



**FLORIDA SOCIETY OF CLINICAL ONCOLOGY**  
**FLASCO BLAST June 9, 2010**  
**FLASCO WEBSITE: [www.flasco.org](http://www.flasco.org)**  
**FLASCO CLINICAL TRIALS NETWORK WEBSITE: [www.fctn.org](http://www.fctn.org)**

**MESSAGE FROM FLASCO PRESIDENT: Gerald Robbins, MD**

**2010 FLASCO Business of Oncology Summit**

The 2010 FLASCO Business of Oncology Summit will be held in Tampa on October 2, 2010. If you have not already done so, please provide Dorothy at the FLASCO Office ([Dorothy.Green@flasco.org](mailto:Dorothy.Green@flasco.org)) with topics that you would like to have considered for this Summit - what topics would be helpful to you in your practice? What topics would make you attend this Summit?

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

**Recent Question:**

Are you aware of any practices or research programs in Florida in which HMO Advantage patients are being asked to pay for 20% of their care if they elect to participate in a clinical trial?

**Response from ASCO:**

ASCO recently published a JOP article about this (see below). Unfortunately, Medicare Advantage plans are currently required to revert to standard Medicare fee-for-service payment policies concerning clinical trials participation. Note: This isn't just in Florida, but nationwide. Unfortunately, MA enrollees to revert to FFS Medicare coverage (80%/20%) until CMS makes some type of change. ASCO has written to CMS on this but to my knowledge, the rules have not changed yet.

We understand that this often has significant financial implications, given that FFS coverage involves a 20% coinsurance and deductible, while MA plans typically do not. As coverage of clinical trials under Medicare continues on an FFS basis, providers receive FFS-based payments for the routine costs of clinical trials. However, this also means that enrollees are subject to FFS coinsurance requirements, which are typically much higher than their Medicare Advantage coinsurance obligations. Under Medicare FFS, beneficiaries must pay 20% of the Medicare-approved amount. Whereas traditional Medicare beneficiaries often carry a Medigap policy that will cover the coinsurance, MA plan beneficiaries may not have access to these plans or other secondary plans. Indeed, avoiding the cost of secondary insurance is an important reason why many seniors choose MA plans in the first place. This is why ASCO and others are trying to get Medicare to update/revise their clinical trials participation and payment policy specific to Medicare Advantage plans.

<http://jop.ascopubs.org/cgi/reprint/5/3/144.pdf>

**DRUG SHORTAGE UPDATES:**

**Heparin Sodium Large Volume Premixed Infusion Solutions**

- Braun (Shortage of Heparin Sodium drug substance that meets current qualification requirements) is working to resolve the issues that have led to the shortage. B. Braun is out of all Heparin Sodium in 5% Dextrose Injection (40 U/mL; 50 U/mL and 100 U/mL) product codes and as soon as availability information is available will provide additional information. Currently, B. Braun has Heparin Sodium in 0.9% Sodium Chloride Injection (2 U/mL) available.
- Baxter (Shortage of finished product that meets current specification) is working to resolve the issues that have led to the shortage but there is not yet a timeline reported for availability. Baxter continues to have available their heparin sodium 1000u/500 ml in 0.9% Sodium Chloride and heparin sodium 2000u/1000ml in 0.9% Sodium Chloride.

- Hospira (Short supply of drug substance and unanticipated issues to implement the new USP Heparin monograph) has all large volume heparin infusion solutions available on allocation. Please also note that APP continues to have all high dose heparin sodium injectable vials available including those vials suitable for compounding large volume infusion solutions; heparin sodium 50,000U/10mL NDC# 63323-0047-10 and heparin sodium 50,000U/5mL NDC# 63323-0542-07 vials. For additional product questions please call APP Customer Service at 1-888-386-1300

#### **FDA UPDATES:**

##### **Hexaminolevulinate hydrochloride (Cysview™)**

On May 28, 2010, the U.S. Food and Drug Administration (FDA) granted approval for hexaminolevulinate hydrochloride (Cysview™ for Intravesical Solution, Photocure ASA), as an optical imaging agent for use in combination with the Karl Storz Photodynamic Diagnostic D-Light C (PDD) System for cystoscopic detection of non-muscle invasive papillary cancer of the bladder for patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. The imaging agent is used with the PDD System to perform cystoscopy with the blue light setting (Mode 2) as an adjunct to the white light setting (Mode 1). Full prescribing information is available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022555s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022555s000lbl.pdf)

