PALOMAR
POMERADO
HEALTH

SPECIALIZING IN YOU

BOARD OF DIRECTORS AGENDA PACKET

February 12, 2007

The mission of Palomar Pomerado Health is to heal, comfort and promote health in the communities we serve.

A California Health Care District (Public Entity)

PALOMAR POMERADO HEALTH
BOARD OF DIRECTORS

Regular meetings of the Board of Directors are usually held on the second Monday of each month at 6:30 p.m., unless indicated otherwise
For an agenda, locations or further information call (858) 675-5106, or visit our website at www.pph.org

MISSION STATEMENT

The Mission of Palomar Pomerado Health is to:
Heal, Comfort, Promote Health in the Communities we Serve

VISION STATEMENT

Palomar Pomerado Health will be the health system of choice for patients, physicians and employees, recognized nationally for the highest quality of clinical care and access to comprehensive services

CORE VALUES

Integrity
To be honest and ethical in all we do, regardless of consequences

Innovation and Creativity
To courageously seek and accept new challenges, take risks, and envision new and endless possibilities

Teamwork
To work together toward a common goal, while valuing our difference

Excellence
To continuously strive to meet the highest standards and to surpass all customer expectations

Compassion
To treat our patients and their families with dignity, respect and empathy at all times and to be considerate and respectful to colleagues

Stewardship
To inspire commitment, accountability and a sense of common ownership by all individuals

Affiliated Entities

Escondido Surgery Center * Palomar Medical Center * Palomar Medical Auxiliary & Gift Shop * Palomar Continuing Care Center * Palomar Pomerado Health Foundation * Palomar Pomerado Home Care * Pomerado Hospital * Pomerado Hospital Auxiliary & Gift Shop * San Marcos Ambulatory Care Center * Ramona Radiology Center * VRC Gateway & Parkway Radiology Center * Villa Pomerado

- Palomar Pomerado Health Concern* Palomar Pomerado Health Source*Palomar Pomerado North County Health Development, Inc.*
- North San Diego County Health Facilities Financing Authority*

PALOMAR POMERADO HEALTH
BOARD OF DIRECTORS
REGULAR MEETING AGENDA

Monday, February 12, 2007

Commences 6:30 p.m.

Pomerado Hospital
Meeting Room E
15615 Pomerado Road
Poway, California

Mission and Vision

"The mission of Palomar Pomerado Health is to heal, comfort and promote health in the communities we serve."

"The vision of PPH is to be the health system of choice for patients, physicians and employees, recognized nationally for the highest quality of clinical care and access to comprehensive services."

Commences at 6:30 p.m. Pomerado Hospital, Meeting Room "E" per public "Notice of Location Change" (attached) dated January 23, 2007 from PMC Graybill to POMERADO HOSPITAL, POWAY for this meeting.

			Time	Page
I.		**CALL TO ORDER**		
II.		**OPENING CEREMONY**	*5 min*	
	A.	Pledge of Allegiance		
	B.	Recitation – Chaplain Bill Hard (due to meeting change from PMC)		
III.		**PUBLIC COMMENTS**	*5*	
		(5 mins allowed per speaker with cumulative total of 15 min per group – for further details & policy see Request for Public Comment notices available in meeting room).		
IV.	*	**MINUTES**	*2*	*1-5*
		Regular Board Meeting – January 8, 2007		
V.	*	**APPROVAL OF AGENDA** *to accept the Consent Items as listed*	*5*	*6-82*
	A.	Consolidated Financial Statements		
	B.	Revolving Fund Transfers/Disbursements – December 2006		
		1. Accounts Payable Invoices $26,935,972.00		
		2. Net Payroll 13,280,131.00		
		Total $40,216,103.00		
	C.	Ratification of Paid Bills		/CONTD...

"In observance of the ADA (Americans with Disabilities Act), please notify us at 858-675-5106, 48 hours prior to the meeting so that we may provide reasonable accommodations"

Asterisks indicate anticipated action;
Action is not limited to those designated items.

D. **December 19, 2006 Minutes of ICOC Annual Meeting**
E. **Agreement to Reimburse PMC Medical Staff for Compensation to Medical Staff Officers, Dept Chairs, QMC Chair**
F. Agreement to Reimburse Pomerado Medical Staff for Compensation to Medical Staff Officers, Clinical Service Directors, Section Chiefs, QMC Chair
G. **December 2006 & YTD FY2007 Financial Report**

VI. PRESENTATIONS -

A. Pharmacy Residency Presentation
- Michael Kruse, PharmD, BCPS, Clinical Pharmacy Specialist/ Residency Program Director, Dept of Pharmacy *10*

VII. REPORTS

A. **Medical Staffs** *15*

* 1. Palomar Medical Center – *Robert D. Trifunovic, M.D.*
a. Credentialing/Reappointments *83-96*
b. Investigational Review Committee Policies & Procedures *97-143*

* 2. Escondido Surgery Center – *Marvin W. Levenson, M.D.*
a. Credentialing/Reappointments *144*

* 3. Pomerado Hospital – *Benjamin Kanter, M.D.*
a. Credentialing/Reappointments *145*

B. **Administrative**

1. President of Palomar Pomerado Health Foundation – *Al Stehly*

a. Update on PPHF Activities *5* *Verbal Report*
including special donation presentation by Jaime Rivas, MD to PPHFoundation on behalf of CEP

b. Poway Rodeo Donation

2. Chairman of the Board – *Marcelo R. Rivera, M.D.* *10* *Verbal Report*

a. Annual CEO Evaluation Meeting February 15

3. President and CEO – *Michael H. Covert, FACHE* *10* *Verbal Report*

a. City of Poway Approval for Pomerado Expansion
b. Pomerado Outpatient Services Pavilion potential opening
c. PPH Workplace Excellence Award by CCE (CAPE - Bronze-level)

Asterisks indicate anticipated action;
Action is not limited to those designated items.

VIII. INFORMATION ITEMS *(Discussion by exception only)* *146-183*

A.	Compensation	Human Resources
B.	Annual Review of Committee Bylaws	Human Resources
C.	Quarterly Turnover Report	Human Resources
D.	Van Pool Service	Human Resources
E.	2007 HR Committee Meeting Dates	Human Resources
F.	Annual Review of Committee Bylaws	Finance
G.	I/T Strategic Plan Update	Finance
H.	Skilled Nursing Facilities Update	Finance
I.	2007 Finance Committee Meeting Dates	Finance

IX. COMMITTEE REPORTS - *None*

X. BOARD MEMBER COMMENTS/AGENDA ITEMS FOR NEXT MONTH

- * March 12 Regular Board Meeting Date – Discussion/ Potential Amendment : **Resolution No. 02.12.07 (01) – 01** 3 *184-185*

XI. ADJOURNMENT *to Closed Session pursuant to Government Code Section 54957 : Public Employee Performance Evaluation : Chief Executive Officer* 30

No anticipated action.

XII. RE-ADJOURNMENT TO OPEN SESSION

No anticipated action

XIII. FINAL ADJOURNMENT

Asterisks indicate anticipated action;
Action is not limited to those designated items.

PALOMAR
POMERADO
HEALTH

SPECIALIZING IN YOU

REGULAR BOARD MEETING

NOTICE OF LOCATION CHANGE
***For* MONDAY, FEBRUARY 12, 2007 REGULAR BOARD MEETING**
COMMENCING 6:30 P.M.

The location of the regularly scheduled meeting of the Board of Directors of Palomar Pomerado Health *(scheduled per Resolution No. 12.11.06 (02) – 29)* has, due to a flooding emergency and resultant continued renovations, made Graybill Auditorium unfit to hold meetings until those renovations are completed. Under California Government Code Section 54594 (E) and as Chairman, it is hereby noticed that the MEETING LOCATION for Monday, February 12, 2007 Regular Board Meeting commencing at 6:30 p.m. has been moved from Palomar Medical Center, Graybill Auditorium, 555 East Valley Parkway, Escondido, California 92025 to:

POMERADO HOSPITAL
15615 Pomerado Road
Poway, California 92064
MEETING ROOM "E", 3rd Floor

Time and date to remain the same ie., MONDAY, FEBRUARY 12, 2007 commencing at 6:30 P.M.

An agenda will be posted at a later date.

DATED: January 23, 2007

Marcelo R. Rivera, M.D.
Chairman, Board of Directors
Palomar Pomerado Health

u\my docs\pph bd mtgs 2007\reg bd mtg 02-12-07\pom location notice:cdm

Palomar Pomerado Health

BOARD OF DIRECTORS
REGULAR BOARD MEETING

Pomerado Hospital, Meeting Room E, Poway
Monday, January, 8, 2007

AGENDA ITEM	DISCUSSION	CONCLUSIONS/ACTION	FOLLOW-UP/RESPONSIBLE PARTY
CALL TO ORDER	6:40 pm Quorum comprised Directors Bassett, Greer, Kleiter, Krider, Powers and Rivera.		
OPENING CEREMONY	The Pledge of Allegiance was recited in unison, followed by an inspirational reading by Chaplain Walden ***(attached)***.		
MISSION AND VISION STATEMENTS			
	The PPH mission and vision statements are as follows: ***The mission of Palomar Pomerado Health is to heal, comfort and promote health in the communities we serve.*** ***The vision of PPH is to be the health system of choice for patients, physicians and employees, recognized nationally for the highest quality of clinical care and access to comprehensive services.***		
NOTICE OF MEETING	Notice of Meeting was mailed consistent with legal requirements		
PUBLIC COMMENTS	None		
APPROVAL OF MINUTES • Regular (Annual) Board December 11, 2006 • Joint Board/Finance Committee Meeting November 14, 2006		**MOTION:** by Kleiter, 2nd by Bassett and carried to approve the December 11, 2006 Regular (Annual) Board minutes as submitted. All in favor. None opposed. **MOTION:** by Kleiter, 2nd by Krider and carried to approve the November 14, 2006 Joint Board/Finance Committee Meeting minutes as submitted. All in favor. None opposed.	

AGENDA ITEM	DISCUSSION	CONCLUSIONS/ACTION	FOLLOW-UP/RESPONSIBLE PARTY
APPROVAL OF AGENDA *to accept the Consent Items as listed*		**MOTION:** by Bassett, 2nd by Krider and carried to approve the Consent Items as submitted. All in favor. None opposed.	
PRESENTATION			
▪ 4th Qtr Compliance Report and Annual Compliance Program Review	Jim Neal, Compliance Officer, provided a 4th Qtr Compliance Report and Annual Review of the Compliance Program ***(report attached to original minutes).*** There were no problems of any substance during this period.	Chairman Rivera thanked Mr. Neal for his informative report.	
REPORTS			
Medical Staff			
Palomar Medical Center			
▪ Credentialing	John Lilley, MD, on behalf of Robert D. Trifunovic, MD., Chief of PMC Medical Staff, presented PMC's requests for approval of Credentialing Recommendations.	**MOTION:** by Krider, 2nd by Powers and carried to approve the PMC Medical Staff Executive Committee credentialing recommendations for the PMC Medical Staff, as presented. All in favor. None opposed. Directors Bassett and Greer abstained to avoid potential conflict of interest.	
Escondido Surgery Center			
▪ Credentialing	John Lilley, MD, on behalf of Marvin W. Levenson, MD, Administrator/ Medical Director of the Escondido Surgery Center, presented requests for approval of Credentialing Recommendations.	**MOTION:** by Krider, 2nd by Powers and carried to approve the PMC Medical Staff Executive Committee credentialing recommendations for the Escondido Surgery Center, as presented. All in favor. None opposed. Director Greer abstained to avoid potential conflict of interest.	
Pomerado Hospital			
▪ Credentialing	Benjamin Kanter, MD., was welcomed by Chairman Rivera on behalf of the Board, as new Chief of Staff for Pomerado Hospital. Dr. Kanter then presented Pomerado Hospital's requests for approval of Credentialing	**MOTION:** by Kleiter, 2nd by Powers and carried to approve the Pomerado Hospital Medical Staff Executive Committee credentialing recommendations for the Pomerado Medical Staff, as presented.	

