

Autumn/Winter
2011
Volume 7 Issue 3



News

NNECOS News is an e-mail publication of Northern New England Clinical Oncology Society

OUTSTANDING NNECOS MEETING! **Respected Presenters and NNECOS Projects and Initiatives** **Highlighted at 2011 Annual Meeting**

The 2011 NNECOS Annual Meeting at the stunning Omni Mount Washington Hotel in Bretton Woods, NH, October 28-29, 2011 did not disappoint!

More than 140 oncology professionals and industry partners were present for an exceptionally robust two-day meeting exploring ways to assure the availability of and access to high quality cancer care in our region.

The majestic beauty of the historic Mount Washington Hotel provided the perfect backdrop for the weekend's events. There was a collegial, collaborative buzz in the air as colleagues from across the region connected to talk about the latest challenges, advances, and opportunities in providing the best care for our region's patients.

Local, regional, and nationally renowned presenters offered an exceptional

array of outstanding educational content (see *online e-binder and abstract book for complete details*), complemented by updates on important NNECOS sponsored projects that have directly benefitted cancer patients in Maine, New Hampshire, and Vermont.



In the words of our attendees:

- *Excellent conference - one of the best I have attended!*
- *"Tremendous meeting, current topics, practical information, well organized."*
- *"This conference was well-organized and full of relevant information."*
- *"Enjoyed all programs at this meeting"*

It's hard to believe, but 2011 marked the **6th Annual NNECOS Abstract Poster and Presentation sessions!** Originally established as a result of a project funded by an ASCO State Affiliate Grant, NNECOS has sustained this project through six annual meetings and is committed to its continuation in 2012. If you haven't had a chance to review this year's submissions, you are encouraged to do so today! Members unable to attend this year's annual meeting were sent a print copy of this year's abstracts via postal mail, and all are invited to access these interesting and informative abstracts **online**.

The recipient of a \$12,500 NNECOS Research Funding Grant for 2009, newly elected NNECOS Board Member, Amy Litterini, PT, DPT presented a general session based largely upon the results of her 18 month study on exercise for individuals with Stage IV cancer. Amy's general session, "Exercise and Cancer: Risk Reduction and Symptom Amelioration," addressed contributing lifestyle factors on cancer risk and incidence, as well as the role of physical activity in cancer symptom management and survival.

Another program that was a direct outgrowth of a NNECOS project was the [NNECOS Collaborative Improvement Network](#). Under the

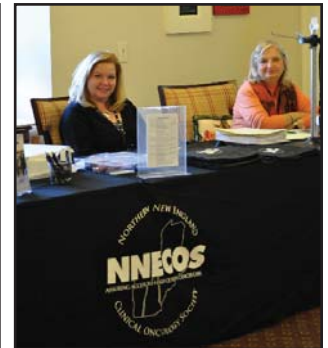
tireless leadership of past NNECOS President, Dr. Andrew Hertler, what originated as a 2010 ASCO State Affiliate Grant, has blossomed into a tri-state collaborative effort to improve the quality of oncology care through unblinded data sharing and collaborative sharing of best practices. To learn more about this NNECOS initiative, visit the [QOPI page](#) under the [Projects and Initiatives](#) section of our website. (To learn more about QOPI®, read *QOPI® Certifies 100th Practice for Delivering High-Quality Cancer Care*)

NNECOS

Collaborative Improvement

NETWORK

Special thanks to the planning committee and our outstanding presenters for making the meeting a success!

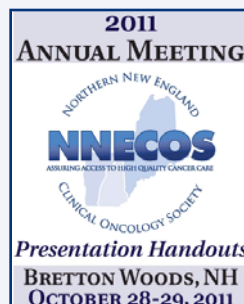


NNECOS Annual Meeting Materials on the Web!

As a special benefit to our members, the complete meeting [e-binder](#), including copies of the presentation slides, is available online in our special members-only section of our website!

