

South Carolina Chapter GOVERNOR'S NEWSLETTER

ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

Winter 2005-06

William N. Boulware, MD, FACP
Governor, South Carolina Chapter



GOVERNOR'S MESSAGE

DEAR COLLEAGUES,

In a departure from past newsletters, this issue will be almost entirely devoted to educating SC ACP members about Medicare Part D. As you know, the Medicare prescription drug coverage represents a drastic change in the Medicare benefits plan. It also appears to be a complex and confusing benefit for our patients who need it the most. Therefore, the SC ACP Chapter sent Governor-Elect, **Dr. Dawn Clancy**, to Washington, D.C. November 1st and 2nd, 2005, for the National Medicare Prescription Drug Congress. The following pages of the newsletter, I am sure, will be an informative and useful reference for your practice.

But before you proceed to the inside of the newsletter, I want to update you on the events of the annual SC ACP Chapter meeting held October 13th to 16th in Charleston, SC. We had excellent Associate presentations to start the meeting. The winners in the Associates competition were: in the student category, **Megan Shuler**; in the Fellows category, **Michael Craig**; and in the Residents category, **Kelly Barth** and **Ashley Beall**. Congratulations to all the winners who will be sent to the Annual ACP meeting in Philadelphia in April 2006 to compete in the national Associates competition. In addition, **Dr. William Pryor** was named the winner of the annual James F. McFarland Award and **Dr. Kay Huntington** was the distinguished recipient of the annual SC ACP Laureate Award. Your new officers and chairs of committees as elected at the annual business meeting are **Dr. Anne Cook**, Secretary, **Dr. Mac Chapman**, Treasurer, **Dr. Dawn Clancy**, Governor-Elect, **Dr. James Adamson**,

Chair of Diversity and Outreach, **Dr. Kimberly Davis**, Chair of Scientific Program, **Dr. John Dubose**, Chair of Credentials and Membership, **Dr. Mike Hawkins**, Chair of Health and Public Policy, **Dr. Mary Beth Poston**, Chair of the Associates, **Dr. Steve Ross**, Chair of the Nominating Committee, **Dr. Chris McLain**, Chair of Quality and Patient Safety, **Dr. Lori Malvern**, Interspecialty Council member, and **Dr. William Robinson**, Medicare Care Advisory member. The meeting was rated as exceptional by the attendees and our national President of the ACP, **Dr. Anderson Hedberg**, so make plans now to join us next year in Hilton Head, SC, October 19th through 22nd, 2006, for the next annual SC Chapter meeting.

Politically, please get behind the effort to change the sustainable growth rate (SGR) formula that is automatically set to provide an average loss of 4% per year to your Medicare fees. Call the ACP hotline 1-888-218-7770 or go to www.acponline.org and click on the Legislative Action Center and send messages to your Congressmen. In South Carolina, please support the legislation to be introduced in January 2006 for E-Prescribing. You can stay in touch by visiting the SC Chapter website (www.acponline.org/chapters) and clicking on the South Carolina chapter and then clicking on our new discussion group.

Lastly, I want to congratulate **Dr. Charles Bryan** MACP on being awarded the Nicholas Davies Memorial Scholarship Award for Scholarly Activities in the Humanities and History of Medicine by the ACP to be bestowed him at the 2007 annual meeting. Thank you for getting involved and allowing me to serve as your governor the last four years!

William N. Boulware MD FACP
Governor

—VISIT OUR CHAPTER WEB SITE—

<http://www.acponline.org/chapters/sc>

MEDICARE

As you read this newsletter South Carolinians are experiencing the biggest change in Medicare since its inception in 1965. They are entering the new age of Medicare . . . the post Medicare Modernization Act (MMA) of 2003 Age of the Prescription Drug Benefit. Over the last several months they have availed themselves of the clear, concise, and easily understood information provided by Medicare to assist them in making their decisions. Being fully educated on all aspects of this new benefit, they have been enrolling in the plans best suited for them. Effective January 1, 2006, their benefit will start. They will experience precipitous drops in monthly medication expenses and will have more cash available to cover their other needs such as food and shelter. Who knows? With the money they save perhaps they will further stimulate the economy through consumerism thus providing more tax revenues to cover the cost of the program while simultaneously paying down the federal deficit. And then all the men and women who are either disabled or over 65 years old will live happily ever after! All thanks to the MMA of 2003 and its prescription drug benefit

