to perform this service. A proposed five-year work review and change in methodology to the practice expense would reduce the current value of 3.2 to 2.57, which is a decrease of 18% to be implemented over a four-year period. Additionally, under the guideline, the DXA technical component uses the hospital outpatient proposed amount, which is lower than the physician fee schedule. The cuts would diminish the impact of their own Healthy People 2010 initiative. I do agree that the requirements for steroid dose should be 5 mg since patients at that level are at increased risk for developing osteoporosis. The use of DXA is integral to the management and treatment of osteoporosis, both from a diagnostic and a therapeutic viewpoint, and it is integral to the practice of rheumatology, since many of our patients are at high risk for the development of osteoporosis.

The new methodology should not be a trial and error policy, and inaccurate data was used to calculate bone densitometer, since the majority of systems are fan beam, and, in most instances, the equipment is not utilized 50% of the time, as was used for the calculation. In our instance, we are running about ten DXAs per week, which is far below 50% utilization.

I think the proposed changes should be delayed until complete and thorough analysis can be conducted, using cost figures based on the appropriate technology. I am requesting Congress to intervene and stop the reduction to the conversion factor and to do so before their October adjournment.

Very truly yours,

Kenneth A. Miller, M.D.
President, Connecticut Rheumatology Association

KAM:jed

Submitter : Dr. joel Yellin **Date:** 09/27/2006

Organization : Rochester Surgical Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. Moneer Khalil** **Date: 09/27/2006**

Organization : **Buffalo Radiation Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-307-Attach-1.DOC

Hitchitt
307

September 18, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed reduction in professional fees for radiation/oncology brachytherapy services.

CMS has proposed drastic cuts in th RVUs assigned to the global fee schedule for HDR breast brachytherapy. They are scheduled to reduce by 20% each year in the transition period and the total reduction for this treatment is -55% as illustrated in the table below.

CPT Code	Description	Units	2006 RVU	2006 Average Rate	2010 RVU	Variance 2010 to 2006	Variance 2010 to 2006
99245	office consult, comprehensive	1	5.91	$224	6.25	$1	0%
77263	physician treatment planning, complex	1	4.41	$167	4.16	($18)	-10%
77470	special treatment procedure	1	14.64	$555	4.55	($391)	-71%
76370	CT for planning	1	4.29	$163	5.48	$35	21%
77370	special medical physics consult	1	3.68	$139	2.51	($49)	-35%
77290	simulation, complex (contour volumes)	1	9.02	$342	15.22	$206	60%
77326	Brachytherapy isodose plan	1	3.78	$143	3.89	($3)	-2%
77300	dose calc	10	2.26	$856	1.80	($209)	-24%
77336	weekly medical	1	3.15	$119	1.08	($81)	-67%

	physics consult						
77280	simulation, simple	5	4.62	$875	5.27	$72	8%
77781	Afterloading HDR brachy (1-4 source positions)	10	23.69	$8,978	6.58	($6,611)	-74%
						($7,049)	***-56%***

NOTE: 2006 CF is $37.8975 with assumption for 2010 using proposed CF of $35.9647; applicable to Physician Fees

The alternative radiation treatment is Whole Beam External Radiation Therapy (WBXTR) where women must endure 6 weeks of radiation. Alternatively, the RVUs for WBXRT increase by 55% or $6,000 during the transition period and will be reimbursed at a proposed rate of more than $9,000 than HDR Breast Brachytherapy. This treatment is extremely beneficial for the patient in that it irradiates less healthy tissue and allows them to return back to their life activities in just five days, however, HDR breast brachytherapy does require more time for the radiation oncologist to plan, calculate and treat with HDR breast brachytherapy. These proposed cuts in RVUs are insufficient to cover the cost and time required to administer HDR breast brachytherapy and will result in the limiting access to this radiation treatment for women who are Medicare beneficiaries.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, HDR breast brachytherapy. I am willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to HDR breast brachytherapy.