AGENDA ITEM	DISCUSSION	CONCLUSIONS/ACTION	FOLLOW-UP/RESPONSIBLE PARTY
	Recommendations.	All in favor. None opposed. Directors Bassett and Greer abstained to avoid potential conflict of interest.	
Administrative			
Chairperson - Palomar Pomerado Health Foundation	Mr. Al Stehly provided his verbal monthly report on Foundation activities, noting that the Foundation would be undertaking a campaign study in March/April to identify a campaign goal and potential leadership. As at end of December, $1.18 million dollars was raised through cash, pledges and planned gifts and has granted $262,500 back to PPH. In addition, a new employee campaign was being developed with a March/April canvass to all employees and Marketing involvement to build awareness. The Board would be able to view these awareness materials when available. PPH family of staff, physicians, District and Foundation Board members support would be sought regarding this campaign. It was stated that the January Foundation Board meeting would feature a presentation on the Da Vinci Robot.		
Chairman of the Board – Palomar Pomerado Health	Marcelo R. Rivera, MD		
• **Review of Board Committee Assignments for Calendar Year 2007**	Chairman Rivera discussed these, noting that there was a change in Chairmanship of Governance Committee to allow the new Board Member to be on this Committee and become familiar with these matters. He assumed everything was fine as he had not heard anything to the contrary.		
• **Annual Board Self-Evaluation; and Annual CEO Evaluation Special Board Meetings**	Chairman Rivera noted that the Board's Annual Self-Evaluation meeting occurs Monday, January 29, and the Annual CEO Evaluation meeting Thursday, February 15.		

AGENDA ITEM	DISCUSSION	CONCLUSIONS/ACTION	FOLLOW-UP/RESPONSIBLE PARTY
	He congratulated everyone on staff for all the good things we continued to undertake within PPH.		
President and CEO	Michael H. Covert		
• **CAPE/Baldrige Award**	Michael Covert informed that PPH was to receive the CAPE/Baldrige Award (bronze). He was deeply appreciative of our commitment to the community of our district. He had received a copy of the Baldrige report and noted that PPH is on their website. Carrie Frederick and others would receive this award on behalf of PPH in April. Mr. Covert continued that the fact PPH had received such an award at first attempt was a great honor, culminating at the end of 2006. We commenced this journey four years previously and such achievement was due to the hard work of thousands of people. This also came at a time of his own four-year anniversary with PPH and he anticipated the coming four years.		
INFORMATION ITEMS	***Discussion by exception only***		
▪ **Human Resources**			
▪ **Community Relations**			
▪ **Facilities and Grounds**			
▪ **Strategic Planning**			
COMMITTEE REPORTS	***None***		
BOARD MEMBER COMMENTS/AGENDA ITEMS FOR NEXT MONTH	Directors Bassett and Greer pointed out that the Regular Board Meeting Tuesday May 15, 2007 appeared to be in conflict with a regular Strategic Planning Committee Meeting, with suggestion for a possible Resolution to revise that Regular Board Meeting date. However, subsequent research found that the Strategic Planning Committee Meetings for 2007 had not yet been scheduled or approved by the new Strategic Planning Committee and there appeared to be no problem with any		

AGENDA ITEM	DISCUSSION	CONCLUSIONS/ACTION	FOLLOW-UP/RESPONSIBLE PARTY
	conflict of the Committee in this regard. Also, Regular Board Meetings would normally take precedence, having been scheduled for the year in December per the Bylaws. Therefore **Tuesday, May 15, 2007** remains as the regular monthly Board Meeting. Director Powers lauded Ms Mary Coalson, PPH Health Education Specialist, in her work for the California Partnership for Access to Treatment in San Diego. In addition, sincere sympathy was extended to Mr. Covert upon the recent loss of his father.		
ADJOURNMENT	**7:00 p.m.**		
SIGNATURES ▪ **Board Secretary** ▪ **Board Assistant**	_____ **Linda C. Greer, R.N.** _____ **Christine D. Meaney**		

PALOMAR POMERADO HEALTH
CONSOLIDATED DISBURSEMENTS
FOR THE MONTH OF
DECEMBER 2006

12/01/06	TO	12/31/06	ACCOUNTS PAYABLE INVOICES	$26,935,972.00
12/01/06	TO	12/29/06	NET PAYROLL	$13,280,131.00
				$40,216,103.00

I hereby state that this is an accurate and total listing of all accounts payable, patient refund and payroll fund disbursements by date and type since the last approval.

CHIEF FINANCIAL OFFICER

APPROVAL OF REVOLVING, PATIENT REFUND AND PAYROLL FUND DISBURSEMENTS:

Treasurer, Board of Directors PPH _____

Secretary, Board of Directors PPH _____

This approved document is to be attached to the last revolving fund disbursement page of the applicable financial month for future audit review.

cc: M. Covert, G. Bracht, R. Hemker, J. Flinn

Independent Citizens' Oversight Committee
Approval of Minutes from Annual Meeting, December 19, 2006

TO: Board Finance Committee

FROM: Independent Citizens' Oversight Committee

MEETING DATE: Tuesday, January 23, 2007

BY: Bob Hemker, CFO

Background: On Tuesday, December 19, 2006, the Palomar Pomerado Health Hospital, Emergency Care, Trauma Center Improvement and Repair Measure Bonds Independent Citizens' Oversight Committee (ICOC) held their annual meeting.

Pursuant to §6.4 of the ICOC PP&G, a draft report of all ICOC meetings is to be submitted to the District Board for inclusion in the Board's public records. The attached minutes from the Annual Meeting of December 19, 2006, have been reviewed by the Chair and the Secretary of the ICOC and approved for presentation to the ICOC members and the District Board.

Budget Impact: N/A

Staff Recommendation: At the Board Finance Committee meeting, the staff recommended approval of the minutes from the ICOC Annual Meeting held on December 19, 2006.

Committee Questions:

COMMITTEE RECOMMENDATION: The Board Finance Committee recommends approval of the minutes from the ICOC Annual Meeting held on December 19, 2006.

Motion: X

Individual Action:

Information:

Required Time:

PARTICIPANT ROSTER

PALOMAR POMERADO HEALTH
HOSPITAL, EMERGENCY CARE, TRAUMA CENTER IMPROVEMENT AND REPAIR MEASURE BONDS
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
ANNUAL MEETING, DECEMBER 19, 2006

Palomar Pomerado Health, Conference Room A, 15255 Innovation Drive, San Diego, CA

PARTICIPANTS	MEETING DATES							
	7/12/05	10/5/05	3/28/06	12/19/06				
MEMBERS								
WILLIAM L. CORWIN (AT LARGE)	P	P	P	P				
MARGUERITE JACKSON DILL, PHD, RN, FAAN (AT LARGE)				P				
STEPHEN FRIAR (AT LARGE)	P	P	P	P				
GEORGE KUNG, M.D. (PHYSICIAN)				P				
EDWARD R. LEHMAN (SR CITIZENS' ORG)	P	P	P	P				
JOHN MCIVER (BUSINESS ORG) – SECRETARY	P	P	P	P				
KATHY LEECH MCKINNEY (AT LARGE)	P	P	P	E				
MARGARET MOIR (AT LARGE)	P	P	P	P				
BOB WELLS (TAXPAYERS' ORG) – VICE CHAIR	P	P	E	P				
STEPHEN P. YERXA (AT LARGE) – CHAIR	P	P	P	P				
DISTRICT SUPPORT STAFF								
BOB HEMKER, CFO	P	P	P	P				
TANYA HOWELL, EXECUTIVE ASST – SCRIBE	P	P	P	P				
GUEST(S)								
KATHLEEN LEAK, BOND COUNSEL ORRICK, HERRINGTON & SUTCLIFFE			P	P				

[P = Present E = Excused A = Absent]

Independent Citizens' Oversight Committee
Meeting Minutes – Tuesday, December 19, 2006

AGENDA ITEM/PURPOSE	DISCUSSION/RECOMMENDATION	ACTION/COMMENTS
I. CALL TO ORDER & ROLL CALL	**The meeting was called to order at 12:10 p.m. by Chair Steve Yerxa, followed by roll call.** ***See roster for attendance.***	
II. INFORMATION ITEM(S)	Bob Hemker informed the ICOC that the agendas and minutes of previous meetings are now available on the PPH Website, as had previously been requested. They can be found by following the ICOC link on the "About Us" page on that site or by typing the address: http://www.pph.org/about.aspx?nd=714.	
III. OATH OF OFFICE	New members Marguerite Jackson Dill, PhD, RN, FAAN, and George Kung, MD, and reappointed member Steve Friar simultaneously read the Oath of Office, then signed copies for the record. Reappointed member Kathy Leech McKinney was absent and will be sworn in at the next meeting.	
IV. PUBLIC COMMENTS	There were no public comments. Ruth Moskowitz of the League of Women Voters was welcomed as an observer.	
V. MINUTES ICOC MEETING MARCH 28, 2006	No discussion.	**MOTION:** By John McIver, seconded by Margaret Moir, and carried to approve the Minutes of the March 28, 2006, ICOC Meeting
VI. DISCUSSION AGENDA		
REPORTS		
A. IDENTIFICATION OF OFFICERS APPOINTED PURSUANT TO ICOC PP&G	• Pursuant to the PP&G, nominations for officers of the ICOC are made to the PPH Board by the Finance Committee. The PPH Board has delegated appointment authority to the Chairs of the Board and the Finance Committee, who made the following reappointments at the Finance Committee meeting on October 31, 2006: o Steve Yerxa was reappointed Chair of the ICOC o Bob Wells was reappointed Vice-Chair of the ICOC o John McIver was reappointed Secretary of the ICOC	**No Action Required**
B. NOTIFICATION TO MEMBERS DILL & KUNG OF MEMBERSHIP CLASSES PURSUANT TO ICOC PP&G	• Pursuant to the PP&G, members who resign shall be replaced via application process, with the new members finishing out the original terms of office o Lee Human, M.D., resigned from his position as the required Physician member (Class of 2006) as he felt that his retirement travel precluded proper fulfillment of his duties to the ICOC ▪ George Kung, M.D., was appointed to finish out Dr. Human's term of office ▪ Physician member – now in second and final term, which will expire July 1, 2008 o Jerry Kaufman resigned from his position as an At Large member (Class of 2008) as his adult son is employed at PPH	**No Action Required**

AGENDA ITEM/PURPOSE	DISCUSSION/RECOMMENDATION	ACTION/COMMENTS
	▪ Marguerite Jackson Dill, PhD, RN, FAAN, was appointed to finish out Mr. Kaufman's term of office – now in first term, which will expire July 1, 2008 • The new members were requested to introduce themselves and provide a little background information o Dr. Dill is an Escondido resident who spent her entire professional career at UCSD. She retired in December 2003, after having served as Director of Epidemiology/Infection Control and Director of Education, Development and Research, and she is currently working part-time as an Administrator with the School of Medicine. She was involved with USCD in the construction of the Thornton Hospital. o Dr. Kung is an OB/Gyn who had a practice in Poway for 25 years and served as Chief of Staff for Pomerado Hospital for two terms. He now practices in San Marcos.	
PRESENTATIONS		
B. REVIEW OF THE DUTIES & ROLES OF THE ICOC	Utilizing Attachment B *(in which sections pertinent to the duties of the ICOC were highlighted)*, as well as referencing the previous Discussion of General Obligation Bonds from the March 28, 2006, meeting (*Pages A-14-18 of the agenda packet)* Kathleen Leak, Esq., Bond Counsel for PPH, from Orrick, Herrington & Sutcliffe, LLP, led a discussion that covered the duties and roles of the ICOC with regard to the issuance and distribution of funds derived from General Obligation (GO) Bonds. • The Constitution of the State of California sets limitations on the use of GO Bonds, stating that they may only be used to purchase "real property" o No direct legal definition for "real property – consensus over time as to what is or is not allowed ▪ Anything truly portable, ordinary repairs, maintenance costs, supplies or labor are not generally allowed ▪ Fixtures that are affixed to or become part of the land/building, labor costs, professional fees, real estate closing costs and other costs directly connected to real property acquisition and improvements are generally allowed • As there are limitations on the use of proceeds from GO Bonds, PPH Measure BB provided citizens with a method by which PPH is accountable to the public, and the PPH Board adopted the Policies, Procedures & Guidelines for the establishment of an Independent Citizens' Oversight Committee (ICOC), to review those expenditures o The ICOC membership includes some individuals with specified skill sets as well as "at large" members o The ICOC's role is to review expenditures after they have been made to confirm that GO Bond proceeds were used appropriately • The ICOC will review expenditures via an annual expense report, prepared after the close of the fiscal year o The first GO Bonds were issued July 7, 2005 o The Annual Report covers only GO Bond expenditures for FY2006 (July 1, 2005 through June 30, 2006)	• **The members of the ICOC will be added to the distribution list for the Audited Financials for PPH, and copies of the FY2006 Audited Financials will be forwarded to the ICOC members via email**

