



**FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – November 4, 2008**  
**FLASCO WEBSITE: [www.flasco.org](http://www.flasco.org)**

**PROGRAM COMMITTEE: Rogério Lilenbaum, MD, Chairman**

**FLASCO Fall Meeting – November 7 & 8, 2008**

You are encouraged to attend the FLASCO Fall Meeting which is being held at the Tampa Airport Marriott Hotel on **November 7 & 8, 2008**. Complete information has been sent to you previously and the information and registration form are available on the FLASCO website: [www.flasco.org](http://www.flasco.org)

**Save the date for Highlights of ASH®**

This year one of the Highlights of ASH is taking place in Miami, FL, on February 6-7, 2009. The following is a direct link to the Highlights information on the ASH Web site: <http://hematology.org/meetings/highlights/index.cfm#2>  
The FLASCO member code is FLH09 – FLASCO special registration fee - \$110. Let's have a good showing of attendees from FLASCO!

**CLINICAL PRACTICE COMMITTEE: Thomas Gaddis, MD, Chairman**

**Drug, Devices and Cosmetics Profession Updates –(Florida Department of Health)**

FDA Issues Final Rule Requiring Toll-Free Number on Medication Labeling – The Food and Drug Administration (FDA) has issued a final rule requiring the labeling for certain medications to include a toll-free number for patients to report side effects. The final rule confirms the interim final rule “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products” and its requirement for the addition of a statement to the labeling for certain human drug products for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act. The statement must include a toll-free number and advise that the number is to be used only for reporting side effects and is not intended for medical advice. This final rule also affirms the interim final rule's addition of a new part 209 to the regulations requiring distribution of the side effects statement. This final rule implements provisions of the Best Pharmaceuticals for Children Act (Public Law 107-109) and the Food and Drug Administration Amendments Act of 2007. The final rule is effective November 28, 2008, and the compliance date is July 1, 2009. More information is available in the Federal Register [Docket No. FDA-2003-N-0313 ].

**DRUG AND INDUSTRY UPDATE:**

**Cephalon** is pleased to inform you that the U.S. Food and Drug Administration (FDA) has approved TREANDA (bendamustine hydrochloride) for Injection for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma (NHL) who have progressed during or within six months of treatment with rituximab or a rituximab-containing regimen

**CMS UPDATES:**

**October 30, 2008 the Centers for Medicare & Medicaid Services (CMS) issued its final Medicare physician fee schedule regulations for 2009.**

The regulation announces that the **Medicare physician conversion factor for 2009 will be \$36.0666**, which represents a decrease from the 2008 conversion factor (\$38.0870). Congress took two actions in the Medicare Improvement for Patients and Providers Act (MIPPA) earlier this year which affected the conversion factor:

- 1) MIPPA provides for a 1.1% update (applied to the 2008 conversion factor) in 2009.

- 2) MIPPA requires that budget neutrality for the physician fee schedule be achieved through adjustments to the physician conversion factor, instead of negative adjustments across relative value units (RVUs) for individual services.

As a result of the last 5-Year Review of physician work, RVUs for certain codes increased. Mandated budget neutrality requirements provide that increased payments for some codes due to relative value changes must be offset by reductions in the values of other codes. Previously CMS achieved this offset by adjusting the RVUs. Now Congress has mandated that the adjustment be made to the conversion factor instead. While the 1.1% update was made and is reflected in the conversion factor, the impact of the budget neutrality adjustment is greater and therefore results in an overall reduction.

The final rule includes a number of provisions in other areas including imaging, e-prescribing, anti-markup, self-referral, and PQRI. We will be reviewing the entire regulation carefully and sending out a comprehensive summary of changes that will affect oncologists, and their estimated impact.

CMS also released the Medicare 2009 Hospital Outpatient Prospective Payment final rule yesterday. The rule finalizes CMS' proposal to reduce drug payments in the outpatient department to ASP+4%. ASCO will also be reviewing and summarizing the hospital outpatient rules shortly.

### **Final 2009 Physician Payment Rule Implements New Electronic Prescribing Incentive Program**

Physicians may earn pay boost of up to 5.1 percent from MIPPA update plus e-prescribing and PQRI incentives.

The Centers for Medicare & Medicaid Services (CMS) has announced a new initiative for physicians to trade in their prescription pads and improve efficiency and safety when ordering drugs for patients with Medicare. The initiative is included in the Medicare Physician Fee Schedule (MPFS) final rule for calendar year 2009. To view the Press Release, go to the web page at [http://www.cms.hhs.gov/apps/media/press\\_releases.asp](http://www.cms.hhs.gov/apps/media/press_releases.asp).