Sincerely,

Moneer A. Khalil MD

Buffalo Radiation Oncology Center
45 Spindrift Drive
Williamsville, NY 14221

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

James Rubenstein, MD Chairman James Rubenstein, MD, Chairman, American College of Radiation Oncology

Submitter : **Dr. David Allison** **Date: 09/27/2006**

Organization : **Carolina Regional Radiology**

Category : **Radiologist**

Issue Areas/Comments

Impact

Impact

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

Submitter : **Dr. David Allison** **Date: 09/27/2006**

Organization : **Carolina Regional Radiology**

Category : **Radiologist**

Issue Areas/Comments

Background

Background

The physicians of Carolina Regional Radiology in Fayetteville, NC are comprised of 21 board certified radiologists serving 4 non-profit county hospitals in addition to 2 outpatient imaging centers in southeastern North Carolina. We perform approximately 475,000 procedures per year in at least 5 counties. This includes all diagnostic imaging modalities (CT, MRI, Ultrasound, Nuclear Medicine, Mammography, PET/CT) as well as interventional and therapeutic procedures along with a clinical practice of radiology. Our patients receive the highest quality of care utilizing cutting edge technology and sub specialized physician skill and expertise. As we are sure you are aware, the state of the art equipment needed to provide quality care for our patients is extremely expensive. Advances in diagnostic medical imaging have no doubt improved the quality of care provided to millions of Medicare beneficiaries over the last several years. A rise in the utilization of imaging has prevented the need for more costly and invasive procedures further down the line in the continuum of patient care.

GENERAL

GENERAL

Therefore, we request that you consider co-sponsoring H.R. 5704, which calls for a two year moratorium on scheduled physician payment reductions for imaging services and requires further study on patient access to imaging services.

Maintaining access to medical imaging is a life-saving privilege, which every American enjoys. We hope that you will work with us to ensure this holds true for future generations.

Impact

Impact

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Submitter : **Dr. Steven Gregoritch** **Date: 09/27/2006**

Organization : **Buffalo Radiation Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-310-Attach-1.DOC

Attach #
310

September 18, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed reduction in professional fees for radiation/oncology brachytherapy services.

CMS has proposed drastic cuts in th RVUs assigned to the global fee schedule for HDR breast brachytherapy. They are scheduled to reduce by 20% each year in the transition period and the total reduction for this treatment is -55% as illustrated in the table below.

CPT Code	Description	Units	2006 RVU	2006 Average Rate	2010 RVU	Variance 2010 to 2006	Variance 2010 to 2006
99245	office consult, comprehensive	1	5.91	$224	6.25	$1	0%
77263	physician treatment planning, complex	1	4.41	$167	4.16	($18)	-10%
77470	special treatment procedure	1	14.64	$555	4.55	($391)	-71%
76370	CT for planning	1	4.29	$163	5.48	$35	21%
77370	special medical physics consult	1	3.68	$139	2.51	($49)	-35%
77290	simulation, complex (contour volumes)	1	9.02	$342	15.22	$206	60%
77326	Brachytherapy isodose plan	1	3.78	$143	3.89	($3)	-2%
77300	dose calc	10	2.26	$856	1.80	($209)	-24%
77336	weekly medical physics consult	1	3.15	$119	1.08	($81)	-67%

77280	simulation, simple	5	4.62	$875	5.27	$72	8%
77781	Afterloading HDR brachy (1-4 source positions)	10	23.69	$8,978	6.58	($6,611)	-74%
						($7,049)	***-56%***

NOTE: 2006 CF is $37.8975 with assumption for 2010 using proposed CF of $35.9647; applicable to Physician Fees

The alternative radiation treatment is Whole Beam External Radiation Therapy (WBXTR) where women must endure 6 weeks of radiation. Alternatively, the RVUs for WBXRT increase by 55% or $6,000 during the transition period and will be reimbursed at a proposed rate of more than $9,000 than HDR Breast Brachytherapy. This treatment is extremely beneficial for the patient in that it irradiates less healthy tissue and allows them to return back to their life activities in just five days, however, HDR breast brachytherapy does require more time for the radiation oncologist to plan, calculate and treat with HDR breast brachytherapy. These proposed cuts in RVUs are insufficient to cover the cost and time required to administer HDR breast brachytherapy and will result in the limiting access to this radiation treatment for women who are Medicare beneficiaries.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, HDR breast brachytherapy. I am willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to HDR breast brachytherapy.

