CDC Report

Friday June 17 , 2005 Oakland, California

Legislative Report: Michael Arnold delivered the legislative report.
The State budget did not pass by the constitutional deadline of June 15. The Democratic leadership decoupled new taxes (for the highest income earners) from the budget so that it could pass. However, it still failed. The Governor has called a special election for November 8, 2005. Republicans have determined that they will gain political power in the special election for budget process reform if they delay the budget. The "mother of all elections" (due to the cost of the special election) will contain the following measures: teacher tenure reform, budget process reform, reapportionment reform, labor union requirements for written approval of political expenditures by union membership, and parental consent for abortions for minors, all supported by the Governor. Both Labor and big Pharma will have competing bills dealing with pharmaceutical issues.
Michael presented three pieces of legislation of which he wanted to make the Board aware.
SB 350 This bill, introduced by Senator Jackie Speir of San Francisco, would have eliminated language that currently allows medi-gap insurers to exclude ESRD patients in California. Michael stated that the bill will not pass as a result of pressure from the insurance industry. The industry is saying that the cost of all coverage will increase if the bill passes and this would result in less access to insurance for Californians.
SB 654 This is one of the end-of-life bills being introduced this year. The Board stated that we should "accept and file" this piece of legislation.
SB 401 This bill, introduced by Senator Deborah Ortiz would prevent marketing to people with specific diseases where information regarding an individual and the disease are released. This prohibition would include information provided by a pharmacist to a patient regarding "other therapies" to treat the disease for which the pharmacist is filling a prescription. Tom Paukert and Carol DiRaimondo discussed issues regarding physician-patient relationships when this type of marketing occurs, but they stated that they did not think the issue would have much effect on the patient as related to the dialysis center. Michael Arnold recommended that the CDC stay out of the fray but he left it to the Board for a decision. The physicians on the CDC Board urged that we send a letter of support to Senator Ortiz for her bill and the remainder of the Board agreed.
Michael brought the issue of *ACR* 250 (last year's resolution) concerning Chronic Kidney Disease Week to the Board for re-approval. This year the dates would be August 8-12. The Board agreed that we should pursue another concurrent resolution this year. Michael Arnold also stated that Assembly Member Jenny Oropezo (Long Beach) will be running for State Senate. She has been supportive of our community in the past and might introduce the resolution for us. Peter Crooks suggested that perhaps CDC should look to a geographic area where there is a vulnerable population with regard to chronic kidney disease to find a sponsor. He also recommended that we update the numbers of patients (last year included 1999 data) for this year's resolution. Michael Arnold requested that the members having information regarding this get in touch with him by next week.

Regulatory Report: The regulatory report was delivered jointly by Karen Dyer and Michael Arnold. Karen and Michael, along with Larry Jones of Innovative Dialysis Systems, met with representatives of the State Department of Health Services in Sacramento on Monday, June 13. The three agenda issues are summarized below.

1. New dialysis facilities are being built to serve the needs of the increasing number of patients with End Stage Renal Disease (ESRD). The dialysis population in California grows by up to 9% annually so it is clear that the current number of dialysis facilities will not be sufficient to handle future needs. The state has made it known that, due to the tier 3 survey level for ESRD facilities, it is possible that an initial licensure visit might be delayed for as long as 12 months, though it is not the intent of the local agencies to wait that long if not necessary.

The issue seems to be more problematic for some areas than for others, perhaps due to the volume of new facility construction, staff shortages, etc. Facilities in San Bernardino and Orange counties have been completed and awaiting licensure since January. These delays are very costly as the facilities have to not only pay rent and basic utilities, but have to be operational. This requires staff to be present on a daily basis.

The California Dialysis Council (CDC) would like to have some input from the state DHS regarding steps or options available to dialysis providers to reduce these costly waiting periods. The end result, otherwise, will be that providers will choose not to build in the state and our patients will have trouble accessing care.

