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Florida Medical Directors Association

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Winter 2005

Progress Report

2002 APEX AWARDS FOR PUBLICATION EXCELLENCE

Serving Physicians Practicing in Florida's Postacute Care Continuum

2004 A Banner Year for FMDA

The Florida Medical Directors Association (FMDA) had a very active and successful year.

Active in terms of its support of issues important to its members and successful in achieving greater industry recognition and in hosting its largest Annual Program ever.

Dr. Victor Gambone, FMDA president, represented FMDA at a number of events hosted by the Florida Medical Association for its Specialty Society affiliates, of which FMDA is one. In addition, Past President Dr. Morris Kutner served on the board of directors of the American Medical Directors Association.

For the first time, FMDA financially supported other not-for-profits including Citizens for a Fair Share, Florida Medical Association's effort to promote tort reform, and Florida Forum, Florida Health Care Association's grassroots campaign to educate family members of patients in Florida nursing homes on the challenges facing the industry and how they impact resident care issues.

Chronology of Events

February: FMDA held its 4th Annual Meeting of the Industry Advisory Board in Tampa.

March: A strong contingent from Florida attended AMDA's Annual Symposium in Phoenix, Arizona.

FMDA was represented at the trade show with a display along with other AMDA state chapters. In addition, its executive director was invited to speak about its Annual Program to AMDA's state chapter presidents, leaders and staff.

April: Hugh Thomas, DO, CMD, moderated a symposium on April 17, at the Hard Rock Hotel in Orlando. Speakers included Walter Martinez, MD, who presented, "An Update on the Management of Alzheimer's Disease," and Morton Morris, DO, JD, who discussed, "Legal Issues in the Nursing Home." Support for this central Florida long-term care symposium was provided by Pfizer.

June: FMDA hosted its first mid-year CME program, titled, "Strategies for Successful Medical Direction in Long-Term Care." The event was presented jointly by FMDA and AMDA, and supported by EverCare. More than 35 physicians, nurse practitioners, and nurses heard from Dr. Howard Tuch on "The Role of Medical Directors in Developing Best Care Practices" and health care attorney Karen Goldsmith with, "A Primer on Liability, Risk Management, and Asset Protection for Physicians." That evening, FMDA hosted a well-attended Town Meeting with the support of AstraZeneca.

• FMDA exhibited at the sixth annual U.S. Geriatric and Long-Term Care Congress in Orlando.

• FMDA exhibited at the Annual Trade Show of Florida Health Care Association in Boca Raton.

July: FMDA exhibited at the Annual Trade Show of Florida Geriatrics Society in Naples

August: FMDA exhibited at the Annual Trade Show of Florida Association of Homes for the Aging in Orlando

October: Just a few weeks after the "Four Hurricanes" blindsided Florida, FMDA hosted its 2004 Annual Program, "Best Practices in Collaborative LTC." Despite mother nature, FMDA enjoyed its best attendance and largest trade show, as more than 450 participants convened at Disney's Contemporary Resort. Another meeting highlight was that FMDA held its first-ever poster presentations.

All in all, 2004 has been a very productive year for the Florida Medical Directors Association.

INSIDE

See 2004 Annual Program Highlights on pages 7–10

President's Letter

Now that our Annual Program has come and gone, I'd just like to thank our amazing speakers who, without a doubt, were key to the success of the educational sessions.

On behalf of Program Director Dr. Carl Suchar, 2004 CME/ Education Committee Chair Dr. Jeffrey Behrens, and the entire committee, please join us in thanking **Susan Acker**, MSN, PhD, supervisor of the Health Standards & Quality Unit, Florida Agency for Health Care Administration; **Lawrence Brandt**, MD, chief of gastroenterology and professor of medicine and surgery, Albert Einstein College of Medicine, New York City; **Ross Brickley**, RPh, MBA, CGP, president, American Society of Consultant Pharmacists; **Jorge C. Busse**, MD, medical director, BMA Miami Metro Dialysis Center, and clinical assistant professor of medicine, University of Miami School of Medicine; **Dan Cannone**, DO, CMD, clinical assistant professor of geriatrics, Ohio University College of Osteopathic Medicine, and president, Consortium Concepts; **Josepha A. Cheong**, MD, associate professor and chief, Geriatric Psychiatry, University of Florida, Gainesville; **Mary Ellen Early**, MSW, senior vice president of Public Policy, Florida Association of Homes for the Aging; **Malcolm Fraser**, MD, CMD, chair, FMDA's Industry Advisory Board; **Brian Kahan**, RPh, JD, Kahan & Associates, Boca Raton, and past-president, American Society of Consultant Pharmacists; **Rich Marasco**, BS Pharm, FASCP, CGP, president, Florida Chapter of the American Society of Consultant Pharmacists; **James R. McCormick**, MD, professor of medicine, Division of Pulmonary and Critical Care Medicine, University of Kentucky Medical Center, Lexington; **Richard Powers**, MD, associate professor of pathology, Division of Neuropathology, University of Alabama at Birmingham; **Brian Robare**, CNHA, CALA, nursing home administrator at The Estates at Carpenters in Lakeland, and president, Florida Chapter of the American College of Health Care Administrators; **Mary Stegman**, MD, medical director, Hope Hospice and Palliative Care, Fort Myers; **Daniel Swagerty Jr.**, MPH, MD, CMD, president, American Medical Directors Association; **Eric Tangalos**, MD, CMD, professor of medicine and chair of primary care internal medicine, Mayo Clinic College of Medicine in Rochester, Minn., and past-president of the American Medical Directors Association; and **Jacqueline Vance**, RNC, CDONA/LTC, director of clinical affairs, American Medical Directors Association.

FMDA
Gratefully Acknowledges. . .

Long-Term Care Group

JANSSEN ORTHO-McNEIL LIFESCAN

Dedicated support for senior America

. . . for its support of

Progress Report

For a pictorial display from the Annual Program, please go to pages 8–9.

