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STATE AND CONSUMERS AFFAIRS AG
DEPARTMENT OF CONSUMER AFF
ARNOLD SCHWARZENEGGER, GOVER

Public Forum on Medicare Part D Plans

Summary of the Meeting February 1, 2007
9:00 am – 11:35 a.m.

BOARD

MEMBERS PRESENT:
William Powers, President
Stanley Goldenberg, RPh, Chairperson
Kenneth H, Schell, PharmD
Ruth M. Conroy, PharmD
D. Timothy Dazé
Clarence K. Hiura, PharmD
Henry Hough
Susan L. Ravan, PharmD
Robert E. Swart, PharmD
Andrea Zinder

STAFF PRESENT:
Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joan Coyne, Supervising Inspector
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General
Anne Sodegren, Legislation and Regulation Manager
Gloria Schultz, Administrative Assistant

President William Powers opened the meeting at 9:00 a.m. Mr. Powers observed that the Medicare Drug Benefit Plan was one of the most important changes in the history of the Medicare program since its inception in the 1960s. The Board of Pharmacy believes that it is important to hold these public forums to allow stakeholders to discuss how the Medicare Drug Benefit program is operating, their concerns with the program and those issues impacting the quality of services being provided to California patients.

President Powers reported that the board's subcommittee on the Medicare Drug Benefit Plan has been meeting for about a year and that committee members have heard testimony from various stakeholders on the concerns, problems, and successes of the program. Chairperson Goldenberg then thanked the members in the audience for their attendance and stated that the board wants to bring resolution to some of the problems

brought before the subcommittee over the last year. He announced the meeting format of forum and that long term care representatives would make the first presentations.

Don Amorosi of Omnicare, Inc. thanked the board for holding the forum and stated that he and his colleague, Mary Lou Gradisek, will be presenting a PowerPoint presentation on the Medicare Part D challenges facing long term care (LTC). He provided a copy of LTC patient protections from Omnicare contracts with Part D plans, many of which were adopted by the Centers for Medicare and Medicaid Services (CMS) as part of its 2007 transition plan. He also provided copies of CMS memos concerning Part D transition of care policy and expectations for the 2007 contract year and "Best Available Data" policies for reconciling CMS low income subsidy status.

Mr. Amorosi's presentation centered around the Part D landscape in California and the challenges that face long term care under Medicare Part D in the areas of transition of care, long term care infusion therapy co-pays and subsidies, and recommended best practices. He included a brief overview of Omnicare's long-term care role in California, the shift in payer mix and the top five plans that service the institutionalized in California.

Mary Lou Gradisek then spoke on the CMS LTC transition policy changes for 2007 and the impact of these changes and the transition policy for LTC. She focused on emergency fills, multiple fills of non-formulary drugs and "refill too soon" limitations, prior authorization requirements for IV therapy medications, and best billing practices for IV therapy. Ms. Gradisek stated that the intent of the CMS transition policy is to make sure that the needs of a LTC patient are specifically addressed and that enrollees have enough time to receive the drugs that are prescribed by the physician and for those drugs that are not covered by the plan, that there is time available for an enrollee to acquire additional documentation, to change to a covered alternate or for the pharmacy to work with the physician to provide the documentation that justifies the medical need for those prescriptions.

Mr. Amorosi then provided a background on issues pharmacies are facing with co-payments and the inability of providing timely information to CMS and the plans regarding full subsidy eligibility for long term care patients. He stated that LTC patients have a combination of Medicaid and Medicare eligibility and are not subject to co-payments. However, there is a delay in getting that LTC eligibility information to CMS and the pharmacies are required by the plans to collect a co-payment before the medication is dispensed. Once a patient's dual eligibility is verified, the plans do not have a legitimate process in place, such as electronic submission capability, to retroactively update the system to reimburse pharmacies for the co-payments. Mr. Amorosi added that CMS has issued best available data guidelines for use at the point of dispensing to determine full-benefit dual eligibles and other low-income subsidy eligible individuals.

In summary, pharmacy liability for co-pays must be resolved, best practices include adoption of already defined industry standards and the continuity of LTC service models requires unique patient protections.

President Powers introduced Charlene Zettel, Director of the Department of Consumer Affairs. Director Zettel thanked the board members for their work and the contribution they make to the patients and consumers of California. She added that Governor Schwarzenegger is committed to increased access to health care and coverage for all Californians, and the Department of Consumer Affairs looks forward to working collaboratively with the board on outreach for the Medicare Drug Benefit Plans.

President Powers thanked the Director for her comments and invited the next presenter to the podium.