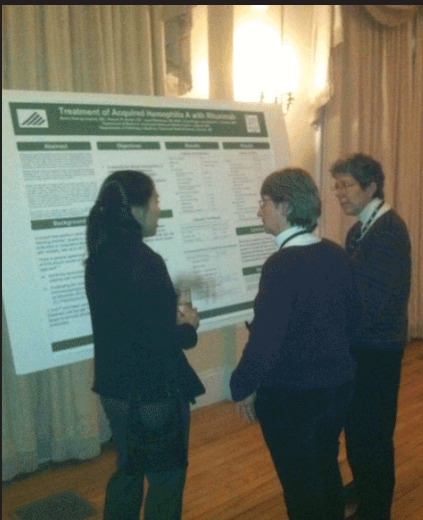
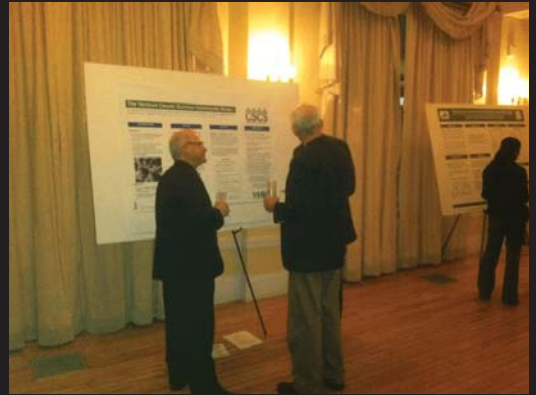
Topics addressed at this year's meeting included:

- Recognition And Screening of Distress in Patients with Cancer
- Are Anthracyclines a Necessary Component of Adjuvant Chemotherapy For Breast Cancer?
- Oral Chemotherapy: Tools for Safety and Compliance
- Alternate Radiation Treatment Schedules for Breast Cancer
- Cancer Care, What Is It Worth?
- Commission On Cancer 2012 Update: Investing In Quality Patient Care
- ASCO: The CPC, State Affiliates and Washington Update



- Integrating End of Life Care into the Treatment Plan for Incurable Cancers
- Antiemetics, Pharmacology and Personalized Medicine
- Axillary Staging for Breast Cancer Patients
- Abstract Presentation Session
- Exercise and Cancer: Risk Reduction and Symptom Amelioration
- The NNECOS Collaborative Improvement Network
- Melanoma 2011: New Approaches to Care and Treatment
- Stereotactic Body Radiotherapy for Early Stage Lung Cancer: Current State and Future Directions

2011 Annual Meeting Scrapbook!



NNECOS BOARD GROWTH **Expanding for Broader Representation of** **Oncology Care Teams Across Northern New England**

Did you know that the original NNECOS Bylaws only allowed for physician representation on the Board of Directors? It's true! In response to the evolving reach and needs of the society, and leadership's commitment to professional collaboration, bylaws changes over the years have expanded the size and representation on the board of directors to its current composition of both physician and non-physician members.

Initially comprised of three physicians from each state, board representation has been expanded to allow for up to four physician and two associate (*other allied health professionals*) representatives from each state, for a total board of no more than 18 members. The present board is comprised of 17 members.

Directors are elected for a term of three years, either by a vote of the membership at the annual

business meeting, or by appointment of the sitting board (in accordance with the bylaws) if a vacancy is filled outside of the typical nomination process. The addition of the second associate member seat for each state became official by a vote of the board at the 2011 annual in person board meeting on the afternoon of Saturday, October 29, 2011.

The NNECOS Board would like to extend a warm welcome to its newest members: Dr. Douglas Weckstein (NH), Dr. Daniel Rausch (ME), Robert Ferguson, PhD (ME), and Amy Litterini, PT, DPT (NH). Read on to learn more about the newest members of the NNECOS Board of Directors below!

Meet Your New Directors!



Robert J. Ferguson, PhD is a Clinical Health Psychologist with Eastern Maine Medical Center, Adjunct Assistant Professor of Psychiatry at Dartmouth Medical School and Clinical Associate, University of Maine Dept. of Psychology. Dr. Ferguson presented one of the two inaugural NNECOS Lunchtime Best Oncology Practice presentations in October 2011.



Daniel C. Rausch, MD is a practicing medical oncologist at Hematology-Oncology Associates in Lewiston, ME, a part of the Central Maine Medical Group. Dr. Rausch earned his MD at Tufts University School of Medicine in Boston, completed his residency in internal medicine at the Lahey Clinic Medical Center, and his hematology/oncology fellowship at St. Elizabeth's Medical Center in Brighton, MA.

Amy Litterini, PT, DPT is an oncology physical therapist and the Director of the Cancer Well-fit Exercise Program for the Center for Cancer Care at Exeter Hospital in Exeter, NH, where she also serves as a Certified Patient Navigator. Amy conducts research on the benefits of cancer, teaches locally in the University of New England PT Program and nationally on the topic of oncology rehabilitation.



Douglas J. Weckstein, MD is a practicing oncologist/hematologist in Southern New Hampshire with NH Oncology/Hematology, PA. He is Principle Investigator of the New Hampshire Oncology Hematology Clinical Trials Network, Medical Director, Derry-Salem Home Health & Hospice and the Chair of the NNECOS Research Evaluation Committee.