Sincerely,

Steven J. Gregorich, MD
Buffalo Radiation Oncology Center
45 Spindrift Drive
Williamsville, NY 14221

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

James Rubenstein,
MD Chairman James Rubenstein, MD, Chairman, American College of Radiation Oncology

Submitter : Dr. Harry Ameredes **Date:** 09/27/2006

Organization : Carolina Regional Radiology

Category : Radiologist

Issue Areas/Comments

Background

Background

The physicians of Carolina Regional Radiology in Fayetteville, NC are comprised of 21 board certified radiologists serving 4 non-profit county hospitals in addition to 2 outpatient imaging centers in southeastern North Carolina. We perform approximately 475,000 procedures per year in at least 5 counties. This includes all diagnostic imaging modalities (CT, MRI, Ultrasound, Nuclear Medicine, Mammography, PET/CT) as well as interventional and therapeutic procedures along with a clinical practice of radiology. Our patients receive the highest quality of care utilizing cutting edge technology and sub specialized physician skill and expertise. As we are sure you are aware, the state of the art equipment needed to provide quality care for our patients is extremely expensive. Advances in diagnostic medical imaging have no doubt improved the quality of care provided to millions of Medicare beneficiaries over the last several years. A rise in the utilization of imaging has prevented the need for more costly and invasive procedures further down the line in the continuum of patient care.

GENERAL

GENERAL

We request that you consider co-sponsoring H.R. 5704, which calls for a two year moratorium on scheduled physician payment reductions for imaging services and requires further study on patient access to imaging services.

Maintaining access to medical imaging is a life-saving privilege, which every American enjoys. We hope that you will work with us to ensure this holds true for future generations.

Impact

Impact

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Submitter : Dr. Demir Bastug **Date:** 09/27/2006

Organization : Carolina Regional Radiology

Category : Radiologist

Issue Areas/Comments

Background

Background

The physicians of Carolina Regional Radiology in Fayetteville, NC are comprised of 21 board certified radiologists serving 4 non-profit county hospitals in addition to 2 outpatient imaging centers in southeastern North Carolina. We perform approximately 475,000 procedures per year in at least 5 counties. This includes all diagnostic imaging modalities (CT, MRI, Ultrasound, Nuclear Medicine, Mammography, PET/CT) as well as interventional and therapeutic procedures along with a clinical practice of radiology. Our patients receive the highest quality of care utilizing cutting edge technology and sub specialized physician skill and expertise. As we are sure you are aware, the state of the art equipment needed to provide quality care for our patients is extremely expensive. Advances in diagnostic medical imaging have no doubt improved the quality of care provided to millions of Medicare beneficiaries over the last several years. A rise in the utilization of imaging has prevented the need for more costly and invasive procedures further down the line in the continuum of patient care.

GENERAL

GENERAL

We request that you consider co-sponsoring H.R. 5704, which calls for a two year moratorium on scheduled physician payment reductions for imaging services and requires further study on patient access to imaging services.

Maintaining access to medical imaging is a life-saving privilege, which every American enjoys. We hope that you will work with us to ensure this holds true for future generations.

Impact

Impact

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Submitter : Dr. George Binder **Date:** 09/27/2006

Organization : Carolina Regional Radiology

Category : Radiologist

Issue Areas/Comments

Background

Background

The physicians of Carolina Regional Radiology in Fayetteville, NC are comprised of 21 board certified radiologists serving 4 non-profit county hospitals in addition to 2 outpatient imaging centers in southeastern North Carolina. We perform approximately 475,000 procedures per year in at least 5 counties. This includes all diagnostic imaging modalities (CT, MRI, Ultrasound, Nuclear Medicine, Mammography, PET/CT) as well as interventional and therapeutic procedures along with a clinical practice of radiology. Our patients receive the highest quality of care utilizing cutting edge technology and sub specialized physician skill and expertise. As we are sure you are aware, the state of the art equipment needed to provide quality care for our patients is extremely expensive. Advances in diagnostic medical imaging have no doubt improved the quality of care provided to millions of Medicare beneficiaries over the last several years. A rise in the utilization of imaging has prevented the need for more costly and invasive procedures further down the line in the continuum of patient care.