Wouldn't it be nice if the above fairy tale was reality? Unfortunately, the only truths in this fairy tale are that the Prescription Drug Benefit of the MMA of 2003 is the biggest change in Medicare since its inception and that the benefit will begin on January 1, 2006. The rest of the story is wishful thinking.

The Second Medicare Congress for the Prescription Drug Benefit held in Washington, DC November 1-2, 2005 brought out the best and the brightest from the public and private sectors to provide insight and guidance into the implications and implementation of the benefit. Speakers included **Mr. Tom Scully**, attorney and former director of the Center for Medicare and Medicaid Services (CMS), and **Dr. Mark McClellan**, internist and present director of CMS. It was interesting to hear each perspective on the Drug benefit. While coming from different disciplines, their mantra was similar - capitalism and free market forces will make sure the benefit works for all. Mr. Scully seemed far more emphatic about market forces while Dr. McClellan seemed to have a better grasp on the up-til-now disenfranchised impoverished seniors and disabled, as it was clear that his goal was for these people to receive their meds whether it was cost-prohibitive to the government or not.

The assembly of speakers also boasted several seasoned politicians including **Senator Charles Grassley** (R-Iowa) and **Congressman Pete Stark** (D-California). The debate over the budget reconciliation was first addressed by Senator Grassley. His argument was as follows: since prescription benefit managers have stepped up to the plate to offer lower premium products than expected, assurances made to the drug companies that they would not initially lose money were no longer necessary. Were these assurances responsible for their willingness to step up to the plate? Secondly, the Senator indicated continuing to pursue Medicare fraud and abuse would help to finance the plan. Scary! For all the warts of his presentation, he was as non-partisan as I have ever heard him. The other legislator on the agenda, however, was a different story.

Congressman Stark, yes, of Stark laws 1 and 2, was extremely partisan in his discussion of the benefit. He first proposed that all doctors could easily afford computerized records in their offices. After all, "what doctor cannot afford a computer?" When challenged by yours truly, he offered the VA program, VISTA, as a solution. The release of this program, however, has been delayed. He had no comment regarding this statement. Additionally, he did not acknowledge the loss in revenues a practice would sustain in the conversion from a paper to an electronic health record (EHR) including training of the physicians and staff, thus limiting the availability to see and bill patients during the implementation. I also mentioned that those revenues lost by physicians did not include the 4.4% cut in place for physician reimbursement (unless stopped by Congress before January 1, 2006.) To this he responded "Now let me tell you about that cut. The doctors will just see more patients and perform more procedures to make up for that cut. Ophthalmologists will just do more cataract surgeries." I then informed Congressman Stark that I was a primary care physician and cared for the chronically ill, elderly population for whom the drug benefit was designed. He then turned the conversation back to electronic health records (EHR). His question to me was as follows: "If the government were to provide free EHR software, wouldn't the increase in productivity more than make up for the 4.4% cut?" I responded that I was a primary care internist from South Carolina caring for chronically ill, elderly patients and that to increase productivity enough to make up the difference, patient care would time would further shorten from the current national average of 10-11 minutes. He answered "I thank you for what you do" and went on to the next, and last, question he would address that day.

After hearing these arguments, I became more concerned than ever that the legislators did not have a clear understanding as to what patients experience and will soon experience. I then heard from industry, defending their direct to consumer advertising, and became even more concerned. (Frequently throughout the conference it occurred to me that the fox was guarding the hen house.)