NNECOS Board Expresses Thanks to Outgoing Board Member Dr. Fred Briccetti

This year's annual meeting marked the end of six years of service on the NNECOS Board of Directors by Frederick M. Briccetti, MD, Medical Director at Dana-Farber/ New Hampshire Oncology-Hematology in Londonderry, NH. Having previously served as the chair of the NNECOS Board of Directors nominating committee, Dr. Briccetti was elected to the board on November 5, 2005. Dr. Briccetti has served on numerous NNECOS educational meeting planning committees, as well as serving tirelessly as chair of the NNECOS Website Committee, a role in which he has graciously agreed to continue into the coming year.



As a token of appreciation, Dr. Briccetti was presented with an engraved book clock at the annual Board of Directors Dinner at the annual meeting. Thank you for Dr. Briccetti for your continued service to the Northern New England Clinical Oncology Society!

NNECOS Issues Letter to Super Committee

Working in conjunction with ASCO's national efforts, NNECOS issued a letter to the Super Committee members on November 18, 2011. In the letter, the NNECOS Board of Directors expressed concern for possible changes in

Medicare reimbursement and the devastating impact they might have on small practices in Northern New England which serve patients who would otherwise not have access to cancer care. *Read the [NNECOS letter](#).*

PATIENT ACCESS

Visit www.nnecos.org/patientaccess for a listing of patient access and assistance programs. Send updates/additions to info@nnecos.org.

The Centers for Medicare & Medicaid Services (CMS) Releases its final Physician Fee Schedule and Revisions to Payment Policies for 2012

The rule, which is titled "Medicare Program; Payment Policies under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012" became available November 1, 2011, at 4:15 pm, and was published in the [Federal Register on November 28, 2011](#).

Taken in aggregate, CMS estimates that in calendar year 2012 under the final rule hematology/oncology will not experience any

overall cut in reimbursement. The actual impact on individual physician practices will depend on the mix of services provided. ASCO is currently analyzing the full impact of the final rule and will share a more detailed summary of the rule.

Join NNECOS for "Medicare Update 2012: What do oncology practices need to know?", a lunchtime webinar presented by our very own Elaine L. Towle, CMPE, on Wednesday, January 11 at 12:30pm.

LUNCHTIME BEST ONCOLOGY PRACTICE SERIES **Successful Pilot Leads to Program Continuation in 2012**

An initiative conceived by current NNECOS President, Dr. Tom Openshaw, NNECOS launched an exciting new pilot program this past September, the NNECOS **Lunchtime Best Oncology Practice Series**. The idea was to offer a series of lunchtime webinars/teleconferences, bringing best oncology practice to oncology professionals across Northern New England. The board approved a pilot implementation of two sessions leading up to the annual meeting, to then be assessed for future program continuation.



The first in the series, **Strategies to promote adherence to self-administered medications in the oncology patient** was presented as a webinar on

Wednesday, September 21st by Donna L. Berry, PhD, RN, AOCN®, FAAN, Director, Phyllis F. Cantor Center for Research in Nursing & Patient Care Services at the Dana-Farber Cancer Institute. Donna led a frank conversation about best practices in assuring patient adherence to home medication safety.

Next up, on October 12th, a teleconference entitled **Assisting Patients with Behavioral Health and Quality Of Life Needs** was presented by Robert J. Ferguson, Ph.D., Clinical Health Psychologist, at Eastern Maine Medical Center, Adjunct Assistant Professor of Psychiatry at Dartmouth Medical School, and Clinical Associate, University of Maine Dept. of

Psychology. Rob led the important discussion about how to best assist oncology patients with behavioral health and quality of life needs.

Due to the success of the initial two presentations, NNECOS is pleased to report that the board has voted to continue the Lunchtime Best Oncology Practice Series initiative in 2012!

Our 2012 series begins with **Medicare Update 2012: What do oncology practices need to know?** Join us Wednesday, January 11, 2012 at 12:30pm for this informative program describing the latest updates for the Medicare program in

both the physician practice and hospital outpatient environment.

NNECOS is fortunate to have access to national presenter, NNECOS board member, Elaine L. Towle,

CMPE to address this timely topic. Elaine is Director, Consulting Services for Oncology Metrics, a Division of Altos Solutions, serves as Consultant Editor of ASCO's *Journal of Oncology Practice*, and holds a graduate certificate in Community Health Care Management from Antioch New England Graduate School.

Share your ideas for future Lunchtime Best Oncology Practice Series presentations by emailing info@nnecos.org.



