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Session 129PD
New Strategies in Disease and Utilization Management

Track: Health

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Summary: The bulk of health care is utilized by a small percentage of the population. New strategies in disease management target the high users and develop utilization management programs specifically for this segment of the insured population. Attendees will learn about new and emerging techniques for optimizing health care utilization.

MR. SCOTT E. GUILLEMETTE: Welcome to New Strategies in Disease and Utilization Management. I am Scott Guillemette. I am a principal at Tillinghast-Towers Perrin, working largely with managed care organizations and their actuarial needs. I work closely with these three physicians on the panel and am very pleased to have them here today.

We've heard about the Pareto Principle a lot these last three days. You know, that 80 percent of the dollars are generated by 20 percent of the people. We're going to find some more interesting statistics in a little bit that are actually more tilted than that. I think what's kind of an interesting de facto here is that managed care has been getting lambasted quite a bit over the last year or two, but disease management programs and focused utilization management actually work quite well. Hopefully the doctors here will support what I'm saying, in that managed care does work if it's focused and done in the right ways and there are more stories to

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Note: The chart(s) referred to in the text can be found at the end of the manuscript.

tell on the managed care front instead of abandoning it immediately. I just think there's a lot more to learn in this area as we see through some of the prior talks in predictive modeling and so forth.

Without further ado, I'd like to introduce the panel. Dr. David Kaplan is a principal with Tillinghast-Towers Perrin. He is the head of our clinical practices and also leads our medical cost trend management initiative. He's a medical doctor from Rush-Presbyterian-St. Luke's Medical Center in Chicago and his pediatric residency is from UCSF Children's Hospital in San Francisco.

Dr. Gordon Norman is the vice president of health care quality for PacifiCare Health Systems. He oversees the quality-improvement-related activities, disease-management programs, health-management activities and health-data analysis for the organization. He has an M.D. and an M.B.A. from Stanford, and he is a family practitioner who practiced largely in New York and later in New Hampshire.

Dr. Ron Geraty is the CEO of Alere Medical, which is a disease-management vendor that primarily serves congestive heart failure (CHF) patients. He is a serial entrepreneur, founding and managing companies like Monarch Health, Assured Health, which later became American Behavioral Health, and American Imaging Management, which is a radiology company

There is a reason why we have these three physicians here—Dr. Kaplan is a consultant; Dr. Norman offers the perspective of the industry; and Dr. Geraty offers the disease-management-vendor aspect of the industry. Dr. Kaplan will start from a very high level to discuss disease management and utilization management programs.

DR. DAVID KAPLAN: When we think about disease management and about what makes sense, we obviously get back to the issue that it's the top claimants spending most of the dollars. What we find is that, in our combined databases, which include our own Tillinghast database and the Medstat database, the top 3 percent of members spend about 43 percent of the dollars, the top 1 percent spends 27 percent and the top 2 percent spends 36 percent of the dollars. So it's a fairly small number of members that are spending the majority of the dollars. I think one can make a good case that, for the other 97 percent of the people, if you have good contracts in place, you can probably step back to a large extent, in terms of what you do. For these 3 percent, this is where the bucks are, and this is where the potential to impact is.

Now, in this 3 percent there are two groups. There are folks who have acute events that are unlikely to occur—a bad automobile accident, a burn, premature triplets—things that are high-cost and high-dollar. You're eating it now, but you're unlikely to be eating it next year.

Then the second group is those who have chronic illnesses that are likely to remain

high-cost as you move forward, and this is the group that's impactable. Now, interestingly, if we look at the top 1 percent, you can really see that it gets to be extraordinary there. The top 0.10 percent of the members spend 98 times as much money as your average member, and, overall, the top 1 percent is spending around 23 times as much. So a small number of people are driving the costs.

When we look at members with very specific diseases, we see that they tend to be expensive. Everyone's got criteria that they use to identify people with certain disease states, and these criteria are looking for folks with at least some modicum of more than just a single diagnosis or episode of asthma; we're really looking for people with some recurrent disease that may be impassable—what we find is that of these people, not surprisingly, the end-stage renal-disease members on a per-member basis are the most expensive.

Dialysis patients are expensive. Chronic renal failure, however, isn't that far behind. Then we have the folks who have both co-morbid coronary artery disease and diabetes. Congestive heart failure patients and oncology patients are very close to each other, each of them 33 times as expensive as your average member. Coronary artery disease is 20 times as expensive, diabetes 18 times, lower back pain 13 times and asthma about 10 times as expensive. So there are specific members who have costs that really are compelling to try to manage and thus we have disease management—a series of interventions targeted at individuals with a specific disease, or in some cases, who are at risk for a specific disease. That said, a disease management program is not a disease management program. Enormous variations occur in programs for the same disease, such as how the programs are structured, what the goals are, what particular cost drivers they're addressing and the kinds of outcomes that they get.

When I want to think about disease-management programs and ask, "Is this disease management program going to have a positive outcome on my medical cost trend?" it's helpful to think about them as falling into two basic categories. There's some folks who, under the rubric of disease management, run what we call population-based disease management programs. These are programs that cover everybody who might be defined as having the disease. It then stratifies them into risk groups and has interventions that are based on the different stratification levels. If someone has just very mild disease or maybe is just at risk for the disease, the intervention might be mailing them educational information; while, if they seem to have more hospitalizations or more problems, the intervention could be something on the order of doing some specific one-on-one educational interventions with them and checking on them periodically. If they're in the sickest category, intervention might include assigning them their own nurse case manager whom they work with very closely on an ongoing basis. So population-based management covers the full spectrum.

Disease-specific case management is the other kind of program, and this really covers, just within a disease category, the high-cost, high-risk members only. It

looks at the folks that are really going to drive the cost, and it has high-intensity interventions based on much more of a case management model. While there's some patient education and patient empowerment, it's a very active model that involves the patient, the physician and tries to have very specific goals such as preventing readmission. It is a very, very intensive type of program.
What are we seeing with these programs? Well, in general with a population-based disease management program, you're unlikely to reduce return on investment for that kind of program in any short time frame, simply because you're doing interventions with a lot of the population that are potentially of dubious value and more significantly are unlikely to impact any major cost event. The problem that we find is when health plans put population-based disease-management programs in place, sometimes they're very unclear as to whether it's a quality program because it's the right thing to do or a cost-control program. And, if you're unclear about what it is, then frequently the way you're measuring it is also very unclear and mixed, and therefore you end up with some interesting answers.

Identification in population-based management covers a wide swatch. They try to catch everyone who has the disease, may have the disease, is taking a drug that may be related to the disease. The goal is to capture the entire population and, as we know, once you've done it and you try to stratify them, it's a very time-consuming and expensive process. You can do some of the stratifications using claims data, but that only gets you so far. Then you actually have to outreach with the patient and actually talk to the patient or talk to his or her physician or send in requests for information to find out indeed if the patient has diseases. We know that in some diseases like congestive heart failure, which our experts will give us more background on, that sometimes using claims data when you actually then go and you talk to people and get down to it, probably only somewhere between a half and two-thirds of the people actually are appropriate for your program. So you end up screening an awful lot of people, and in other disease states the amount of level or screening can be greater , and it's a very time-consuming, expensive process, often done by someone who is very expensive, like a nurse.

Then even when you go ahead and you do all that—you stratify them, you try to enroll them—you find that the active participation yield is low. Unless the disease is having a dramatic impact on their lives, most people are just not interested in being enrolled and having the reality of having this disease thrown in their faces, so you find that you've put these programs together, you do all the right things and you end up getting 6 percent of your asthmatics enrolled. When you try and look at what we are doing for asthma, it becomes an interesting challenge.

Many dollars are spent on targeted educational materials. The value of these mailings is, at best, unproven. The issue is that most of them miss the teachable moment. If I want to give you some educational material about asthma and get you to read it, if you get it tomorrow and you haven't had an asthma attack in six months, it becomes junk mail. The likelihood of you giving it more than a passing glance is fairly small. On the other hand, if you were in the ER having an acute

asthma attack and the nurse or the doctor in the ER hands you educational material on asthma, the chance of it getting read is greater, because it's a teachable moment and, indeed, educational materials are probably most effective closer to the point of medical contact. Then outcomes are often difficult to measure in these population-based management programs because you've got lots of different kinds of interventions going to different people and, therefore, the measurements become challenging.

The other group is disease-specific case management programs. These look to focus programs and resources, and we're seeing many health plans begin to move more toward disease-specific case management. These programs are really looking at the people who are spending the bucks and are most likely able to be engaged and impacted. The emphasis is on member empowerment, giving people the information to control their disease; early recognition of exacerbations; and admission preventions. The single biggest unit cost is an admission. Drug compliance, working with the physicians to make sure we have the patient getting the best practices, encouraging alternative levels of care where appropriate and just coordinating the care are other important issues.

The programs generally center around specialty-trained nurses in that particular disease state providing support and information to members across the entire continuum of care. Sometimes these programs are done internally and sometimes they're vendored out to disease-management companies. and we can certainly, during the question-and-answer portion, talk about the merits of both.

In my experience, I've seen that the programs most likely to have a positive return on investment are congestive heart failure programs, end-stage renal disease (ESRD) programs, pre-ESRD programs, wound-care programs, diabetes with co-morbid heart disease programs, high-risk maternity programs in the Medicaid population and oncology programs. Programs that may have a positive return on investment, depending often on how good the identification is and how good the stratification is, include rare diseases, secondary cardiovascular disease programs—that's prevention after the first heart attack, certain interventions—and chronic obstructive pulmonary disease (COPD), which is mostly in the elderly population.

In our experience, programs unlikely to have a positive return on investment, not meaning that they're things that you may not want to do for quality's sake, but often do not have positive return on investment in our experience, are asthma programs, coronary artery disease by itself for everyone, diabetes by itself as a program and high-risk maternity programs in a commercial population. These often just duplicate existing services in our feel-good programs, marketing programs.

DR. GORDON NORMAN: Let me tell you a little bit about PacifiCare. Those of you who are from the West Coast, Southwest or Northwest may have heard of PacifiCare. It's both a commercial and Medicare managed-care and health-services company with its origins in sort of a classic lock-in, gatekeeper model. Capitated

HMO and a considerable market share is still within that space of managed care, that ever-declining space of managed care. In California, we've typically been the third- or fourth-largest health plan. We are the largest Medicare HMO in the United States, and have been since we were one of the first back in 1985. As challenging as that is, we continue to be the leader in that area, so we need to extract benefits from disease management as described by David.