Another esteemed speaker of the Medicare Congress was **Dr. Carolyn Clancy** (no relation), the director of the Agency for Healthcare Research and Quality (AHRQ). Her speech was both interesting and disconcerting. The AHRQ is the agency designated to fund research evaluating the quality of healthcare being delivered.

continued on page 3

Unfortunately, it is under funded and research is suffering. She did, however, advise about a new site for which they are responsible. It is the John M. Eisenberg Clinical Decisions and Communications Science Center and can be found at <http://effectivehealthcare.ahrq.gov/dsc/index.cfm>. Its purpose is to ‘take a systematic approach to translating knowledge about effective health care into understandable, actionable language for all decision makers. An important function of the Center is to present the often complex scientific information in a format that stakeholders and the public can easily understand.’ So, despite their decreasing budget of late they continue to work tirelessly to help us better care for and explain that care to our patients.

CONCURRENT BREAK-OUT SESSIONS

The implementation of MMA and Medicare Part D is proceeding at an ever increasing rate. Medicare beneficiaries must have choices by law; up to 2 choices, with at least 1 being a prescription drug only plan. Reality: plans are springing up everywhere, up to 46 in South Carolina alone. Question now is: are there too many choices? And what will happen if those choices disappear in the years to come? Patients who have employer-sponsored retiree drug coverage are particularly vulnerable. The government is subsidizing with tax-free dollars as incentive for those employers not to drop their drug coverage benefit, but will the subsidy be enough? And then there is the infamous ‘do-nut hole.’ Out of 29 million Medicare beneficiaries it is estimated that 6.9 million could experience out-of-pocket drug spending in the ‘do-nut hole.’ It is against that back drop, that I will try to summarize the concurrent sessions the SC ACP council asked me to attend.

Session I: Medicaid and MMA Administrative Challenges: Determining Eligibility and Enrollment for Low-Income Beneficiaries

This first concurrent session I attended, though informative, left many substantive questions unanswered. All of the staples were presented: all plans must have basic benefits (standard) and they may offer supplemental benefits (enhanced). Those patients presently enrolled in Medicare and Medicaid (the ‘dual eligibles’) will lose their Medicaid on 12/31/05. They will automatically be enrolled in a Part D plan if they have not chosen one by that time. Therein lies the rub - how will those who are presently considered ‘dual eligibles’ choose their Part D plans, and into what type of plan will they be placed if they do not make their own choices.

The general consensus among the session’s attendees was that dual eligible patients have not been contacted early enough about the upcoming change to their benefits. Additionally, while the majority of these patients are, by definition, financially disadvantaged, many are educationally disadvantaged, as well. Against such a back drop the session participants expressed concerns about how dual eligible patients will make informed decisions regarding Part D. The CMS representative assured the audience that information was readily available online and through 1-800- Medicare; however she had no answers to concerns that many of these patients do not own or know how to use a computer and may not be educated enough to understand all correspondence they are receiving. Additionally, upon calling the Medicare assistance number, will they be able to accurately read all of their meds aloud to a representative on the other end of a telephone?

As CMS will automatically enroll patients who do not make a choice by January 1, 2005 into one of the plans available in their state, session participants inquired as to how that would occur; would there be someone trying to match their medication profiles with plans that were most closely aligned to their profiles? To this there was no answer offered. The representative went back to the fact that information regarding plans was online and available by phone And so the questions to and answers from the CMS representative went.

A speaker from Idaho expressed the more pro-active approach his state has taken with media outreach; increased full time and temporary staff to handle the increased workload; and even a 2-1-1 state referral hotline. This pro-active approach, however, requires resources to accomplish, and those resources are becoming ever scarcer. With the migration of dual eligibles into Medicare Part D, states will lose their Medicaid drug rebates, gain new administrative costs, and incur the controversial “clawback” liability for dual eligibles. Since dually eligible patients will no longer be getting their medications from the states, instead of the states having a windfall (from the money they were using to buy meds that they will no longer be buying), the states will be sending that money to Washington for the feds to use to buy meds for those same patients. That is the ‘clawback.’ So, in many ways, Part D has unfunded mandates, or even mandates for which states must pay the feds. That is enough about the first session.