NNECOS *Lunchtime* **BEST ONCOLOGY PRACTICE** **S E R I E S**



Check us out on the web at www.nnecos.org!

Members can access their existing account through a simple login process.

- click "forgot password"
- enter your email address in the box when prompted
- follow the email instructions to "reset" your password

SAVE THE DATES FOR EDUCATION IN 2012

2012 SPRING MEETING SET FOR TUESDAY, MAY 15, 2012

The 2012 Spring Meeting planning committee has begun its efforts in lining up a terrific program for this year's meeting. Scheduled for Tuesday, May 15, 2012 at the Grappone Center in Concord, NH, there promises to be a plentiful selection of engaging, timely topics to discuss. Topics presently under consideration



include quality, patient access/support, oncology patient-centered medical home (OPCMH) and prior authorizations, as well as the traditional annual updates in medical and radiation oncology billing. This year's meeting will also feature an "extension" event on Saturday, May 19, 2012. *Read on to learn more!*

NNECOS OCN REVIEW COURSE, SATURDAY, MAY 19, 2012

NNECOS is delighted to announce that plans are in the works for our first ever review course designed to help nurses prepare to take the Oncology Nursing Certification Examination. A day-long course is being planned for Saturday, May 19, 2012 at the Grappone Center in Concord, NH. Being planned in conjunction with/as an

extension of our Annual Spring Meeting scheduled for Tuesday, May 15, 2012, participation will be limited to the first 30 registrants. Significantly discounted registration rates will be offered to current NNECOS members. Additional information will be posted at www.nnecos.org and sent out to NNECOS members as it becomes available.

WE'RE GOING BACK! ***2012 NNECOS Annual Meeting Returns to the Samoset Resort*** ***October 19-20, 2012***

The 2011 Annual Meeting is going to be difficult to top, but the 2012 Annual Meeting Planning Committee is up to the challenge. As we return to the beautiful, ocean side Samoset Resort, attendees will be sure to enjoy the relaxing atmosphere while attending the excellent presentations that NNECOS is known for, and ever-meaningful networking with colleagues from across the region. As in the past, the meeting



is set as a two day event, beginning on Friday, and ending late afternoon on Saturday. The 2012 Annual Meeting Planning Committee is chaired by current NNECOS President, Dr. Tom Openshaw. If you have suggestions you'd like to share with the committee or would like to become more involved, please email info@nnecos.org.

QOPI® Certifies 100th Practice for Delivering High-Quality Cancer Care

Less than two years since launching the first national program to help oncology practices deliver the highest quality of cancer care, ASCO and its affiliate, the Quality Oncology Practice Initiative Certification Program, announced today that more than 100 practices have achieved QOPI certification. The QOPI Certification Program certifies that outpatient oncology offices meet the highest national standards in quality and safety for cancer care delivery.



“We are delighted that more than 100 oncology practices in the United States have already taken steps to ensure that the cancer care they provide is consistent with the highest national quality standards,” said Allen S. Lichter, MD, CEO of ASCO and president of the QOPI Certification Program. “QOPI certification demonstrates a practice’s commitment to excellence and ongoing quality measurement and improvement. Achieving the QOPI standard of excellence reflects a practice is providing the highest quality treatment and care for their patients.”

Launched by ASCO in 2006, QOPI enables practices to examine the quality of care they provide to patients based on evidence-based guidelines and established quality measures. Its rigorous set of more than 100 quality measures was developed by practicing oncologists and quality experts, and spans the continuum of cancer care. Practices that participate receive detailed reports that indicate their performance on these quality metrics and offer insights into specific areas for improvement.

The QOPI Certification Program was launched in January 2010. The first 16 practices were certified just six months later, and today’s milestone of 100 certified practices was achieved in just under two years.

The first step towards achieving QOPI certification is participation in QOPI data collection. Beyond that, practices/institutions must undergo an extensive review by a team of ASCO professionals and oncology physicians and nurses at least once every three years. The practices performance is evaluated by:

Participation in QOPI and achieving above the threshold score across the 24 rigorous measures required for certification.

Meeting 17 Certification Standards based on the ASCO/ONS Chemotherapy Administration Safety Standards , which address:

- Treatment planning
- Excellence in staff training and education
- Chemotherapy orders and drug preparation
- Patient consent and education
- Safe chemotherapy administration
- Monitoring and assessment of patient well-being

For a continuously updated list of QOPI-certified practices, please go to: <http://qopi.asco.org/certifiedpractices>. For more information about the program, please visit: <http://qopi.asco.org/certification>.

To learn more about becoming part of the unique [**NNECOS Collaborative Improvement Network for QOPI®**](#) , [**visit our webpage**](#).

