National Alliance of Medicare Set-Aside Professionals

Volume 3, No. 1

Quarterly Newsletter

Inside this issue:

President's Letter	1
Off Label Drug Use	2-4
Meet the New Board Members	5
Committee Updates	6
Committee Duties	7-9
Breaking Drug News	9
NAMSAP Organizational chart	10
Partners & Sponsorship	11
Announcements	12

President's Letter to NAMSAP Membership

Dear NAMSAP Members,

First and foremost, I hope all of you have the time to enjoy and share in the Holiday Season and have had a great start to 2011.

2011 promises to be another exciting year in our field, with the delay in liability reporting it appears we will have another year of fine tuning the eventual reporting. The issues surrounding Liability MSA will continue to swirl as we await word from CMS as to what their guidelines will be. As importantly, what will be the reaction of the Trial Attorneys to any guidelines issued. I am sure we can all look forward to a most interesting year in the world of MSAs.

NAMSAP has many plans and goals for the coming year. You have received an invitation to participate in a survey of members to help your Board of Directors fine tune our planning and goals. Obviously, Education and Webinars will continue as our primary focus, but we will be involved in the full range of MSA issues. We continue to work with MARC and other groups as they respond and advocate for changes that would affect our industry. Your Vice President, Jon Gice of Travelers Insurance, has taken the lead with our Committee Chairs to continue to improve the benefits of membership in NAMSAP through our committee structure and programs. Your Treasurer, David Korch of EPS Settlements, is working closely with our Executive Director to fine tune the budget and program offerings. All of the Board Members will be working directly with the committees to assist wherever we can with the growth of the organization and through service to our members.

Saving the best for last, I want to remind all of you that our motto for this year has been adapted from the host city for this year's Annual Education Conference: "Let the Good Times Roll!" We are well into the planning for our fall meeting in New Orleans. We have added a new sub-committee headed by Gary Patereau of LASIE, to act as a site specific committee to help make this one of our best meetings ever. Then we begin planning for the next meeting which will occur in Early 2012. It is going to be a busy year for all of us.

We look forward to your active involvement in NAMSAP !

Sincerely,

Michael E. Westcott

President NAMSAP

Michael E. Westcott
President, NAMSAP

By Dane Higgins, MBA, Pharm. D
Tim Covington, MS, Pharm. D

Introduction
On May 14, 2010, the Centers for Medicare and Medicaid Services (CMS) released a memorandum on off-label drug use and when this use is or is not covered by Medicare Part D and thus appropriate to include in a Medicare Workers' Compensation Set-aside Agreement (WCMSA). The memorandum stated the following…

> "For a Part D drug to be covered by Medicare, and thus included properly in a WCMSA, the drug should be prescribed for an outpatient use that is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(I) of 42 U.S.C. Section 1396r-8."

For Medicare Set-aside (MSA) professionals, this memo may present several questions and concerns. Unless one is involved with the Medicare Part D program, CMS's references to "off-label" drug use and the "compendia" may be foreign.

What is "off-label" drug use?
For drugs to be marketed in the United States, manufactures must first complete the rigorous Food and Drug Administration (FDA) approval process. This process requires that manufactures demonstrate that a medication is safe and effective in clinical trials. The clinical trial process culminates in a Phase III trial that documents a medication's efficacy, safety and side-effect profile in a large group of individuals (typically 1,000 to 3,000). Researchers outline inclusion and exclusion criteria that determine which patients are enrolled in the clinical trial. The trial population can be highly unique to a specific type of patient, such as patients with breakthrough cancer pain, or more general and allow use for pain of any etiology. Ultimately, the phase III clinical trial will determine a medication's FDA-approved indication.

Drugs approved by the FDA are granted a label that provides clinicians with information on the medication, including indications, contraindications, warnings, precautions, side effects, drug interactions, and administration and dosing guidelines. Drug labels are provided on each medication container supplied to pharmacies and they can be accessed electronically at the FDA's website (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/). Every drug is approved for specific uses or indications as outlined in the medication's labeling. The FDA-approved use is based on the objective, evidence-based Phase III clinical trial process described above. Therefore, FDA-approved uses have been demonstrated to be safe and effective based on the clinical trial process and extensive human testing.

Once a drug is approved by the FDA, there are no regulations to prohibit physicians from prescribing a medication for any therapeutic use. When a drug is prescribed for a use that is not FDA-approved (as described in the indication section of package labeling), it is said to be used "off-label".