In other news, I represented FMDA at the FMA Specialty Society Section Meeting in Tampa on November 5, 2004. The report from FMA President Dennis Agliano summarizes well the results of FMDA's support of FMA's effort to achieve tort reform.

To echo his message, I want to let everyone know how low the opposition went. Everyone saw the deceptive television advertisements but even worse, it was reported at multiple polling facilities across the state that supporters of the trial bar were dressed in white coats holding signs "Vote NO on Amendment 3." Despite our success, we still have a long way to go before professional liability insurance premiums improve. Some say 3–5 years but

Continued on page 5

E-Letter to the Editor

I am sending you a commentary I wrote for *The Washington Times* to make our members aware of the serious problem with imported drugs into the US. . . and the harmful — even fatal — effect this system has already had on many persons receiving such drugs. There is no way we can afford the manpower and money to do a satisfactory job to prevent fraud, counterfeiting, and alteration of drug contents in order to justify such importation. The general public has no concept of this, and I urge you to do all you can to spread the word to prevent your friends and family from potential harm if one participates in this scheme. If this bill passes in Congress it will open more doors for much greater importation of potentially harmful substances. Thanks for your attention.

Bob Windom, MD

Wishful Thinking

By Robert E. Windom
July 8, 2004, *The Washington Times*

Edward Joseph Flynn, the legendary Democratic boss of the Bronx and political counselor to FDR, had a favorite piece of advice for anyone who cared to listen, "Don't confuse wishes with facts."

Unfortunately, the sponsors of legislation introduced by Sen. Edward Kennedy and Byron Dorgan to permit drug importation have chosen to ignore this advice. They try to use wishful thinking to convince themselves and members of the American public that opening America's borders to imported drugs is an instant and risk-free method to lower the cost of prescription drugs.

The bill would allow the importation of drugs from 20 different countries, including drugs not approved by the Food and Drug Administration, into the United States, while offering vague promises that money will somehow be found to beef up that agency for the mammoth job of policing the quality and content of drugs from around the world.

Legalizing drug importation won't work. That's the opinion of virtually every public health expert in the United States, including the FDA itself. Even Mr. Ted Kennedy held that position until the Medicare drug benefit passed. Indeed, until a few years ago that opinion also was shared by Dr. David Kessler, the former FDA commissioner who recently elected to provide a series of accommodating answers to a series of orchestrated questions from Mr. Kennedy. The resulting Q&A has become a publicly circulated rationale for the patently unworkable Kennedy-Dorgan bill. The bill promises money that won't be forthcoming for protection that won't be possible. Despite the best intentions of its sponsors, the bill would allow foreign drugs that are substandard, counterfeit or, God forbid, intentionally contaminated by terrorists to flood the United States as legal imports.

As a physician and former assistant secretary for health under Ronald Reagan, I feel obliged to put at least the major fallacies in that Q&A under the microscope of reality. According to the authors, a capped one percent user fee on the value of imported drugs would give the FDA the financial resources it needs to police drug imports. That one percent fee is pulled from thin air, since no one knows what the value of legally imported drugs would be, nor does anyone know how it will be collected. We do know from recent FDA testimony that the cost of policing drug imports would run into the "hundreds of millions of dollars," so there is no guarantee that the user fees would even come close to covering the cost. Even if money were no object, FDA officials have been candid about saying that they would be hard-pressed to guarantee the safety and purity of every imported prescription drug, as they do with our domestic drug supply. The FDA will have no power to hold foreign exporters accountable for the drugs they send to the United States, and consumers might have no recourse if they were injured. Furthermore, this legislation doesn't require, but instead presumes, that imported drugs would be FDA-approved. In fact, the legislation permits the importation of drugs that have not been approved by the FDA, and indeed there is nothing in this legislation that would prohibit the importation of drugs that are not even approved by health authorities in their country of origin. Additionally, many governments do not have the ability to ensure the safety of drugs developed in their own countries and have no intention to do so. To date, many persons have had serious and often fatal reactions to these imported drugs. Some preparations have had no active ingredient, and others have had additional ingredients not intended to be in the product.

With regard to the effect of this proposal on America's world-leading pharmaceutical and biotech R&D enterprise, there is no question that the importation of drugs will have a crippling effect on research sponsored by industry that far outweighs that provided by the federal government. As a final reality check on the Kennedy-Dorgan legislation, though, I would just point to the timing. It would go into effect 90 days after passage, an impossibly short time for the FDA to recruit the army of inspectors and technicians needed to even attempt to police drug imports around the world. On such a high-stakes issue involving the safety of our drug supply and the well-being of our citizens, we cannot afford to confuse wishes with facts.

Dr. Robert E. Windom was assistant secretary for health in the Department of Health and Human Services during the Reagan administration. He is currently the Regulatory Affairs Advisor to FMDA and an ex-officio member of the Board of Directors.

Documenting Anticipated Negative Resident Outcomes

Robin A. Bleier, RN, CDONA/LTC, CLC, LHRM, RB Health Partners, Inc.
2nd Vice President, Florida Association Directors of Nursing Administration/LTC

The documentation of anticipated negative outcomes is an exceptionally important task for health care professionals. Although this is very important in acute and home health care settings, those of us in long-term care should view this as critical. Due to the highly litigious environment we all live and work in, rules and regulations, the increased awareness of the general public, and due to Florida SNFs' new risk management requirements from SB1202, excellent documentation is increasingly important. Even with the best of care, certain negative outcomes may occur. However, it is essential that a proactive documentation paper trail be in place concurrent with a proactive clinical process for minimizing risks to the patients/residents we serve, and our facilities. To do this correctly, this takes all members of the team, including physicians and physician extenders.