Session II: Marketing Part D Plans: Fraud and Abuse

The second session I attended was on a topic near and dear to all of our hearts - fraud and abuse. The most interesting aspect of the session was that Chief Justice Rehnquist's daughter was one of the 2 presenters. That having been said, the session did not really give a lot of new information for anyone who has been dealing with Medicare for the last 12 years. The federal government is ramping up their ability to investigate for fraud and abuse with this new benefit.

The presenters went over the applicable statutes including the Anti-Kickback Statute, the Public Contracts Anti-Kickback Statute, the False Claims Act, and Stark I and II. Additionally they reminded the audience that should their states have stricter laws, the stricter laws will always be the ones under which investigations will occur.

When I asked about the implications for meetings such as our annual scientific session, they responded that the current Pharma guidelines apply, without change, however they will likely be more closely evaluated in light of Part D. Additionally, CMS will continue to do trend analysis, but at an increased pace since adding Part D into the mix.

A few figures that were presented: Monetary recovery for CMS in FY 2004 under the False Claims Act totaled \$667,782,529, 83% of which (\$553,626,506) was under qui tam provisions of the False Claims Act. The total amount of monies recovered for the federal government under the False Claims Act since 1986 is >\$13,500,000,000 - staggering figures. Perhaps that explains why CMS continues to go after fraud and abuse so vigilantly. Additionally, marketing is big business, as we all know. Last year CMS calculated an annual drug expenditure of \$207 billion and CMS projects an annual drug spending of \$519 billion in 2013, 15.5% of total health expenditures. And in 2003, Abbott spent \$1.7 billion (9%) on Research and Development (R&D) but \$5.1 billion (26%) on Marketing/Selling, General, and Administrative Expenditures. This compares to Bristol Myers Squibb's \$2.3 billion R&D (11%) and \$6.1 billion marketing (29%); Glaxo Smith Kline's \$5 billion R&D (13%) and \$13.6 billion marketing (35%); Merck's \$3.2 billion R&D (14%) and \$8.4 billion marketing (28%); Pfizer \$7.1 billion R&D and \$15.2 billion marketing (34%); and Roche's \$3.7 billion R&D (15%) and \$7.8 billion marketing (32%).

Just a few more points about fraud and abuse; the Associate US Attorney in Philadelphia, Jim Sheehan, has been quoted as stating "every detailing activity between sales representatives and physicians as well as every drug covered is subject to federal oversight." A recent case involving Pfizer, Inc, Warner Lambert Company LLS, and the Parke Davis Division resulted in a \$430 million global settlement and a 5-year corporate integrity agreement between Pfizer and the OIG for marketing Neurontin for off label uses not approved by the FDA (mood stabilization).

So, where can we find help - through the Office of the Inspector General (www.oig.hhs.gov). There you will find Fraud Alerts, Advisory Opinions, Fraud Bulletins, Model Compliance Plans, Voluntary Disclosure Guidelines, Notices to Beneficiaries, and Fraud hotlines. Other potentially useful websites include the Department of Justice (www.usdoj.gov) and Food and Drug Administration (www.fda.gov) web-sites.

Session III: MMA, Private Plans and Competition: Formulary Design - Balancing Cost and Access

In this session the guidelines for formulary design were outlined. By mandate, each Part D plan must include at least 2 drugs in each category that are not therapeutically equivalent and bioequivalent. CMS will determine whether the plans' categorization schemes are discriminatory against certain types of patients or not (in an attempt to avoid cherry picking in the past). To that end, plans must submit their formularies annually to CMS for approval. Formularies can be updated at certain times of the year; CMS will meet quarterly to consider changes to the plans' drug lists, will review therapeutic categories annually, but will hold all formularies steady during the open enrollment period from November 15 to March 1 each year.