How common is "off-label" drug use?
It is estimated that 20% to 25% of all prescription drug use is off-label; however, it occurs more frequently with certain medications and in certain patient populations. For example, studies have shown that 83% of all gabapentin (Neurontin®) use and 90% of all Actiq® (fentanyl lozenge) use is off-label. Off-label use is also common in certain patient populations, such as children, cancer patients, and in chronic pain.

Is "off-label" use appropriate?
Prescribing medications off-label can be highly appropriate or inappropriate, depending on evidence available to support off-label use. Many off-label uses are considered standards of practice and are incorporated into national treatment guidelines. For example, the use of aspirin in diabetics for the primary prevention of a heart attack or stroke is an off-label use that is considered a standard of care by the American Diabetes Association. Despite not being approved for this indication by the FDA, medical evidence has demonstrated that the use of aspirin in certain diabetics can reduce ones risk for a heart attack or stroke. However, off-label uses can also be considered inappropriate. For example, Actiq® (the fentanyl lozenge or "lollipop") and Fentora® (fentanyl buccal tablet) are only FDA approved in the treatment of breakthrough cancer pain, yet the majority of their use is off-label for chronic orthopedic pain. The use of these agents for chronic non

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-cancer pain is particularly concerning given the potential safety risks associated with these products. The FDA has released a public health advisory concerning the off-label use of Fentora® and the potential for death when used inappropriately; therefore, the off-label use of these agents in non-cancer pain is typically considered inappropriate.

Ultimately, the appropriateness of an off-label use will depend on the quality and quantity of evidence supporting the safety and effectiveness of the off-label use. Clinicians must consider both efficacy and safety. Without objective, evidenced-based clinical trials to support an off-label use, such use must be critically questioned. The appropriateness of a specific off-label use often falls into a grey area inviting subjectivity and leaving doubt as to whether or not a particular off-label use is appropriate. In an effort to assist clinicians and insurers in evaluating appropriate and inappropriate off-label uses, many evidence-based compendia review evidence regarding off-label uses of drugs and make recommendations concerning whether or not such use is appropriate.

Ultimately, the appropriateness of an off-label use will depend on the quality and quantity of evidence supporting the safety and effectiveness of the off-label use.

What are CMS recognized compendia?
A drug is covered by Medicare if it is not excluded from coverage (e.g., benzodiazepines, erectile dysfunction agents) and is prescribed for a FDA-approved indication as outlined in package labeling or is prescribed off-label for a use that is supported by one or more citations in one of these compendia:

- American Hospital Formulary Service (AHFS) Drug Information
- United States Pharmacopeia-Drug Information (USPDI) or its successor publications
- Drugdex Information System

In 2007, Micromedex (the publisher of Drugdex) replaced USPDI; therefore, the two primary compendia to consider when evaluating off-label drug use are AHFS and Micromedex. In 2008, CMS began recognizing Clinical Pharmacology and the National Comprehensive Cancer Network Guidelines for cancer indications only. Other off-label compendia (e.g., Facts and Comparisons) are available for clinician consideration.

What should I consider when reviewing off-label compendia?
When clinicians are using off-label compendia to determine the appropriateness of a specific off-label use, several issues are likely to occur. Some common issues include the following:

Compendia Recommendations are Based on Opinions - A 2007 AHRQ (Agency for Healthcare Research and Quality) study of the compendia stated that the decision to include an off-label use in the compendia was based on…"judgment by editorial staff regarding the quality and quantity of evidence, and the magnitude of benefit versus harms". Since recommendations are based on the opinions of a small number of individuals from the compendia's editorial staff, recommendations can vary significantly from compendia to compendia.

Lack of Standardization – Each compendium has its own internal review processes and procedures to determine the appropriateness of an off-label use.

Inconsistent Recognition Among the Compendia – As recommendations on the appropriateness of off-label use is based on opinions, one may find that the compendia differ on what is appropriate or inappropriate concerning the same medication.

Interpretability to Real World Practice – Recommendations from the compendia may be difficult to interpret in clinical practice. For example, Micromedex will recommend an off-label use as appropriate in "some cases" (IIb) or in "most cases" (IIa); however, guidance is not provided on how to determine if a particular patient falls into the "some case" category.