AGENDA ITEM/PURPOSE	DISCUSSION/RECOMMENDATION	ACTION/COMMENTS
	o The ICOC will determine if the expenditures were authorized by Measure BB and will prepare a report of their findings for presentation to the PPH Board ▪ The PPH Board will review the ICOC's report and respond • The ICOC will be disbanded once all GO Bonds have been expended (in approximately 2013) • Ms. Leak then entertained and discussed questions from the membership o Examples of improper use of GO Bonds: ▪ Purchase of land in Temecula – not within the boundaries of the District ▪ Purchase of a McDonald's franchise – doesn't fit the definition	
B. District Expenditure Report for FYE June 30, 2006	Utilizing *Attachment C*, Bob Hemker, CFO for PPH, led a discussion regarding the GO Bond expenditures • An annual expense report will be prepared after the close of the fiscal year o The PPH Fiscal Year ends on June 30th, and the external audit is generally completed by the end of October following FY close o The Annual Expense Report will cover only GO Bond expenditures o Whole picture will be available by putting the Annual Report together with the District's Audited Financial Statements, which will be made available for the ICOC's review ▪ GO Bonds are entered on the PPH books, clearly separated so that they can be extrapolated • The Master Facilities Plan (MFP) and Plan of Finance (PoF – *see attached chart)* are both PPH Board approved o No single source of funding, with different types of funding interspersed throughout the life of the PoF ▪ Cash Contributions include working capital & philanthropic donations ▪ $180 million par Revenue Bonds were issued in December 2006, and the 1993 debt was also refinanced ▪ Bond Anticipation Notes (BANs) can be used to bridge funding prior to issuance of GO or Revenue Bonds o Multiple campuses are covered by the MFP, PoF & Measure BB o Use of Measure BB funds can be spread across all campuses, as long as those uses fall under the definition of appropriate funding ▪ Measure BB authorized the issuance of $496 million ▪ PPH promised taxpayers to maintain a yearly property tax of $17.75 per $100K of assessed value (1) Expectation is that assessed values will go up (conservative estimate of 5% annually) ▪ GO Bonds cannot be issued all at once as they must be spent down within the first three years in order to ensure their tax-exempt status is maintained ▪ $496 million in GO Bonds will be combined with other sources of funding to finance the entire MFP o GO Bonds are limited in use (facilities, land, etc., but not movable equipment),	• **MOTION:** By Margaret Moir, seconded by John McIver and carried to refer inquiries made of any ICOC member by the press/public to the Chairman of the ICOC • **At the request of the Chair, Interim reports will be made to the ICOC on a quarterly basis, prefaced by a 2-3 page summary**

AGENDA ITEM/PURPOSE	DISCUSSION/RECOMMENDATION	ACTION/COMMENTS
	whereas Revenue Bonds can also be used for equipment o The Financing Team is continually reassessing the timing of the various financing tools based on market opportunities and construction needs • Expenditures to date are primarily related to land purchases and A&E (Architecture & Engineering) o The expenditure Report itself was not audited, but the auditing firm of Deloitte & Touche reviewed the $80 million GO Bond issue as a part of the District's annual financial audit o On purchases, the auditors verify that we gained an asset, not whether it was appropriate for purchase with GO Bond funds • Purchase procedures o A requisition must be made to the Paying Agent (Wells Fargo Corporate Trust Section) for every single draw, with supporting documents o The Paying Agent verifies the certifications within the requisition and releases funds if consistent with the Paying Agent Agreement o Tab E in the agenda packet contains copies of all requisitions ▪ All originals that went to the Paying Agent were signed by Bob Hemker, the authorized representative to whom authority for expenditures was delegated by the PPH Board (that authority is also delegated to CEO Michael Covert) • Chairman Yerxa inquired as to proper protocol should a member of the ICOC be contacted by the media o A motion was made for queries to be forwarded to the CFO, who would inquire further of bond counsel if necessary, then return answers to the ICOC for review and action o After further discussion about the appropriateness of PPH responding to queries made of an independent committee, the above motion was tabled *(see Action/Comments)* • Bob Hemker detailed the contents of each tab in Attachment C o TAB A – a recap of the first tranche of bonds issued, including maturity dates o TAB B – a banking recap of June 30, 2006, and current bank statements o TAB C – a requisition schedule, noting costs of issuance funds ▪ Reviewed by Bond Counsel to ensure tax-exempt status of bonds o TAB D – $7 million for land and buildings has already been paid out of PPH reserves and is pending CEQA review/approval ▪ Will be reimbursed from GO Bonds when approved o TAB E – each requisition made of the Paying Agent o In response to specific inquiries made by members of the ICOC: ▪ The "signage" purchased from Home Depot on page E5 refers to design/architectural efforts to date ▪ Mock-ups are life-size and fall under design & development (1) The use of mock-ups has been the basis for re-design in some areas ▪ The "honorarium" to Tim Vanderveen on page E46 was for speaking/conducting a seminar during one of the Centers for Health design	

AGENDA ITEM/PURPOSE	DISCUSSION/RECOMMENDATION	ACTION/COMMENTS
	(1) It and the twelve or so others under that title or "professional services" were deemed by Management to fit GO Bond expenditures in the design/development category ▪ If the ICOC disagrees with an assessment of expenditures being paid from GO Bond proceeds, the report would include a statement that might include, "...except line items..." (1) If the PPH Board were to agree with the ICOC, then the GO proceeds would be reimbursed and another source of funding would be used for those items (2) If the PPH Board were to disagree with the ICOC, then they would report that fact back to the ICOC ▪ The POM OSP is noted in several line items within the requisitions, although it was noted that it is ineligible for GO Bond funding (1) Bob Hemker noted the discrepancy and will have the issue reviewed & corrected as appropriate ▪ There are separations of monies for each project in Finance books and records, but those are not detailed at this summary level ▪ Costs for architects have been approximately $14 million for all projects (1) The detail is behind the draws, invoiced by project (2) It is outside the scope of the ICOC to review proposed architectural expenditures	
C. ANNUAL REPORT OF THE COMMITTEE TO THE PPH BOARD	Chairman Steve Yerxa stated that a succinct report would be prepared, indicating that the ICOC met, what was reviewed, whether there were any discrepancies to report, and that their questions were satisfactorily answered by PPH staff and Bond Counsel • Mr. Yerxa will work with PPH staff to put the report together • The report will be distributed to the ICOC via email o All comments will be reviewed and incorporated into the report as appropriate o If no comments are received within ten (10) days of report distribution, it will be assumed to be correct o The report will then be forwarded to the PPH Board pursuant to the PP&G	

Independent Citizens' Oversight Committee
Meeting Minutes – Tuesday, December 19, 2006

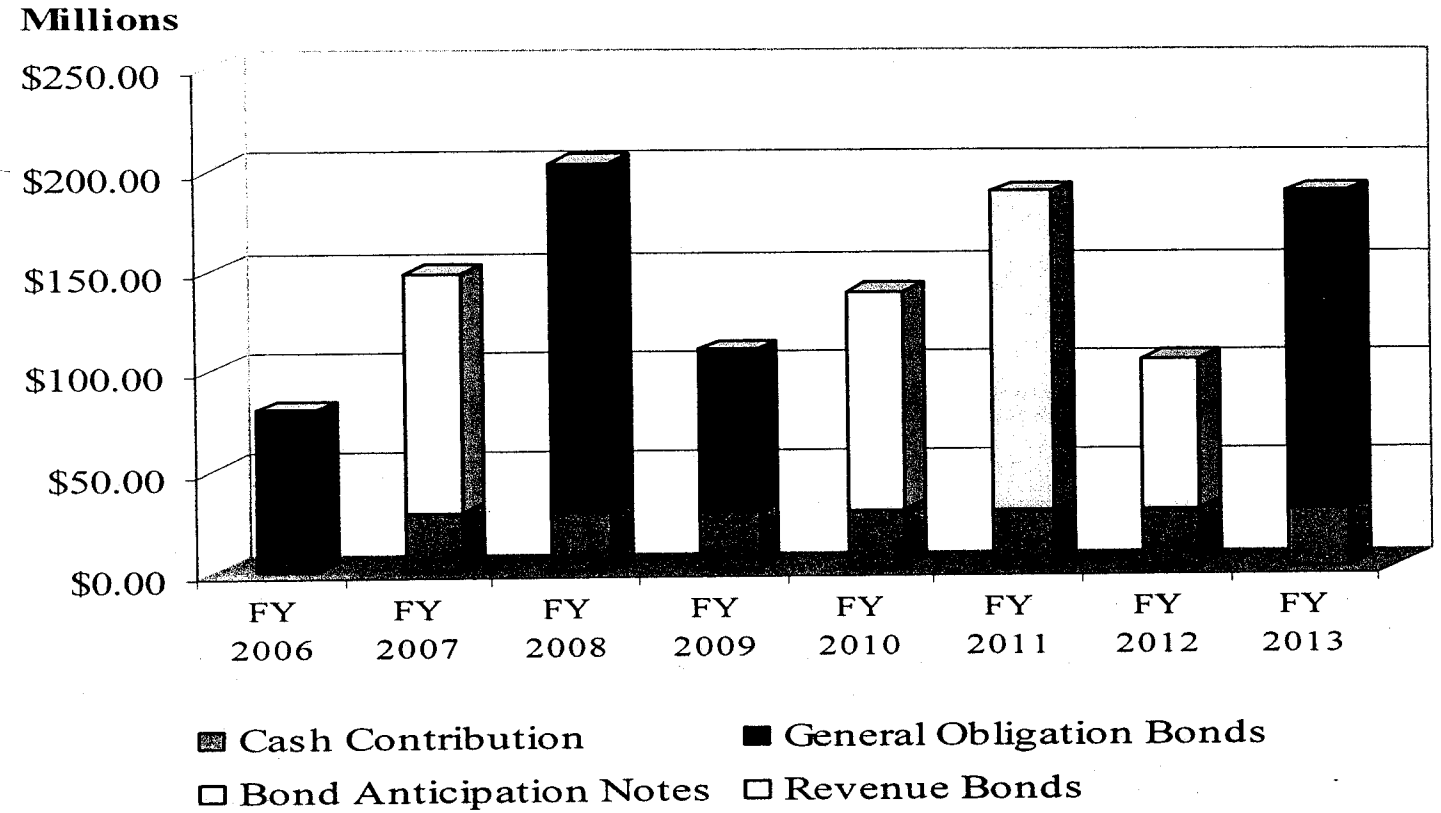
AGENDA ITEM/PURPOSE	DISCUSSION/RECOMMENDATION	ACTION/COMMENTS
D. BOARD MEMBER COMMENTS/AGENDA ITEMS FOR NEXT MEETING	• The ICOC requested that two terms used during the meeting be defined: o **OSHPD** – The Office of State Health Planning & Development ▪ California State Agency responsible for approving hospital projects ▪ Can't build hospital buildings w/out OSHPD approval, receipt of which can take as long as 12-18 months o **Tranche** – a debt term meaning "a portion of the entire" ▪ The first series of GO Bonds was an "$80 million tranche of the $496 million" • Holding special meetings when the quarterly reports are received was proposed, but consensus was that it would likely be difficult to get them scheduled in a timely manner on short notice • When would site visits be appropriate? o The mock-ups at the warehouse space on Enterprise Street in Escondido will be taken down the middle of January ▪ If members of the ICOC would like to tour the mock-ups, they should let Tanya Howell know so that arrangements can be made prior to disassembly o As the ERTC is still just dirt; there have been no significant changes to PMC East; and the POM OSP is going up, with staging work completion (i.e., roadways, parking structure, chassis for tower), but not part of GO funding, site tours to the various campuses are likely premature at this time • **Next meeting is Tuesday, September 25, 2007, 3:00 p.m., in Conference Room A at the Administrative Offices of PPH, 15255 Innovation Drive, San Diego, CA *(incorrectly noticed on agenda as September 27, 2007)***	• **Tanya Howell will work with Marcia Jackson to arrange a site tour of the mockup rooms at the Enterprise Street warehouse and will notify members of the ICOC so they may make arrangements to attend as available** • **The schedule for the Strategic Planning Committee – which provides a quarterly update to the PPH Board – will be distributed by Tanya Howell to the ICOC; and future agendas will also be forwarded so that members may attend as guests when items of interest are slated for discussion**
E. ADJOURNMENT	Meeting adjourned at 2:02 p.m.	• **MOTION:** By Bob Wells, seconded by Ed Lehman and carried to adjourn the meeting