Prior to 2000, PacifiCare was not very active in case-based disease management. If you will think of this as a life cycle of disease starting from risk, which is probably genetic originally, and then various risk factors, early signs and symptoms of disease, going out to overt disease, this side of the equation consists of population-based programs or, if you will, health improvement programs. We were very active in this arena, as were most of our competitors. Why, given the questionable ROI that David mentioned? Because it's the right thing to do if you're a managed-care plan. Because your purchasers expect you to be doing it, your consumers in many cases expect you to do it; they won't read it necessarily, but they expect you to be doing it nonetheless. And because your competitors are doing it, so if there's not a positive ROI, there may be a positive penalty for non-investments in this arena with regard to marketing and market share.

We had disease management or the active management of patients with chronic illness behind what I call the veil of capitation. We were the most capitated health plan in California, the most capitated state in the union. What that meant is that for our organized medical groups in Independent Practice Associations (IPAs), virtually 99.8 percent of institutional and professional care was capitated to these organized medical groups. It was they who developed approaches to case management or disease management, because they held all the risks. So the first rule of disease management is he or she who has the risk is the disease manager of record.

Fast forward to 2000. Our risk starts to shift, particularly institutional risk in California and even earlier than 2000 elsewhere, reverting from capitation to other forms of payment where the plan ultimately held the risk—per diem and fee schedules, direct contract models—so, suddenly, in a very short period of time our company becomes disease managers. Why? He or she who holds the risk is the disease manager. So, we were exposed to risk across the continuum. We had need to convert our health improvement programs into full-blown, population-based and case-based health-management programs or add disease management to health improvement. And we had a short time to do that.

How was this going to fit into our spectrum of services provided for our continual member needs? Well, we still are going to do preventive health management. Again, it's the right thing to do. It may be a questionable ROI, but after all, this is managed care and if you're not managing this, you're probably not managing much of anything. Despite rumors to the contrary, what we lovingly used to call utilization management has not died. It may not be as blunt or clumsy as it was 10 years ago, but acute episode management continues to exist. It needs to continue to

exist in my estimation, done in a more focused fashion on outlier groups, both performance-based and data-driven and includes not just the inpatient length of stay, but the transitions between inpatient step-down care, rehab, outpatient sites of care—which are more and more prevalent, home health, home transfusion, infusion therapy—and the continuity of care issues between all those transitions and providers of care.

In the chronically ill space, here we have classic chronic disease management or case-based disease management, and we'll talk about the programs that we target. Then we have special populations that are not joined by their having a common disease, but a common condition. So we'll talk about what we mean by frail members, who for any variety of reasons, have a set of defined needs that need to be met and may not be met by the provider delivery system. ER frequent utilizers, again a common characteristic, but not necessarily common underlying need; pre-catastrophic care, we'll touch on terminally ill members; and then finally the sort of classic, which has been around forever, catastrophic care. These are complex, high-cost, high-intensity cases that have to be managed, and typically the provider delivery system does not tie all the loose ends together, so it's a role for the plan.

OK, it's 2000, we're getting the risk back, we have to define what we're going to do and where we're going to go. David Kaplan is not publishing this talk for our benefit, so we have to figure out what diseases cost us. How are we going to target with appropriate investments to make a reasonable ROI on our efforts? We start by defining the base-line prevalence of our diseases, the PMPM cost in utilization and defining the high-cost Pareto groups. I'll show you that analysis in a moment. We assess where the criteria for doing disease management for a condition are met, because that's what determines whether the disease state is intervenable or not and the feasibility of the potential opportunity. David mentioned ROI but didn't specify a time horizon as to whether the various conditions in his last slide produced an ROI. It's quite possible that intervening at the right level for some diseases like uncomplicated diabetes does, in fact, produce an ROI if you can wait three to five years to get it. In our industry, with margins within a good year that are typically under 5 percent, nobody can wait three to five years. There typically is a 15 to 20 percent turnover of commercial population every year. There used to be not nearly that much in the senior, but that's begun to change. So ROI is ever in a shortening time horizon. That's just a requirement of the industry.

Then you have to figure out whether these programs will save and how much they'll save. There is some literature, although precious little, relative to the million articles that are printed every year in medical journals. Of course, the vendors will tell you what they can save. Consultants are glad to be paid to tell you what you can save. Industry groups and meetings provide some peer-to-peer information exchange, and you can always run pilots, which we have done in several cases that are often very illuminating, but not that easy to set up. You often wonder if it isn't easier to just go ahead and do a full-bore implementation, but it does contain the

risk to some extent.

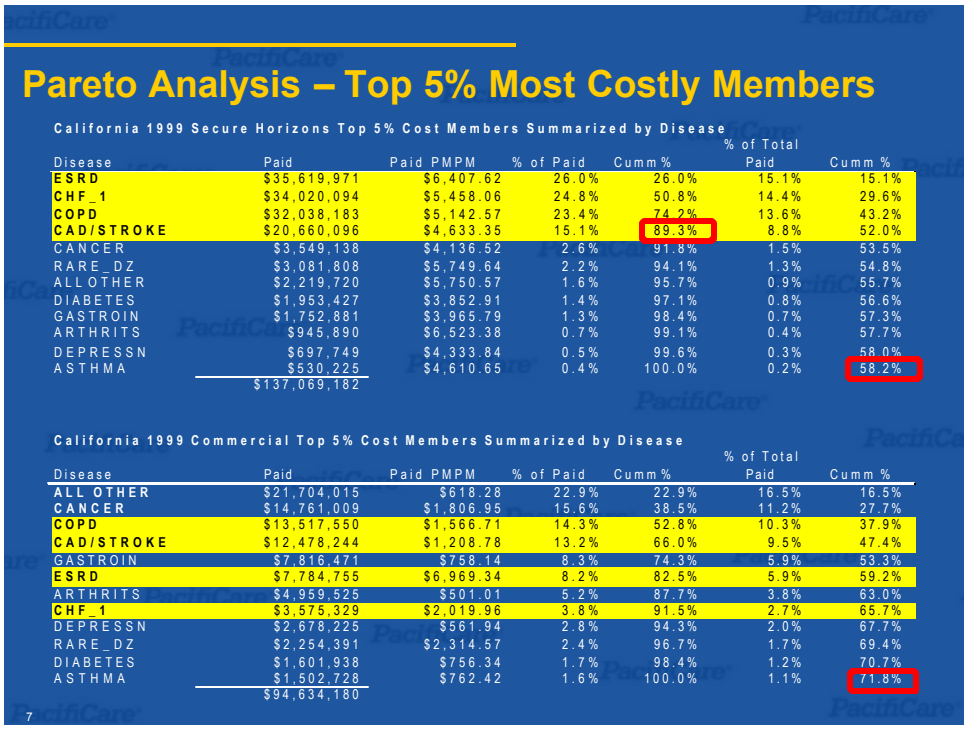
So what are those criteria for disease management? Well, it's got to be a fairly prevalent chronic disease, right? There's got to be some money at stake. It's got to have high-dollar volume and/or high utilization, which means high-dollar volume, a high risk of adverse clinical outcomes, a wide variation of treatment approaches and/or common departure from evidence-based best treatment. That one's not a problem, because I assure you there's rampant variation in the way everything is treated. There's potential for member and provider interventions to actually improve outcomes. You would think that's straightforward, but sometimes that is the one that is most questionable. And there are standardized metrics for assessing the outcomes. In addition to these classics that almost everyone would say in our business, the economics had to allow for suitable ROI in a suitable timeframe, and a suitable timeframe is typically one year. Time for results is reasonable and adaptable to multiple network models and risk scenarios, because the PacifiCare network in Colorado doesn't look very much like the network in Arizona, versus Oregon, versus Washington, Texas, Oklahoma or California. So who bears professional risk, institutional risk, pharmacy risk varies, and you have to have these models adapt to that.

Back in 1999, to get started, we looked back a prior year at our senior population and our commercial population. David's statistics are a blend. Are they, or is it strictly commercial on your data that you provided?

DR. KAPLAN: Commercial.

DR. NORMAN: Commercial only. OK. Commercial is interesting, but the big money is here in the larger senior plans, so we had a specific focus on trying to attack senior plans. Table 1 shows the institutional claim types for the top 5 percent most costly members in 1999 for PacifiCare of California, when indeed a minority of the members did we have risk for. What we found is the top 5 percent of members constituted 58 percent of the total paid claims for institutional claim types. That's inpatient, outpatient surgery, ambulance, all the things that are institutional claim types—if you will, everything other than professional ambulatory services and pharmacy. In rank order, by the disease that accounted for the majority of their costs, these are the total costs of the members who are defined by ESRD, CHF, chronic obstructive pulmonary disease (COPD) and coronary artery disease (CAD) stroke, following which is cancer and rare disease. So four diseases actually made up 89 percent of this 58 percent, so we have the extreme Pareto phenomenon that David referred to earlier.

Table 1



Pareto Analysis – Top 5% Most Costly Members

California 1999 Secure Horizons Top 5% Cost Members Summarized by Disease

Disease	Paid	Paid PMPM	% of Paid	Cumm %	% of Total Paid	Cumm %
ESRD	$35,619,971	$6,407.62	26.0%	26.0%	15.1%	15.1%
CHF_1	$34,020,094	$5,458.06	24.8%	50.8%	14.4%	29.6%
COPD	$32,038,183	$5,142.57	23.4%	74.2%	13.6%	43.2%
CAD/STROKE	$20,660,096	$4,633.35	15.1%	89.3%	8.8%	52.0%
CANCER	$3,549,138	$4,136.52	2.6%	91.8%	1.5%	53.5%
RARE_DZ	$3,081,808	$5,749.64	2.2%	94.1%	1.3%	54.8%
ALLOTHER	$2,219,720	$5,750.57	1.6%	95.7%	0.9%	55.7%
DIABETES	$1,953,427	$3,852.91	1.4%	97.1%	0.8%	56.6%
GASTROIN	$1,752,881	$3,965.79	1.3%	98.4%	0.7%	57.3%
ARTHRITS	$945,890	$6,523.38	0.7%	99.1%	0.4%	57.7%
DEPRESSN	$697,749	$4,333.84	0.5%	99.6%	0.3%	58.0%
ASTHMA	$530,225	$4,610.65	0.4%	100.0%	0.2%	58.2%
	$137,069,182					

California 1999 Commercial Top 5% Cost Members Summarized by Disease

Disease	Paid	Paid PMPM	% of Paid	Cumm %	% of Total Paid	Cumm %
ALL OTHER	$21,704,015	$618.28	22.9%	22.9%	16.5%	16.5%
CANCER	$14,761,009	$1,806.95	15.6%	38.5%	11.2%	27.7%
COPD	$13,517,550	$1,566.71	14.3%	52.8%	10.3%	37.9%
CAD/STROKE	$12,478,244	$1,208.78	13.2%	66.0%	9.5%	47.4%
GASTROIN	$7,816,471	$758.14	8.3%	74.3%	5.9%	53.3%
ESRD	$7,784,755	$6,969.34	8.2%	82.5%	5.9%	59.2%
ARTHRITS	$4,959,525	$501.01	5.2%	87.7%	3.8%	63.0%
CHF_1	$3,575,329	$2,019.96	3.8%	91.5%	2.7%	65.7%
DEPRESSN	$2,678,225	$561.94	2.8%	94.3%	2.0%	67.7%
RARE_DZ	$2,254,391	$2,314.57	2.4%	96.7%	1.7%	69.4%
DIABETES	$1,601,938	$756.34	1.7%	98.4%	1.2%	70.7%
ASTHMA	$1,502,728	$762.42	1.6%	100.0%	1.1%	71.8%
	$94,634,180					

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The commercial population is not quite so straightforward, because the No. 1 category of cost is All Other. All Other is acts of God. It's the car accident; it's the preemie triplets, although that's often an act of an infertility specialist. Cancer here is No. 2, and we do see COPD, CAD stroke, ESRD and CHF within the top eight. The top 5 percent most costly members here is an even more exaggerated Pareto group. Seventy-two percent of the total institutional costs came from these 5 percent of members. So, while it's hard to figure out a disease-management program for All Other—I haven't met the vendor yet that does that—there are opportunities here and topmost is cancer, which we'll come back to.