GENERAL

GENERAL

We request that you consider co-sponsoring H.R. 5704, which calls for a two year moratorium on scheduled physician payment reductions for imaging services and requires further study on patient access to imaging services.

Maintaining access to medical imaging is a life-saving privilege, which every American enjoys. We hope that you will work with us to ensure this holds true for future generations.

Impact

Impact

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Submitter : Dr. Fred Caruso **Date:** 09/27/2006

Organization : Carolina Regional Radiology

Category : Radiologist

Issue Areas/Comments

Background

Background

The physicians of Carolina Regional Radiology in Fayetteville, NC are comprised of 21 board certified radiologists serving 4 non-profit county hospitals in addition to 2 outpatient imaging centers in southeastern North Carolina. We perform approximately 475,000 procedures per year in at least 5 counties. This includes all diagnostic imaging modalities (CT, MRI, Ultrasound, Nuclear Medicine, Mammography, PET/CT) as well as interventional and therapeutic procedures along with a clinical practice of radiology. Our patients receive the highest quality of care utilizing cutting edge technology and sub specialized physician skill and expertise. As we are sure you are aware, the state of the art equipment needed to provide quality care for our patients is extremely expensive. Advances in diagnostic medical imaging have no doubt improved the quality of care provided to millions of Medicare beneficiaries over the last several years. A rise in the utilization of imaging has prevented the need for more costly and invasive procedures further down the line in the continuum of patient care.

GENERAL

GENERAL

We request that you consider co-sponsoring H.R. 5704, which calls for a two year moratorium on scheduled physician payment reductions for imaging services and requires further study on patient access to imaging services.

Maintaining access to medical imaging is a life-saving privilege, which every American enjoys. We hope that you will work with us to ensure this holds true for future generations.

Impact

Impact

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Submitter : Dr. Beverly Davis **Date:** 09/27/2006

Organization : Carolina Regional Radiology

Category : Radiologist

Issue Areas/Comments

Background

Background

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

GENERAL

GENERAL

We request that you consider co-sponsoring H.R. 5704, which calls for a two year moratorium on scheduled physician payment reductions for imaging services and requires further study on patient access to imaging services.

Maintaining access to medical imaging is a life-saving privilege, which every American enjoys. We hope that you will work with us to ensure this holds true for future generations.

Impact

Impact

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Submitter : Dr. Bruce Distell **Date:** 09/27/2006

Organization : Carolina Regional Radiology

Category : Radiologist

Issue Areas/Comments

Background

Background

The first of the nine cuts slated to take place Jan. 1, 2007 results in 5% reduction in reimbursement. We estimate this to have a negative 17% impact on our outpatient Medicare patient payments in our practice initially, to say nothing of the eventual 40% reduction projected by 2015. 14% of the North Carolina population is on Medicare and these cuts will negatively impact 78,973 North Carolina employees. In addition, there are 460,660 TRICARE beneficiaries who will also have restricted access. This particularly affects our practice which serves a large military population (both retired and active) in Cumberland county, which is where Ft. Bragg and Pope Air Force Base are located. This will inevitably compromise our ability to provide care for this patient population and the patients will suffer in the end as a result of this limited access.

GENERAL

GENERAL

We request that you consider co-sponsoring H.R. 5704, which calls for a two year moratorium on scheduled physician payment reductions for imaging services and requires further study on patient access to imaging services.

Maintaining access to medical imaging is a life-saving privilege, which every American enjoys. We hope that you will work with us to ensure this holds true for future generations.