Kim Aksentijenic of Kyffin Pharmacy introduced herself and stated that her pharmacy serves Los Angeles County long-term care and assisted living patients. Ms. Aksentijenic clarified that the Part D program is a real time, point of sale process developed for ambulatory patients who can go to the pharmacy, get their prescriptions and the pharmacist processes a point of sale transaction and obtains a promise of payment from the Part D plan. The LTC environment however does not operate in real time and relies on the facility to provide information as to a patient's eligibility that oftentimes creates a rebilling issue due to erroneous information and the necessity of using clinical staff to resolve reimbursement issues.

Ms. Aksentijenic continued with the issues surrounding LTC prior authorizations and physician approval for prior authorizations. In the LTC environment, the facility, the consulting pharmacist, the dispensing pharmacist and the pharmacy all have the clinical information on a patient. The physician does not have the clinical data available to make a decision so it is a problem when the Part D plans require a physician to be the primary point person in the prior authorization process. Some physicians will not participate in the prior authorization process; this then may result in a LTC patient not getting the medication a physician has ordered. She added that compliance packaging has also proved to be an issue. LTC relies on compliance package to facilitate the patients receiving their medications correctly. A problem arises when a 31-day supply is dispensed, which results in a double co-pay for the patient.

Ms. Aksentijenic concluded by relaying incidents where LTC patients whose medications were previously approved under Part A were unable to receive medications due to Part D plans denying coverage. This denial prohibits a consistent treatment plan and the ability to properly control patient pain.

Chairperson Goldenberg questioned the time it takes to get prior authorizations signed. Ms. Aksentijenic explained the process and responded that she has an employee who processes prior authorizations full-time. She stated that some plans accept the form without a physician's signature and others contact the physician based on information provided on the form. She added that Kyffin is not notified of the approval or denial of a prior authorization. Her employee either has to call the Part D plan or submit a trial claim to determine approval. There is a lack of communication to the pharmacy as the actual provider and caregiver.

Ms. Aksentijenic agreed with Chairperson Goldenberg's comment that if the standardized form provided by CMS was available electronically and that the status of a prior authorization could be checked on-line, a significant amount of time would be saved.

David Solomon of Kyffin also thanked the board on the work they have been doing the past year on Part D and reported on the financial ramifications of Part D. He stated that Kyffin's personnel costs, delivery and receivables costs have increased but its overall business has not increased. He added that Kyffin is trying to deal with these changes while assuring that its clients experience the least amount of change in their daily medication routine. Kyffin has spent an enormous amount of time and money to ensure that prior authorizations are completed, that co-payments are collected and costs are not consistently absorbed. As with other pharmacy caregivers, Kyffin is not forcing the facilities to reimburse for the co-pays or for non-covered charges – especially when an eligibility status occurs retroactively. The pharmacies are absorbing these costs.

Mr. Solomon reported that since 2005 Kyffin Pharmacy has sponsored numerous education outreach programs to their facilities addressing what information is needed by Kyffin from the facilities in order to provide continuation of care to their LTC clients. He noted that there seems to be a lack of support from CMS in this education process.

Chairperson Goldenberg reported he has queried facilities asking what they would do when a pharmacy is faced with a situation where the drug is so expensive they cannot provide it but the doctor feels the care and the medication must continue. The majority of the facilities responded that they would transfer the patient to an acute care hospital, which then creates additional costs and an enormous amount of trauma to an elderly patient. He added that the care of patients is being compromised, the cost of care increases with the changes in Medicare coverage and reimbursement, and the frail elderly patient is subject to trauma if transferred out of the facility. The system has to be resolved so that the frail elderly are not placed in harm's way. He stated that because a response has not been received from the plans and CMS concerning the problems and frustrations the subcommittee has been discussing the last year, the issue is being brought before the full board to address this concern of harm to the frail elderly as it is now time to take action.

Mr. Hough stated that an electronic database, enabling the proper identification of a patient's eligibility status is a key issue towards resolving the points introduced by the speakers. This is an authority matter where direction must be given to mandate the establishment of such a database.

Chairperson Goldenberg introduced representatives of CMS and thanked them for attending the forum and expressed a hope that they would provide a response to these concerns.

Jeff Flick, Regional Administrator for the San Francisco office of CMS, stated he appreciated the opportunity to participate in this forum. He introduced Lucy Saldana, Region 9 pharmacist with CMS. Mr. Flick stated that the information learned in the forum is very beneficial. He added that he feels very good about the Part D Program. Although there is room for improvement; the program has come an incredible distance in one year. Today, in the State of California, 97 percent of the Medicare beneficiaries have comprehensive prescription drug coverage, whereas 14 months ago only about 55 percent of the Medicare beneficiaries enjoyed comprehensive prescription drug coverage. With regard to the LTC portion of the Part D plans, Mr. Flick will take the specific issues and problems discussed in today's forum back to their industry collaborative (ICE), a roundtable of stakeholders who work together to solve Part D problems. In the last year, this collaborative effort has resulted in several policy changes although there are still concerns and issues that are being addressed.