OK, so we know what diseases we're going to attack; how are we going to do it? Are we going to build all these from scratch? Yes, we have some case managers. Yes, we've got some physicians. We've got some capabilities. But there are all these vendors out here who claim to have experience and economy of scale. After a relatively intensive, but short, period of research, our preferences became fairly evident to us. Where the major focus is the primary disease driving the majority of the members' utilization costs, where specialized skills are not easily developed or recruited, in case you hadn't noticed the nursing shortage, where the use of proprietary tools is part of a useful intervention, where economies of scale and scope may pertain, where performance data may be available and performance risk may be accepted, we had a preference for outsourcing these programs. Speed-to-implementation is probably another factor I should have put up there.
When would we insource a program? Where the major task is support and

integration of multiple unmet member needs that are driving excessive resource consumption, as opposed to a clinical disease state; where generalists and social-management skills are more critical than clinical specialty skills in managing the member; where integrating community resources is an important part of the total plan; and where no proprietary tools are necessarily needed.

Now, when I say outsourcing, there's outsourcing and there's outsourcing. One form of outsourcing is turnkey outsourcing. I contract with a vendor, I do a massive data dump of all our claims experience. You, the vendor, tell me who was sick, who wasn't, who is eligible, who you're going to enroll, how much you save for me at the end of Time X. That's not our kind of outsourcing. Our kind of outsourcing is to work with a vendor to leverage the intellectual capacity and experience, proprietary tools, experienced and specialized staff, but to do most of the analytics ourselves; and before we ever start doing anything with a vendor, we have generally both looked at a claim set and identified prevalence and PMPM baseline costs to mutual satisfaction within 2 or 3 percent, just to know that we're talking the same language.

Having gone through all this, we decided our most promising choices were in this order, ESRD, CHF, CAD stroke, COPD. That's reflective of our predominance of seniors in our population, but we also knew there was an opportunity for cancer, because it was up there in senior and it was No. 2 in commercial. The rare complex disease medley, and that's a name essentially created by the vendor, but it deals with rheumatoid arthritis, seizure disorder, hemophilia, sickle-cell disease, neonatal care, which is the post-birth side of the high-risk maternity care and asthma. The appealing insourced case-management candidate for us were end-of-life care where the problem may be cancer or other chronic disease and there's need for home health, family support, hospice intervention; or advanced medical directives for frail members who aren't quite at the end-of-life stage, and they have chronic disease, they're disabled, many may be homebound; and we thought ER-frequent utilizers, who for whatever reason, be it access, chronic disease or compliance, are just are popping into the ER an awful lot.

How do we figure out who to go with? Well, we exhausted all the resources that we could, and at the end of the day our question was, "Who's going to provide the best results?" Does their disease management model make clinical, operational and economic sense to us? Is the business model fitting with other programs we already have in place?. That could be the biggest obstacle of all. Is there credible past performance with other large health plans or anybody? Are they willing to put fees at risk for aggressive performance targets? That was very important to us. Do they agree to population-based savings guarantees? Does the company have critical mass and capitalization, agree to financial disclosure and is it willing to negotiate a win/win deal? Are they doing business with other plans in existing markets? If so, that's at least easier for the delivery system to cope with than the third or fourth ESRD vendor that they have to contend with. And do we have positive pilot experiences, positive testimonials, other recent contracts acquired by

the vendor or, in fact, cancelled contracts that shed some light on their ability to perform?

All of these are rolled up into the following selection: who we are working with in our programs, but I'm not going to dwell on the programs per se. Alere, who is with us today is our CHF partner, and that's predominantly a member-centric focus on self care, symptom escalation and weight gain using a proprietary monitor24/7 cardiology contact, alerts to the physicians and the members when prompted by symptoms or weight change and acute intervention in order to impact ER and inpatient total bed days. If you have CHF, some medical misbehavior on your part does not take very long to result in a trip to the ER in pulmonary edema if you're a so-called Class 3 patient. With other diseases such as diabetes, your medical misbehavior may not pay off into anything meaningful to you for a period of years, and in some cases, decades. So that deals with the teachable moment, and it deals with ROI. If you're going to be likely to eat a bag of Doritos with a six-pack of beer watching the soccer game, we have got to find out what's going on very quickly and intervene if we're going to spare that average two-times-a-year trip to the hospital for our CHF patients.

We have a CAD and stroke program. It's CAD and stroke, because atherosclerosis is atherosclerosis. It leads to both of these and fundamentally this is a physician-centric, evidence-based medicine approach to better management of underlying sclerosis. It stratifies patients through ambulatory heart monitoring, which is not commonly done in clinical practice. It utilizes the vendor's cardiology to review medications, labs, blood pressure, symptoms and EKG to define the optimal management and where the gaps are in current management. It diverts referrals to cardiologists for patients who can be comfortably managed by primary-care doctors with the benefit of this program and their cardiologists and the major difference is, why would you care? Because their cardiologists aren't procedure-driven and community cardiologists typically are. Finally, the impact is on cardiac testing, revascularization rates and inpatient myocardial infarction (MI) admission.

For ESRD, Renaissance is our vendor. It's mostly a member-centric program to support patients in dialysis. It provides assessment education, reinforcement and medication, lifestyle by dialysis nurses. It integrates the care they're receiving from their primary doctor and a variety of other specialists, because these people also have heart disease and lung disease. When we can identify them upstream on the basis of lab data, we can do an even better job and the impact again is on ER and inpatient days.

For COPD, chronic obstructive pulmonary disease, our vendor is called AirLogix. Again, it's a member-centric program supporting emphysema and chronic bronchitis patients, using respiratory technicians in both the field and telephonic support roles, focusing on compliance with appropriate meds, pulmonary rehabilitation, exercise, chronic-care management, winter-flu prevention, upper respiratory infection (URI) management and again reduced ER and inpatient days is the anticipated ROI.

With regard to cancer Quality Oncology it augments treating physicians, education and support of members. It reviews treatment plans for the best evidence-based protocols. It educates members about disease treatment and expected or possible complications. It integrates palliative with curative care. I'll come back to that some more. Again, there is an impact on ER and inpatient days to reduce complications and there is an avoidance of futile or unwanted treatment.

Regarding diabetes, we are negotiating with Pfizer Health Solutions for a program that stratifies the diabetic population to identify the poorly controlled and/or high-utilization members who don't yet have CHF, CAD, ESRD. If they had those programs, they're going to be in a CHF program, which, by the way, also manages the diabetes in those co-morbid members, which is a significant percentage, between 40 and 60 percent of the population. Again, if they have CAD, a large percentage of those will have diabetes. So we don't ignore the diabetes. The diabetes gets dealt with, but the CAD is the focus. Same for ESRD. That's how they got ESRD. Again, there is an impact on the ER and inpatient days and a progression to further end organ damage.

OK, what do we do with insource programs? We identify frail members by the combination of the number and type of diagnosis, frequency of hospitalization and RX utilization and basically an apparent formula we've derived, not a predictive model at this point. These people have multiple needs, caregivers and barriers that need to be addressed through case management, where we coordinate both our medical and non-medical services, transportation being one common gap. There is a link to community resources where available, psychosocial support and guidance and an attempt to impact once again the ER and inpatient utilization morbidity.

End of life. These people are identified by their diagnoses and by active provider referral. Their care needs are assessed, the gaps identified. They're informed about terminal-care options, specifically hospice for early hospice referral, advanced medical directives of counseling and support is provided. Again, there is an impact on ER and inpatient utilization, particularly in deaths in the acute-care setting where nobody really wanted that to happen.

And now for results—the often-elusive component of disease management. I'm going to give you results in a similar format for a number of our programs. Chart 1 results are confined to California. SH means Secure Horizons, our senior Medicare plan, CO means commercial. So the bottom two graphs are commercial, the top two are seniors, and on the left we have a graph that shows days per thousand and on the right we have paid PMPM for all institutional claim types. So it's not total cost, but it is total institutional cost, which is the bulk of the cost.
Now, I'm showing you two sets of bars but there's a third set of bars, which is actually the contractually relevant set of bars, and that is what happened to the total population between baseline and the contract period. When you put them all up here, it starts to get congested, so I focus on the enrolled versus the not-enrolled subpopulation so you could see what's going on. The relevant actuarial

phenomenon is what's happening to the eligible population in aggregate because that analysis typically avoids the problem of regression and cherry picking, which are the Achilles Heels of disease management contracts. So turquoise is going to be the baseline, typically a year preceding the contract period and the intervention period is the year of the first intervention.

The people that got enrolled by the vendor and the people that didn't get enrolled all met the same eligibility criteria. It's possible that some of the not enrolled may have been approached and refused. Some may have had exclusion criteria. For instance, in CHF if they have end-stage renal disease we don't enroll them in CHF, we divert them to ESRD.

This chart shows a number of member months. We enrolled fewer here than not enrolled. This percentage has improved since that time, but notably there are 55 percent fewer bed days compared to baseline, whereas the not enrolled has a flat trend. Now, some years you'll take a flat trend, OK?. Medicine isn't trending at 0 percent; it's trending overall 6, 7, 8 percent. Drugs are 22 percent, so maybe there's a spillover on the not enrolled, but this is an obvious difference and in paid PMPM, a similar magnitude, 51 percent less PMPM paid for institutional costs and a 1 percent increase on not enrolled. It certainly looks like the vendor's doing something here. That's on seniors. In California alone this appeared to save net of the fees paid, not the net of indirect costs. This isn't fully loaded allocated, but there are net savings of $6.3 million. One program, one plan, one segment of the population.