2. We understand from the State Department of Health Services that free-standing home dialysis training programs are no longer licensed by California. They continue to be Medicare certified and DHS provides the certification visits under contractual relationship with CMS. The dialysis community has no objection to the removal of licensure as there are a number of states that do not license dialysis providers at any level. However, since the state has historically licensed these free-standing training facilities, there are insurers, particularly managed care organizations (MCO) that are accustomed to requiring a copy of the training facility's license before they will allow the patients covered by their plan to be trained at the facility. To date, the DHS has not issued any written document for the free-standing home training facilities indicating that it no longer licenses them. This has become problematic for some facilities. The CDC would like to request that the DHS issue formal documentation of the elimination of the licensure process for this type of facility.
3. It has come to the attention of the CDC that one of their members has built and has been awaiting licensure and/or Medicare Certification for a free-standing home <u>hemodialysis</u> training program since June of 2004. Since Medicare wishes to increase the number of beneficiaries dialyzing in their homes, failure to license and/or certify a free-standing home hemodialysis training program would seem counterintuitive.

The California Dialysis Council would like to work with the state Department of Health Services to answer any questions and provide support for areas that may be causing any confusion with regard to this issue.

Larry Jones additionally addressed the issue of home hemodialysis in Skilled Nursing Facilities (SNF). The number of people with ESRD living in SNFs has increased over time and the acuity level for those people has also increased. It can be disruptive for patients to be transported to dialysis in a free-standing facility as well as being resource intensive for the ESRD facility.

The principal representatives with whom CDC met at the State offices were Brenda Klutz, Deputy Director for Licensing and Certification, and Scott Vivona, Chief of Field Operations for the Coastal Area. Karen and Michael both stated that they thought the meeting had a positive tone and that the State seemed willing to work with the community towards resolution. The following summarizes the meeting.

Brenda Klutz explained the "Tier" system as follows. Tiers are established by the federal government. Tier One represents those types of providers who have statutorily established frequency for survey/certification. (Ex: home health each 36 months, SNF every 15 months, homes for the disabled every 12 months) EMTALA investigations also fall under Tier One. Tier Two is comprised chiefly of complaints of a serious nature; for example immediate jeopardy must be investigated within 48 hours and allegation of harm must be investigated within two weeks. Tier Three includes other provider types, including ESRD.

Licensing and Certification (L&C)(State) has lost 140 positions (70 of which were field personnel) in the past couple of years. There have been hiring freezes as well as outright elimination of positions. Last year L&C was unable to conduct their Tier One surveys within the statutory limits and as a result the federal government withheld significant funding.

Brenda Klutz suggests that CDC members write their representatives in support of a proposed $12 million national increase in certification dollars. These dollars would be distributed in accord with need by CMS. (The Board approved support of this increase by consensus and Michael Arnold will get more information from Brenda Klutz on the topic and forward it to the membership.)

On the topic of initial licensure visits, Scott Vivona stated that the State has actually never stated that there could be a twelve month waiting period. He wanted to clarify that the 12-month period was not an official California interpretation. Brenda Klutz said that it was certainly not the intent of the State to reduce accessibility to health care services for the citizens of California and that DHS would work with CDC as much as possible to reduce the prolonged waiting period. She had a few suggestions that were "thoughts" and not necessarily operational. They

are as follows.

1. The DHS has authority to contract out with other agencies with whom they have a comfort level to perform initial licensure visits. The ESRD facility would then pay the fee for the visit to the contracted agency. An example of precedent for this would be the Joint Commission and their visits to hospitals. At times, if the DHS is unable to accompany JCAHO on a site visit, they accept the JCAHO evaluation of licensure status as their own. The question, of course, is **who** the agency might be.
2. DHS has authority from the State and even within their hiring constraints to utilize the services of annuitant retired surveyors for special purpose. If they were able to find ESRD specialist retired surveyors, this would be one option.
3. For certification (federal) visits only, a facility might be able to achieve a "deemed status". This system is currently utilized by the federal government in acute care and in surgi-centers. This would not alleviate the initial licensure visit issue and would involve working with CMS officials in Baltimore so is maybe beyond the scope of CDC.
4. Brenda stated that there is precedent in primary care clinics for a "provisional licensure" that might be offered for providers already doing business in the State and known to be in "good-standing." DHS would have to define the components of "good-standing." This provisional license would be good for a period of 30-45 days in which the provider would be able to begin treating patients and then would have the final licensure and Medicare certification visit performed concomitantly. This seemed like the best alternative but if CDC wishes to move forward with this for this year, it will have to be drafted and attached to a bill that is in process. This would have to be achieved by July 8- a time crunch to be sure.