An excellent example of this is something that we all work with: pressure ulcers. This can be found in pressure ulcer requirements/regulations (F314). Contained in these are guidelines to the surveyors that include clinical reasons why a pressure sore might be termed "unavoidable." These clinical reasons include diseases, conditions, treatments, and laboratory values, which could negatively impact healing and/or result in actual pressure ulcer formation.

Then, why is it that even with such provisions, facilities, staff, and physicians frequently find themselves receiving citations and/or involved in litigation in conjunction with "unavoidable" pressure ulcers? The answer to this is really quite simple. The team of the director of nursing services, nurse managers, charge nurses, therapists, dietary staff, and CNAs, lead by the physician, do not adequately document that the development of the pressure ulcer(s) was:

(a) Unavoidable (prior to development or in relation to an existing sore not healing in the "normal" or expected fashion);

(b) What clinical conditions result in the sore being unavoidable (again prior to);

(c) What proactive aggressive steps were taken to prevent the sore from developing—even though the expectation was that the sore could and/or would occur?; and

(d) How, even with the best of care, and all standards met, the ulcer occurred, and what may yet happen (additional ulcers, infection, maybe even death).

Frequently, during record review it can be found that much of the data necessary to classify an ulcer as "unavoidable" is documented by various members of the health care team. However, the problem often is that no one has gathered all of the pieces together so that the reader (staff, surveyors, attorneys, etc.) can easily extrapolate the data. The facility is responsible for demonstrating proper assessments of the residents and their risk factors through risk assessments.

It remains a fact that when negative clinical outcomes occur it does not necessarily mean the practitioners, caregivers, or facility did anything wrong.

In conclusion, it is imperative that we all understand and ensure that an aggressive approach is developed, implemented, and documented to treat patients/residents with potential for — or actual — pressure ulcer formation. It is also critical to ensure that wounds are properly diagnosed, especially when it is not a pressure ulcer but might have characteristics that could accidentally result in inappropriate labeling as one.

It remains a fact that when negative clinical outcomes occur it does not necessarily mean the practitioners, caregivers, or facility did anything wrong. Less than optimum outcomes do happen but, especially when anticipated, it is essential that this be understood in clinical documentation.

Remember, it is easier and less expensive to stay out of trouble than it is to get out of trouble.

Robin A. Bleier is a licensed health care risk manger and operational consultant in long-term care. For more information about Ms. Bleier and/or her company's services, you can e-mail her at robinbleier@yahoo.com or call (727) 744-2021.

Interpretive Guidelines Still in Development

Early in 2004, the Centers for Medicare & Medicaid Services (CMS) made public a draft of proposed changes to the interpretive guidelines of long-term care (LTC) facilities for two key requirements: medical director (F501) and quality assurance (F520 and F521). The stated goal of the draft was to update the guidance to surveyors in making appropriate determinations of severity for deficiencies cited under these tags. A copy of the original draft is available from the FMDA Web site at www.fmda.org/advocacy.html.

Working with a panel of expert clinicians and surveyors, the draft was developed in response to studies conducted by the Institute of Medicine and the Office of the Inspector General. These studies seemed to suggest that what was needed was a clarification of the medical director role and whether greater authority should be placed on this vital LTC position.

FMDA's view when this was announced was that if government and industry insiders really are concerned about enhancing the role of medical direction in LTC, attention must also be given to the existing challenges facing physicians before adding new requirements that may be unrealistic or impossible to implement simply because there are not enough physicians who can live with the additional barriers placed in front of them.

We're not saying these new guidelines aren't needed, appropriate, or welcome. But, there are physicians who love their work in nursing homes but cannot find affordable liability insurance. There are nursing homes that are unwilling to provide errors-and omissions insurance coverage to medical directors for their administrative duties. There are Medicare and Medicaid reimbursement rates that discourage physicians from practicing in nursing homes. There are often unrealistic expectations of medical directors partly based on the fact that most are part-time positions. There are savvy trial lawyers who anticipate the introduction of new nursing home regulations as if they were a new business opportunity. Also, as far as administration and paper trails go, there are probably no records that physicians keep — and that doing the work and keeping track of what is done would be a problem because medical directors are not provided with secretaries to perform such tasks.

While many might agree with the intent of the proposed guidelines, a careful review of the draft language reveals that serious considerations need to be given to the final form and language these guidelines might take. To highlight this need, you may wish to review the formal comments made by the American Medical Directors Association (AMDA), which is the national professional association of 8,300 members who practice as medical directors and attending physicians in nursing homes and other long-term care facilities. FMDA is the state affiliate of AMDA.

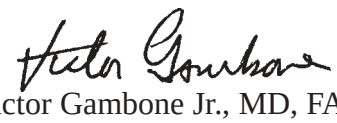
As a follow-up, Polly Weaver, chief, Bureau of Field Operations, Florida Agency for Health Care Administration, advised FMDA at the end of November 2004 that, "Feedback from CMS is basically status quo... CMS in Baltimore has confirmed that 'the panel of national experts' reconvened in August to review the public comments regarding the proposed changes. Currently, the panel's revisions are undergoing further internal review at CMS. They do not expect the final release this year. It could be in the spring of 2005 before this is released.

"Additionally, CMS did indicate that the next Program Issuance to be released will be the one relative to urinary tract infections" (F315). This change is likely to be released in final within the next 60 days," Weaver added.

PRESIDENT'S LETTER
— Continued from page 2

that is yet to be seen. The impact of Amendments 7 and 8 remain, unclear. Both amendments require clarification by the legislature before implementation. The "three strikes you're out" Amendment 8 does not apply to court settlements. It does apply to settlements with the Board of Medicine, final court judgments, and final judgments in arbitration proceedings.

As these and other issues unravel over the months, we will keep you advised of the outcomes as they unfold. All the best for the New Year!



Victor Gambone Jr., MD, FAFP, CMD

AMDA and ASCP Announce Joint Position

The Beers List of Potentially Inappropriate Medications in Older Adults is Reviewed

Background

Publication of "Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults" (1) again raises many of the same issues about the list's development and uses — intended and unintentional — since its original publication in 1991 and subsequent 1997 revision (2,3).