Commercial. Do commercial members have congestive heart failure? You bet they do. About a tenth as many, but still they use bed days, and here we get a 62 percent reduction in bed days of the enrolled versus a 10 percent reduction on those not enrolled. How did we get any impact on those not enrolled? Well, there could be a spillover effect. We do other things in utilization management to focus on the length of stay, so some of this could have been an actual length-of-stay reduction. In point of fact, all of this relates to a reduction in admissions. Admits per thousand is responsible for virtually all of the disease management impact on bed days, not length of stay. Occasionally, on a single case you may see a length of stay, but it's not a population phenomenon, and in dollars it's 49 percent versus 11 percent.

There is a similar analysis for chronic obstructive pulmonary disease (Chart 2). This is almost only for seniors (i.e., the over-65 population). The enrolled seniors experienced a thirty-seven percent drop in their inpatient bed days, while the not enrolled seniors experienced a 4 percent drop. The enrolled seniors experienced a 28 percent drop in PMPM, while the not enrolled experienced only a 3 percent drop. It's a very similar looking phenomenon.

End-stage renal disease (Chart 3). How come there are not two sets of bars? Because everybody gets enrolled. Everybody who is sick enough to have dialysis,

who becomes ineligible, gets enrolled in the program, so there is no not enrolled. so what happened here? Twenty-six percent dropped to baseline on days, and there is an 8 percent drop on PMPM on the seniors. In the commercial population there is a 43 percent drop in days and an 8 percent increase. How can this be? How can we have fewer bed days, but a higher-cost PMPM? Because with only 875 member months in this experience between April 1, 2001 and Nov. 30, 2001, we had some outliers. It only takes three or four high-dollar outlier cases to blow this number up, but over time, as that gets balanced by more volume, I'm sure we'll see this number come down as long as this phenomenon continues.

I'm a doctor; I'm talking ROI, right? Where's the quality improvement? Where's the clinical improvement? It's there. Obviously we wouldn't get this ROI unless something were happening that was fundamentally positive in the quality arena, but in CHF and COPD, in CAD and ESRD, a variety of clinical and service metrics are showing the kinds of improvements that you expect with improved care. In some cases, there is profoundly improved care. In post-MI patients, there is a 45 percent increase in beta-blocker use. Everyone should be on beta-blocker use. Typically in an unmanaged population it runs 60 or 70 percent. We're above 90 percent for our population.

What about the insource program? We use the same analytics. Why not? We can define eligibles, we know who got enrolled, we know who didn't, we know what we paid, we know what the bed days were, so for our frail member program we see a 29 percent drop in the enrolled population relative to a 1 percent drop in bed days (Chart 4). Over unpaid it's a 17 percent drop versus zero. That's in the senior. Down here in the commercial it's not quite so evident what's going on. There is a ten percent drop in the enrolled, and an 8 percent drop in the non-enrolled, but below there is a 16 percent reduction in paid PMPM versus a 4 percent increase in pay. It looks like something comparable is going on, maybe not of the same magnitude.

For end-of-life care, we have to use slightly different statistics (Chart 5). These people don't stay in the program the whole year. They, unfortunately, have their end of life, so we have not-very-elegant measures called percent of inpatient deaths and paid per death, so it compresses the days and the dollars into whatever length of time of that year before they die. What we're seeing in the enrolled population is a 24 percent reduction in inpatient deaths versus a 12 percent increase. How do I know that's a good thing? Because I know our plan started at baseline with an excess over national averages of patients dying in the hospital. So, in general, when patients are given the choice, who are not in the midst of therapy, would generally prefer to not be in the hospital full of tubes and with all of the complications of being in a hospital. They prefer not to be in the hospital if they have that choice, and in many cases they weren't given the choice. Now they are. Here we see a 6 percent drop in paid versus a 1 percent increase. We think this is positive and justifies our program.

Just to show you that we don't hide our failures, Chart 6 demonstrates frequent ER utilizer care. The story of this one is told in these top two numbers. We define frequent utilizers too liberally, so we got 119,000 eligibles of whom we could only touch 1 percent. Now, having touched 1 percent, we got 17 percent fewer days and 5 percent fewer dollars, whereas the other population went up. That looks positive. Over here, the numbers are10 percent versus 16. That's not good. Over here we have a 47 percent increase in paid PMPM versus the 23 in the people we didn't touch. That's really not good. Maybe we were reminding these people that they were ER frequent flyers and they headed right for the ER because they were anxious about it for whatever reason, and I think the reason is we define frequent by criteria that is too liberal. This program has been stopped until we reanalyze defined subsets for whom this intervention makes sense, then we'll resurrect it again.

Cancer is the newest program we're implementing across our enterprise. Why cancer? There's a shortage of medical oncologists. They are all either too busy, or at least appear to be too busy for their patients to answer their questions and provide complete information. Some of these doctors are unfamiliar with the oversight of total patient care. They are cancer doctors, not people doctors. Technical sophisticated treatment is typically emphasized over education, empathy and preparation for end of life.

Unfortunately, this tends to be true of oncologists. Physicians tend to use the most convenient setting for them, not their patients, and everyone has difficulty discussing and dealing with death—in some cases the doctor more than the patient. Some of you may be aware that in U.S. medicine we are trained to know that death is the enemy, quality of life is secondary to quantity and that the doctor's job is to maximize quantity of life at all costs so that the preparation for death is avoided. Futile care is offered routinely and suffering is common with dignity elusive. Elsewhere in the world, death is generally regarded, even by the medical profession, as inevitable. Quality of life is the primary goal. The doctor's job is to maximize quality of life by alleviating suffering and preparing for death; futile care is rare—sometimes care at all can be rare—and dignity is often preserved. That's a pretty striking contrast.

So what do we do in cancer DM? We take the traditional practice model that says once they're diagnosed we're going down the curative path. . We will get into futile treatment. We will get into untested treatment. We will get into unwanted treatment. Why? Because this is America. We have a rescue ethos. Anything that might help is worth doing if somebody else will pay. Do we talk about complications? Do we talk about dignity? Do we ask if you want to be stuck in a bed throwing up the last two weeks of your life? Not as a rule. Finally, when we throw up our hands and say this isn't going to work, we literally have tried everything, there is nothing left even futilely that is worth trying, we resort to palliative care; a new team of professionals moves in, curative people move out, the palliators come in, the hospital nurses come in. If you're lucky, it's less than a

month until the end of your life and there's some attention to pain management at that point in time, palliation and end-of-life preparation. No one ever told you about advanced medical directives.

The cancer DM approach says that there is a natural segue in these two processes (Chart 7). Yes, let's go full-bore, cure mode right off the bat, with appropriate tested evidence-based treatment, but let's not neglect social counseling, nutrition, pain management, fatigue, cancer rehab and advanced-care planning so that if we're not winning the battle, there could be an appropriately early hospital referral for good ongoing symptom management and death with dignity at the end.

Our company today has our original four outsourced programs across pretty much all of our enterprise. We're launching commercial oncology disease management. We are designing our diabetes pilot that I mentioned. We are pursuing pediatric asthma, although, like David, we believe that's a very difficult one to do with a demonstrated ROI. We're trying to figure out how. We have looked at the rare-disease medley. We're trying to maximize appropriate early-provider referrals. It's a nice thing to be able to identify these long-standing patients through claims, but claims only get you so far. The lag is the problem. I need the newly diagnosed people, and I need to know about them today. Only the providers can tell me about that. We need increased penetration in our non-capitated provider groups, and we want our capitated providers to go the same route with these same vendors because the program's proven, and we can share data, we can show them how to identify the patients. They'll do it. It will be their deal. They'll use it for their whole book of business, not just our members, but why shouldn't they? The fact is they should, and many of them have. We're implementing these programs for our growing PPO and administrative services only (ASO) business as well.

We're continuing to in-source our approach to the disease management of frail members and end-of-life members. As I mentioned, we're redesigning ER frequent flyers. We do selective catastrophic case management, but increasingly it's quite select. If we maximize appropriate and early-provider referrals for these programs as well, the sooner we know the better. We integrate the workflow with outsourced vendors. That sounds very simple, but sometimes it is a bit complicated because we've got lots of moving parts and different people and hand-offs. We are focusing a lot of energy on pre-catastrophic case management through predictive modeling. We've explored all the models that the SOA in an earlier session has explored and then some, and we've worked with a number of other people to try and identify the best tool out there. We even developed one of our own in-house. It looks to us like no model today. It on a stand-alone basis is capable of sufficient predictive accuracy. For the target members for whom we are willing to invest case-management dollars without some further filtering or screening, that may be a very brief condensed intake process by phone, it may be an HRA instrument, it may be some hybrid of those, but that's where we think the state of that industry is.

We're applying our DM learnings to other outsourced services. We have hospital contracts all over the place. We're getting neonatal ICU contracts in place. We're improving the integration, not only across co-morbidities for a single member, but across our vendors, between our vendors and ourselves and between our providers and everybody. And we're trying to subject our disease management performance to rigorous challenges.

We've recently applied for the CMS disease-management demonstration program, which I think along with Alere and another one of our vendors, provides an opportunity to show what these programs can do in that unmined huge population of fee-for-service Medicare members, who've had no disease management or pharmacy benefits, for a long time. We also are trying to participate in a PPO demonstration program where disease management will impact that program. We sought external validation of our savings methodology, and Tillinghast-Towers Perrin has been very helpful in that regard. We're also increasingly collaborating with purchasers to audit our DM capability and effectiveness.

So today we do consider ourselves a full-service health-management company with both population-based and case-based programs, and we are building disease management into our pyramid of services, into our brand promise, our quality initiatives, our results, our National Committee for Quality Assurance (NCQA) accreditation, our medical management strategies, our member satisfaction, our competence as an organization and hopefully we will sustain financial performance and membership growth.

DR. RON GERATY: Alere just isn't a name. It is Latin for "to care for, to support." It has nothing to do specifically with congestive heart failure, and I want you to know that we try and make it very simple for our own staff and for the people that we work with. We have one major goal and that is to keep people who have advanced congestive heart failure out of the hospital. If you think of one thing that we do, that really is our one objective. Now, there are a number of other things that fall out from that as well, but our single focus is keeping people with advanced congestive heart failure out of the hospital.

Now I want to give you a quick overview of what congestive heart failure is, because it will lead you to understanding why we do what we do. First of all, it's a progressive chronic heart disease with diverse ideologies. You heard Dr. Norman talking about diabetes, end-stage renal disease and coronary artery disease. All of those are precursors to a common final pathway, which is congestive heart failure. Its symptoms are fluid retention and pulmonary congestion in congestive heart failure.