And the Winner Is....

Congratulations to Kate Vieira and Elaine Owen, the winners of our Member and Constituent Survey raffle. Kate has earned complimentary registration to her choice of a 2012 NNECOS

educational meeting, while Elaine has won a complimentary 2012 membership. Thanks to all who participated in the survey and congratulations again to Kate and Elaine!

NNECOS BOARD OF DIRECTORS HOSTS 2ND ANNUAL PLATINUM ROUNDTABLE BREAKFAST

Before the sun began to rise over the majestic presidential mountain range in Bretton Woods, NH, a group of more than 30 NNECOS leaders and Platinum Industry Supporters met to discuss issues of importance impacting oncology care in Northern New England.



A variety of topics were discussed at this year's roundtable, including: collaboration/initiatives with payers, society goals/partnership opportunities, the impact and causes of drug shortages, impact of payer arrangements on

This second annual breakfast event again provided a unique forum for frank conversation about the state of oncology care in the region and how the society can work together with our industry partners on areas of common interest. Outgoing NNECOS President, Dr. Denis Hammond extended to the group a warm welcome, commenting on the rich experience of last year's breakfast which made getting up before the sun again this year worthwhile.

practice, increasing industry value to practice through educational resources, industry resources for practices and patients including facilitating reimbursement, initiatives to sustain private practice, The Physician Payments Sunshine Act, connecting staff with appropriate pharmaceutical resources and personalized medicine. The NNECOS Board of Directors will once again review the detailed notes from this meeting at it's annual retreat in January and consider them in setting the course for the society's activities in 2012.

NNECOS Creates Advisory Board

In recognition of the benefit derived from the collaborative dialogue with its partners at the now annual Platinum Roundtable Breakfast, the NNECOS Board of Directors has decided to formalize this relationship by creating an Advisory Board. As an exclusive benefit to Platinum members, the NNECOS Board of Directors will

consult, from time to time, with its Advisory Board members (one from each Platinum company) on integrating efforts to support NNECOS' mission on a range of issues including access to cancer care, cancer research and education of cancer care professionals.

NNECOS Classifieds!



NNECOS offers its members an opportunity to advertise both job postings and situations wanted on our website and in our e-newsletter. This has been designed as a networking opportunity; NNECOS does not intervene in any negotiations between the parties involved. There is no cost for NNECOS members to place a notice. Submit your posting to info@nnecos.org.

NNECOS 2012 Membership Revised Structure, Discounts, and Awards!

The NNECOS Board of Directors is pleased to announce a series of membership discount initiatives for 2012.

Individual Membership

The individual membership rates will remain the same for 2012, at \$175 for physician members, and \$35 for associate members.

Group Membership*

New in 2012, NNECOS will offer group membership discounts to help broaden our reach and increase membership accessibility to oncology professionals cross the region. Group memberships will be based on the number of physicians in their practice group at a given site or the physician “denominator.”

Here’s how the structure works:

- Practice **sites** in which **50% or more** of physicians join qualify for a group membership discount as follows:
 - \$150 physician dues
(\$25 discount ~ 14% discount)
 - \$25 associate dues
(\$10 discount ~ 28% discount)
- Practice **sites** in which **all** physicians join qualify for an enhanced group membership discount as follows:
 - \$150 physician dues
(\$25 discount)
 - **Complimentary** associate member dues for associate members at that site
(100% discount).
 - Receipt of NNECOS Membership Award, available in desktop or plaque signifying commitment to exemplary care.

Auto-renewal Discount*

- Members electing the “auto-renewal” option will receive a one-time 10% discount off of membership dues upon the first “auto-renewal” payment.
- Membership would renew perpetually until the member “opts out”.

Multi-Year Membership Discount*

- Provide a two-year membership option at the following rates:
 - Active membership dues: \$325 for two years
 - Associate membership dues: \$60 for two years

****One discount per membership. If a member qualifies for more than one discount, the largest discount will apply.***



Join or renew your NNECOS membership online today at
www.nnecos.org/join or www.nnecos.org/renew!

[Exploring the NNECOS Website](#)

RSS

[What's this Orange Box about?](#)

You may have noticed that in certain special sections of the NNECOS website, you will see a little orange rectangle with the letters RSS inside, as pictured above. Hover your cursor over that box, and you will see that you have the option to “subscribe” to the Rich Site Summary (RSS) Feed. Go ahead and click on that box, and select your method to “subscribe” to the changes on that page. By activating this subscription, the site will automatically send you concise updates when content on that page changes. The “[News](#)” and “[Education & Events](#)” pages are set-up with RSS Feeds for your convenience.