DRAFT REVIEWED AND APPROVED FOR SUBMISSION TO DISTRICT BOARD	CHAIR	Steven P. Yerxa	
	SECRETARY	John McIver	
APPROVED BY DISTRICT BOARD	CHAIR	Marcelo Rivera, M.D	
	SECRETARY	Linda Greer, R.N.	

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

Phased, Integrated Plan of Finance (updated as of June 2006)

- Issue Revenue Bonds in conjunction with GO Bonds and Bond Anticipation Notes allows PPH to
  - ✓ Meet projected construction draw schedule in a timely fashion and maintain $17.75 tax promised to voters
- PPH maintains the flexibility to adjust the timing of Revenue and GO bonds to meet construction needs and take advantage of market opportunities



KaufmanHall

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PALOMAR MEDICAL CENTER
ADMINISTRATIVE SERVICES AGREEMENTS
MEDICAL STAFF OFFICERS, DEPARTMENT CHAIRS, QMC CHAIR

TO: Board of Directors

FROM: Board Finance Committee
Tuesday, January 23, 2007

MEETING DATE: Monday, February 12, 2007

BY: Gerald E. Bracht, Chief Administrative Officer

BACKGROUND: Palomar Medical Center Medical Staff Officers and Department Chairs are provided a stipend for services performed as required by the Medical Staff By-laws. The Agreement serves to document the relationship of the Medical Staff Officers and Department Chairs to PPH, and the duties to be performed as consideration for the stipend to assure compliance with Federal regulations.

Presented at the Board Finance Committee meeting was the Administrative Services Agreement for the Medical Staff Officers, Department Chairs and QMC Chair.

The Agreement encompasses the roles of fourteen (14) individuals at Palomar Medical Center:

Chief of Staff – Robert D. Trifunovic, M.D.
Chief of Staff Elect – John J. Lilley, M.D.
Chairman, Department of Surgery – John T. Steele, M.D.
Chairman, Department of Medicine – John J. Lilley, M.D.
Chairman, Department of OB/GYN – Gregory Langford, M.D.
Chairman, Department of Pediatrics – David Golembeski, M.D.
Chairman, Department of Emergency Medicine – Jaime Rivas, M.D.
Chairman, Department of Radiology – Gary Spoto, M.D.
Chairman, Department of Trauma – Thomas S. Velky, M.D.
Chairman, Department of Anesthesia – Pierre Lotzof, M.D.
Chairman, Department of Pathology – Lachlan Macleay, M.D.
Chairman, Department of Family Practice – Nicholas Jauregui, M.D.
Chairman, Department of Orthopaedics – Paul Milling, M.D.
Chairman, Quality Management Committee – Daniel Harrison, M.D.

The attached Agreement Abstract is the same for all fourteen (14) individuals.

BUDGET IMPACT: None.

STAFF RECOMMENDATION: At the Board Finance Committee meeting, staff recommended approval of the Administrative Services Agreement: Three-year term for the Chief of Staff and Chief of Staff Elect (January 1, 2006 to December 31, 2008); two-year & four-month term for the Surgery Department Chair; and two-year term for all other Department Chairs and the QMC Chair (January 1, 2006 to December 31, 2007).

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION: The Board Finance Committee recommends approval of the Administrative Services Agreement: Three-year term for the Chief of Staff and Chief of Staff Elect (January 1, 2006 to December 31, 2008); two-year & four-month term for the Surgery Department Chair; and two-year term for all other Department Chairs and the QMC Chair (January 1, 2006 to December 31, 2007).

Motion: X

Individual Action:

Information:

Required Time:

PALOMAR POMERADO HEALTH - AGREEMENT ABSTRACT

Section Reference	Term/Condition	Term/Condition Criteria
	TITLE	Administrative Services Agreement
	AGREEMENT DATE	January 1, 2006 (and September 1, 2006, for Chair, Department of Surgery)
	PARTIES	Medical Staff Officers and Department/QMC Chairs, Palomar Medical Center Medical Staff and PPH
	PURPOSE	To provide administrative services on behalf of Palomar Medical Center Medical Staff in accordance with Medical Staff Bylaws
	SCOPE OF SERVICES	As per duties defined in Palomar Medical Center Medical Staff Bylaws
	PROCUREMENT METHOD	☐ **Request For Proposal** ■ **Discretionary**
	TERM	January 1, 2006 – December 31, 2008 – Chief of Staff & Chief of Staff Elect September 1, 2006 – December 31, 2008 – Chair, Department of Surgery January 1, 2006 – December 31, 2007 – Chairmen, Quality Management Committee and Departments of Orthopaedics, Medicine, Anesthesia, Emergency Medicine, Family Practice, Radiology, OB/GYN, Pediatrics, Trauma, and Pathology.
	RENEWAL	None
	TERMINATION	As described under §4
	COMPENSATION METHODOLOGY	Monthly after submission of payment documentation.
	BUDGETED	■ YES ☐ NO – IMPACT:
	EXCLUSIVITY	■ NO ☐ YES – EXPLAIN:
	JUSTIFICATION	These are positions elected or appointed by the Medical Staff in accordance with Medical Staff Bylaws.
	POSITION POSTED	☐ YES ■ NO **Methodology & Response:** Elected/Appointed by the Palomar Medical Center Medical Staff
	ALTERNATIVES/IMPACT	N/A
	DUTIES	Defined in the Palomar Medical Center Medical Staff Bylaws.
	COMMENTS	This new agreement template was developed by legal counsel. The positions are voted upon by Active members of the Medical Staff.
	APPROVALS REQUIRED	■ VP ■CFO ■CEO ■BOD Committee FINANCE ■BOD

PALOMAR POMERADO HEALTH - AGREEMENT ABSTRACT

Section Reference	Term/Condition	Term/Condition Criteria
	TITLE	Administrative Services Agreement
	AGREEMENT DATE	January 1, 2007
	PARTIES	Medical Staff Officers and Department/QMC Chairs, Palomar Medical Center Medical Staff and PPH
	PURPOSE	To provide administrative services on behalf of Palomar Medical Center Medical Staff in accordance with Medical Staff Bylaws
	SCOPE OF SERVICES	As per duties defined in Palomar Medical Center Medical Staff Bylaws
	PROCUREMENT METHOD	☐ **Request For Proposal** ■ **Discretionary**
	TERM	January 1, 2007 – December 31, 2007 - Chief of Staff, Chief of Staff Elect, Chair, Quality Management Committee, and Chairmen Departments of Surgery, Orthopaedics, Medicine, Anesthesia, Emergency Medicine, Family Practice, Radiology, OB/GYN, Pediatrics, Trauma, and Pathology.
	RENEWAL	None
	TERMINATION	As described under §4
	COMPENSATION METHODOLOGY	Monthly after submission of payment documentation.
	BUDGETED	■ YES ☐ NO – IMPACT:
	EXCLUSIVITY	■ NO ☐ YES – EXPLAIN:
	JUSTIFICATION	These are positions elected or appointed by the Medical Staff in accordance with Medical Staff Bylaws.
	POSITION POSTED	☐ YES ■ NO **Methodology & Response:** Elected/Appointed by the Palomar Medical Center Medical Staff
	ALTERNATIVES/IMPACT	N/A
	DUTIES	Defined in the Palomar Medical Center Medical Staff Bylaws.
	COMMENTS	This new agreement template was developed by legal counsel. The positions are voted upon by Active members of the Medical Staff.
	APPROVALS REQUIRED	■ VP ■CFO ■CEO ■BOD Committee FINANCE ■BOD

ADMINISTRATION

PALOMAR
POMERADO
HEALTH

December 6, 2006

Robert D. Trifunovic, M.D.
Palomar Medical Center Medical Staff
555 East Valley Parkway
Escondido, CA 92025

Re: Agreement to reimburse Medical Staff for Department Chair, QMC Chair, Chief of Staff and Chief of Staff Elect Compensation

Dear Doctor Trifunovic:

Palomar Pomerado Health ("PPH"), a hospital district organized under California Health & Safety Code, Division 23 and Palomar Medical Center Medical Staff ("Medical Staff") hereby enter into this letter agreement ("Letter Agreement") by the terms of which PPH will reimburse Medical Staff for a portion of the compensation provided by Medical Staff to certain physicians under department and committee chair/officer agreements. PPH is the owner and operator of Palomar Medical Center ("hospital") located at 555 East Valley Parkway, Escondido, California.

1. **Department Chair, QMC Chair, Chief of Staff and Chief of Staff Elect Agreements**

Medical Staff has entered into those arrangements listed on Exhibit A (the "Arrangements") with certain physicians ("Physicians") to chair departments/committees, or to serve as Chief of Staff or Chief of Staff Elect at Hospital. Medical Staff represents and warrants that the duties and responsibilities are set out in the Medical Staff Bylaws and other documents. Medical Staff further represents and warrants that its arrangements with the Physicians provide compensation that is fair market value for the services provided and is not determined in any manner that takes into account the value or volume of referrals or other business generated by the Physician to PPH.

2. **Financial Terms**

Medical Staff shall be solely responsible for compensating Physicians pursuant to the terms of the Arrangements. Medical Staff shall submit to PPH documentation reflecting the compensation provided by Medical Staff to the Physicians pursuant to the Arrangements no later than the tenth (10^{th}) day of each month. PPH shall provide reimbursement to Medical Staff as follows:

1) seventy-five percent (75%) of the amounts provided to the Chief of Staff Elect;

and

2) fifty percent (50%) of the amounts provided to the Physicians pursuant to all of the other Arrangements.

PPH shall provide such reimbursement within ten (10) business days after Medical Staff's submission to PPH of the payment documentation. PPH shall provide such reimbursement in recognition of the fact that the Physicians, by the terms of their agreements with Medical Staff, provide services which in part benefit PPH.

3. **Term**

This letter agreement will have a term of one year, beginning January 1, 2006, and ending January 1, 2007, unless sooner terminated as otherwise provided in the agreement contemplated by this letter of intent.