A copy of the final rule (CMS-1403-FC) is available at:

<http://www.cms.hhs.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=4&sortOrder=descending&itemID=CMS1216674&intNumPerPage=10>

### **CMS releases details on 2009 permanent Recovery Audit Contractors (RACs) program**

The Centers for Medicare and Medicaid Services (CMS) recently made several announcements regarding the permanent Recovery Audit Contractors (RACs) program.

The permanent RAC program evolved from the three-year RAC demonstration project stipulated by the Medicare Modernization Act (MMA) of 2003. The purposes of the RACs are to identify overpayments and underpayments by CMS. The Tax Relief and Health Care Act (TRHCA) of 2006 made the RAC program permanent and authorized CMS to expand it to all 50 states by 2010.

Unlike the demonstration project, the permanent RAC program limits the medical-record review period to three years and prohibits audits on claims paid before Oct. 1, 2007. The program requires RACs to have a physician medical director and certified coders available to discuss denials with providers. RAC auditors must provide clinical credentials to providers upon request.

#### RAC Medical Record Request Limits

##### **Summary of Medical Record Limits (for FY 2009)**

- **Inpatient Hospital, IRF, SNF, Hospice**

10% of avg mthly Medicare claims (max of 200) per 45 days

- **Other Part A Billers (Outpatient Hospital, HH)**

1% of average monthly Medicare services (max of 200) per 45 days

- **Physicians**

Solo Practitioner: **10** medical records per 45 days  
Partnership of 2-5 individuals: **20** medical records per 45 days  
Group of 6-15 individuals: **30** medical records per 45 days  
Large Group (16+ individuals): **50** medical records per 45 days

• **Other Part B Billers (DME, Lab)**

**1%** of average monthly Medicare services per 45 days

**Inpatient Hospital, IRF, SNF, Hospice by NPI**

10% of average monthly Medicare paid claims per 45 days

Maximum of 200 medical records per 45 days

• **Example 1: Local Community Hospital**

1,200 Medicare paid claims in 2007

Divided by 12 = average 100 Medicare paid claims per month

x 10% = 10

**Limit = 10 medical records per 45 days**

• **Example 2: Major Medical Center**

12,000 Medicare paid claims in 2007

Divided by 12 = avg 1,000 Medicare paid claims per month

x 10% = 100

**Limit = 100 medical records per 45 days**

**Other Part A Billers (Outpatient Hospital, Home Health, etc) by NPI**

1% of average monthly Medicare paid services per 45 days

Maximum of 200 medical records per 45 days

• **Example 1:**

1,500 Medicare paid services in 2007

Divided by 12 = avg 125 Medicare paid services per month

x 1% = 1.25

**Limit = 2 records/45 days**

• **Example 2:**

360,000 Medicare paid services in 2007

Divided by 12 = avg 30,000 Medicare paid services per month

x 1% = 300

**Limit = 200 records/45 days (capped at the maximum)**

**Physicians (by NPI)**

• **Solo Practitioner**

**Limit = 10 medical records/45 days**

• **Partnership of 2-5 individuals**

**Limit = 20 medical records/45 days**

• **Group of 6-15 individuals**

**Limit = 30 medical records/45 days**

• **Large Group (16+ individuals)**

**Limit = 50 medical records/45 days**

**Other Part B Billers (DME, Ambulance, Lab) by NPI**

1% of average monthly Medicare paid services per 45 days

Maximum of 200 medical records per 45 days

• Example 1:

1,500 Medicare paid services in 2007  
Divided by 12 = avg 125 Medicare paid services per month  
x 1% = 1.25

**Limit = 2 records/45 days**

• Example 2:

360,000 Medicare paid services in 2007  
Divided by 12 = avg 30,000 Medicare paid services per month  
x 1% = 300

**Limit = 200 records/45 days (capped at the maximum)**

CMS also announced the four entities that received national RAC contracts. CMS intends to add more states to these contracts in 2009. The contractors are

Region A: Diversified Collection Services Inc. in Maine , New Hampshire , Vermont , Massachusetts , Rhode Island and New York ;

Region B: CGI Technologies and Solutions Inc in Michigan , Indiana and Minnesota ;

Region C: Connolly Consulting Associates Inc. in South Carolina , **Florida** , Colorado and New Mexico ; and

Region D: HealthDataInsights Inc. in Montana , Wyoming , North Dakota , South Dakota , Utah and Arizona .