Lag Time – The lag time from when data is published in medical journals to when recognized compendia are updated to reflect new clinical trial data can be significant. Therefore, compendia may consider an off-label use appropriate or inappropriate, while new medical data addressing safety and/or efficacy contradicts these recommendations.

While the use of recognized compendia for evaluating off-label drug use is not perfect, it is clearly superior to any other process available. The use of compendia incorporates an evidence-based process to evaluate off-label medication use.

What are the implications for off-label use in MSAs?
MSA professionals must now review all of the patient's medications along with the claimant's individual diagnoses against (1) FDA-approved indications as cited in package labeling and (2) acceptable off-label uses in CMS recognized compendia. FDA-approved indications can be accessed on the FDA's web-site (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/) or within the compendia (e.g., AHFS, Micromedex). For medications that are being used off-label, AHFS and Micromedex must be reviewed to determine if the off-label use in question is appropriate and thus a Part D or WCMSA eligible drug. The table below references several commonly used medications that could be considered as inappropriately used off-label and, therefore, non-Medicare eligible drugs.

Drug(s)	FDA-Approved Indication(s)	AHFS Accepted Off-Label Use(s)	Micromedex Accepted Off-Label Use(s)
Muscle Relaxants (e.g., Soma®, Skelaxin®, Flexeril®)	Treatment of muscle spasms associated with acute (i.e., short-term) painful musculoskeletal conditions	None	Numerous off-label uses, but none for the treatment of chronic muscle spasms. Examples include… Fibromyalgia (Flexeril®) TMJ Disorder (Flexeril®)
Lyrica®	Diabetic peripheral neuropathy Post herpetic neuralgia Seizure disorder Fibromyalgia	None	Central Neuropathic Pain Familial Dysautonomia Generalized Anxiety Disorder
Lidoderm®	Relief of allodynia (painful hypersensitivity) and chronic pain in post herpetic neuralgia	None	Diabetic neuropathy Burn
Provigil®	Excessive sleepiness associated with narcolepsy Obstructive sleep apnea Shift work sleep disorder	None	Adverse Reaction to Drug – Somnolence ADHD Fibromyalgia Sleep Deprivation Steinert Myotonic Dystrophy Syndrome

Most of the medications listed in the chart above should be considered off-label for MSA purposes and not Part D eligible benefits; however, an evidence-based justification must be included in the WCMSA proposal. MSA professionals have reported that CMS is typically accepting Lyrica® as a non-Medicare eligible drug and mixed results have been reported regarding Lidoderm®. With an evidence-based rationale that sites FDA-approved package labeling and Medicare-recognized compendia, MSA professionals should be able to justify the agents above and several other drugs as non-Medicare eligible benefits. Once these agents are transitioned to non-Medicare agents, beneficiaries and claimants cannot use funds from their WCMSA to pay for these non-covered Part D drugs.

With an evidence-based rationale that sites FDA-approved package labeling and Medicare-recognized compendia, MSA professionals should be able to justify the agents above and several other drugs as non-Medicare eligible benefits.

Authors
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Covington Healthcare Associates, LLC, is a national healthcare consulting firm focused on creating client value by addressing both quality of care and cost of care issues in the complex domain of drug therapy management. Covington Healthcare Associates, LLC, serves clients enrolling over 3.0 million beneficiaries, which includes one of the largest Medicare Rx plans in the nation. Covington Healthcare Associates, LLC, also serve as consultants to MSA vendors, workers comp insurers, TPAs, and other organizations.

Meet the New Board Members

Treasurer

David J. Korch, JD, AIC, SCLA

David J. Korch, JD, AIC, SCLA is the National Director of Workers Compensation Services for EPS Settlement Group as a national resource for the brokerage staff in the negotiation and settlement of workers compensation claims and third party claims with a workers' compensation component through the utilization of structured settlements. He has been in the insurance industry for over 30 years as a multi-line claim handler, supervisor, claim manager, home office claim consultant and structured settlement broker. He was associated, for over 17 years, as a large loss settlement consultant with structured settlement programs at The Travelers and The Hartford specializing in the settlement of workers compensation claims

During his tenure at The Hartford he held positions as a Home Office Consultant and assistant director in the Secured Benefit Services division where he had oversight of The Hartford's retained assets program and assisted workers compensation and liability claim personnel in all claim offices with proactive handling and resolution of complex catastrophic injury claims through the utilization of all available settlement tools including structured settlements, Medicare Set-Aside Accounts, Medicaid disability trusts, custodial medical accounts and high risk health insurance pools He led the development of the in-house Medicare Allocation unit reflecting a saving of approximately $1.26 million annually in vendor expenses.