[RESOURCES JUST A CLICK AWAY!](#)

The NNECOS website features a host of “[Resources](#)” in this content area that may be of interest to our membership. We encourage you to take a few minutes to explore this area, which includes a listing of Member Practices (is your practice listed?), [Patient Access Programs](#), [FDA Approvals](#), [J-Code & Q-Code Updates](#), [Legislative Contact Information](#), [NNECOS Classified](#), and [Community Resources](#).

[Regional Educational Programs](#)

Under the “[Education and Events](#)” section of our website, find information about a variety of upcoming opportunities sponsored by Member Organizations, Industry partners, and Non-Profit organizations. Upcoming events currently listed include:

**New Hampshire
Comprehensive Cancer Collaboration
7th Annual Meeting**
Wednesday, March 21, 2012

Cancer Survivorship: Four Dimensional Approach
to a National Challenge

**Northeastern Genitourinary
Oncology Symposium**
April 13-14, 2012
Hilton Hotel
Burlington, VT

[Projects & Initiatives](#)

A wealth of information about past, present, and future projects of the society awaits readers in the Projects & Initiatives area of our website. Take a few moments to look around and see what opportunities await to enrich your practice! Consider joining the [NNECOS Collaborative Improvement Network](#), take the [NNECOS Survey](#), start thinking about a future [Abstract](#) or [Research Funding Proposal](#), or learn more about our ground-breaking [Oncology Care in Rural Northern New England Project](#) that was published in ASCO’s Journal of Oncology Practice!

Highlights from ASCO's Latest Oncology Practice Insider



As SGR Deadline Nears, Tell Congress to Take Action

In an all too familiar scenario, the December 31 expiration date for the Sustainable Growth Rate patch is quickly approaching, and Congress is in a stalemate on how to proceed with a fix. Although it is still unclear what sort of plan Congress will pass, they are committed to finding a solution, even if temporary, to the impending 27.4 percent cut.

Using ASCO's ACT Network, please take a minute to send a message to your members of Congress encouraging them to remain focused on finding a long-term solution. Short-term patches lead to uncertainty that makes it difficult to operate any business, and ASCO believes your practice is no exception. Congress needs to hear from you about these challenges. It will only take a minute to weigh in on this ongoing problem.

Adapting to Changes in Medicare for 2012

ASCO will be hosting the Adapting to Changes in Medicare for 2012 national audiconference on Wednesday, January 4, 2012 from 4:00 PM to 5:30 PM ET. The call will provide highlights on the 2012 Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, updates on various Medicare programs such as PQRS and EHR, and review coding and billing changes for 2012.

Registration information will be provided soon on <http://asco.org/janaudiocall>.

ASCO and ONS Release Updated Chemotherapy Administration Standards

ASCO and the Oncology Nursing Society (ONS) have released updates to their joint chemotherapy administration standards. Originally published in 2009, the standards have now been expanded to clarify the standards in response to feedback received. The most significant change made to the standards was to extend their scope to the inpatient setting. This change reflects the conviction that the same standards for chemotherapy administration safety should apply in all settings. To read the updated standards, please click here.

National Provider Call: Physician Quality Reporting System & Electronic Prescribing Incentive Program

CMS will host a national provider call Tuesday, December 20, 2011; 1:30-3pm ET on the Physician Quality Reporting System (PQRS) & Electronic Prescribing (eRx) Incentive Program. Subject matter experts will provide an overview on electronic health record (EHR) and registry based reporting options that are available for eligible professionals (EPs) participating or looking to participate in the PQRS and/or

eRx Incentive Program.

To Register please visit <http://www.eventsvc.com/bl-technologies/>. Registration will close at 12pm ET on Tuesday, December 20, 2011 or when available space has been filled.

ASCO Assists with GAO Report on Drug Shortages; FDA Issues Rule for Better Managing Shortages

ASCO provided its perspective on a recently released U.S. Government Accountability Office report recommending that Congress strengthen the Food and Drug Administration's ability to respond to drug shortages. In preparing the report, released on December 15, GAO asked representatives from ASCO, the American Society of Anesthesiologists and the Infectious Diseases Society of America to each identify 5 shortages of sterile injectable drugs that were specific to their members' practice areas, occurred between January 2009 and June 2011, and had a significant impact on patient care. The report based its analysis on those 15 drug shortages.

In short the report determined that:

- The number of drug shortages has grown substantially since 2006, and many shortages involved generic injectable drugs.
- Twelve of the 15 drug shortages GAO reviewed were primarily caused by manufacturing issues.
- FDA has responded to known drug shortages with actions to address their underlying causes and to increase availability.