The Second issue we discussed with the DHS team was the issue of "home training facilities" no longer being licensed. We told the representatives that there are P.D. training facilities having issues both with managed care providers and with equipment/supply companies wanting to have a copy of the State license. Since that has historically been available, it is problematic that we have nothing in writing from the State saying that they no longer license this type of provider. Brenda stated that she understood our predicament and that she would discuss the issue with their legal department. Scott said that he had been told to write letters only to individual providers requesting them. Brenda said that if the State has made that decision, she could see no reason not to put it in writing. Michael Arnold told Brenda that she could just send one letter to the CDC if that would make it easier and that we would distribute the letter to our members.

The last issue on the original agenda dealt with the home hemodialysis training program that Dr. Minasian has been trying to have licensed/certified since June 2004. Apparently there are other free-standing home hemodialysis training programs in California (operated by WellBound). Brenda was unaware of the difficulty and said she would check with Eric Stone at Los Angeles County DHS to determine what the delay might be.

Larry Jones brought up the additional issue of home hemodialysis training for patients residing in a SNF. That seemed to be a bit less clear in the minds of the DHS personnel although Larry directed them to a March 2004 CMS clarification of certification requirements and coordination of care for residents in LTC facilities who receive ESRD services. There seemed to be additional confusion around the 1991 "dialysis agency" legislation. Brenda stated that the DHS might look at a special category of licensure for home hemodialysis in SNFs and that DHS could request permission to provide the ESRD community technical assistance in this area. They were aware of Larry Day's "model" which his group has presented to them and Brenda stated that she believes it may be in the hands of Region IX at this time. We stated that CDC is not clear as to what exactly the "model" is but that Larry Day and his group will be coming to the Board Meeting on Friday of this week in Oakland.

Larry Day began the presentation of his program by stating that his application has been pending since November, 2003. He described his "model" as a program for providing dialysis in Skilled Nursing Facilities in a separate dialysis area having five or six stations for staff assisted dialysis. Each patient would have their own machine as is required for home hemodialysis. He would have a
Training Facility that would never be used for training as the patients who would be involved in his plan would be unable to dialyze themselves. He would, however, provide ancillary services as required by Medicare from the Training Facility. The staff-assisted dialysis would not be on a one-to-one basis and Mr. Day stated that there are no rules regarding a staff-to-patient ratio that would cover the plan. He further stated that CMS has approved his model and has told the State to certify his facility. He did state that there are OSHPD issues at this time as the SNF is unable to afford to build the dialysis area to

OSHPD standards and he stated he is working to remove this obstacle.

Jennifer Nazarko, RN, the nurse responsible for a DaVita program that is dialyzing patients in SNF settings, but using a "acute dialysis" model also attended the meeting. Since Medicare states that a SNF is a patient's home, they require that the home patient be dialyzed either in a certified ESRD facility or as a home dialysis patient under the supervision of a certified ESRD facility. Jennifer stated that she had been told by the Department of Health Services to stop operation in one of the facilities where she has been dialyzing patients and anticipates it will happen again. Mary Brattich stated that since this is a home dialysis situation, it would probably be problematic under the current definition of ESRD care. However, she also stated that San Diego will allow individuals on a case-by-case basis to be dialyzed in this manner secondary to significant acuity.

Tom Paukert objected to including these new models in our efforts to effect more timely licensure. Michael Arnold recommended that we pursue the three original issues for resolution and suggested that perhaps Larry Day's issue would be resolved under the third issue which involves the Licensure /certification of free-standing home hemodialysis facilities. There was significant discussion regarding the options as presented by the DHS personnel. The Board was not of one mind regarding the best approach for reducing the waiting time for initial licensure. Carol DiRaimondo moved that the Board and the regulatory subcommittee working with DHS should proceed with the established priority as outlined in the above agenda. She also moved that an upcoming Board meeting should be structured with expert speakers on the topics as well as on the topic of dialysis in Skilled Nursing Facilities. Tom Paukert seconded the motion and the motion passed without dissent.

NRAA Report: Mike Paget reported that the main work of NRAA at this time is the support of the Kidney Care Quality & Improvement Act. Mike also stated that CDC sent email to the membership on June 7th for support of the Act. He requested copies back from those who wrote in support, but has not received any to date. Several members stated that they had written in support of the Act prior to the June 7th email.
MedPAC issued a report to Congress this past week which focused on the differential between hospital and free-standing dialysis reimbursement. The thrust was that the reimbursement should be made the same without regard to the location of the facility. They want to combine the composite and add-on rates. Secondly they are working on the Average Selling Price (ASP) and they reiterated older issues, especially around bundling.
Mike also reported that the original plan for the CDC website was that it would include California-only issues since there are other vehicles for national issues. However, there are occasionally issues that come up that are of a national nature but would be of interest to CDC members. An example is the new MedLearn Matters issue regarding the physician's guide to Medicare coverage for kidney patients. It was agreed that he will send the membership a link to these type of issues.