He was the recipient of the 1996 *Chairman's Award of Excellence* for work with quadriplegics, paraplegics and traumatic brain injury claims in workers compensation, 1996 Recipient of *P&C Claim Award of Excellence* for work in resolution of quadriplegic, paraplegic and traumatic brain injury claims in Worker's Compensation with excess of $70 million in documented savings. He has been involved with hundreds of face to face negotiations and mediations on all cases involving quadriplegic, paraplegic and traumatic brain injured workers.

He holds a BS in Music Education, West Chester University, West Chester, PA and received his Juris Doctorate from LaSalle University, Mandeville, LA. He holds his Associate in Claims from the American Education Institute and is a Senior Claims Law Associate through the American Education Institute. He is certified as a Continuing Education Instructor in Casualty Claims by the State of North Carolina.

Secretary

Douglas L. Shaw

Chief Operating Officer, Medivest

Medivest Benefit Advisors, Inc. and Medivest Allocation Services, Inc. (Medivest). Medivest provides Medicare Set-Aside (MSA) allocations that accurately project the claimant's future medical needs and Medivest is the national leader in the professional administration of custodial accounts used in settlement of workers' compensation and liability cases.

Rafael Gonzalez

Over the last 15 years, Rafael has served as Chair of the Florida Bar Workers' Compensation Section and the Academy of Florida Trial Lawyers Workers' Compensation Section. Rafael has also served as President of the FSU College of Law Alumni Association, was appointed by Governor Jeb Bush to the Florida Rehabilitation Council, appointed by Hillsborough County Commissioner, and now US Representative, Kathy Castor to its Human Relations Council, and appointed by Mayor Pam Iorio to the City of Tampa Hispanic Advisory Council.

Since 2008, Rafael has been serving as Chief Executive Officer of The Center for Medicare Set Aside Administration and The Center for Lien Resolution in Clearwater, Florida. As CEO, he oversees the Centers' national Medicare compliance efforts, which includes mandatory insurer reporting, conditional payments resolution, and Medicare set aside allocation,

Leslie Schumacher

For over 10 years, Leslie has been involved in Medicare Secondary Payer Compliance. Leslie is a Registered Nurse who actively holds Certified Life Care Planner and Certified Nurse Life Care Planner as well as Medicare Set Aside Consultant Certified and Certified Medicare Secondary Payer Professional credentials. A graduate of Drexel University, Leslie also holds the following additional certifications: Certified Case Manager, Certified Rehabilitation Registered Nurse, Legal Nurse Consultant Certified, Medicare Secondary Payer Professional and Certified Nurse Life Care Planner. Leslie maintains professional affiliations with the National Alliance of Medicare Set Aside Professionals (NAMSAP), American Association of Legal Nurse Consultants (AALNC), International Association of Life Care Planners (IALCP) and International Association of Rehabilitation Professionals (IARP). Leslie is a Board Member of IARP; former chairperson of the Education Committee and current Board Member of NAMSAP as well as former ICHCC (International Commission for Health Care Certification) Commissioner of Medicare Set Aside Allocations. She has also been appointed to the position of adjunct professor of Medicare Set Aside education with the University of Florida. Leslie is currently President of PlanPoint, a national provider of Medicare Set Aside Allocations as well as all other aspects of Medicare Secondary Payer compliance. Leslie's unique and engaging speaking style coupled with her extensive experience in nursing, Life Care Planning and Medicare Secondary Payer compliance has made her a featured speaker at industry conferences nationwide.

The Communications Committee:

The Communication Committee's primary duty is the publication of the NAMSAP News Newsletter once per quarter. We have had a few members drop off the committee and we are looking for some replacements. The Communication Committee will also be working with the Webmaster to help to make the website more user friendly. Any suggestions you have please send them to April Pettengill, Committee Chair at April@alpmedicalconsultants.com

Membership Committee:

In an effort to encourage NAMSAP members to renew, the Membership Committee contacted those members who were had not renewed. Currently, there are there are 492 current NAMSAP memberships. The breakdown is as follows:

Professional Members = 309;
Associate Members = 7;
Partner Professional Members = 22;
Partner Reps = 154.