The list was adopted nearly verbatim in the CMS surveyor guidance for Federal Tags F329 and 429, in effect codifying it with the power of federal regulation, although Dr. Beers himself has denied that this was ever the intention of publishing the list. AMDA and other stakeholders have previously questioned the wisdom of including any "checklist" of medications as part of regulations (4,5).

The 2003 update sought to improve the list by focusing on drugs and drug-disease combinations in particular:

1. Addressing new products or product information;
2. Changing severity ratings; and
3. Identifying new conditions.

The results: 11 medications/medication classes were eliminated, four were modified, 25 new medications/medication classes independent of diagnoses and 19 medications/medication classes considering diagnoses were added as potentially inappropriate.

A serious reservation about the original list and its latest revision remains: The list is not based on an evidence-based methodology. Instead, the authors again reviewed the geriatric pharmacology literature to develop statements concerning clinical prescribing for older adults. Then a small panel of 12 experts reviewed these statements and rendered their opinions about the appropriateness of prescribing under the described clinical scenarios. They addressed whether a medication/medication class "should generally be avoided in persons 65 years or older because they are either ineffective or they pose unnecessarily high risk for older persons and a safer alternative is available," and "medications that should not be used in older persons known to have specific medical conditions"(1). There were no exceptions for palliative care or cases of severe chronic disease. While this methodology offers useful general guidelines for inappropriate prescribing, its lack of a recognized, evidence-based methodology limits its applicability.

While the list clearly addresses *potential* problematic prescribing for older adults and has been used constructively by many, persons without adequate clinical expertise may use the list inappropriately as an absolute prohibition against prescribing certain medications. Ironically, this approach can potentially cause errors that would undermine the intent of the surveyor guidance that includes the list.

ASCP and AMDA believe:

• The Beers list is a helpful general guide regarding potentially inappropriate use of medications for older adults, but it must be used in conjunction with a patient-centered care process.

• Ultimately, decisions about medication prescribing must be clinically based and consider the patient's total clinical picture, including the entire medication regimen, history of medication use, comorbidities, functional status, and prognosis.

• Checklist approaches should not substitute for the necessary steps in the care process for appropriate prescribing.

• The Beers list should be used as a general guide for assessing the potential inappropriateness of medications, not as an isolated justification for any recommendation, including discontinuation of a medication.

ASCP and AMDA endorse the following principles for appropriate medication prescribing and management for older adults:

Decisions about prescriptions must be (4):

1. Evidence-based;
2. Made in the context of the patient's entire medical and psychosocial condition, prognosis, quality of life, and patient's or surrogate's wishes;
3. Made in conjunction with a qualified prescriber with first-person knowledge of the individual patient's complete clinical profile and history, not withstanding emergency medical coverage;
4. Made in the context that overuse, underuse, and inappropriate use of medications are equally important quality-of-care concerns; and
5. Made without improper use or disclosure of confidential, individual protected medical information

Continued on next page

that is not necessary for direct patient care.

In addition, medication management in older adults should include these steps (5):

1. Identifying the presence and nature of the resident's symptom, disease, condition, impairment, or risk;
2. Assessing the resident to identify the cause of the problem, or document why an assessment was not performed;
3. Gathering and assessing information about the resident's current medications and treatments as well as responses and adverse reactions to previous medications and treatments;
4. Identifying and documenting the reason(s) why the disease, condition, symptom, or impairment needs to be treated or why it is decided not to provide treatment;
5. Choosing an appropriate medication or modifying an existing drug regimen;
6. Identifying and documenting the objective(s) of treatment;
7. Considering and documenting the benefits and risks of treatment;
8. Considering and documenting possible drug interactions;
9. Ordering the selected agent;
10. Ordering appropriate precautions in administering the drug, including instructions for resident monitoring;
11. Assessing and documenting the resident's status during or at the end of treatment;
12. Assessing the resident for possible ADRs; and
13. Modifying the medication regimen as indicated by its effectiveness or by the presence of complications.

In conclusion, practitioners who understand the principles underlying the proper prescribing and management of medications in nursing facilities should be better able to apply these principles in providing patient-centered care. Consultant pharmacists and medical directors should collaborate with facility staff to ensure appropriate interpretation and use of any guidelines on medication use, including those from CMS.

References:

1. Fick DM, Cooper, JW, Wade WE, et al. Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *Arch Intern Med* 163:2716-2724. December 2003.
2. Beers MH, et al. Explicit Criteria for Determining Inappropriate Medication Use in Nursing Home Residents. *Arch Intern Med* 151:1825-1832. September 1991.
3. Beers MH. Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly. *Arch Intern Med* 157:1531-1536. July 28,1997.
4. American Medical Directors Association. Pharmacy Physicians Relations and Appropriate Prescribing for LTC Patients. Columbia, MD: AMDA 2003.
5. American Medical Directors Association. Multidisciplinary Medication Management Tool Kit. Chapter 11. Pages 74-78. Columbia, MD: AMDA 2003.