For those of you who have seen CHF patients, they usually have swelling of the legs and they usually have trouble breathing because they're retaining fluids. That fluid retention is one of the primary things that we work with. For patients who have congestive heart failure, their being involved with their own treatment is

absolutely critical to a positive outcome. It's not something that a doctor can just do to a patient. The patient really needs to participate in the care. There are almost 5 million patients with congestive heart failure in the U.S. The overall incidence of congestive heart failure is 1.5 to 2 percent in the general population and 6 to 10 percent in people over 65. CHF is the No. 1 cause of hospital admissions in the U.S. for the over-65 population, not No. 1 overall, but in the senior population. The total direct Medicare costs in 1998 were over $7 billion.

I'm not going to spend a lot of time on CHF demographics, other than to highlight the part in green (Chart 8). It's important to realize that once somebody has been diagnosed with advanced congestive heart failure, and I'm going to talk about that in a moment, the odds of their being hospitalized again are 47 percent within six months. So these are people who typically are hospitalized two to two-and-a-half times a year. Each hospitalization runs around $7,000, so it's easy to figure out that a cost for a patient with advanced CHF is going to be at least $14,000 a year with the two hospitalizations a year.

Now, Class 3 and 4 of congestive heart failure patients are the patients who are extremely ill (Chart 9)—one way of looking at it would be if they've been in an emergency room at least once with a diagnosis of congestive heart failure or they've been hospitalized once at least with advanced congestive heart failure. The real classification system is if a patient has so much trouble with his or her congestive heart failure that the patient unable to climb a flight of stairs without becoming short of breath or exercise without becoming short of breath, then the person becomes a CHF 3 or 4.

Now, understanding CHF is important to understanding what we do. The typical paradigm of a patient with advanced CHF is he or she begins to start getting into trouble in an acute phase of the illness, and one of the things Dr. Norman talked about was eating Doritos. Doritos have high salt content. Somebody goes out and has Chinese food, has Mexican food, eats a Weight Watchers meal, all of those with high salt content, and in Day 1 they start putting on weight and that weight gain is really not as a result of the food, but as a result of the salt and they start retaining fluids. If you pick that up in days 1 to 3, in days 1 to 4, an intervention such as a water pill solves the problem. If you wait until days 5 or 6 after that and the patient has retained the fluid, the heart becomes unable to pump, and the only way the patient can be treated in days 6 or 7 with that is by going into the hospital because IV fluids are needed. The oral pill is not adequate treatment. Once the patient starts being diarrhesed in the hospital, his or her electrolytes need to be managed very carefully. So it's a relatively simple paradigm. If the patient takes care of him or herself, if the doctor stays very closely involved with the patient, the patient stays out of the hospital. But if a doctor is seeing a patient once a week, which is pretty dramatic, the doctor would still get into trouble with a lot of patients because this illness wouldn't have been identified in days 3 or 4.

So what do we do? As I mentioned, our focus is really keeping people out of the

hospital. We link objective information with subjective information. We put an electronic scale in the home , and the patients report their symptoms over a device that we put into the home with health care experts, and the nurse is actually monitoring what's happening with her typically, 200 to 300 patients every single day. She looks at the symptoms, and if there are any issues, calls the patient and intervenes to have him or her talk to the doctor and get that magical water pill.

I would say that the three legs to the stool that we consider very important are the objective information—the weight; the subjective information—the symptoms that the patient's giving, but also that sense of being linked to somebody whose watching over them; and then the third leg is getting actionable information to a doctor who can actually do something about it. So we create value for the payer, we improve patient care for the physicians and we empower patients to take better care of themselves.

Biometric measurement is the symptomatic measurement, which are the symptoms that the patient reports; the compliance monitoring, which is when we talk to the patient by educating him or her, the teachable moment that Dr. Norman and Dr. Kaplan talked about in which, when a patient begins to put on weight, he or she is much more interested in talking about diet than he or she would be when that hasn't happened; and then our ability to get that proactive alert out to a physician, and I'll actually show you a copy of the alert that we sent out in just a moment.

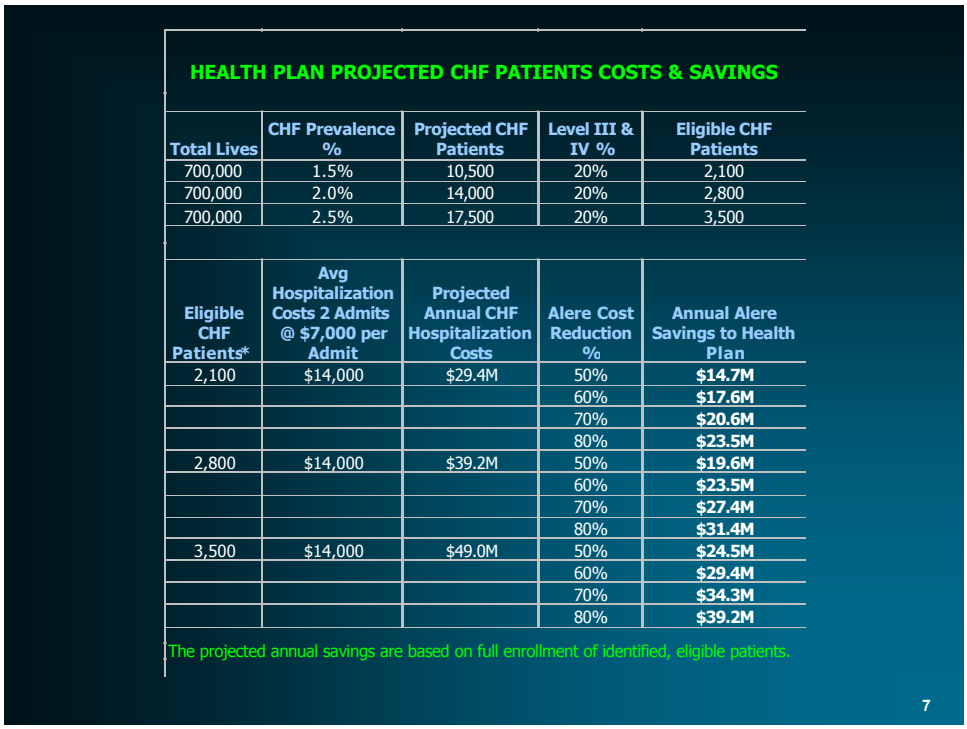
Now, we're not a traditional disease-management vendor in the sense that most disease-management vendors typically have a treatment algorithm that they recommend that the doctor follows. We try to stay somewhat agnostic as to what the doctor's doing. Now, we're not truly agnostic, but one of the things that we find works well in working with physicians is giving them good diagnostic information about the patient—then they naturally know what to do. If they're interested in a teachable moment, we actually are happy to give it to them, but that's one of the ways that we're not a traditional disease-management vendor. We're not a typical device company, even though we put a device out in the home, because we don't just put the device out, we actually have nurses that monitor what's happening, and we're not a typical case-management vendor either, because we actually don't manage the total care of the patient, we send actionable information to the physician.

This addresses what Dr. Norman and Dr. Kaplan talked about, which shows that if you are working with an HMO that is covering 700,000 lives and you look at the prevalence, the more patients that you can enroll, obviously the much more dramatic impact you have on overall savings.

Table 2 shows the average number of admissions, the penetration, the cost per hospitalization and if you put all of those things together, you find the results that Dr. Norman presented. Our experience with several thousand patients with

PacifiCare is that we save PacifiCare and their patients approximately 55 percent of costs over the first year of working with them in a senior population.

Table 2



HEALTH PLAN PROJECTED CHF PATIENTS COSTS & SAVINGS

Total Lives	CHF Prevalence %	Projected CHF Patients	Level III & IV %	Eligible CHF Patients
700,000	1.5%	10,500	20%	2,100
700,000	2.0%	14,000	20%	2,800
700,000	2.5%	17,500	20%	3,500

Eligible CHF Patients*	Avg Hospitalization Costs 2 Admits @ $7,000 per Admit	Projected Annual CHF Hospitalization Costs	Alere Cost Reduction %	Annual Alere Savings to Health Plan
2,100	$14,000	$29.4M	50%	**$14.7M**
			60%	**$17.6M**
			70%	**$20.6M**
			80%	**$23.5M**
2,800	$14,000	$39.2M	50%	**$19.6M**
			60%	**$23.5M**
			70%	**$27.4M**
			80%	**$31.4M**
3,500	$14,000	$49.0M	50%	**$24.5M**
			60%	**$29.4M**
			70%	**$34.3M**
			80%	**$39.2M**

The projected annual savings are based on full enrollment of identified, eligible patients.

7

As far as results, I think there are a number of things that are really very, very compelling, and one of the first one is patient compliance. We have 95 percent compliance with the approach that we use. If a patient steps on a scale and answers the question at least once a day, we define that as the patient being compliant. We ask the patient to step on the scale twice a day; if we ask the patient to step on it in the morning and again before bed, then he or she usually does it at least once a day.

So that's how we measure patient compliance, but getting anybody to do anything 95 percent of the time is very impressive. I can tell you listening in to the conversations between the nurses and the patients, the patients really like the fact that there is a health-care professional who is actually watching what's happening with them every single day, and so that relationship that develops between the nurse and the patient, I think, is very, very important to this patient compliance. We actually have patients from Oregon and Washington who are driving to southern California to visit people, and will drive through and stop in Reno so they can meet the nurse they've been talking to on the telephone. So it's more than the objective weight measurement. I believe it's that subjective relationship, and I'll hear the

patient say to the nurse over the phone, "You remember last Tuesday when I put on three pounds? I went out for Mexican food the night before and I knew what to do, so I took an extra water pill and my weight was under control. That compliance, I think, is a result of the objective as well as the subjective information.

The other thing that's important is the hospitalization-rate impact that we have. As Dr. Norman mentioned, the important questions are: Do we save money? and Do we save hospitalization? The typical hospitalization rate for patients with advanced CHF as I told you before is 2 to 2.4 admissions for every patient every year. Using our system, the hospitalization rate has been under 0.2 across all of the health plans that we work with. With HealthPartners' 120 patients, we had a 3-to-1 ROI with them. This last year we saved them as a single health plan approximately $2 million. With Ochsner, a smaller health plan, we saved them over $1 million. And you saw Dr. Norman's presentation where we saved them, with one state, over $6 million. So it's not just the patients that appreciate it. I can tell you the health plans very much appreciate it as well.

This really summarizes the compliance number that I gave you before. This summarizes the hospitalization, the outcome summary. As I said, it was under 0.2 percent. It's actually 0.16 across, and this is to demonstrate that it's not just with a single plan; it's over all of our relationships.