Impact

Impact

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

The planned drastic reductions in the Medicare technical reimbursements for outpatient imaging included in the Deficit Reduction Act of 2005 (Section 5102(B)) are intolerable. Assuming private third party insurers and HMO's drop their reimbursements commensurately, we believe that many facilities similar to ours will be forced to close or severely limit their hours and/or services if these cuts take effect on January 1, 2007. The cuts found in the final version of the DRA were in neither the House nor the Senate versions of the legislation that passed each chamber, but were inserted into the bill during conference. Some of the payment cuts are as high as 50 percent for vitally important medical procedures such as MRI s of the brain which are used to diagnose brain tumors and PET/CT which could confirm that a mass is benign and obviate the need for expensive and unpleasant surgery. The DRA provision arbitrarily allows CMS to reimburse physicians for the technical component of imaging services at the lower of either the Medicare Physician Fee Schedule (MPFS) rate or the Hospital Outpatient Prospective Payment (HOPPS) rate. The HOPPS rate was never intended to reflect the costs of providing individual physician services and instead was developed to reimburse hospitals for related medical services, which are packaged and paid as a whole. The members of the North Carolina Radiological Society believe that picking and choosing between payment systems based on whichever is cheaper, invalidates and corrupts both systems, not only for imaging, but for all of medicine. This is not only bad policy, but methodologically unjustifiable.

Submitter :

Date: 09/27/2006

Organization :

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1321-P-317-Attach-1.PDF

Attachment
317

FOLEY
HOAG LLP
ATTORNEYS AT LAW

Brian Carey
Boston Office
617-832-1712
bcarey@foleyhoag.com

September 27, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1321-P

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; ASP Issues

Dear Administrator McClellan:

Thank you for this opportunity to comment on the proposed revisions to the physician fee schedule for calendar year (CY) 2007. This comment addresses manufacturers' reporting requirements under the average sales price (ASP) system. Since finalizing the ASP rule, CMS has provided guidance on its website in the form of "Questions and Answers." This letter requests that CMS clarify in the final rule that drug manufacturers are required to report ASP data for *all* sales of a given Part B drug. Such a clarification is consistent with the Medicare statute and regulations, and would help to ensure that ASP accurately reflects the market prices of Part B drugs.

Summary

There has been some confusion among manufacturers regarding whether sales of Part B drugs for non-Medicare-covered uses must be reported for purposes of calculating ASP. In creating the ASP system, Congress intended to enable CMS to capture more accurately the market prices of drug products. Pursuant to the Section 1847A of the Social Security Act (SSA), if a drug is covered under Part B, manufacturers are required to report sales data for all of their sales of that drug. CMS should clarify in the final rule that drug manufacturers are required to report ASP data for *all* of the NDCs assigned to a given Part B drug, and that they are prohibited from selectively omitting sales data for certain non-covered uses of the product.

Seaport World Trade Center West / 155 Seaport Blvd. / Boston, MA 02210-2600 / TEL: 617.832.1000 / FAX: 617.832.7000
Foley Hoag LLP BOSTON WASHINGTON, DC www.foleyhoag.com

I. The ASP Reporting System was Designed to Capture the Market Price of Drug Products

When Congress created the ASP system through the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), its basic goal was to better align Medicare payment rates for Part B drugs with their actual price in the marketplace. The purpose of the ASP system is thus to ensure that Medicare payment rates are consistent with the widely available market price (WAMP) of Part B drugs. Congress defines WAMP as "the price that a prudent physician or supplier would pay for the drug or biological," net discounts and rebates.[1]

To this end, Congress created a statutory mechanism under which WAMP acts as an explicit check on manufacturer-reported ASP. Specifically, the MMA requires the DHHS Office of Inspector General (OIG) to compare ASP data for sales of Part B drugs with both WAMP and average manufacturer's price (AMP).[2] The fact that the MMA authorizes the DHHS Secretary to *substitute* WAMP for the manufacturer-reported ASP indicates that Congress considers WAMP the best measure of what Medicare *should* be paying for a drug. That is, Congress views the statutory ASP methodology as a proxy for the actual price that prudent physicians and suppliers would pay for Part B drugs in the marketplace. As the proposed rule itself states in a related context, CMS's goal in administering the ASP system "is to ensure that ASP is an accurate reflection of market prices for Part B drugs."[3]

II. The MMA Requires Manufacturers to Report Sales Data for All Sales of a Part B Drug

The MMA and CMS regulations require manufacturers to report *all* sales of a given Part B drug. Some Part B drugs are sold for both covered and non-covered uses. When Congress established the ASP reporting requirements, it did not distinguish between covered and non-covered sales of a Part B drug. The statute states that ASP is based on "*the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological . . . .*" The only sales exempted from the ASP calculation are sales calculated for "best price" under section 1927(c)(1)(C)(i), and sales at a nominal charge.