4. **Termination**

PPH will have the right to terminate the agreement upon the occurrence of any of the following events:

(i) With or without cause, in either case without penalty, upon ninety (90) days written notice to Medical Staff.
(ii) Any breach of the Agreement by Medical Staff which is not cured within thirty (30) days after written notice is given by PPH to Medical Staff.
(iii) Upon such other conditions as agreed upon by Medical Staff and PPH.

5. **Publicity**

Except as required by law, no party shall make any public announcement with respect to the agreement proposed by this letter of intent without the express written consent of the other parties.

6. **Controlling Law**

This letter of intent shall be governed by and construed and enforced in accordance with the laws of the State of California.

7. **Counterparts**

This letter agreement may be executed in counterparts, each of which shall be an original, but all of which together shall constitute one and the same agreement.

Sincerely,

Michael H. Covert
President/CEO
Palomar Pomerado Health

Accepted and agreed to by Medical Staff as of 12/29, 2006

Robert D. Trifunovic, M.D.
Chief of Staff

Exhibit A

Physician	Position	Term	Monthly Comp.
Robert D. Trifunovic, M.D.	Chief of Staff	01/01/06-12/31/08	
John J. Lilley, M.D.	Chief of Staff Elect	01/01/06-12/31/08	
John T. Steele, M.D.	Chair, Surgery Dept.	09/01/06-12/31/08	
John J. Lilley, M.D.	Chair, Medicine Dept.	01/01/06-12/31/07	
Gregory A. Langford, M.D.	Chair, OB/GYN Dept.	01/01/06-12/31/07	
David J. Golembeski, M.D.	Chair, Pediatric Dept.	01/01/06-12/31/07	
Jaime B. Rivas, M.D.	Chair, Emergency Medicine Dept.	01/01/06-12/31/07	
Gary P. Spoto, M.D.	Chair, Radiology Dept.	01/01/06-12/31/07	
Thomas S. Velky, M.D.	Chair, Trauma Dept.	01/01/06-12/31/07	
Pierre R. Lotzof, M.D.	Chair, Anesthesia Dept.	01/01/06-12/31/07	
Lachlan Macleay, M.D.	Chair, Pathology Dept.	01/01/06-12/31/07	
Nicholas J. Jauregui, M.D.	Chair, Family Practice Dept.	01/01/06-12/31/07	
Paul C. Milling, M.D.	Chair, Ortho/Rehab Dept.	01/01/06-12/31/07	
Daniel C. Harrison, M.D.	Chair, QMC	01/01/06-12/31/07	

POMERADO HOSPITAL
ADMINISTRATIVE SERVICES AGREEMENT
MEDICAL STAFF OFFICERS, CLINICAL SERVICE DIRECTORS, SECTION CHIEFS, QMC CHAIR

TO: Board of Directors

FROM: Board Finance Committee
Tuesday, January 23, 2007

MEETING DATE: Monday, February 12, 2007

BY: Jim Flinn, FACHE, Chief Administrative Officer, Pomerado Hospital

BACKGROUND: Pomerado Hospital Medical Staff Officers are compensated for services performed as required by the Medical Staff Bylaws. The Agreement serves to document the relationship of the Medical Staff Officers, Clinical Service Directors, Section Chiefs and QMC Chair to PPH, and the duties to be performed as consideration for the stipend to assure compliance with Federal regulations.

Presented at the Board Finance Committee meeting was a two-year Administrative Services Agreement for the Chief of Staff, Chief of Staff Elect, Clinical Service Directors, Section Chiefs and Chairperson for the Quality Management Committee.

This Agreement encompasses the roles of eleven (11) individuals at Pomerado Hospital:

Chief of Staff – Benjamin Kanter, M.D.
Chief of Staff Elect – Franklin Martin, M.D.
Clinical Service Director, Surgery – Kyle Potts, M.D.
Clinical Service Director, Diagnostic Services – Gary Spoto, M.D.
Clinical Service Director, Primary Care – Alan Conrad, M.D.
Clinical Service Director, Maternal Child – Timothy Maresh, M.D.
Section Chief, Pediatrics – Nabil Fatayerji, M.D.
Section Chief, Emergency Medicine – Jaime Rivas, M.D.
Section Chief, Pathology – Jerry Kolins, M.D.
Section Chief, Anesthesia – Marc Gipsman, M.D.
Chairman, Quality Management Committee – Roger Acheatel, M.D.

The attached Agreement Abstract is the same for all eleven (11) individuals.

BUDGET IMPACT: None

STAFF RECOMMENDATION: At the Board Finance Committee meeting, staff recommended approval of the two-year (January 1, 2007 to December 31, 2008) Administrative Services Agreement for the Medical Staff Officers, Clinical Service Directors, Section Chiefs and QMC Chair.

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION: The Board Finance Committee recommends Approval of the two-year **(January 1, 2007 to December 31, 2008)** Administrative Services Agreement for the Medical Staff Officers, Clinical Service Directors, Section Chiefs and QMC Chair.

Motion: X

Individual Action:

Information:

Required Time:

PALOMAR POMERADO HEALTH - AGREEMENT ABSTRACT

Section Reference	Term/Condition	Term/Condition Criteria
	TITLE	Administrative Services Agreement
	AGREEMENT DATE	January 1, 2007
	PARTIES	Medical Staff Officers and Division Directors, Section Chiefs/QMC Chair, Pomerado Hospital Medical Staff and PPH
	PURPOSE	To provide administrative services on behalf of Pomerado Hospital Medical Staff in accordance with Medical Staff Bylaws
	SCOPE OF SERVICES	As per duties defined in Pomerado Hospital Medical Staff Bylaws
	PROCUREMENT METHOD	☐ **Request For Proposal** ■ **Discretionary**
	TERM	January 1, 2007 – December 31, 2008 - Chief of Staff, Chief of Staff Elect, Quality Management Chair, Clinical Service Directors, Surgery, Diagnostic Services, Primary Care & Maternal Child, and Section Chiefs, Anesthesia, Emergency Medicine, Pathology and Pediatrics.
	RENEWAL	None
	TERMINATION	As described under §5.2 through §5.5
	COMPENSATION METHODOLOGY	Monthly upon submission of required monthly time reports
	BUDGETED	■ YES ☐ NO – IMPACT:
	EXCLUSIVITY	■ NO ☐ YES – EXPLAIN:
	JUSTIFICATION	These are positions elected by the Medical Staff in accordance with Medical Staff Bylaws.
	POSITION POSTED	☐ YES ☐ NO **Methodology & Response:** N/A – Elected by the Pomerado Hospital Medical Staff
	ALTERNATIVES/IMPACT	N/A
	DUTIES	Defined in the Pomerado Hospital Medical Staff Bylaws. May include: ■ **Provision for Staff Education** ■ **Provision for Medical Staff Education** ■ **Provision for participation in Quality Improvement**
	COMMENTS	Agreement templates were developed by legal counsel. The positions are voted upon by Active members of the Medical Staff.
	APPROVALS REQUIRED	■ VP ■CFO ■CEO ■BOD Committee FINANCE ■BOD

ADMINISTRATION

PALOMAR POMERADO HEALTH

January 1, 2007

Pomerado Hospital Medical Staff
15615 Pomerado Road
Poway, CA 92064

Re: Agreement to reimburse Medical Staff for Division Director, Section Chief, QMC Chair, Chief of Staff and Chief of Staff Elect Compensation.

Dear Dr. Benjamin Kanter:

Palomar Pomerado Health ("PPH"), a hospital district organized under California Health & Safety Code, Division 23 and Pomerado Hospital Medical Staff ("Medical Staff") hereby enter into this letter agreement ("Letter Agreement") by the terms of which PPH will reimburse Medical Staff for a portion of the compensation provided by Medical Staff to certain physicians under division director and other administrative agreements. PPH is the owner and operator of Pomerado Hospital ("Hospital") located at 15615 Pomerado Road, Poway, CA 92064.

1. **Division Director, Section Chief, QMC Chair, Chief of Staff and Chief of Staff Elect Agreements**

Medical Staff has entered into those arrangements listed on Exhibit A (the "Arrangements") with certain physicians ("Physicians") to serve as division directors, section chiefs, QMC chair or to serve as Chief of Staff or Chief of Staff Elect at Hospital. Medical Staff represents and warrants that the duties and responsibilities are set out in the Medical Staff Bylaws and other documents. Medical Staff further represents and warrants that its arrangements with the Physicians provide compensation that is fair market value for the services provided and is not determined in any manner that takes into account the value or volume of referrals or other business generated by the Physician to PPH.

2. **Financial Terms**

Medical Staff shall be solely responsible for compensating Physicians pursuant to the terms of the Arrangements. Medical Staff shall submit to PPH documentation reflecting the compensation provided by Medical Staff to the Physicians pursuant to the Arrangements no later than the tenth (10th) day of each month. PPH shall provide reimbursement to Medical Staff for fifty percent (50%) of the amounts provided to the Physicians pursuant to the Arrangements. PPH shall provide such reimbursement within ten (10) business days after Medical Staff's

PPH shall provide such reimbursement within ten (10) business days after Medical Staff's submission to PPH of the payment documentation. PPH shall provide such reimbursement in recognition of the fact that the Physicians, by the terms of their agreements with Medical Staff, provide services which benefit PPH.

3. **Term**

This letter agreement will have a term of two years, beginning January 1, 2007, and ending December 31, 2008, unless sooner terminated as otherwise provided in the agreement contemplated by this letter of intent.

4. **Termination**

PPH will have the right to terminate the agreement upon the occurrence of any of the following events:

(i) With or without cause, in either case without penalty, upon ninety (90) days written notice to Medical Staff.

(ii) Any breach of the Agreement by Medical Staff which is not cured within thirty (30) days after written notice is given by PPH to Medical Staff.

(iii) Upon such other conditions as agreed upon by Medical Staff and PPH.

5. **Publicity**

Except as required by law, no party shall make any public announcement with respect to the agreement proposed by this letter of intent without the express written consent of the other parties.

6. **Controlling Law**

This letter of intent shall be governed by and construed and enforced in accordance with the laws of the State of California.

7. **Counterparts**

This letter agreement may be executed in counterparts, each of which shall be an original, but all of which together shall constitute one and the same agreement.

Sincerely,

Michael Covert
President/CEO
Palomar Pomerado Health

Accepted and agreed to by Medical Staff as of 11-28, 2006
Pomerado Hospital Medical Staff

Exhibit A

Physician	Position	Term	Monthly Compensation
Benjamin Kanter, M.D.	Chief of Staff	1/01/07 - 12/31/08	
Franklin Martin, M.D.	Chief of Staff-Elect	1/01/07 - 12/31/08	
Kyle Potts, M.D.	Clinical Service Director Surgery	1/01/07 - 12/31/08	
Gary Spoto, M.D.	Clinical Service Director Diagnostic Services	1/01/07 - 12/31/08	
Alan Conrad, M.D.	Clinical Service Director Primary Care	1/01/07 - 12/31/08	
Timothy Maresh, M.D.	Clinical Service Director Maternal Child	1/01/07 - 12/31/08	
Nabil Fatayerji, M.D.	Section Chief of Pediatrics	1/01/07 - 12/31/08	
Jaime Rivas, M.D.	Section Chief of Emergency Medicine	1/01/07 - 12/31/08	
Jerry Kolins, M.D.	Section Chief of Pathology	1/01/07 - 12/31/08	
Marc Gipsman, M.D.	Section Chief of Anesthesia	1/01/07 - 12/31/08	
Roger Acheatel, M.D.	QMC Chair	1/01/07 – 12/31/08	

December 2006 & YTD FY2007 Financial Report

TO: Board of Directors

FROM: Board Finance Committee
Tuesday, January 23, 2007

MEETING DATE: Monday, February 12, 2007

FROM: Robert Hemker, CFO

Background: The Board Financial Reports (unaudited) for December 2006 and YTD FY2007 were submitted for the Committee's review and approval.