#### **MEDICAID UPDATES:**

##### **FL Medicaid 2010 rates update:**

A staff member from FL Medicaid has stated that the pricing by HP (Hewlett Packard) should be completed by July 1, 2010, and that after that an updated fee schedule for 2010 will be created based on the HP pricing data. There is a letter going out to the providers in the next week or so.

##### **National Drug Code (NDC) Requirement for Physician Administered Drugs**

Effective July 1, 2010, Medicaid will deny claims for physician-administered drugs billed with HCPCS codes, such as the J-codes, without the corresponding NDC number on the CMS-1500 claim form. This requirement also applies to Medicare/Medicaid crossover claims. The NDC must reflect the correct amount and dosage provided to the Medicaid recipient.

Florida Medicaid reimburses physician-administered drugs for which the manufacturer has a federal rebate agreement, per Section 1927 of the Social Security Act [42 U.S.C. 1396r-8]. Only drugs that have a rebate are considered for Medicaid reimbursement; all others are not reimbursed. The current list of manufacturers with drug rebate agreements is available on our Web site at <http://www.ahca.myflorida.com/>. At the top of the page, click on **Site Menu**, then **Division of Medicaid**. Next, scroll down to **What is Occurring in Medicaid** and then, **Current List of Drug Rebate Manufacturers**.

Information on the proper billing of HCPCS codes for drugs is found in the Medicaid Provider Reimbursement Handbook, CMS-1500 Claim Form. All Medicaid policy handbooks may be accessed online at <http://www.mymedicaid-florida.com/>. Please click on **Public Information for Providers**, then **Provider Support** in the box on the left side of the page, and then select **Provider Handbooks**.

If you have any questions about this change, please contact your local Medicaid area office.

#### **EDUCATIONAL OPPORTUNITY:**

##### **20th Annual Mayo Clinic Hematology/Oncology Reviews**

**Thursday July 29th – Saturday July 31st, 2010**

The Ritz-Carlton Amelia Island, Amelia Island, Florida

Get Updated and Connected

**11th Annual Fellows' Research Presentations**

**Register online:** [www.mayo.edu/cme/hematology-oncology/index.html](http://www.mayo.edu/cme/hematology-oncology/index.html)

**CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2010)**

FLASCO Members extend a big thanks to all of our 2010 Corporate Members/Sponsors (Companies listed below have either paid 2010 dues or have submitted letters of intent)

<b><u>DIAMOND</u></b>	<b><u>PLATINUM</u></b>	<b><u>GOLD</u></b>	<b><u>SILVER</u></b>	<b><u>BRONZE</u></b>
Celgene	Abraxis	Allos Therapeutics	Genzyme	Alexion Pharmaceuticals
Cephalon	AMGEN	Bristol Myers Squibb	Meda Pharmaceutical	Biogen Idec
Eli Lilly	AstraZeneca	Genomic Health		The France Foundation
Genentech	Bayer Onyx	Millennium Pharmaceuticals		
Novartis	Eisai, Inc.	US Oncology		
Sanofi-Aventis	GlaxoSmithKline	OSI Pharmaceutical		
	Oncology Supply/ION			
	Pfizer			
	Ortho Biotech			

**FLASCO MEETINGS:**

**October 2, 2010** – FLASCO Business of Oncology Summit – Tampa

**November 5-6, 2010** – FLASCO Fall Meeting – Miami

**April 15-16, 2011** – FLASCO Annual Meeting & Spring Session - Tampa

**OTHER MEETINGS/WEBCASTS**

**October 7-10, 2010** The Association of Physician Assistants in Oncology (APAO), 13<sup>th</sup> Annual APAO Conference, The Ritz Carlton – Amelia Island, Florida **For more information, please visit [www.focus-ed.net/apao](http://www.focus-ed.net/apao)**

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