* Footnote : *American Medical Directors Association. AMDA and ASCP Joint Position Statement on the Beers List of Potentially Inappropriate Medications in Older Adults. Columbia, MD: American Medical Directors Association, 2004.*

2004 Annual Trade Show

The Florida Medical Directors Association gratefully acknowledges the support of these exhibitors:

Abbott Laboratories, Access Home Health, Amgen, AstraZeneca, Aventis Pharmaceuticals, Bayer Pharmaceuticals, Biovail Pharmaceuticals, Boehringer Ingelheim, Bristol-Myers Squibb, Cunningham Group, Eli Lilly & Company, Evercare, FFF Enterprises, Florida Chapter of the American Society of Consultant Pharmacists, Florida Geriatrics Society, Forest Pharmaceuticals, GlaxoSmithKline, Health Care Answering Services, Health Source Associates, Healthpoint, Janssen Long-Term Care Group & ElderCare, Kyphon, Merck & Company, Novartis Pharmaceuticals, Organon Pharmaceuticals, Ortho Biotech, Ortho-McNeil, Pfizer, Sanofi-Synthelabo, Specialty Medical Products Inc., TAP Pharmaceuticals, Teva Neuroscience, Vitas Innovative Hospice Care, Vohra Health Services, Watson Pharma, and Wyeth

Pictorial Review of 2004 Annual Program

Saturday morning panelists (from left):
AHCA's Susan Acker, ASCP President Ross Brickley,
AMDA President Dr. Dan Swagerty, and Dr. Richard Powers

ASCP past-president Brian Kahan,
attorney and pharmacist

Program Director Dr. Carl Suchar (left) introduces Pat Preston.

Industry Advisory Board (IAB) honors outgoing co-chair
Sam Daniel (holding plaque): (from left) Dr. John Potomski,
Dr. Victor Gambone, IAB co-chair Dave Reis, IAB co-chair
Dr. Malcolm Fraser, Sam Daniel, and Dr. Carl Suchar

Presenter Dr. Dan Cannone

Dr. Lawrence Brandt

Pictorial Review of 2004 Annual Program

Dr. Josepha Cheong completes her presentation as moderator and FMDA President Dr. Victor Gambone, looks on.

FL-ASCP President-elect Toni Harrison (from left), Florida Geriatric Society's immediate past president Dr. Donna Jacobi, and FMDA's Dr. Malcolm Fraser

Lisbeth Schwebke, PharmD, first to take advantage of early registration for 2005, submits registration form to Malcolm Fraser, co-chair, FMDA Industry Advisory Board

Dr. Eric Tangalos, AMDA past-president, answers questions during his lecture.

Moderator Joan Burritt (left) introduces speakers Dr. Mary Stegman and Rich Marasco.

Poster presenter Barbara Phillips (center) with Poster Committee reviewers Dr. Nashuara Pandya and Dr. Malcolm Fraser.

Thank You!

FMDA wishes to thank the following organizations for providing support of our educational sessions for the 2004 Annual Program:

Industry-supported symposiums made possible by unrestricted educational grants from
Ortho-McNeil Pharmaceutical
Amgen
Boehringer Ingelheim

Programs funded by educational grants from
AstraZeneca
Creative Educational Concepts Foundation
Eli Lilly & Company
TAP Pharmaceutical

Saturday Morning Panel discussion supported by ***Pfizer***

Administrator's breakout session sponsored by the
Florida Chapter of the American College of Health Care Administrators

FMDA wishes to thank the following organizations for providing support of the 2004 Annual Program:

Abbott Laboratories
Name Badge Holders
Welcome Reception & Entertainment
FMDA Board Meeting

Biovail
Saturday Afternoon Coffee Break

Boehringer Ingelheim
Tote Bags
Sunday's Continental Breakfast

Forest Laboratories
Sunday's Coffee Break

Teva Neuroscience
Continental Breakfast in Exhibit Hall

Novartis
President's Wine & Cheese Reception

Organon
Sunday's Post-conference FMDA Meetings

FMDA wishes to thank the following companies for their support throughout 2004:

Forest Laboratories *— Town Meeting in West Palm Beach*
AstraZeneca *— Town Meeting in Saint Petersburg*
Amgen — www.fmda.org *Web site sponsor*
Janssen LTC Group and Eldercare — Progress Report *newsletter*
Janssen LTC Group and Eldercare *— FMDA E-mail Newsclips*

Proposed Changes to the State Operations Manual for Pharmacy Services and Unnecessary Drugs Section

On Oct. 15, 2004, the Centers for Medicare & Medicaid Services (CMS) released proposed changes to the nursing facility State Operations Manual (SOM). These changes relate to the Pharmacy Services and Unnecessary Drugs sections of the SOM. These are the first substantive changes to the SOM since 1999 regarding these sections of the manual.

A major change with these proposed guidelines is the introduction of a systematic approach to medication use. The care process (assessment, diagnosis, treatment, and monitoring) and the medication-related problem framework (indication, effectiveness, safety) are both described and medication issues are placed into these frameworks. Existing medication guidelines have generally been reorganized, some have been deleted, and some new ones have been added.

Because of the length and complexity of this document, CMS is providing a 90-day comment period. Comments to CMS on these proposed changes were due by Jan. 14, 2005.

General Comments:

This is an excerpt of comments made by an AMDA member that we thought was relevant to this discussion.

"Would like to set up a meeting to look at our current processes for coordination of pharmacy services in facilities. What we receive regarding prospective, ongoing, and retrospective DRR is not always coordinated with myself, medical director, in my facilities. The current and draft documents of the SOM ask that the consultant pharmacist make aware to the DON and the medical director DRR issues. I want to be notified separately, not through nursing. I need the communication to be timely, easy to understand, clinically relevant, and simple to respond to and comply with to aide in our team effort to care for the patient.

"I recently cared for a nursing home patient who was on Amiodarone 400 tid x 2 weeks before I was able to ascertain that this was the case. Pt c/o nausea, when looking at the admit orders it was written for 400 qd. It wasn't until I went to the MAR that I discovered the error. This came from the pharmacy — filled as ordered.

"If they sent a note I didn't receive one and no call was ever made to the physician directly (me). I take responsibility for not looking at the MAR sooner, but this is supposed to be a team effort. I admit and would welcome the help. Also this is a nursing failure as they should be familiar with standard doses and question something like this dose.

"I'm sick of all the turf battles, and want things to be more patient-focused. It seems all are talking the talk, but not realizing any real consistent patient benefit."