Education Committee:

The Education Committee is currently working on the 2010 NAMSAP Annual Meeting and Educational Conference, which will be September 29th and 30th, in Washington, DC.

Webinar Sub-committee: Below are the topics in which the Webinar Sub-Committee will be conducting webinars. The plan is to conduct one webinar every 45 days or 5-6 in 2011.

- Legal or case law update, as well as legislative update
- Special Needs Trusts
- Trends in Medicare Set Aside submissions
- Treatment guidelines and updates
- Update on Medicare/Non-Medicare Service Coding

If you are interested in presenting any of these topics please contact Matt Larkin at mlarkin@expereahealthcare.com.

The Legislative and Law Committee:

The committee has been renamed by the BOD to reflect the true purpose and the connection between legislative issues and the courts. All of the committee members are excited to be on the committee and work hard to educate members of the NAMSAP community on legislative and legal developments in Medicare Secondary Payer compliance issues.

We are planning to meeting in the near future and set goals for the committee and start working on our respective areas of expertise. In the coming months, our committee will be responsible for the following items:

- Review current legislative issues that might affect the NAMSAP membership;
- Develop a system of alerting the membership to legislative & and case law challenges;
- Monitor and analyze legal developments related to the Medicare Secondary Payer Act (MSP);
- Monitor federal agencies and contractors responsible for the implementation and enforcement of the MSP; and
- Draft appropriate template letters that members can use to send to legislators or other groups like the MARC in response to particular issues.

The Board of Directors has defined the duties of each of the committees and subcommittees.

In an effort to make your membership meaningful and the most beneficial for you, the board of directors has defined the duties and responsibilities of each committee. The general make up of each committee is explained here broken down by each committee.

Composition and Terms of Office

Each Committee shall be appointed by the President, on the recommendation of the Board of Directors. The Sub-Committee will consist of a Chair, with at least four but no more than eight additional members. The Chair of the Sub-Committee is appointed by the President and ideally would have already served on the Committee for at least one year. Members will be appointed by the Chair for a two year term with the possibility to be re-appointed for additional terms.

Reporting Duties:

The Chair of each committee will provide written monthly reports to the Education Committee Chair and the Board of Directors and will meet with the Board during the Annual Meeting.

Education Committee

Purpose

The Education Committee exists to create, update, and support all NAMSAP educational offerings, including, but not limited to, the MSA program, the recertification program, Webinars, and the education presented at the Annual Meeting and Educational Conference, supported by the NAMSAP National Office. New programs may be proposed by the Education Committee, subject to approval by the Board of Directors.

Duties

The Education Committee will conduct monthly telephonic meetings to:

- Review the progress of the MSA and recertification programs;
- Develop and manage an annual calendar of Webinar educational offerings, including recruiting speakers and sending out notices to the membership, with the support of the National Office;
- Oversee and assist the Annual Meeting Sub-Committee in development of that education program.

At the beginning of each year, the Committee should identify a year-long calendar of educational offerings and work with the National Office to construct an appropriate system of promotional mailings/notices (either physical mailings or broadcast emails) and a follow-up system to those mailings.

Annual Meeting Sub-Committee

Purpose

The Annual Meeting Sub-Committee exists to develop the educational programming for the NAMSAP Annual Meeting and Educational Conference, as well as the social functions, with the support of the staff at the NAMSAP National Office.

Duties

The Annual Meeting Sub-Committee will conduct monthly telephonic meetings to:

- Review progress on the development of the annual program,
- Select venues and composition of social and food events, after proposals are gathered by the National Office, and
- Communicate with the membership on a regular basis, via web site postings and broadcast emails as various elements of the program are finalized.

The Annual Meeting Sub-Committee will coordinate all efforts with the Education Committee. The Sub-Committee will assist in coordinating the on-site requirements for speakers, as well as ensuring their arrivals. The Sub- Committee will finalize the program at least four weeks before the annual meeting, so that it can be submitted for accreditation to the preferred bodies.

Communication Committee

Purpose

The Communications Committee exists to monitor and produce communications strategies to the members about the association's activities, supported by the NAMSAP National Office.

Duties

The Communications Committee will conduct monthly telephonic meetings to:

- Review current communications modes, such as the Web site, electronic newsletters, and broadcast emails,
- Suggest new methods of communication, and
- Produce periodic electronic newsletters.