The patient actually answers the questions with the device that we put in the home. The patients describe it as the talking scale, because they step on the scale in the morning, and the box asks: Are you now weighing? All the patient does is press a yes/no, yes I'm weighing. The next question typically is: Did you take your medicines last night? Yes/no. Did you have trouble breathing in the night and have to use more pillows? Yes/no.

It's a few simple questions. The patient steps off the scale and that's it; the patient knows that the nurse is reviewing the information, and if the nurse in fact identifies a problem with the patient, a fax alert is sent out to the physician's office, and it gives a 30-day weight history; it gives a 30-day symptom history; it identifies the reason we're sending the alert today; and then it lists for the doctor all of the medications the patient's on.

After we send that alert, it's something doctors are comfortable with. They get a lab report or a fax report or an X-ray report, they take a look at it and then we call approximately two hours later to confirm that they received the alert and they're going to do something about it. But, as I said earlier, we don't tell the doctor what to do, we just make sure that the doctor realizes that their patient may be getting into trouble with CHF and will do something about it.

MR. WILLIAM BREMER: I'm with my own small consulting company in Maine. I just want to say for the record this was absolutely the best presentation I have attended in this whole meeting. This was useful; it was incredible.

MS. SUSAN MAXWELL: I have a question for Dr. Norman, and it's in regard to the example of your cancer disease management program. One thing that I did not see within your presentation, and it may be part of your program, is discussion of choices, options, pluses and minuses of various treatment options or palliative care with the patient and in particular with regard to cancer. Obviously there are a number of clinical trials going on around the country where the whole group receives the best of the generally accepted standard treatments. I didn't see anything about that within your presentation and I'd like you to address that a little bit.

DR. NORMAN: You are correct that it was not covered in the presentation. It is absolutely a critical part of the program itself. All treatment protocol suggested by treating oncologists for members in this program are reviewed by academic clinical oncologists associated with the vending company, Quality Oncology. Thankfully, the vast majority of those fall well within accepted evidence-based medicine, and where there are clinical trials suggested, again those are reviewed for compliance with the National Institute of Health (NIH) and the institutional review board protections. Oncology nurses are the case managers who discuss treatment options with the patients, and there is a liberal component of discussion of choices, side effects and anticipated downstream consequences that are an essential part of that program.

DR. KAPLAN: In my experience with this particular program, member decision support is the key element. When the treatment doesn't work, you go to the doctor and he says, "OK, the tumor is still growing; the cancer has come back. This is what we do next," and there's never a discussion about the fact that if it works, you will live for six months. Now, you'll be sick as a dog for five of them, but the definition of "work" is very difficult. We have found that these programs work by giving the members decision support—the right information so that they can indeed choose whether they want aggressive or non-aggressive treatment. Now, we can also leave aside the enormous financial incentives through the way we reimburse injectable and chemotherapy to the treating physician to do one more chemotherapy treatment. Some reimbursement mechanisms unknowingly encourage more treatment where it is not warranted. Thus, the mechanism may incent additional ordering of services. An old, very sick joke in medicine goes the reason that we put nails in coffins is to keep the oncologist from giving just one more chemotherapy treatment.

FROM THE FLOOR: Our company provides low-touch and often mail-in intervention programs. I have a comment for Dr. Kaplan and a question for Dr. Norman. My comment is that you said that mailings are at best unproven. We actually have a study that's peer-reviewed and published, and I can't remember the citation, but it cites the results of 100,000 members who were mailed intervention. The study shows fairly significant differences between the people who participated in the program and those who didn't participate in the program—a significant positive outcome.

My question for Dr. Norman is, when we've studied our outcomes with more intensive interventions, we see that there is a fairly significant difference between people who participate in the programs and people who don't, and in fact the people who don't participate appear to be self-selecting in some way, and their outcomes when you look at their claims, in fact, are higher than the control groups, because we've done a lot of controlled studies. I'm interested in knowing if PacifiCare has done any controlled studies and what the results are when you put together the intervention group, the non-enrolled group and compare that with a similar group of controls.

DR. NORMAN: I'd like to comment on your comment before taking your question. I think I agree with both of you that mailed information, which may or may not have a teachable moment, does not have anywhere near the impact of some of these more focused, targeted, interpersonal interactions, but thankfully their cost is relatively low and they don't need to have that great an impact to sometimes produce some degree of ROI. With regard to your question, we are very interested in the phenomenon that you spoke of, the self-selection or the selecting-out. What to do with the devoutly uninterested population is always a quandary. We really aren't in the business of doing randomized controlled trials. We have a population to manage, and the employer premium for this year really isn't interested in forming a control group for anything. If we think we have some basis for an intervention that's going to be helpful in terms of either improved health outcomes or mitigating health-care-cost inflation, we are constrained from doing randomized controlled trials fairly significantly. That's just the nature of the model. Now, we will do cross-sectional and longitudinal analyses to try and get some insight into what's going on and the selecting-out population for our programs—which are, by the way, opt-out and not opt-in programs—interests us a great deal. We've looked at stages of change work, but what are you going to do with those who are not in a pre-contemplative stage? Well, we tend to come back to them repeatedly from different angles, trying different channels of contact—Web, print, voice, cajole, minor rewards and various non-economic inducements that are all unstudied, uncontrolled and in some cases, I hope, successful.

MR. KENNETH LAU: My question is directed to Dr. Norman and possibly Dr. Kaplan. My question is, how much of the improvement showing in your results is coming from the regression to the mean? The second question is, are any of these things done based on the intention to treat or the intention to intervene rather than grouping the people by intention to treat or intervene? Then you can solve the problem that Mr. Duncan was talking about.

DR. NORMAN: The results, and again I indicated that the most important bars to us in assessing results is the missing set of bars that is total population, where every single identified eligible is tracked between baseline and treatment period so there should be no regression to the mean possible to explain that outcome, since we're not taking a subset of high-utilizers. It's a total population of the diseased

members as defined contractually. I think your point on intention to treat is a valid analytic approach for looking at analysis. In terms of the results being perhaps factitious in related to regression on a population basis, that should not be the case. If we were only enrolling high-utilizers and comparing them, that would be a different story. That's not the way we actually assess, even though I broke it out to portray the difference between the enrolled and non-enrolled population.

DR. KAPLAN: And I think your point is an excellent one that you have to list the whole population. Otherwise, and certainly for diseases like asthma, where the identifying incident that gets you into the program is clearly high cost and more likely than not to reoccur in the following year, really skews the study. If you look at the entire population, I think that's the best way to deal with the regression-to-the-mean issue.

MR. THOMAS LEBOWITZ: One of the issues that recently came up, and we've been talking about it throughout the seminar, has been this notion of disinterested cases. When I look at a company like Alere, it looks like they're still coming in late in the game. I mean if people were more interested in their health and not getting coronary artery disease, then there are so many steps that could be taken so much earlier in life in terms of lifestyle, exercise and diet. It just seems like it's almost a futile step really, really late in the game. In a dental practice you wouldn't come to somebody whose got one tooth left and say well you should really start brushing and flossing, yet it seems like we've got the same thing going on here as a whole. I'm just wondering if members of the panel would like to address that.

DR. NORMAN: The admittedly late arrivals to our efforts may be at a level where now they are willing to engage in these activities where previously they may not have been. You're describing the public health dilemma of the last 25 years. What does it take for a fundamentally unhealthy society to get interested in a healthful lifestyle, which is a far greater contributing factor to the total cost of morbidity to the society than anything managed care or disease management can do, and has done or will do? I'll be on record with that statement. In fact, you could pose the argument that managed care, as constructed in the United States over the last decade or so, with the $5 co-pay essentially entitling you to any and all services, any and all drugs, irrespective of cost, has abated the moral hazard problem that we have had with health insurance in the first place.

Why bother with the painful, distasteful deprivation and emotionally unsatisfying lifestyle changes if I can go get salvation downstream from my misbehavior?. It's a dilemma. I think what we're going to see, not motivated by public health policy, but in fact by cost crisis once again, is that greater share of cost by members is going to cause some second thoughts about behavior prevention and downstream moral hazard. It's too bad that public health hasn't found a way to be more impactful on public policy and public behavior, but it's an ongoing dilemma.

DR. GERATY: One thing I think is important to keep in mind is that we really are

trying to do this from an evidence-based approach, and just thinking about the population of patients that we work with, we're just working with the most advanced CHF patients. We'd like to know how to predict from 1s and 2s who is going to become a 3 and a 4, and it turns out that even though we have only a single focus, and even though we've given a lot of study to this and cardiologists in general have, it's hard to predict which 1s and 2s are going to become the 3s and 4s. So as soon as we find the evidence, we're interested in going there, which then goes to in our working with the 3s and 4s. Our approach is relatively simplistic—I mean the paradigm, looks at weight and symptoms, why not pulse, respirations, blood pressure, you know, glucose level, a bunch of other things that are all important factors too?

It turns out that some of the data that comes back is relatively confusing in terms of taking action. Blood pressures are all over the place, and if you send doctors notices about a patient whose blood pressure went up briefly over a period of time, it becomes like crying wolf. You know, they want to ignore it. You know, when they hear from Alere, they know they have to do something; otherwise we don't bother them. So part of it is evidence-based, part of it is actionable and yet I think you're absolutely right. We need to get more evidence to figure out how we can intervene earlier and earlier so this doesn't happen.

MR. PATRICK COLLINS: I just had a quick question for Mr. Norman on the measurement issue going forward in the second, third, fourth years of these programs. What's your game plan, what's your strategy for changing the baseline over time, and what are you thinking in terms of goals that you get some savings in one year? Are you hoping to get continued savings or manageable trend, and how are you managing that process?

DR. NORMAN: Most of our contracts have not been of such a long-term duration that we've had to build in reestablishment of baseline procedures downstream. On a two-to-three-year horizon, we think utilizing the size of population in our baseline figure is sufficient when in each successive year we neutralize the calculation from unit-cost changes, which are not the liability of the vendor. So we're looking at pure utilization impact on cost, absent any unit cost changes that are brought about by contracting.

What we expect year on year for improvement varies by program. Every program has a slightly different curve of how quickly it begins to accrue benefits and how long it takes to reach sort of the sustainable equilibrium that we think will prevail. In the case of CHF, it's very quick that we hit the equilibrium point and we expect in year 2, just because there's a ramp up in year 1, to actually have increased savings, but year 3 would probably be flat on year 2 relative to original base line. My biggest fear in this business is that the life span of a CFO is such and sometimes an actuary, that by the time I get out to years 2 and 3 and they ask, "What did you save over last year?" I'm going to say, "Wrong question," and they're going to say, "No, it's my question, what did you pay for this year?" They're going to say, "Why

are you doing this program?" and I'm going to have to remind them about the original baseline and the recidivism that will go right back to that number, for CHF surely within one year, for ESRD probably one year, COPD two years, CAD three years. We'll surely go through that I'm afraid, but we're adhering to the year 1 baseline as the reference point for all years of the two- and three-year contract typically.