Budget Impact: N/A

Staff Recommendation: At the Board Finance Committee meeting, the staff recommended approval.

Committee Questions:

COMMITTEE RECOMMENDATION: The Board Finance Committee recommends approval of the Board Financial Reports (unaudited) for December 2006 and Fiscal YTD 2007.

Motion: X

Individual Action:

Information:

Required Time:

Financial Statements

Tim Nguyen
Corporate Controller
January 23, 2007

PALOMAR POMERADO HEALTH

PALOMAR
POMERADO
HEALTH
SPECIALIZING IN YOU

Board Financial Report
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PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

PALOMAR POMERADO HEALTH
DECEMBER 2006 FINANCIAL RESULTS
EXECUTIVE SUMMARY and HIGHLIGHTS

Statistics:

CONSOLIDATED	Nov-06	Dec-06	Nov vs Dec % Change	Dec-06 Budget	Act vs Bud % Variance	YTD Actual	YTD Budget	Act vs Bud % Variance
Patient Days Acute	8,610	9,559	11.0%	9,922	-3.7%	54,854	58,892	-6.9%
Patient Days SNF	6,278	6,503	3.6%	6,591	-1.3%	38,831	39,120	-0.7%
ADC Acute	287	308	7.3%	320	-3.8%	298	320	-6.9%
ADC SNF	209	210	0.5%	213	-1.4%	211	213	-0.9%
Surgeries CVS Cas	9	12	33.3%	11	9.1%	64	64	0.0%
Surgeries Total	980	916	-6.5%	1,041	-12.0%	5,825	6,178	-5.7%
Number of Births	444	444	0.0%	499	-11.0%	2833	2962	-4.4%
NORTH								
Patient Days Acute	6,607	7,153	8.3%	7,396	-3.3%	41,150	43,898	-6.3%
Patient Days SNF	2,617	2,665	1.8%	2,747	-3.0%	16,084	16,304	-1.3%
ADC Acute	220	231	5.0%	239	-3.3%	224	239	-6.3%
ADC SNF	87	86	-1.1%	89	-3.4%	87	89	-2.2%
SOUTH								
Patient Days Acute	2,003	2,406	20.1%	2,526	-4.8%	13,704	14,994	-8.6%
Patient Days SNF	3,661	3,838	4.8%	3,844	-0.2%	22,747	22,816	-0.3%
ADC Acute	67	78	16.4%	81	-3.7%	74	81	-8.6%
ADC SNF	122	124	1.6%	124	0.0%	124	124	0.0%

[redacted]

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

PALOMAR POMERADO HEALTH
DECEMBER 2006 FINANCIAL RESULTS
EXECUTIVE SUMMARY and HIGHLIGHTS (cont'd)

Balance Sheet:

Current Cash & Cash Equivalents increased $2.4 million from $100.9 million in November to $103.3 million in December. The increase is mainly due to the increase in the 1% Ad Valorem property taxes collected in December. Total Cash and Investments are $104.5 million, compared to $121.6 million at June 30, 2006. Days Cash on Hand went from 109 days in November to 106 days in December compared to 128 in June.

Net Accounts Receivable increased to $90.1 million in December as compared to $87.6 million in November. Gross A/R days increased from 53.7 days in November to 54.1 days in December. December patient account collections including capitation are $29.7 million compared to budget of $29.8 million. December YTD collections are $163.6 million compared to budget of $178.8 million.

Construction in Progress increased $4.1 million from $111.7 million in November to $115.8 million in December. The increase is attributed to Pomerado parking structure construction costs $2.5 million and A & E Services $1.5 million.

Other Current Liabilities decreased $500 thousand from $18.0 million to $17.5 million primarily due to the realization of Deferred Property Tax Revenue of $1.1 million in December and an increase of $500 thousand in capitation liability.

PALOMAR POMERADO HEALTH
DECEMBER 2006 FINANCIAL RESULTS
EXECUTIVE SUMMARY and HIGHLIGHTS (cont'd)

Income Statement:

Gross Patient Revenue for YTD December reflects an unfavorable budget variance of $24.6 million. This unfavorable variance is composed of $28.6 million unfavorable volume variance and $4.0 million favorable rate variance.

Routine revenue (inpatient room and board) reflects an unfavorable $9.3 million budget variance. North is responsible for $7.4 million of this variance.

Inpatient Ancillary revenue represents a $19.1 million unfavorable budget variance. North reflects an unfavorable variance of $5.8 million and South reflects $13.3 million unfavorable variance. The main contributors to North's unfavorable variance are Emergency Room, Pharmacy, Respiratory Therapy, Surgery, and supply departments totaling $10.6 million lower than budget. The main contributors to South's unfavorable variance is Surgery, Surgery Patient Supply and Pharmacy departments totaling $13.8 million lower than budget.

Outpatient revenue reflects a favorable budget variance of $3.8 million. North has a $4.2 million favorable variance and South has a $0.4 million favorable variance. These two amounts are decreased by Outreach's $0.8 million unfavorable variance.

PALOMAR POMERADO HEALTH
DECEMBER 2006 FINANCIAL RESULTS
EXECUTIVE SUMMARY and HIGHLIGHTS (cont'd)

Income Statement (cont'd):

Deductions from Revenue reflect a YTD favorable variance of $18.8 million. This is due to lower-than-budgeted volume and budgeted gross revenue. Total Deductions from Revenue is 69.08% of gross revenue compared to a budget of 69.35%. Deductions from Revenue (excluding Bad Debt/Charity/Undocumented expenses) is 63.94% of YTD Gross Revenue compared to budget of 64.78%.

The net capitation reflects a favorable budget variance of $1.0 million. Cap Premium and Out of Network Claim Expense both show an unfavorable budget variance of $1.6 million and $1.8 million respectively. Cap Valuation shows a favorable variance of $4.4 million to offset.

Other Operating Revenue reflects a YTD unfavorable budget variance of $827 thousand. This is due primarily to the Foundation where actual PPH funding requests are $304 thousand below budget, and PPNC Health Development where actual grants are $323 thousand below budget.

Salaries, Wages & Contract Labor has a YTD favorable budget variance of $2.7 million. This variance is mostly attributable to lower-than-budgeted volumes and staff flexing. The breakdown is as follows:

Consolidated	92,018,168	94,615,352	2,597,184
North	53,159,854	54,070,450	910,596
South	22,248,359	23,421,292	1,172,933
Central	12,179,697	12,887,758	708,061
Outreach	4,430,258	4,235,852	(194,406)

PALOMAR POMERADO HEALTH
DECEMBER 2006 FINANCIAL RESULTS
EXECUTIVE SUMMARY and HIGHLIGHTS (cont'd)

Income Statement (cont'd):

Benefits Expense has a YTD unfavorable budget variance of $411 thousand. This variance is primarily due to the employer's contribution towards deferred compensation which is unfavorable by $331 thousand and Workers Compensation which is unfavorable by $208 thousand . These are partially offset by a favorable variance in FICA.

Supplies Expense reflects YTD favorable budget variance of $2.9 million. This favorable variance is composed of a $1.5 million favorable volume variance and $1.4 million favorable rate variance. The favorable variance is pharmacy at $1.3 million, prosthesis at $546 thousand, other medical and non-medical at $630 thousand and other general supplies at $424 thousand.

Prof Fees & Purchased Services reflects a YTD unfavorable budget variance of $1.7 million. The unfavorable variance of $821 thousand in professional fees is due to higher legal fees, rehabilitation therapy fees and Pomerado ED calls. The unfavorable variance of $838 thousand in purchased services is due to purchased contracted services.

Non-Operating Income reflects a favorable YTD variance of $1.1 million in December. This is due to a favorable investment income variance. Investment income reflects a 5.0% investment rate-of-return through December compared to budget of 4.25%.

Ratios & Margins:

All required bond covenant ratios were achieved in December 2006.

[redacted]

Palomar Pomerado Health
Balanced Scorecard
Financial Indicators
December 31, 2006

October	November	December					YTD 2007				
Actual	Actual	Actual	Budget / PY	Variance	% Actual to Budget		Actual	Budget	Variance	% Actual to Budget	Prior Year Actual
						PPH Indicators:					
4.4%	4.6%	10.0%	9.9%	-5.3%	101.0%	OEBITDA Margin w/Prop Tax	8.8%	9.8%	-1.0%		7.6%
$ 2,697.64	$ 2,643.70	$ 2,576.57	$2,483.14	$ (160.56)	103.8%	Expenses/Wtd Day	2,558.35	$2,488.58	$ (69.77)	102.8%	2,407.46
$ 1,622.50	$ 1,561.40	$ 1,556.33	$1,478.51	$ (82.89)		SWB/Wtd Day	1,521.64	$1,480.10	$ (41.54)	102.8%	1,411.01
6.38	6.15	6.24	6.12	$ (0.03)	102.0%	Prod FTE's/Adj Occupied Bed	6.15	6.12	(0.03)	100.5%	6.11
12,431	12,042	12,813	13,089	$ (1,047.00)		Weighted Patient Days	75,536	79,133	(3,597)		74,668
						PPH North Indicators:					
1.5%	4.9%	14.3%	9.8%	-4.9%	146.9%	OEBITDA Margin w/Prop Tax	9.5%	9.6%	-0.1%	99.0%	7.3%
$ 2,606.31	$ 2,494.84	$ 2,441.50	$2,362.48	$ (132.36)	103.3%	Expenses/Wtd Day	2,438.27	$2,367.72	$ (70.55)	103.0%	2,288.71
$ 1,365.10	$ 1,272.60	$ 1,254.46	$1,224.57	$ (48.03)	102.4%	SWB/Wtd Day	1,265.83	$1,225.76	$ (40.07)	103.3%	1,191.22
5.42	5.19	5.23	5.08	$ (0.11)	103.0%	Prod FTE's/Adj Occupied Bed	5.21	5.08	(0.13)	102.6%	5.14
8,475	8,434	8,911	9,269	$ (835.00)		Weighted Patient Days	52,207	54,625	(2,418)		52,893
						PPH South Indicators:					
11.1%	2.1%	-1.7%	6.9%	-4.8%		OEBITDA Margin w/Prop Tax	5.6%	6.8%	-1.2%		5.3%
$ 2,450.64	$ 2,515.07	$ 2,435.03	$2,398.74	$ (116.33)	101.5%	Expenses/Wtd Day	2,419.54	$2,403.14	$ (16.40)	100.7%	2,396.79
$ 1,285.60	$ 1,274.59	$ 1,260.40	$1,270.24	$ (4.35)		SWB/Wtd Day	1,249.34	$1,271.39	$ 22.05		1,249.93
5.46	5.45	5.54	5.58	$ 0.13		Prod FTE's/Adj Occupied Bed	5.47	5.58	0.11		5.76
3,713	3,429	3,700	3,606	$ (177.00)		Weighted Patient Days	21,852	22,655	(803)		20,663

Weighted Patient Days is compared with Prior Year Actual

PALOMAR POMERADO HEALTH

PALOMAR POMERADO HEALTH
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Admissions – Acute