Information may be found at:

<http://www.cms.hhs.gov/RAC/Downloads/RAC%20Medical%20Record%20Request%20Limits.pdf>

Release of the 2009 HCPCS Annual Update

The Centers for Medicare and Medicaid Services is pleased to announce the scheduled release of modifications to the Healthcare Common Procedure Coding System (HCPCS) code set. These changes have been posted to the HCPCS website at <http://www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/>

All changes are effective January 1, 2009, unless otherwise indicated in the effective date column

**FLASCO CLINICAL TRIALS UPDATE: Randal Henderson, MD, Chairman**

The FLASCO Cancer Trials Network has just activated the Eli Lilly trial H3E-MC-JMIG at Hematology Oncology Associates in Lake Worth. Dr. Surenda Sirpal is the Principal Investigator.

This a Phase III trial for patients with Stage IIIA and IIIB (no pleural effusion) NSCLC (nonsquamous) using concurrent chemoradiation followed by chemotherapy consolidation.

Patients will be randomized between the experimental arm (Arm A; pemetrexed, cisplatin, and concurrent thoracic radiation therapy (TRT) for 3 cycles, followed by consolidation pemetrexed for 4 cycles), and the control arm (Arm B; etoposide, cisplatin, and concurrent TRT for 2 cycles, followed by consolidation with cytotoxic platinum-based doublet regimen of choice [excluding pemetrexed] for a maximum of 2 cycles).

FCTN and Pfizer are completing the contracting process and will activate Pfizer A4021016 in the network in 1-2 weeks. A4021016 is for first line treatment of chemotherapy-naive patients with locally advanced (Stage IIIB with pleural effusion) or metastatic (Stage IV or recurrent) Non-Small Cell Lung Cancer (NSCLC) with a primary tumor histology of squamous cell, large cell or adenosquamous carcinoma (non-adenocarcinoma histology).

Patients will be randomized to standard platinum-based doublet chemotherapy consisting of paclitaxel and carboplatin plus or minus CP-751,871 administered in 3-week cycles for a maximum of 6 cycles.

CP-751,871 is a fully human monoclonal antibody against the insulin-like growth factor 1 receptor (IGF-1R).

Sites chosen to participate in this study are:

Cancer Care of North Florida  
Waseemullah Khan, MD, Principal Investigator

Lakeland Regional Cancer Center  
Madhavi L.Venigalla, MD, Principal Investigator

Florida Hospital Cancer Institute,  
Lee Zehngbot, MD, Principal Investigator

Florida Cancer Institute  
Gerald Robbins, MD, Principal Investigator

Holy Cross Hospital  
Martin Gutierrez, MD, Principal Investigator

FCTN would like to thank the representatives of Eli Lilly and Pfizer who have worked diligently with us to launch these studies.

**EDUCATIONAL OPPORTUNITIES:Sanofi-Aventis PACT+ Provider Portal Webcast**

**Nursing Liability Center Webcast**

10 Documentation Tips That May Keep You Out of Trouble - In this webcast, learn key documentation tips that may help you defend yourself in a malpractice lawsuit and perhaps keep you out of court in the first place!

[http://www.accelacommunications.com/microsite/liability\\_center/](http://www.accelacommunications.com/microsite/liability_center/)

**Webcast Series On Advanced Rcc And Imatinib-Resistant Gist**

Pfizer is sponsoring both Oncologist and Nurse Webcast on Advanced RCC and Imatinib-Resistant GIST. There are multiple dates for Oncologist: Nov.5, and 19. Nurse dates are: Nov. 11 and 18. You may register at:

[www.PfizerOncology.com/webcast](http://www.PfizerOncology.com/webcast) or call the registration line at 1-877-426-3662. Enter Promotion Code: DR276W

**CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2008)**

FLASCO Members extends a big thanks to all of our 2008 Corporate Members/Sponsors

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Alexion

Genzyme

**FLASCO EVENTS:**

**November 6, 2008** - ACCC Regional Oncology Economic and Management Symposia – Tampa Airport Marriott Hotel

**November 7-8, 2008** – FLASCO Fall Meeting – Tampa Airport Marriott Hotel

**January 17-18, 2009** – Clinical Breakthroughs & Challenges in Hematologic Malignancies – Grand Floridian Resort – Lake Buena Vista

**February 6 & 7, 2009** – Highlights of ASH - Miami

**February 27 & 28, 2009** – FLASCO Spring Meeting – Marriott Sawgrass – Jacksonville

**March 20, 2009** – Statewide PA & NP Conference, Moffitt Cancer Center – Tampa

**November 6-7, 2009** – FLASCO Fall Meeting – Tampa Airport Marriott Hotel

**OTHER EVENTS:**

December 6-9, 2008 – ASH Annual meeting – San Francisco

February 26-28, 2009 – ASCO - GU Symposium, Orlando World Center Marriott

March 22-24, 2009 - 2009 AOHA Assembly Conference – Los Angeles, California

June 13-17, 2009 – AMA Annual Meeting – Chicago, IL

July 23-26, 2009 – FMA Annual Meeting – Boca Raton, FL

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