Chart 1

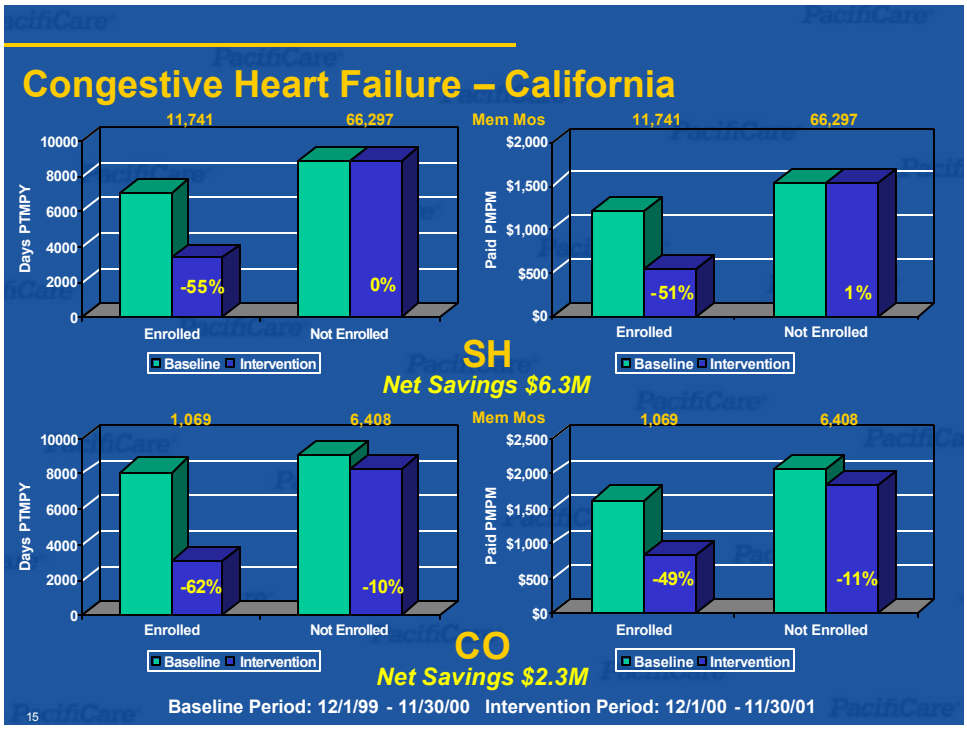
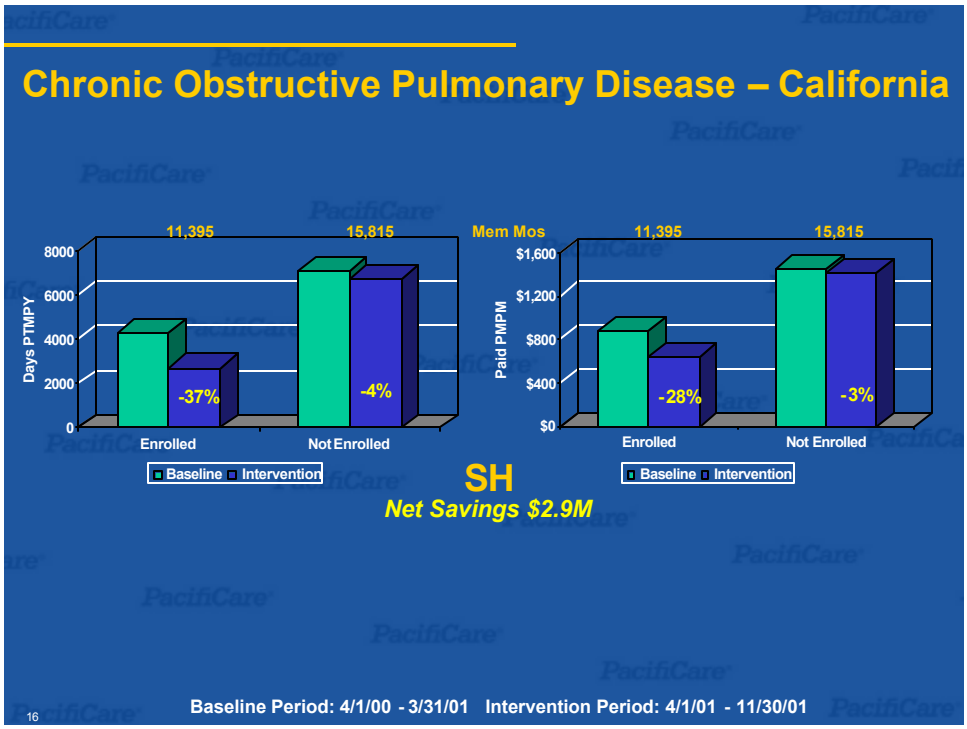


Chart 2



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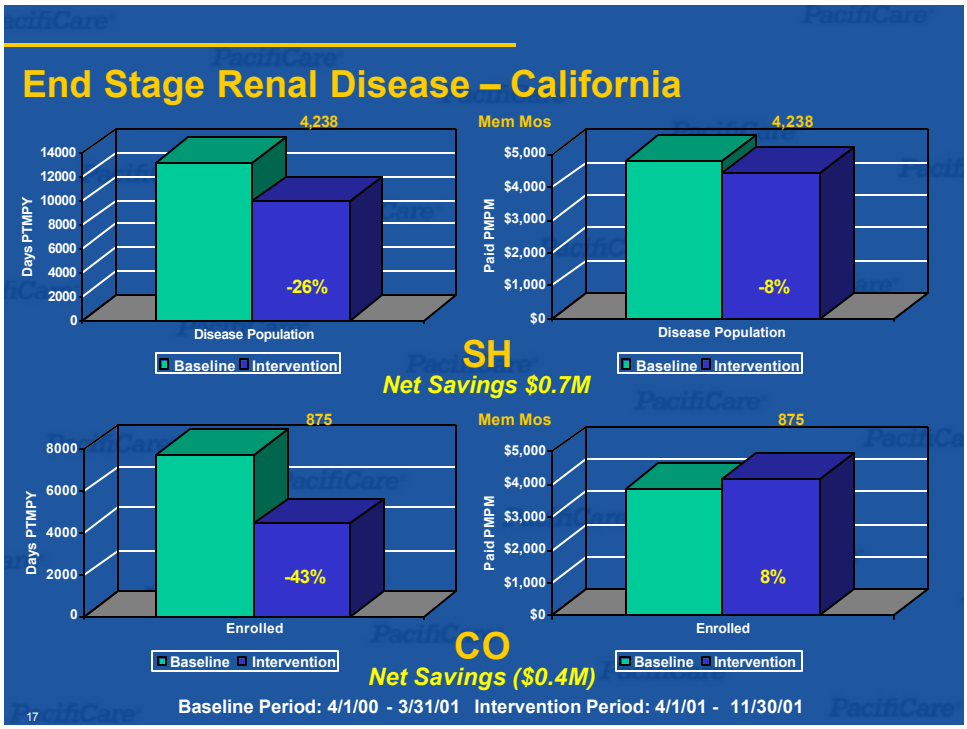

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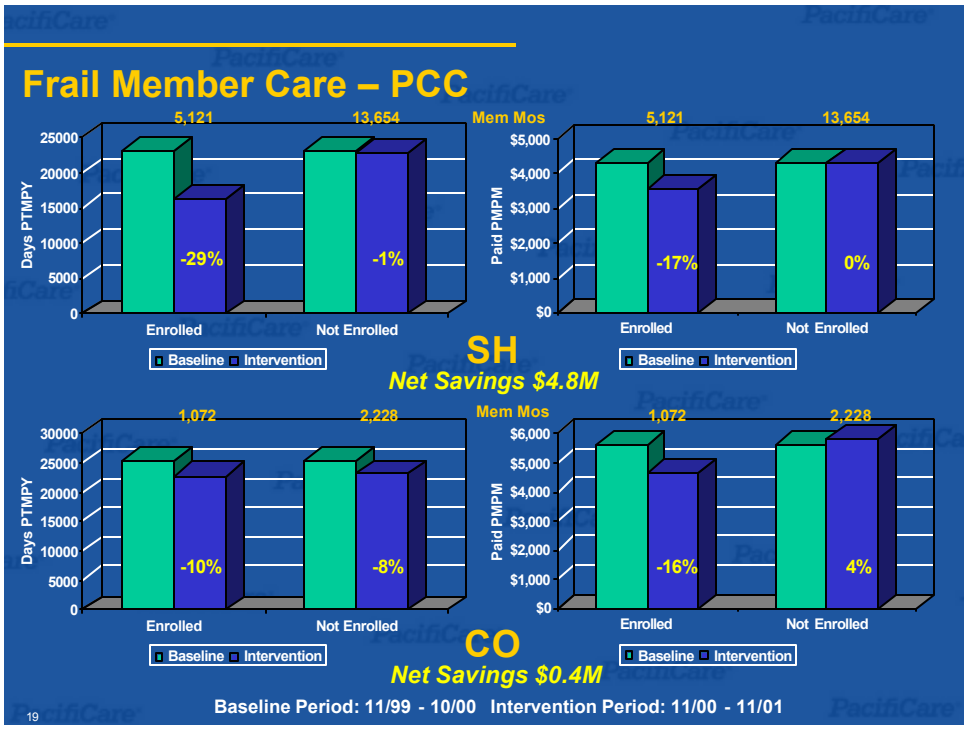

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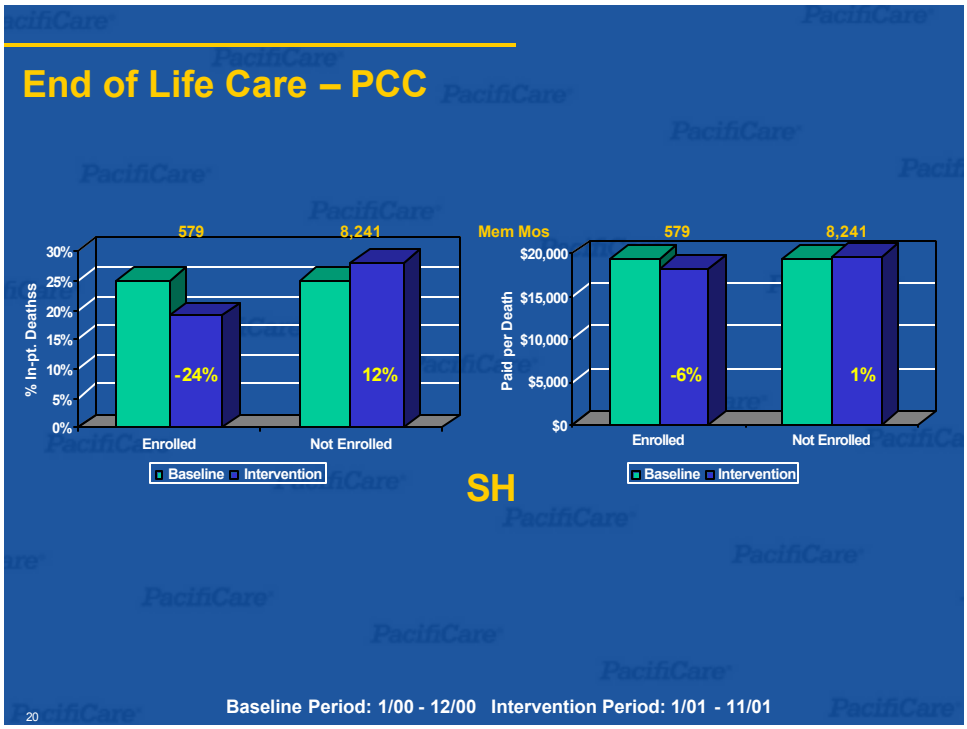