PALOMAR POMERADO HEALTH
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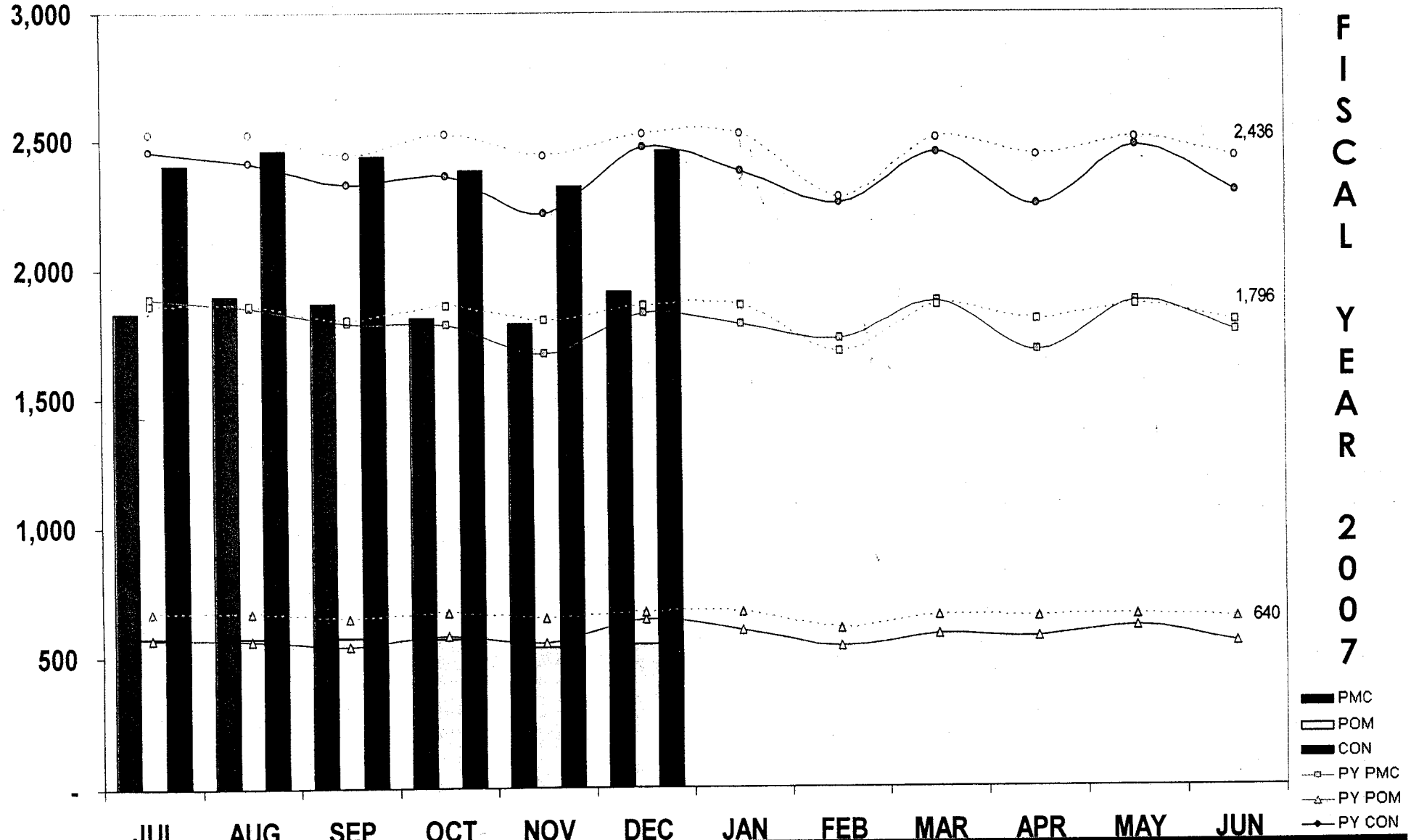

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	1,832	1,895	1,871	1,816	1,791	1,915	-	-	-	-	-	-	11,120	11,040
POM	570	569	572	568	532	545	-	-	-	-	-	-	3,356	3,942
CON	2,402	2,464	2,443	2,384	2,323	2,460	-	-	-	-	-	-	14,476	14,982

Patient Days - Acute

PALOMAR POMERADO HEALTH
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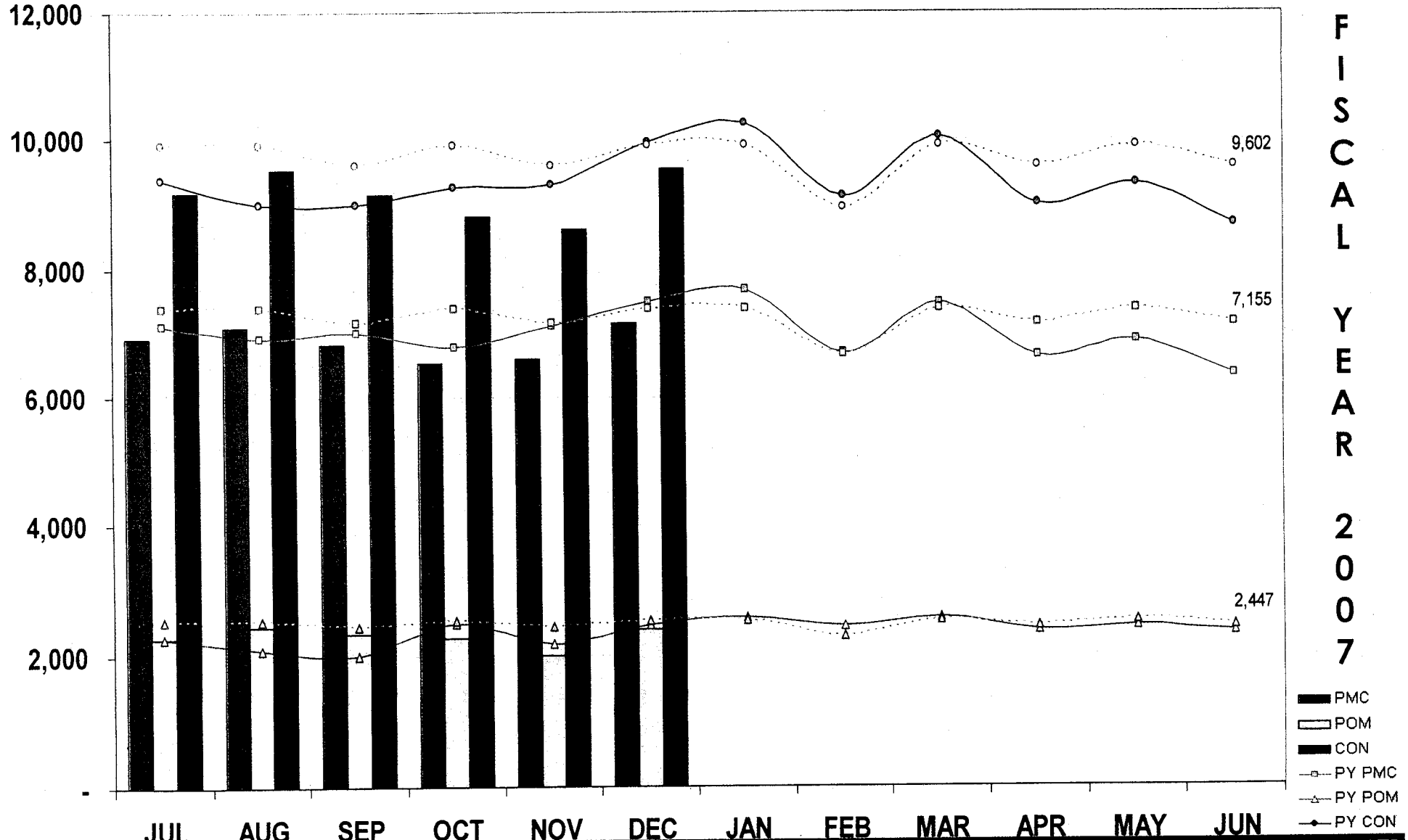

FISCAL YEAR 2007

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	6,919	7,102	6,822	6,547	6,607	7,153	-	-	-	-	-	-	41,150	43,898
POM	2,261	2,433	2,329	2,272	2,003	2,406	-	-	-	-	-	-	13,704	14,994
CON	9,180	9,535	9,151	8,819	8,610	9,559	-	-	-	-	-	-	54,854	58,892

Average Daily Census - Acute

PALOMAR POMERADO HEALTH
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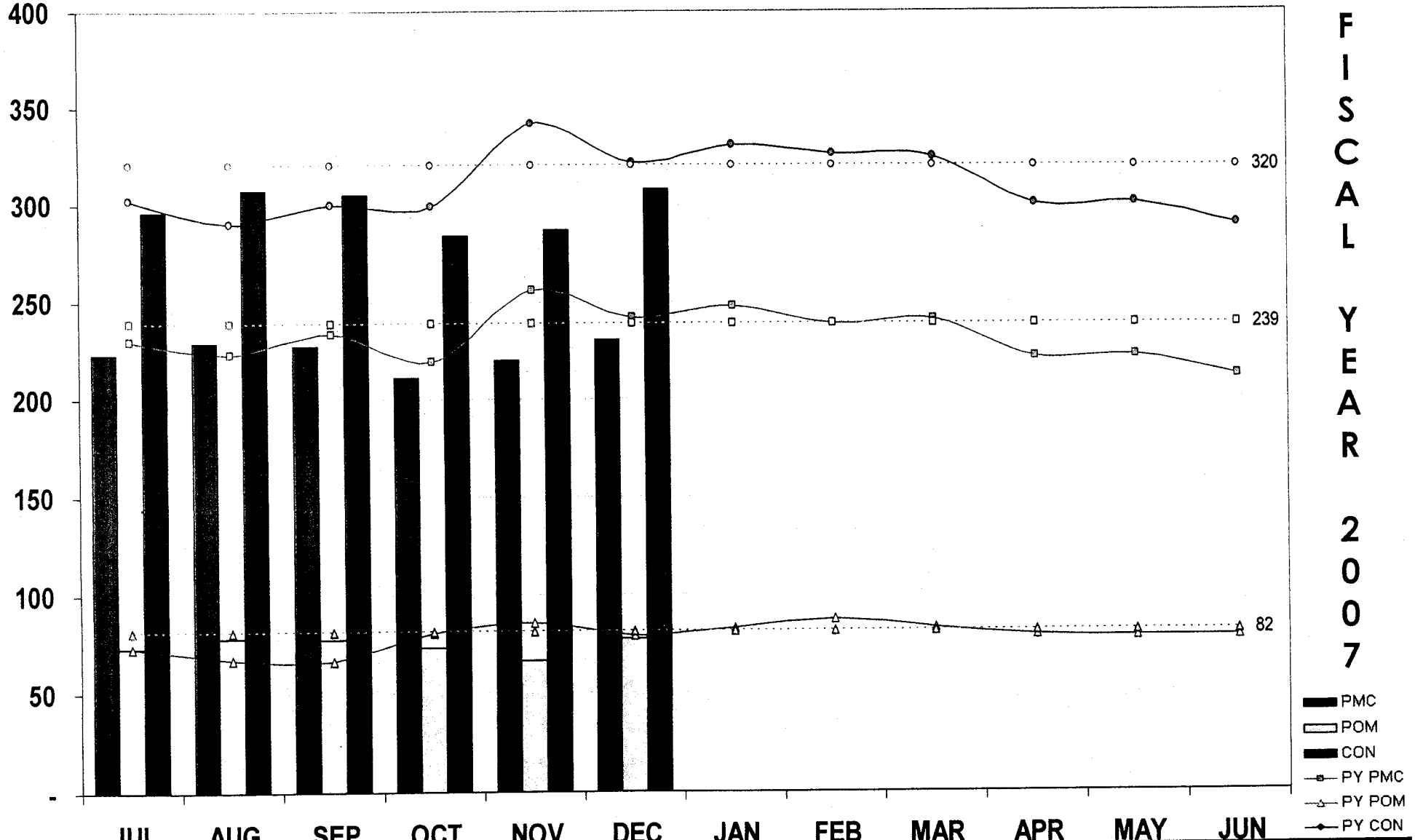

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	223	229	227	211	220	231	-	-	-	-	-	-	224	239
POM	73	78	78	73	67	78	-	-	-	-	-	-	74	81
CON	296	308	305	284	287	308	-	-	-	-	-	-	298	320

Surgeries (In-Patient)