Not unexpectedly, factors that will drive formularies will include evidence of care, costs, and the population base. Additionally, if there is a drug for which there are multiple competitors in a category that does not make it on formulary, the manufactures will have to demonstrate the drug's cost-effectiveness as well as superior outcomes in and among the elderly and disabled patient population demonstrate. In order to manage the formularies, prior authorization, step therapy, tier placement, generic substitution, and therapeutic substitutions will be employed as well as cost-sharing and mail service versus retail access to meds.

A couple of 'set in stone' design issues at this juncture involve the scope of formularies. By law there is a minimum benefit design necessary for a plan to offer Part D prescription drug coverage, and enhancements are possible. Additionally, any alternative prescription drug coverage (such as by a retiree's former employer) must be actuarially equivalent to the standard benefit defined by law.

Session IV: Fee for Service Trends: Evidence-Based Medicine

Of all the sessions I attended, the fee for service trends were the ones from which I expected to get the most information and help and they did not deliver. I will, however, summarize as best I can. As far as 'Integrating Evidence into Policy,' as the 1st speaker's talk was titled, it was a confusing maze of how CMS will take suggestions from the community regarding a potential benefit, such as the Automatic Implantable Cardioverter Defibrillators, evaluate the modality requested, have time for public comment, and then render an opinion as to whether or not the modality will be covered nationally. She was quick to point out that 90% of coverage issues are handled at the local level and only about 10% are covered at the national level. In order for such a modality to be covered there must be a sufficient level of confidence to conclude that the modality improves net health outcomes, is generalizable to the Medicare population, and generalizable to the general provider community. Of course the requests that they will receive for Part D review will be any meds that are not covered by Part B already - such as antiemetics for cancer but not antiemetics for gastroenteritis. While this one is already decided, I use it to illustrate how difficult it will be to know when a drug is part B or part D. A quasi rule of thumb they offered was that if the physician administers the drug in the office it is a part B drug; if the patient self-administers, it is part D.

The decisions that will be sent down from CMS regarding national coverage are National Coverage allowed, National Coverage disallowed, and National Coverage allowed with restrictions. There was a detailed and complex diagram shown depicting how a modality would enter and flow through the process. At the end of this session I kept thinking "CMS decisions are like politics; it's all local." Luckily, we have active Medicare Advisory Committee members for SC ACP, Drs. **William Robinson** and **John Black**, who can help us maneuver through the maze. For anyone wanting further information, the speakers gave the following website: www.cms.gov/coverage.

Session V: Fee for Service Trends: Pay for Performance (P4P)

It was with great anticipation that I entered this session, and with great disappointment that I left. The original speaker from CMS was unable to attend and there were no handouts for her. There was a speaker who spoke to P4P for radiology groups, but that was hardly helpful to me as an internist. So, while I would love to write that I gained great insight to the P4P movement, I remain as confused and concerned as I was on entering.

Summary

Hopefully in the preceding pages I have given you a flavor for what many policy wonks and politicians on Capitol Hill are saying regarding this largest expansion in Medicare since its inception. Unfortunately, it appeared throughout the Congress that there are far more unknowns than knowns, but the benefit is going ahead. We will all just have to be vigilant in our dealings with Pharma and ready to help our patients as best we can when they are trying to choose a plan and have not gotten all the answers they want from the 1-800-MEDICARE hotline. The following site has some useful links: <http://www.medicare.gov/>.

In summary, this is clearly a work in progress and hopefully one that will not prove detrimental to our patients.

PAY YOUR DUES ONLINE

For your convenience, you can now pay your dues online. The process of paying your dues online is easy. All you will need is your user ID and password (instructions are on the site, should you need to register). To ensure your privacy and maintain security, open your Internet browser, go to ACP Online Web site and click on the "Pay Your Dues" link.

The new online payment option is designed as a convenience for members, although all College members will still receive print bills for the upcoming year and will be able to also pay dues by mail, phone or fax. If you wish to pay by phone, please call Customer Service at 1-800-523-1546, ext. 2600 or directly at 215-351-2600 (M-F, 9:00 a.m. to 5 p.m. ET). You can also submit your credit card payment by faxing us at 215-351-2799.