The Committee will coordinate all efforts with the Executive Offices that will provide support in producing the newsletters, updates to the Website and sending broadcast emails to the membership, or selected sub-sections of the membership, as well as any other ad hoc reports or support as needed.

At the beginning of each year, the Committee should identify a production schedule for the electronic newsletter, identify members of the committee who will take ownership for writing and production of various parts of the newsletter, set up a rotation among the committee members to act as "watchdog" for portions of the Web site in order to keep it updated, and set any other goals that the committee wishes, pending approval of the Board of Directors.

Legislative and Law Committee

Purpose

The Legislative & Law Committee exists to inform the Board and the membership of any upcoming legislation that might affect the Medicare Set-Aside profession and keep updated on the development of case law related to the Medicare Secondary Payer Act (MSP).

Duties

The Legislative & Law Committee will conduct monthly telephonic meetings to:

- Review current legislative issues that might affect the NAMSAP membership;
- Develop a system of alerting the membership to legislative & and case law challenges;
- Monitor and analyze legal developments related to the Medicare Secondary Payer Act (MSP);
- Monitor federal agencies and contractors responsible for the implementation and enforcement of the MSP; and
- Draft appropriate template letters that members can use to send to legislators or other groups like the MARC in response to particular issues.

Membership Committee

Purpose

The Membership Committee exists to encourage the recruitment and retention of members throughout the United States, supported by the NAMSAP National Office.

Duties

The Membership Committee will conduct monthly telephonic meetings to:

- Review current membership issues,
- Update on recruitment of new member efforts, and
- Updated on strategies on minimizing and/or returning non-renewals.

The Committee will coordinate all efforts with the Executive Offices that will provide monthly membership reports and any other ad hoc reports or support as needed. Each Committee Member should review these reports and work the National Office to contact non-renewed members.

At the beginning of each year, the Committee should identify related organizations to target for membership recruitment and work with the National Office to construct an appropriate system of targeting mailings (either physical mailings or broadcast emails) and a follow-up system to those mailings.

Webinar Sub-Committee

Purpose

The Webinar Sub-Committee exists to develop and execute a schedule of educational webinars by coordinating topics and presentations with presenters, supported by the NAMSAP National Office.

Duties

The Webinar Sub-Committee will conduct monthly telephonic meetings to:

- Plan and coordinate educational webinar topics and their presenter(s),
- Update the existing schedule and past presentations, and
- Update strategies for boosting attendance to and publicizing the educational webinars.

The Webinar Sub-Committee will coordinate all efforts with the Education Committee. At the beginning of each year, the Sub-Committee should identify a year-long calendar of educational offerings and work with the National Office to construct an appropriate system of promotional mailings/notices (either physical mailings or broadcast emails) and a follow-up system to those mailings.

Breaking News From the Drug Front!

Allergan's **Botox®** (onabotulinumtoxinA) is approved by the U.S. Food and Drug Administration (FDA) to prevent headaches in adults with chronic migraine. Patients with chronic migraine have a history of migraine and suffer from headaches on 15 or more days per month with headaches lasting for four hours a day or longer. To prevent chronic migraine, trained medical specialists administer 31 injections of Botox neurotoxin into seven specific head and neck sites for a total of 155U per treatment session. The approval of Botox for this expanded indication is based on the results of two, Phase III PREEMPT studies in nearly 1,400 adults with chronic migraine. At the week 24 primary endpoint, the studies showed that patients treated with Botox experienced a significant decrease in the frequency of headache days compared to patients treated with placebo (7.8 and 9.2 fewer days for the Botox group, versus 6.4 and 6.9 days for the placebo group).

Botox, a neuromuscular blocker that is injected directly into affected muscles, has been on the market since 1989. It also approved to treat cervical dystonia (neck muscle spasms and head tilting), severe axillary hyperhidrosis (underarm sweating), blepharospasm (eyelid contractions), strabismus (crossed eyes), and upper limb spasticity. Full prescribing information can be found at: www.botox.com.