"We also get long pages of documents with admission orders that list every interaction known to humankind. This is not helpful. What we need is clinically relevant recommendations based on individual patient characteristics being considered. A request for dosage reduction based on CrCl, which pharmacy does not do for us, would be appropriate and beneficial. I want to work together, but need to see some effort from pharmacy to be team players in the DRR process and not just regulatory compliance paper pushers. I know how you relate to this personally and feel much better about the pharmacy; still I am not sure pharmacy leadership understands or is aware of what is going on in day-to-day operations.

"The draft does mention that closer monitoring on DRR for short-stay patients is warranted; although the language is vague, the spirit of the comments is evident and appropriate for quality patient care. We need to work on this — as it is a much overlooked population in our facilities and from a clinical standpoint a population that could benefit most from a DRR!

"I'm sick of all the turf battles, and want things to be more patient-focused. It seems all are talking the talk, but not realizing any real consistent patient benefit."

CMS Online Manual System

Program instructions are day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. They are used by CMS program components, contractors, and state survey agencies to administer CMS programs. For many others, they are a good source of technical and professional information about the Medicare and Medicaid programs.

CMS manuals are currently undergoing a transformation. As we update the manual instructions, we move the updated material into the new Internet-only manuals and eliminate the corresponding material from the outgoing paper-based manuals. We will continue this phase-out/phase-in process until all manual instructions are included in the Internet-only manuals. In the meantime, you should check both sets of manuals for current policy and procedures.

Providers are encouraged to visit an ancillary site, *The CMS Provider Update*, for a more customized presentation of transmittals, as well as information on regulations.

For an opportunity to purchase our paper-based manuals, please visit our *Availability of Medicare & Medicaid Manuals* (www.cms.hhs.gov/manuals/) page.

Medicare to Pay Hospitals More for Overnight Patients

Hospitals will get about $5 billion more in Medicare payments for patients who stay overnight in fiscal 2005, the Centers for Medicare and Medicaid Services has announced.

Bloomberg/Philadelphia Inquirer. www.philly.com/mld/inquirer/business/9308632.htm?1c

Lilly Plans Broad Access to Results of Drug Trials

Seeking to defuse criticism that pharmaceutical companies hush up negative results in clinical trials, U.S. drugmaker Eli Lilly & Co. plans to disclose extensive data on almost all clinical trials, past and present, for the drugs it sells. *Wall Street Journal*

OMB Projects Increased Medicare Spending by $67B Over Next Five Years — Federal Deficit to Reach $445B this Year

The federal budget deficit for fiscal year 2004 will be about $445 billion, including increased projections for Medicare spending, according to an Office of Management and Budget report recently released, the *Washington Post* reports. The projected budget deficit is the "highest ever," but remains less than previous White House estimates of $521 billion, according to the *Post* (Milbank, *Washington Post*, 7/31). White House officials reduced their earlier estimate because of an unexpected increase in revenue, which was "partly offset" by an unexpected $6 billion increase in spending that was "largely for Medicaid and Medicare," the AP/Raleigh *News & Observer* reports. The report also increased Medicare spending by $67 billion over the next five years, with $26 billion of the increase reflecting costs not included in President Bush's budget proposal released in February. (Fram, AP/Raleigh *News & Observer*, 7/31.)

California Governor Delays Medi-Cal Overhaul

California Gov. Arnold Schwarzenegger has delayed the release of his plan to overhaul the state's Medi-Cal program until January, when it will be included in the 2005–2006 budget.

San Francisco Chronicle. http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2004/08/03/BAG5781N6N1.DTL

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AMDA Public Policy Committee Responds to Proposed HHS Regulations to Implement Key Portions of the New Medicare Law

The Department of Health and Human Services (HHS) has released its proposed regulation for key portions of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) in a whopping 1,956-page document.

The regulation has two major components: the new Medicare prescription drug benefit and revisions to Medicare managed care plans, now called Medicare Advantage. We are providing you with analysis of the provisions of most interest to medical directors and attending physicians in long-term care regarding the drug benefit, on which AMDA solicits your comments, as well as a general summary of the regulation, which is for your information.

The new benefits are to be implemented Jan. 1, 2006.

CMS solicited comments regarding drugs that may require specific guidance regarding their coverage under Part D, and any gaps that may exist in the combined coverage of Parts B and D. Should the regulation specify that if a drug is not on the formulary, beneficiaries may pay out of pocket? Although there are procedures for expedited reconsideration (see below), beneficiaries may wish to begin drug therapy immediately. Another key issue may be the exclusion of benzodiazepines. How significant a problem is that? How significant is the exclusion of drugs to address weight loss?

AMDA Comment: For health care professionals, this may be the most controversial part of the regulation. If the choice of medications available on the formulary (either USP or the one developed by the plans) is limited to a small number, or are not the most appropriate medications to use in the frail elderly population, appeals will be available, but will present, at best, additional administrative procedures and delay in beginning the appropriate medication.

CMS specifically solicits comments regarding special treatment or alternatives needed to account for unique medical needs of a special population. This is an invitation for AMDA to make a case that Medicare and Medicaid beneficiaries in nursing facilities (and arguably those certified as eligible for nursing home care through home- and community-based waivers or PACE) should have an open formulary. If you think that should be the case, please share your specific reasons or examples of why that is needed with AMDA. Are there other classes of enrollees with unique medical needs that AMDA would argue should be under an open formulary?

AMDA Comment: Presumably AMDA supports the requirement to include on the committee at least one physician expert in care of the elderly and disabled.

CMS interprets statutory language as requiring that P&T committee decisions be binding but is soliciting comments. Arguably the P&T committee might be clinically oriented and less susceptible to economic considerations. Does AMDA want to support the proposal that the decision of the P&T committee should be binding?

LONG-TERM CARE FACILITY

Long-term care facilities are currently defined as skilled nursing facilities and nursing facilities that meet Medicare or Medicaid conditions of participation. CMS is considering expanding the definition to include other long-term care facilities, at least intermediate care facilities for the mentally retarded (ICFs/MR) that contract with a long-term care pharmacy to provide medication, in order to extend Part D coverage to dual eligibles residing in ICFs/MR.