He stated that ICE can address many of the issues discussed here today and he is very interested in pursuing electronic data transmission, keeping in mind the necessity of data security. Mr. Flick added that there are positive aspects to the program such as medication therapy management, e-prescribing and prior authorizations, but the stakeholders must keep working together to realize these benefits without a negative impact. The encouraging aspect is that the entire health care stakeholder community has a history of being able to work together to solve problems and to continue to improve the program.

Mr. Flick acknowledged that it has been difficult getting dedicated physicians for LTC patients who can respond quickly when problems arise. He agreed that nursing homes do need the ability to engage physicians quickly and that perhaps CMS could assist in resolving that problem.

Mr. Goldenberg asked Mr. Flick whether CMS's authority to speak directly to the plans is limited. He added that the feedback that the board is getting from all the stakeholders is that CMS has very little authority over the plans. Mr. Goldenberg asked how the board could be assured that CMS is working with the plans to resolve problems and that plans will listen to CMS.

Mr. Flick responded that CMS works well with the plans through the ICE collaborative efforts. There are times when an issue cannot be resolved through collaboration and cooperation and at these times, CMS does talk with their central office to deal with the specifics. He stated that every plan signs a contract with CMS, the terms of these contracts are very specific and CMS does have a lot of authority over those contracts and will terminate a contract for serious noncompliances. However, CMS does work with a plan to ensure compliance with the Medicare program.

President Powers stated that from listening to the presenters, there are systemic problems in the system that will need to be resolved through the ICE collaborative.

Mr. Flick responded that most of the issues that were raised today could be resolved through ICE. As in the past, CMS has changed policies based on recommendations from the collaborative.

Mr. Goldenberg questioned whether it would be a fair expectation of the board that the ICE collaborative would be discussing problems heard in today's forum and the board could anticipate some timely action by the plans and CMS to remedy these problems and help California's seniors.

Mr. Flick answered that CMS's focus is to work with ICE as a collaborative effort in resolving issues. CMS is not purposely mandating directions and timeframes. He stated that it was important to understand the environment of this collaborative effort – that there are requests from all the stakeholders, including the plans for assistance with certain issues, and that it makes for a better process to have the stakeholders working together.

Dr. Saldana of CMS stated that e-prescribing should resolve many of the issues that were discussed today. E-prescribing is on a fast track and by 2008 the ability for e-prescribing should be in place. There was a question from the board as to whether the health insurance plans would use e-prescribing and electronic databases and if CMS could work towards a legislative mandate to require the use of electronic databases. Mr. Flick responded that CMS does not lobby for legislative change, but he agreed that CMS could communicate to legislators where change is needed. It was commented that if California took the lead in this area, it would assist the Medicare Part D program nationally.

Chairperson Goldenberg announced that Terry Miller of the Department of Health Services would speak next, followed by representatives of the plans.

Dr. Miller reported that as Chairperson Goldenberg stated, that prior to Part D, the pharmacists could submit a treatment authorization request via facsimile through the Medicare program. Currently, with CMS requirements related to Part D, the treatment request must be submitted from the physician which then puts the onus on the physician who is not used to routinely working with the plans. The former system whereby pharmacies pursued authorizations for drug coverage worked well with the Medicaid and Medi-Cal programs in California, and now it is a significant issue for prescribers.

Dr. Miller stated that with respect to emergency drug benefits, the California Legislature approved an emergency drug benefit to assist patients who could not get their medications via the Part D plan for one year. Although this benefit recently expired, the Department of Health Services has seen a significant decrease over the last year in the number of claims submitted to the emergency drug program. Ms. Miller indicated that this decrease indicates a significant improvement in the Part D program. However, she

agreed that there are still issues that need improvement, specifically in the arena of LTC and home infusion.

John Jones from Prescription Solutions stated that his organization serves two large prescription drug programs and that Prescription Solutions is a representative on the ICE collaborative. He stated that it is very difficult for ICE to address an issue on a conceptual basis. ICE works better responding to specific facts where they can develop mechanisms to prevent specific problems from reoccurring. ICE is committed to making the process better.

Mr. Jones stated that they are routinely communicating with CMS and notifying them of problems. He added that CMS does have authority over the plans and the plans performance is considered at the time of contract renewal. Customer service is important to Prescription Solutions, if there is a problem they need to know about it so they can fix it. These board forums and the ICE collaborative provide them with the opportunity to hear the issues. Mr. Jones agreed that e-prescribing would be very beneficial but many physicians are reluctant to go that route. However, by 2008 a financial leverage should be in place where electronic submissions by physicians will be required before payments are made.