Cymbalta Approved for Chronic Musculoskeletal Pain

Lilly's Cymbalta® (duloxetine hydrochloride) delayed-release capsules received a new indication for the management of chronic musculoskeletal pain. For this indication, the recommended dose is 60 mg once daily. Dosing may be started at 30 mg once daily for one week to allow patients to adjust to the medication, then increasing to 60 mg once daily. Cymbalta also has indications for treating major depressive disorder, general anxiety disorder, diabetic peripheral neuropathic pain and fibromyalgia. Because of its multiple indications, Cymbalta may be used for treating several aspects of work-related injuries. The updated prescribing information can be found at: www.cymbalta.com.

Darvocet, Darvon, and Propoxyphene To Be Removed from the Market

The FDA notified healthcare professionals that Xanodyne Pharmaceuticals has agreed to withdraw Propoxyphene, an opioid pain reliever used to treat mild to moderate pain, from the U.S. market at the request of the FDA, due to new data showing that the drug can cause serious toxicity to the heart, even when used at therapeutic doses. The FDA concluded that the safety risks of Propoxyphene outweigh its benefits for pain relief at recommended doses. The FDA requested that the generic manufacturers of Propoxyphene-containing products remove their products as well.

Acetaminophen Doses in Pain Medication:

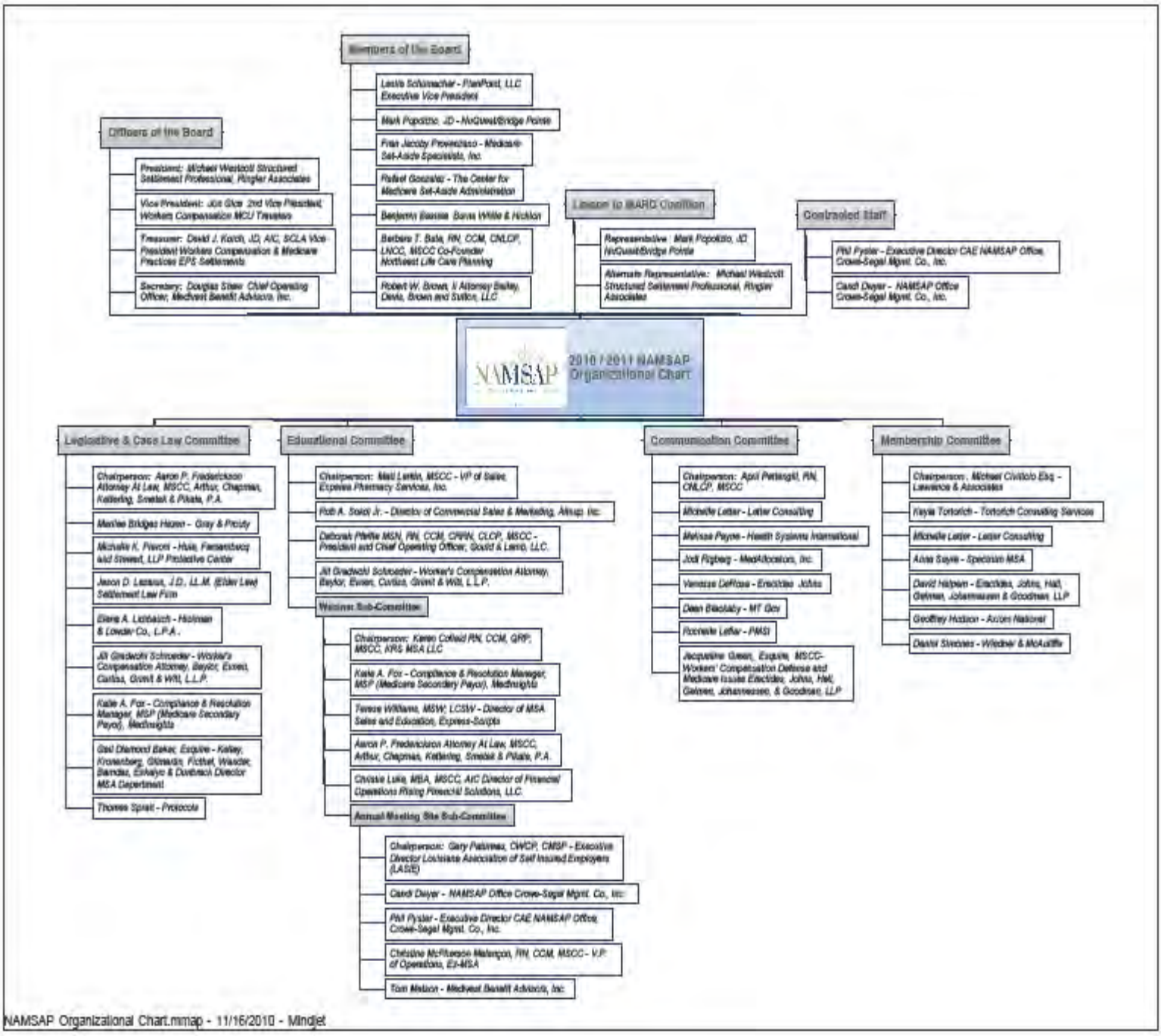
The FDA is requesting manufacturers of acetaminophen combination pain medications to limit the acetaminophen content to 325 mg per dosage unit. Manufacturers have 3 years to comply. Acetaminophen (also known as APAP) is combined with Hydrocodone and goes by various brand names such as Lortab®, Norco®, Vicodin®, Xodol®, and more. When combined with Oxycodone it goes by brand names such as Percocet®, Roxicet®, Tylox® and more. Some of these products contain as much as 750 mg of acetaminophen per tablet or capsule. The FDA's concern is based on acetaminophen's capacity to cause liver damage when used at high doses. It is currently recommended that acetaminophen intake be limited to 4000 mg daily.