ESRD Network Up-Date: Arlene Sukolsky presented the Network #17 report. The Network continues to strive for improvement under the Fistula First program. Network #17, at last review, is among the top five Networks for AV fistula rates in the country and is at 46.5% currently. The Network will be announcing an increase in its AV fistula prevalence goal for the calendar year 2005 to 44%.
DVD/CD surgical training videos, featuring Dr. Larry Spergel and Dr. William Jennings, will be provided free to interested vascular surgeons and nephrologists. The training can also be accessed via www.fistulafirst.org, but there is a $25 fee to apply for CME credits.
The Network plans to re-inform facilities about the availability (in English and Spanish) of the Network's Advance Health Care Directives guides for patients and facilities. Arlene stated that this is particularly timely in light of the Terri Schiavo case. Both guides are available on the Network #17 website.
The new CMS 2728 form is effective June 1, 2005.
A supply of a two-sided card with emergency tips has been sent to Network #17 facilities for their patients' education. A list of emergency affiliation partners has been sent to all facilities and to state

survey agencies.
A professional training tool kit for Decreasing Dialysis Provider Conflict has been developed through a CMS contract with the Forum of Networks and will be sent to all facilities in the next several weeks.
Allison Kregness, RN, will join the Network staff in July as the new Quality Improvement Director.

Medicare/ Medi-Cal Report: Cindy LaMunyon reported that the case mix adjustment under the Medicare Modernization Act seems to be working. The mix utilizes age, weight and height. California is experiencing a composite rate decrease under the new case mix while other geographic areas are experiencing an increase.
An upcoming contractor consolidation will result in a new Medicare category entitled Medicare Administrative Contractor (MAC) and will consolidate Part B Carriers and Fiscal Intermediaries. Cindy will present more information on this topic at a future Board meeting.
The National Provider Identifier (NPI) as mandated under HIPAA will become effective on May 23, 2007. Providers are encouraged by Medicare to begin the process of obtaining their NPI early. Effective July 1, 2005, paper applications can be submitted. Application may also be submitted by website: https://nppes.cms.hhs.gov .
A new ICD-9-CM code for ESRD will become effective on October 1. The new code will be 585.6. The old 585 (ESRD) category has been enlarged to include chronic kidney disease categories. Cindy stated that she has found something in writing that verifies this is the correct code.
The Medi-Cal EPO policy changes which became effective in April of this year have resulted in increased reimbursement for EPO.
NHIC: Carol DiRaimondo reminded the Board that she has been the official CDC representative to the NHIC CAC and that Brian Wong was her alternate. However, since Dr. Wong is no longer on the Board, CDC needs to elect a new alternate. Carol stated that she is willing to continue being the primary representative and nominated Tom Paukert to be the new alternate. Tom accepted the nomination and the Board elected Carol DiRaimondo as the primary representative and Tom Paukert as the alternate.

CDC Program Committee: Mary Brattich reported that the Annual Meeting is scheduled for April 27-29, 2006 at the Wyndham Hotel in Palm Springs. She welcomes input regarding topics or speakers.

Mike Paget reminded those in attendance that the 2006 meeting will be held in conjunction with the NRAA. He asked if the Board wishes to consider a discount for registrants for both of the meetings. The Board agreed that it would be appropriate.

Other Business:

1. Committee assignments were discussed and it was agreed that the Executive Committee would finalize the list.
2. Rosemary Fox of Satellite Healthcare stated that a law firm has been placing advertisements in big city, low cost newspapers from San Diego to the Bay Area suggesting to dialysis patients that if they are hospitalized within 48 hours of a dialysis treatment and they have a fever, they might wish to contact the law firm. These ads have been running for at least the past month. Since such advertisement is not illegal, this was brought up as an informational issue.

Next Open Board Meeting

August 19, 2005 Los Angeles

As usual there will be no Board Meeting in July

For more information and a registration form, please visit our web site at:

http://www.caldialysis.org/next_meeting.htm