Unfortunately, FDA is constrained in its ability to protect public health from drug shortages.

Also on December 15, FDA issued an interim final rule for better managing drug shortages. Its requirements include:

Defining the term "discontinuance" to include both permanent and temporary interruptions in the manufacturing of a drug; FDA need be notified of temporary interruptions only if the interruption could lead to a disruption in supply. Requiring that the manufacturer notify the FDA of any known or planned discontinuance six months in advance, or as soon as possible if circumstances lead to an unplanned discontinuance which will occur in less than six months. Defining "sole manufacturer" in the regulation to mean "an applicant that is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, whether the product is manufactured by the applicant or for the applicant

under contract with one or more different entities. Clarifying that a sole manufacturer means the only applicant currently supplying the U.S. market with the drug product. It does not mean sole NDA or ANDA holder. A manufacturer is considered a sole manufacturer even if other manufacturers hold an approved NDA or ANDA for the same product, if the other applicants are no longer manufacturing (or have never manufactured) the product for sale in the United States. Clarifying that a drug manufacturer is responsible for determining if it is the sole manufacturer of a drug product. The interim final rule will be effective 30 days after it is published in the Federal Register.

January ASP Files Released

The average sales price (ASP) files for the first quarter of 2012 have been released by the Centers for Medicare & Medicaid Services (CMS). The agency notes that prices for 19 of the 50 higher volume drugs decreased. ASP data is calculated from data submitted by drug manufacturers. The ASP prices are effective as of January 1, 2012 through March 31, 2012 and can be viewed or downloaded from CMS' site. Don't forget to update your practice systems to reflect the January rates!

Drug Shortage Updates

- ***Leucovorin Availability: Update and Details on Importation***
- ***DOXIL® Supply Shortage***

January 1, 2012 Version 5010 Deadline

The compliance deadline for the transition to Version 5010 is only two weeks away! Though the Centers for Medicare & Medicaid Services (CMS) has announced an enforcement discretionary period of 90 days for Version 5010 compliance, the deadline remains January 1, 2012. Enforcement will not be exercised until April 1, 2012; however, it is important that organizations continue to complete the transition to Version 5010 as soon as possible, if they have not done so already.

New Webpage Provides Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs Payment and Registration Data (Part A and B)

CMS has created a new webpage where you can find Medicare and Medicaid EHR Incentive Program payment and registration data. The page includes up-to-date information about the programs through October 2011. The new webpage will be your resource for updates regarding the programs' registration, payment, and state Medicaid launches.

REMS Changes to Nplate and Promacta

The Food & Drug Administration (FDA) has approved changes to the Risk Evaluation and Mitigation Strategies (REMS) for romiplostim (Nplate for subcutaneous injection, Amgen Inc.) and eltrombopag (Promacta tablets, GlaxoSmithKline LLC) to remove the restricted distribution programs and the safety reporting requirements that were part of the REMS. Prescriber, institution, pharmacy, and patient enrollment and these data collection requirements are no longer necessary. More information can be found on FDA's site.

ASCO Suggests Modifications to FDA's Opioid REMS Blueprint

In comments to the Food and Drug Administration on a draft Blueprint for Prescriber Education for Long-Acting/Extended

Release Opioid Risk Evaluation and Mitigation Strategy, ASCO said it was pleased with the agency's decision to specify that education would be developed and offered by trusted continuing education providers.

ASCO's letter made several recommendations for modifying the FDA proposal. These include emphasizing the importance of physician-patient discussions on the benefits as well as the risks of opioids, and providing educational information on proper pain assessment, management of the patient with substance abuse, alternatives to opioid pain management, and pain management in the context of end-of-life care.

ASCO said it doesn't agree with FDA's approach to encourage opioid companies to establish goals for the number of prescribers trained and collect information from continuing education providers on people who complete training programs.

Proposed Delay in Stage 2 of the EHR Meaningful Use Incentive Program

The Centers of Medicare and Medicaid Services is proposing a delay in Stage 2 of their Medicare EHR incentive program (meaningful use). Currently, eligible professionals who are attesting for Stage 1 this year would need to meet the Stage 2 criteria as soon as October 2013. Medical providers and EHR vendors have raised concerns that this timeline is insufficient for adequate preparation and implementation of the Stage 2 criteria. Therefore, CMS will propose that 2014 be the deadline to meet Stage 2 for eligible professionals attesting this year. This will only affect the Medicare incentives and not the Medicaid program.