This is a reaction to the statistic that over 50% of all cases of acetaminophen related liver failures are attributed to acetaminophen containing prescription drugs. The current announcement appears to be a compromise from the previous recommendation to eliminate the acetaminophen combination pain medications (i.e. Lortab, Percocet®) from the market altogether. This compromise may reduce the number of liver failure attributed to acetaminophen containing pain medication but it doesn't address the real problem. The real problem may be closer related to the opioids component of the medication. Limiting the amount of acetaminophen will not limit the use of opioids. It may actually increase it.

A patient that is currently on a product such as Lorcet® (10 mg Hydrocodone/650 mg acetaminophen) should be advised to take no more than 6 tablets a day (3900 mg daily acetaminophen). With the new regulation, the manufacturer has to limit the dosage of acetaminophen to 325 mg but the Hydrocodone dosage can remain the same. The patient can take up to 12 tablets a day of this new dosage thereby doubling the Hydrocodone intake while staying under the daily maximum dosage of acetaminophen.

NAMSAP Organizational Chart:

The chart below shows the Officers, members of the board, and the committees.



Sponsorship and Partner Information

Platinum Sponsors

Medivest professionally administers medical custodial accounts, provides premier MSA Allocations and other innovative solutions to preserve, protect and stretch settlement dollars in workers' compensation and liability disputes. www.medivest.com

Gold Sponsors:
Experea Healthcare
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Silver Sponsors:
The Center for Lien Resolution
The Center for Medicare Set-Aside Administration
The Center for Special Needs Trust
Concierge Medical and Risk Consultants
Corvel
KP Underwriting, LLC
LASIE
NuQuest/Bridge Pointe
PMSI Settlement Solutions
Protocols, LLC
Rising Medical Solutions

National Alliance of Medicare Set-Aside Professionals

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The mission of NAMSAP is to foster the highest standards of integrity and competence among Medicare Set-Aside Professionals and those they serve.

NAMSAP is the only non-profit association exclusively addressing the issues and challenges of the Medicare Secondary Payer Statute and its impact on workers' compensation and liability settlements. Through the voluntary efforts of our members, NAMSAP is a forum for the exchange of ideas and is a leading resource for information and news in this constantly evolving area of practice. The collective knowledge of our members and NAMSAP's resources will provide you with the ingredients essential to your success!

Announcements

Call for Articles:
The Communications Committee would like to extend an offering to all interested authors. We are currently receiving articles for the 3rd quarter newsletter to be published in July. We currently have three categories for articles: Legal, Legislative, and Medical. If you are interested in contributing to one of these categories, or have an idea for a new category, please contact April Pettengill, Chairperson for the Communications Committee. You can contact April by email at april@alpmedicalconsultants.com, or call her at (802) 849-2956.

"Letters to the Editor":
In addition to contributing authors, every interested member is invited to send their "Letters to the Editor", or provide comments on articles that are published in the newsletter.

CMS Updates:

One of the primary goals of the Communications Committee is to provide updates on each CMS regional office. If you have an experience with a particular regional office of CMS, please submit those to April so we can share those with other members of NAMSAP.