Chairperson Goldenberg asked whether Mr. Jones's organization and its affiliates could address electronic connectivity now and not wait for the ICE collaborative. Mr. Jones responded that the Prescription Solutions has a system that is currently working. He added that e-prescribing will move the industry toward an electronic interface. If the board is looking at an interim solution before e-prescribing, Mr. Jones questioned whether that would be a good use of resources as Prescription Solutions has a system in place that is currently working.

Chairperson Goldenberg indicated that the board heard today that the system is not working effectively and there are issues that need to be resolved. Mr. Jones stated that when he is notified of a problem and given the specific details of that problem, he would facilitate a resolution. He added that he would continue to assist with the facilitation of communication at all levels so that ICE can be a meaningful process.

Timothy Cutler, assistant clinical professor at the UCSF School of Pharmacy highlighted specific Medicare Part D issues facing providers, pharmacists, and patients in California. He provided examples of patients' confusion with plan options, misinformation from brokers, brokers attempting to sell additional coverage to patients and patients being over insured. He emphasized the large amount of misinformation that patients receive from the plans and brokers. He stated that with the number of eligible patients, number of prescription drug plans and number of brokers, there are not enough educators to provide Part D outreach educational activities to the seniors of California. Mr. Cutler added that brokers are not subject to the same regulatory provisions that pharmacists are in terms of information that can be provided to patients. That is a problem and something should be done to protect beneficiaries from those brokers who are imparting misinformation to patients. He also spoke to the continuing

delays in coverage for the dual eligibles and provided patient examples of this gap in coverage.

Dr. Cutler then highlighted recommendations for improving the system such as the continued coordination of communication efforts between the plans and CMS to prevent gaps in coverage from occurring, and the communication must be easier between the patient, the health plan and the system. CMS should have one system in place, similar to Medi-Cal in terms of a safety net provided to patients and a standardized prior authorization process.

Michael Rigas of Crescent Healthcare, a home infusion company, reported on Crescent Healthcare's experience over the last twelve months with Medicare Part D program. He provided a PowerPoint handout and briefly summarized the highpoints from that handout. Crescent Healthcare serviced over 850 home IV patients in 2006. Very few of those patients were able to afford a co-pay unless they had assistance with a secondary plan or Medi-Cal and their costs to administer to those patients were two to three times the costs of other payment systems. The ability to manage these patients on an ongoing basis will become more difficult as processing gets more complicated. Dr. Rigas added that obtaining prior authorizations might take 5 to 7 business days for complex therapies. He provided a brief overview of special issues of importance to the home infusion industry that included billing issues with multiple ingredients – prescription billing is based on the most expensive first active ingredient only; concerns about the future stability of pricing structures and plans with specialty drug copays. Also, due to the 2007 changes made by the Part D Plans as a result of issues in 2006, Crescent Healthcare has to navigate through new copay policies that have a dramatic impact on their patients. Also many Part D Plans and MA-PDS have their own pharmacy out-of state, so when Crescent sends the prior authorization through, the prescription is filled by the plans' own pharmacies and the prescription arrives directly to the patient, with no items to mix it, no pump, no pharmacist or nurse, and no way to infuse it. He added, in response to a question from the board, that there is a delay in obtaining prior authorizations and once received, there is oftentimes a billing issue as a brand is approved, but not the generic.

Dr. Rigas then provided specific examples of home infusion patients who were having problems continuing to receive the treatment and medications that they had under previous coverage Part B coverage but can now not get under Part D. Dr. Rigas concluded that Part D does not provide adequate coverage for Home Infusion Therapy resulting in patients having to stay in a hospital, go to a skilled nursing facility, or having to pay large amounts of money out-of-pocket. He stated that there are definite benefits with Part D coverage, especially for patients who would have no coverage at all, but there are still significant issues relating to coverage and billing that need to be addressed.

Chairperson Goldenberg requested Jeff Flick and John Jones to provide their thoughts on today's presentations. Mr. Jones stated LTC and home infusion therapy are areas where the industry and CMS wants to work well but they were not areas that were

initially part of the Part D congressional discussions. He complimented CMS on their handling of these issues and their methods of working with them.

Chairperson Goldenberg stated that there are significant issues involved - the health and well being of the patient, the health and well being of an industry that exists that offers much better care, and there it is more than just an issue of lower costs – it is better care at home. He added that the board would continue to meet to hear the issues and assist in the resolution process. He thanked everyone for coming and requested that they send in their suggestions as to what the board can do legislatively to help.

President Powers also thanked everyone for their participation and announced that due to continuing interest and today's time constraints that did not allow all interested attendees to address the board, the board will hold another public forum on Medicare Part D Plans in March. He added that written testimony may be submitted to the board's Executive Officer, Virginia Herold who will ensure that it is distributed to all board members.

The forum ended at 11:35 a.m.