Unfortunately, this change will not be formalized for a few months. CMS will not officially propose this delay until spring of next year. The regulation will then need to pass through the federal rule making process, which includes a public comment period, before becoming finalized. For more information, email ehr@asco.org or contact CMS directly.

Help Your Patients Once Cancer Treatment Ends

Download or order ASCO's latest patient education booklet for cancer survivors. Cancer Survivorship: Next Steps for Patients and Their Families includes information on common survivorship challenges and coping strategies, the importance of follow-up care, managing late effects, and a glossary of survivorship terms and a list of resources.

Additional Topics In this Issue Include:

- **GU Cancers Symposium Housing and Early Registration Deadline Approaching**
- **ASCO, Journal of Clinical Oncology Relaunch Disease-Specific Cancer Portals**
- **JCO Rapid Communications: Fast-Tracked Article Now Available**
- **New Early Release Articles from JOP**
- **Deadline Extended - Call for Papers: Payer/Provider Relationships in Oncology**

YOUR FEEDBACK IS IMPORTANT TO US

We are interested in your feedback and suggestions. Please send your comments and suggestions for future issues to info@nnecos.org.



Feel free to forward this issue of NNECOS News to your colleagues who may not be current members of Northern New England Clinical Oncology Society. If you would prefer not to receive future e-mail correspondence from NNECOS, please reply to this message and type “remove” in the subject line.

NEWS FROM OUR SUPPORTERS

“News from our Supporters” will be included in NNECOS News on a space available basis, with preference being given to supporters who have not shared news in the previous two issues. Send your submissions to info@nnecos.org.

FDA APPROVALS



FDA Approves two new indications for Amgen’s Prolia® (denosumab)

The U.S. Food and Drug Administration (FDA) has approved the following new indications:

- Prolia® is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia® also reduced the incidence of vertebral fractures.
- Prolia® is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Seattle Genetics Announces FDA Accelerated Approval of ADCETRIS™ (Brentuximab Vedotin) for Two Indications

The U.S. Food and Drug Administration (FDA) has granted accelerated approval of ADCETRIS™ (brentuximab vedotin) for two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with systemic anaplastic large cell lymphoma (ALCL) after failure of at least one prior multi-agent chemotherapy regimen. The indications for ADCETRIS are based on response rate.

FDA Approves Pfizer’s XALKORI® (crizotinib) As First And Only Therapy Specifically For Patients With Locally Advanced Or Metastatic ALK-Positive Non-Small Cell Lung Cancer

The U.S. Food and Drug Administration (FDA) has approved XALKORI® (crizotinib) capsules, the first-ever therapy targeting anaplastic lymphoma kinase (ALK), for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is ALK-positive as detected by an FDA-approved test. The effectiveness of XALKORI is based on objective response rates (ORR) and, as XALKORI received accelerated approval from the FDA.

New J-Codes & Q-Codes

Permanent J-Code for Halaven® (eribulin mesylate) Injection effective January 1, 2012

The Centers for Medicare & Medicaid Services (CMS) has assigned a permanent Healthcare Common Procedure Coding System (HCPCS) J-code for Halaven, J9179. This new code will replace both the temporary C-code used in the hospital outpatient setting as well as the miscellaneous HCPCS codes used in other settings, including J9999 and J3490.

Unique HCPCS J-code for Halaven J9179, Injection, eribulin mesylate, 0.1 mg, 10 billable units per 1 mg/2 mL single-dose vial. J9179 can be used with all Medicare/Medicaid claims and most private commercial payors (coding requirements may vary). Because Halaven has been issued a billing unit of 0.1 mg by CMS, providers wishing to bill for one single dose 1 mg/ 2 mL vial of Halaven may bill 10 units. Billing units can be reported in box 24G on the CMS-1500 claim form for physician offices and box 46 on the CMS-1450 (UB-04) claim form for the hospital outpatient department. J9179 can be reported in box 24D on the CMS-1500 claim form for physician offices and box 44 on the CMS-1450 (UB-04) claim form for the hospital outpatient department.

New J-Codes for Prolia® (denosumab) and XGEVA® (denosumab) effective January 1, 2012

The Centers for Medicare and Medicaid Services (CMS) have established a product-specific Healthcare Common Procedures Coding System (HCPCS) J-code, or permanent code, for Prolia® (denosumab) and XGEVA® (denosumab). Effective for dates of service on or after January 1, 2012, the new J-code for both Prolia® and XGEVA® is J0897.

The new J-code, J0897 for Prolia® and for XGEVA®, should be used instead of the current miscellaneous J-code (J3590) as well as the current C-code (C9272) when processing claims forms with dates of service on or after January 1, 2012.

Happy New Year!