---

[1] SSA § 1847A(d)(5)(A).

[2] SSA § 1847A(d)(2). AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." SSA § 1927(k)(1).

[3] 71 Fed. Reg. at 49004.

Omitting sales data for indications not covered by Medicare would distort the market price. In some cases, a vast majority of the sales of a Part B drug may be for non-covered indications. In cases where a drug product is priced lower for non-covered sales than for covered sales, the exclusion of the former has the potential to understate the true market price, thus artificially inflating the drug's ASP and, with it, the Medicare payment rate. CMS should therefore make explicit that Section 1847A of the SSA and its implementing regulations prohibit manufacturers from insulating a significant portion of a Part B drug's sales from the ASP reporting requirement.

III. Non-Covered NDCs are not Exempt from ASP Reporting Requirements

There is no exemption from ASP reporting requirements of sales data for non-covered NDCs.[4] To the contrary, the statutory language itself requires manufacturers to report sales data for ***all*** of the NDCs assigned to a Part B drug product. The provision setting forth manufacturers' reporting requirements for single source drugs is illustrative, specifying that ASP is to be calculated for "***all National Drug Codes assigned to such drug or biological product.***"[5]

Although the statute and regulations setting forth the ASP framework require drug manufacturers to report ASP data for each drug product by its NDC(s), this legal framework does not exempt manufacturers' sales of non-covered NDCs from ASP reporting requirements. The SSA provides that "the manufacturer's 'average sales price' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—(A) the manufacturer's sales to all purchasers . . . in the United States for such drug or biological . . . ."[6] The regulation implementing the ASP system similarly states that "[t]he manufacturer's average sales price for a quarter for a drug or biological represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code."[7]

The fact that drug manufacturers report ASP data for each drug product by its NDC(s), however, does not alter that drug products, and not NDCs, are the subjects of the ASP system. Section 1847A(b)(2)(B) defines the basic ASP unit as the lowest

---

[4] *See* FDA, National Drug Code Directory (available at http://www.fda.gov/cder/ndc/). National Drug Codes, which are administered by the U.S. Food and Drug Administration (FDA), are unique ten-digit, three-segment numbers that identify the labeler, product, and trade package size of drug products that are manufactured, prepared, propagated, compounded, or processed by registered establishments for commercial distribution in the United States.

[5] SSA § 1847A(b)(4)(A).

[6] SSA § 1847A(c)(1)(A).

[7] 42 C.F.R. § 414.804.

identifiable quantity of the drug—such as a single tablet, or a milligram of molecules.[8] Further, CMS classifies drugs for reimbursement purposes according to standardized procedural codes, called Healthcare Common Procedure Coding System (HCPCS) codes. HCPCS codes identify the drug and dosage, but do not identify the manufacturer(s) or packaging size(s). Multiple brand name products and NDCs are often included within a single HCPCS code.[9] The quantity of a given drug described in an NDC frequently differs both from the quantity of the same drug described in another NDC, and from the corresponding HCPCS code.

Request for Clarification

We respectfully request that the final rule include the following clarification:

The statutory requirement that manufacturers report ASP data by 11-digit NDCs applies to all sales of a given Part B drug. Manufacturers must submit ASP data for each NDC assigned to a Part B drug, including those NDCs that describe non-covered sales of the that drug. When at least one of the NDCs assigned to a given drug product is eligible for coverage under Part B, the manufacturer of that drug product is required to submit sales data for all of the NDCs assigned to that drug product.

Thank you for your consideration of this issue.

Very truly yours,

Brian Carey

[8] Acting under the DHHS Secretary's statutory discretion to adopt an alternative unit for ASP reporting, CMS directed manufacturers to report drug sales by the quantity of the drug represented by each NDC.

[9] When an HCPCS code is comprised of more than one NDC, the ASP must be volume-weighted to account for the relative volume of each component NDC sold during that quarter.