AMDA Comment: Should AMDA support expanding the definition to include other long-term care facilities?

AMDA Comment: CMS solicits comments on the MTPT, particularly regarding best practices. Does AMDA want to ask for inclusion of a physician who is an expert in the care of the elderly and disabled in the development of MTPT? Does AMDA want to propose that MTPT be performed by physicians as well as pharmacists? Other recommendations?

AMDA Comment: These grievance procedures present a burden to beneficiaries, whose conditions may deteriorate during these lengthy appeals without the medication their physician believes is medically necessary. The procedures also present a significant administrative burden to physicians, who will be called upon to document the record and make the case for the drug or dosages they believe their patient needs.

Medicare's New Preventive Benefits and 2005 Physician Payment Increases

The Centers for Medicare & Medicaid Services (CMS) issued Medicare's final rule for physician payment for 2005, with new benefits and higher payments for preventive services including a "Welcome to Medicare Physical" and increased payment rates to physicians. The expanded benefits and increased payments result from the Medicare Modernization Act of 2003 (MMA) and are included in the 2005 Physician Fee Schedule rule, which will become effective January 1.

The Physician Fee Schedule sets rates for how Medicare pays more than 875,000 physicians and other health care professionals. In 2005, CMS projects that aggregate spending under the fee schedule will increase 4 percent to $55.3 billion, up from $53.1 billion in 2004. The spending increase is due in part to an MMA provision that increased physician payment rates by 1.5 percent, a move that negated a previous law's planned cut of payment rates by 3.3 percent for 2005.

In addition, the final rule implements a new "Welcome to Medicare Physical" for all new beneficiaries. This exam gives physicians the opportunity to make an overall assessment of a patient's health, and provide counseling on nutrition and other steps to stay healthy. Medicare also provides new coverage for screenings for cardiovascular disease and diabetes.

"Too many beneficiaries haven't used services that make it possible to detect and treat illnesses before they lead to serious health problems and avoidable health care costs," said CMS administrator Mark McClellan, MD, PhD. "Under the new law, we've modernized Medicare to include preventive benefits and appropriate payments for these services, and we intend to close the prevention gap for seniors."

CMS has made two changes to the proposed payment provisions for the physical to ensure that beneficiaries get the maximum value from this service. Physicians can bill and be paid separately for the screening electrocardiogram, in addition to the payment for the physical. The rule also lets a physician bill for a more extensive office visit when performed at the same time as the physical, as long as the services are medically necessary.

The final rule also dramatically increases payments for vaccinations and other types of injections, reflecting Medicare's rapid action on recommendations from the American Medical Association's Drug Administration Workgroup to assure appropriate payment for all drug administration services. For example, payments for administering the influenza vaccine will rise from $8 to $18. Physicians can also be paid for injections and vaccinations, even when performed on the same day as other Medicare-covered services. Medicare currently does not allow payment for injections provided on the same day as other Medicare services.

Other provisions designed to expand beneficiary access to high-quality care include:

• Expanding access to a broader array of health care professionals. For example, the rule lets psychologists receive payment for administering diagnostic psychological tests and supervising the administration of these tests.

• Clarifying that Medicare will pay for care plan oversight for those who get home health care provided by non-physician professionals if state law authorizes them to provide those services.

• New coverage for a one-time evaluation and counseling from a physician employed by a hospice to determine appropriate end-of-life services for terminally ill beneficiaries.

• Expanding access to state-of-the-art treatments. For example, the rule removes restrictions on payments for low osmolar contrast medium (LOCM) because it has become standard practice among radiologists even though it is more expensive than other contrast materials.

• Covering routine clinical costs in studies of certain potentially life-saving investigational devices.

Based on public comments, CMS has also made significant changes in Medicare's approach to paying for drugs administered in the physician's office, and for services related to the use of those drugs, which are covered in Medicare Part B.

The final rule adopts 18 new codes to be used for billing for administering drugs, developed by the American Medical Association's (AMA) CPT Editorial Board. Because new permanent codes will not be included in the CPT until 2006, CMS has developed these temporary codes to allow physicians to be paid for these services beginning January 1, 2005. The rule also accepts the relative values (which are used to determine payment rates) for these codes that were recommended by the AMA's Relative Value Update Committee (RUC).

These higher payments are based on American Society for Clinical Oncology survey data, and include payment for staff time to prepare pharmaceuticals and physician work for supervising of pharmaceutical preparation. One of the important changes Medicare is adopting based on the AMA Workgroup's recommendations is that Medicare will allow the physician to receive additional payments when a second drug is infused. As a result, Medicare payment rates in 2005 for drug administration services will be more than 120 percent higher than in 2003, and physicians will have more opportunities to bill for the administration services they are providing.

CMS also recently clarified that oncologists may bill Medicare separately for managing significant adverse drug reactions related to chemotherapy administration, using existing codes for office visits, including higher level,

prolonged service, and critical care services. With input from physician organizations, Medicare will soon issue a coding guidance to assure appropriate billing for these services, providing additional revenues for practices that have not used these billing codes appropriately.

In the final regulation, CMS is establishing new payment rates for most Part B drugs that will be set at 106 percent of the average sales price (ASP), based on the most recently available data from manufacturers. Drug payment rates will also be updated on a quarterly basis. In a separate rule, published in the September 16 *Federal Register*, CMS adopted a modification to the ASP methodology that changes how manufacturers account for discounts and rebates, in order to produce more stability and predictability in drug pricing. The ASP price data used for the estimates in the final rule is from the second quarter, and includes price information on drugs that account for 99 percent of billed services. CMS has just received third-quarter data and expects to publish it soon, and will also review findings of an independent analysis of ASPs by the Government Accountability Office (GAO). Overall, CMS does not expect substantial changes between second- and third-quarter price data.