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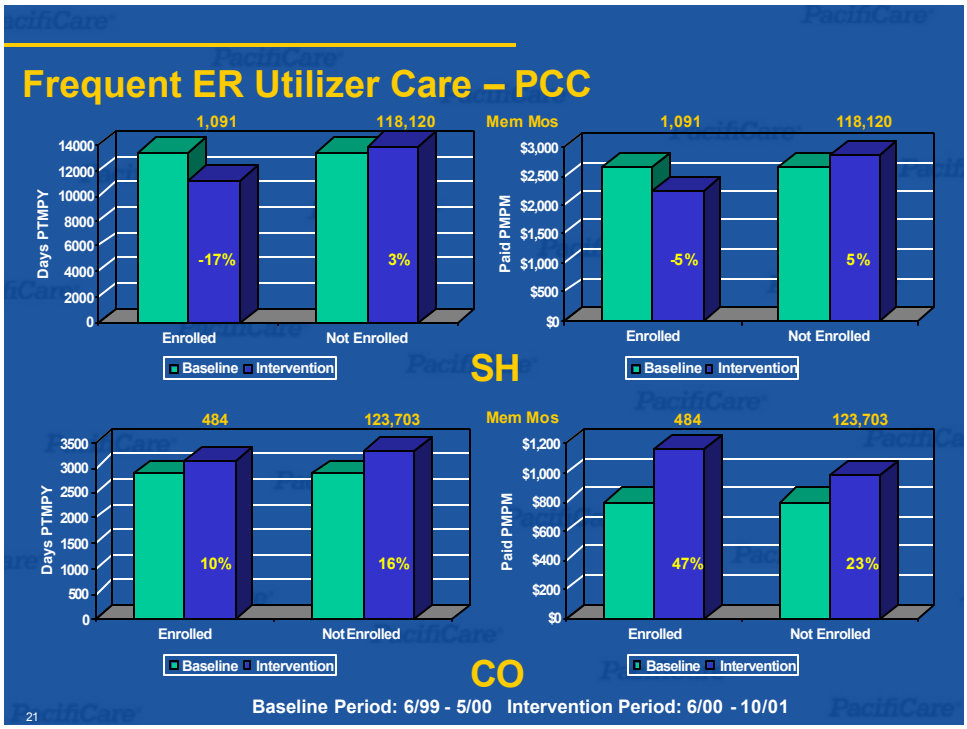

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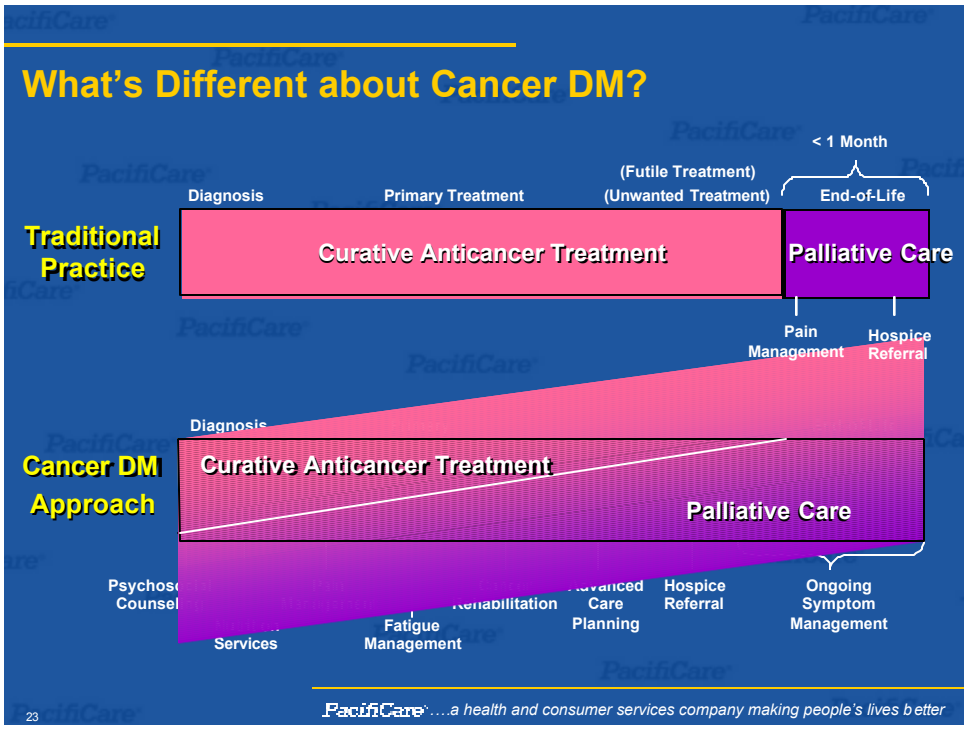

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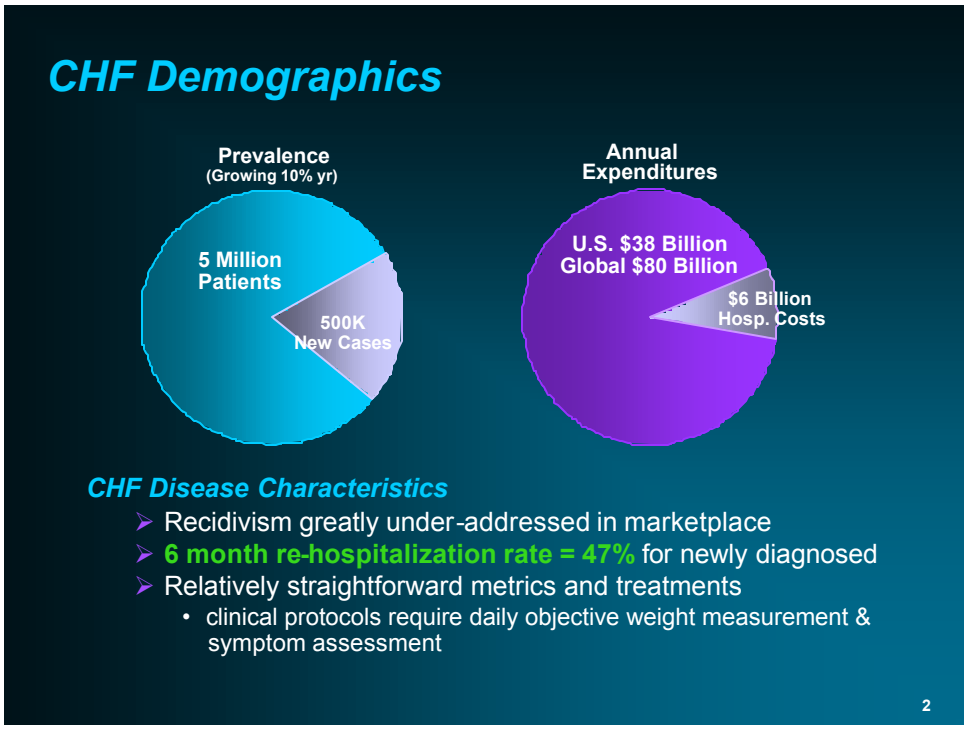

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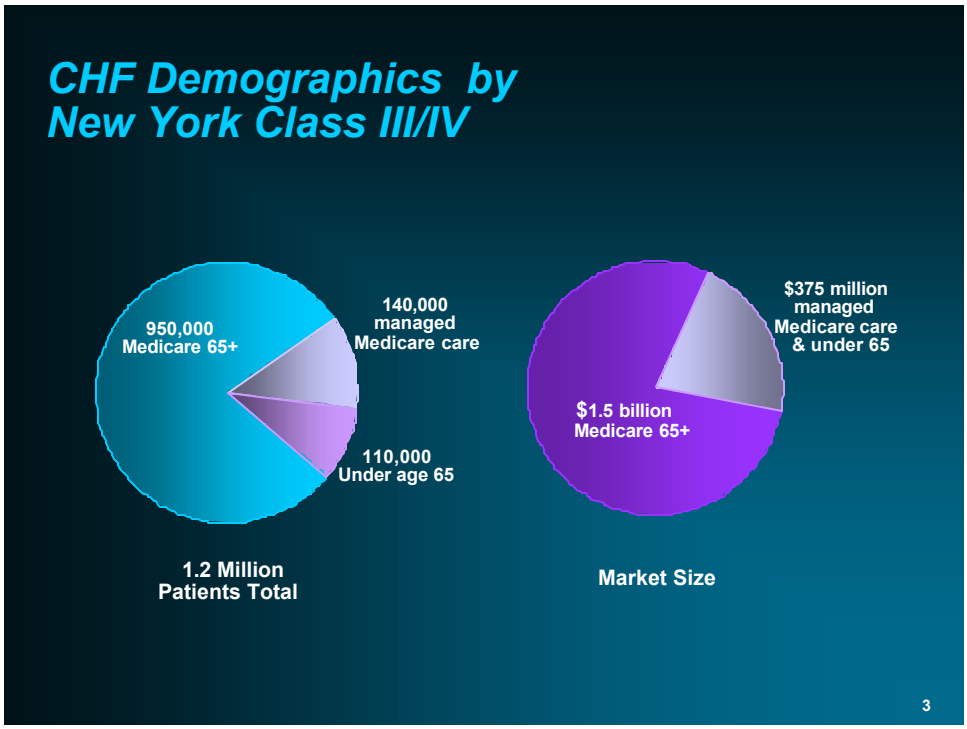
CHF Demographics by New York Class III/IV
950,000 Medicare 65+
140,000 managed Medicare care
110,000 Under age 65
1.2 Million Patients Total
$1.5 billion Medicare 65+
$375 million managed Medicare care & under 65
Market Size
3