"Under the new law, we've modernized Medicare to include preventive benefits and appropriate payments for these services, and we intend to close the prevention gap for seniors."

The impact analysis of the combined payment changes related to oncology shows that these savings are very similar to savings projected at the time of passage of the Medicare law. Altogether, the changes in drug administration payments are expected to add 5 percent per patient to Medicare payments (not counting the CMS clarifications about billing for complications), and the demonstration program is expected to add another 15 percent to oncologists' physician fee schedule payments. CMS actuarial projections indicate that utilization and revenues for ambulatory oncology practices are expected to continue to increase in 2005.

Further, to help provide broader access to low-priced drugs, Medicare is collaborating with oncology specialty groups to make it easier for physicians to find lower prices on drugs. A recent survey by the American Society of Clinical Oncology of some of its members found that both low- and high-volume practices are able to obtain low prices for drugs, and Medicare's new support for finding favorable prices is expected to broaden the availability of such savings.

The rule also implements MMA changes in payment rates for inhalation therapy drugs used to treat respiratory disorders such as chronic obstructive pulmonary disease. Two of these drugs — albuterol sulfate and ipratroprium bromide — are currently paid at 80 percent of the average wholesale price (AWP). The final rule, as the MMA required, bases the payment rate on ASP, which will result in much more accurate payments, as the Government Accountability Office documented recently in an independent analysis. In response to comments, CMS also will provide a dispensing fee for supplying inhalation therapy. The 2005 dispensing fee will be $57 for 30 days of therapy or $80 for 90 days. The rule also reduces the paperwork associated with billing for inhaled drugs.

The final rule also establishes a payment for supplying immunotherapy drugs to transplant patients, in conjunction with Medicare's previous implementation of more accurate payment for immunotherapy drugs. In response to comments, CMS will pay a dispensing fee of $50 for a new transplant patient and $24 for a transplant patient who has already been undergoing post-transplant therapy.

The final rule also substantially increases the payment for clotting factor, from 5 cents in the proposed rule to 14 cents. The payment will go to most providers of blood clotting factors, not just to hemophilia treatment centers or home health agencies.

The rule also changes how Medicare pays for services to beneficiaries with end-stage renal disease (ESRD). It eliminates the cross-subsidy in payments for drugs used in ESRD treatment so Medicare's payment reflects the acquisition costs of the drugs, while increasing payment rates for ESRD providers by the amount of the drug cross-subsidy. The payment rates for ESRD facilities will for the first time be adjusted to reflect the higher costs of treating some patients, such as those with extremely low body mass indices. Payment rates will also be adjusted for factors such as age and body surface area.

More accurate payments means that providers of ESRD care will be paid more fairly for the treatments required for the different types of patients, providing better financial incentives for appropriate care. In this final rule, both independent and hospital-based facilities will receive an 8.7 percent increase in their composite payment rate, in addition to a 1.6 percent update for services under the proposal.

The final rule also enhances other physician payments. In addition to the 1.5 percent increase in physician payments, Medicare will also offer a 5 percent quarterly incentive payment to doctors practicing in "physician scarcity areas." Those areas are listed on the CMS Web site at www.cms.hhs.gov/providers/bonuspayment. Also, CMS will pay physicians who use telecommunications technology to provide monthly management services for rural beneficiaries who are on dialysis. As a result, CMS expects that rural beneficiaries with end-stage renal disease will get better support for high-quality care.

The final rule was published in the November 15, 2004, *Federal Register* and became effective January 1, 2005.

The display copy can be found at: www.cms.hhs.gov/regulations/pfs/2005/1429fc.asp.

Florida Medical Directors Association
200 Butler Street, Suite 305
West Palm Beach, FL 33407
(561) 659-5581 • fax: (561) 659-1291
www.fmda.org

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FMDA Joins Two Statewide Initiatives

Coalition of Health Care Provider Organizations to Promote Responsible Medicaid Reform

According to the Tallahassee-based Florida Association of Homes for the Aging (FAHA), there is a Medicaid waiver under consideration by Florida and a few other states that will have the greatest adverse consequences for states with large population growth and low current per-capita Medicaid spending. Florida is one of the fastest growing states in the nation and a conservative spender. It ranks 39 out of 48 states, excluding Hawaii and Washington, in per capita spending on Medicaid as a whole, and 44 out of 48 states on per capita spending on elders.

Therefore, the cost benefits of a Medicaid waiver must be carefully evaluated against the risks. If Florida is locked into a specific federal allocation that is not adequately adjusted over time, the end result could be catastrophic for both the state and its citizens, particularly elders who are dependent on Medicaid for long-term care. The commitment to create a more integrated system of long-term care with a better balance between institutional and community-based services must be matched by a commitment to fully fund that system as care needs and the number of people served increase.

Through Medicaid, more than two million Floridians receive much needed care and services that they could not afford otherwise. FAHA suggests that efforts to reform Medicaid and long-term care in Florida should not be done in a vacuum. There must be a thorough analysis of the impact of proposed changes on access to services and care, consumer choice, and quality.

Another concern about the Medicaid waiver is that the reform process should be methodical with opportunities for stakeholders to have meaningful input. Medicaid is far too important a program to relegate changes to policy makers alone.

For more information about the coalition and its goals, please go to our Web site at **www.fmda.org/reform.html**.

FMDA Joins Statewide Florida Pain Initiative

FMDA has accepted an invitation to participate in a March 2005 Florida Pain Coalition Inaugural Meeting in Orlando. The mission of the coalition is to address under-treated chronic pain, which continues to be a significant health care problem in the state of Florida.

The coalition is made up of representatives from multiple health care organizations with an interest in improving health care in Florida in general, and improved access to pain management specifically. In addition to increasing legislative awareness of the under-treatment of pain, they will look at advocating the re-establishment of the Florida Pain Commission that existed from 1995–1996.