PALOMAR POMERADO HEALTH
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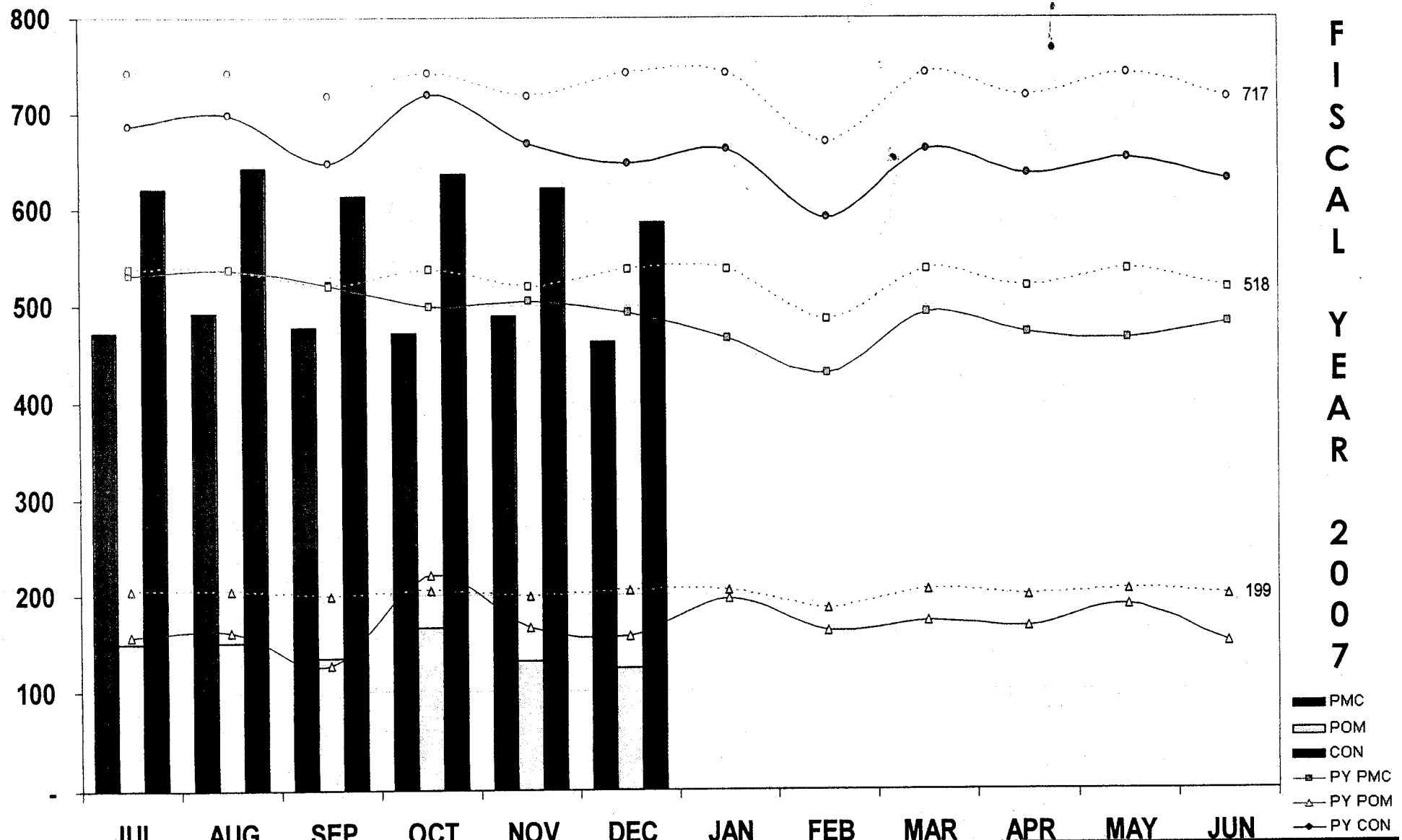

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	471	492	478	471	490	463	-	-	-	-	-	-	2,865	3,186
POM	150	151	135	166	132	124	-	-	-	-	-	-	858	1,218
CON	621	643	613	637	622	587	-	-	-	-	-	-	3,723	4,404

Surgeries (Out-Patient)

PALOMAR POMERADO HEALTH
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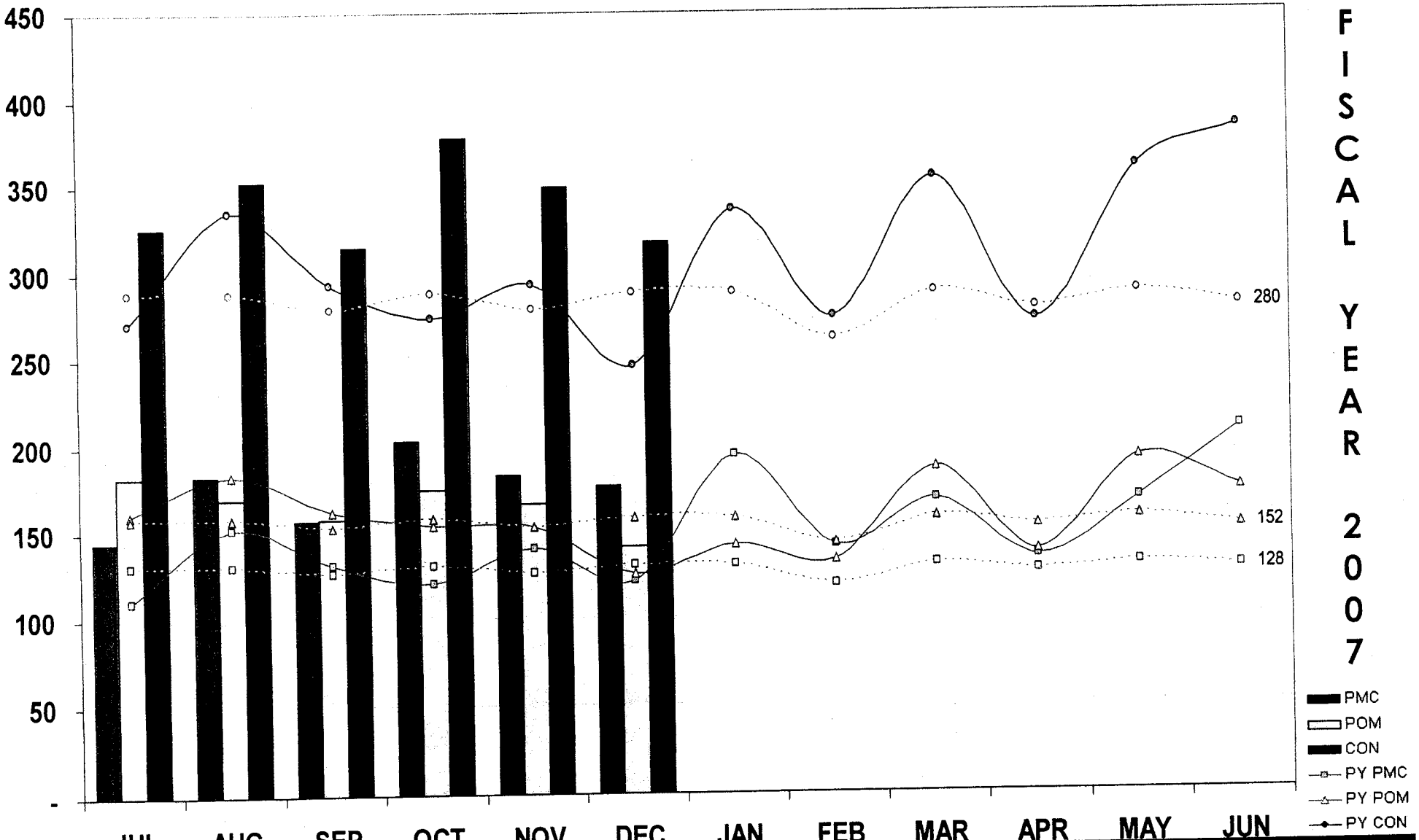

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	144	183	157	203	183	176	-	-	-	-	-	-	1,046	772
POM	182	170	158	175	166	141	-	-	-	-	-	-	992	938
CON	326	353	315	378	349	317	-	-	-	-	-	-	2,038	1,710

Surgeries – CVS (PMC)

PALOMAR POMERADO HEALTH
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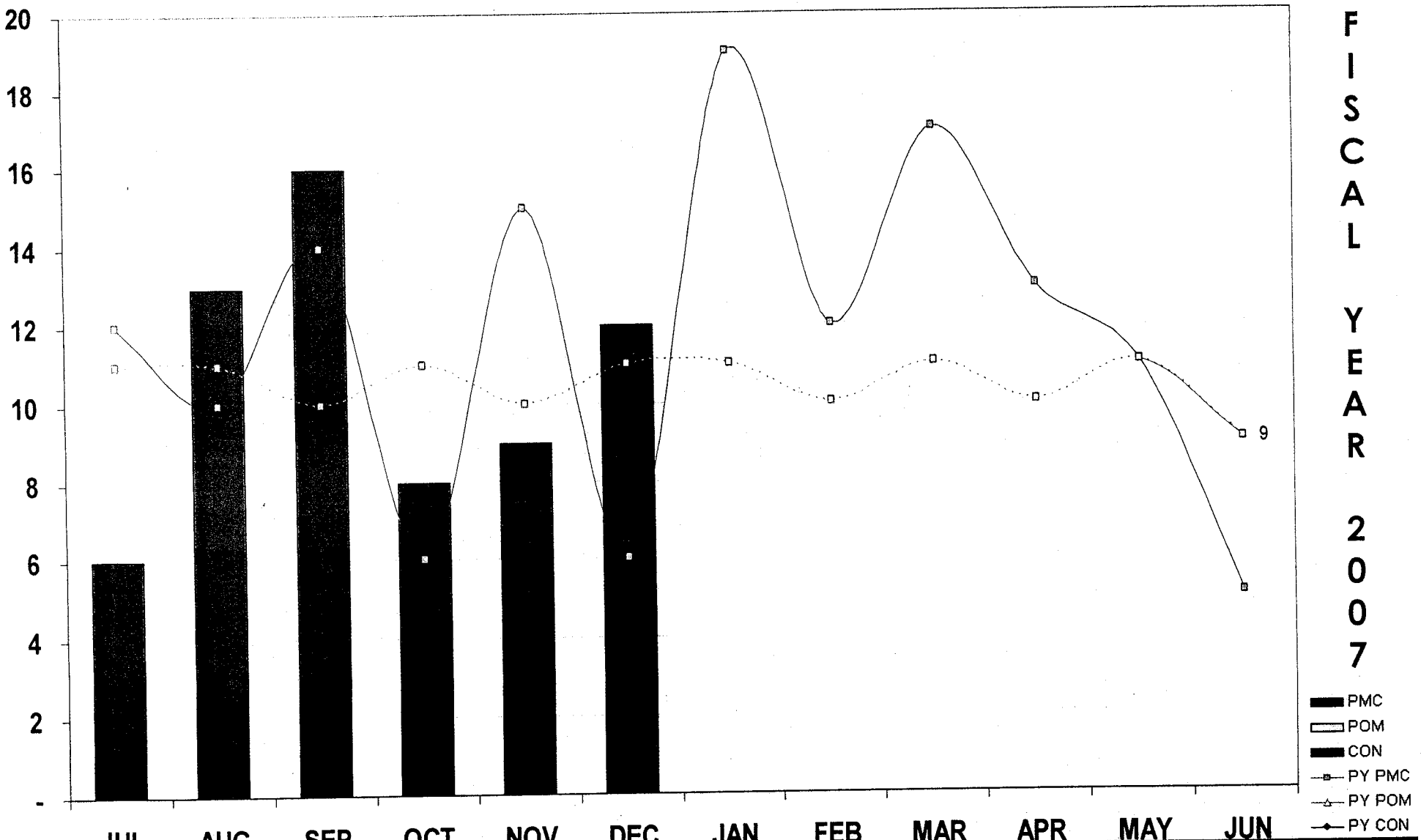

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	6	13	16	8	9	12	-	-	-	-	-	-	64	64

Total Surgeries

PALOMAR POMERADO HEALTH
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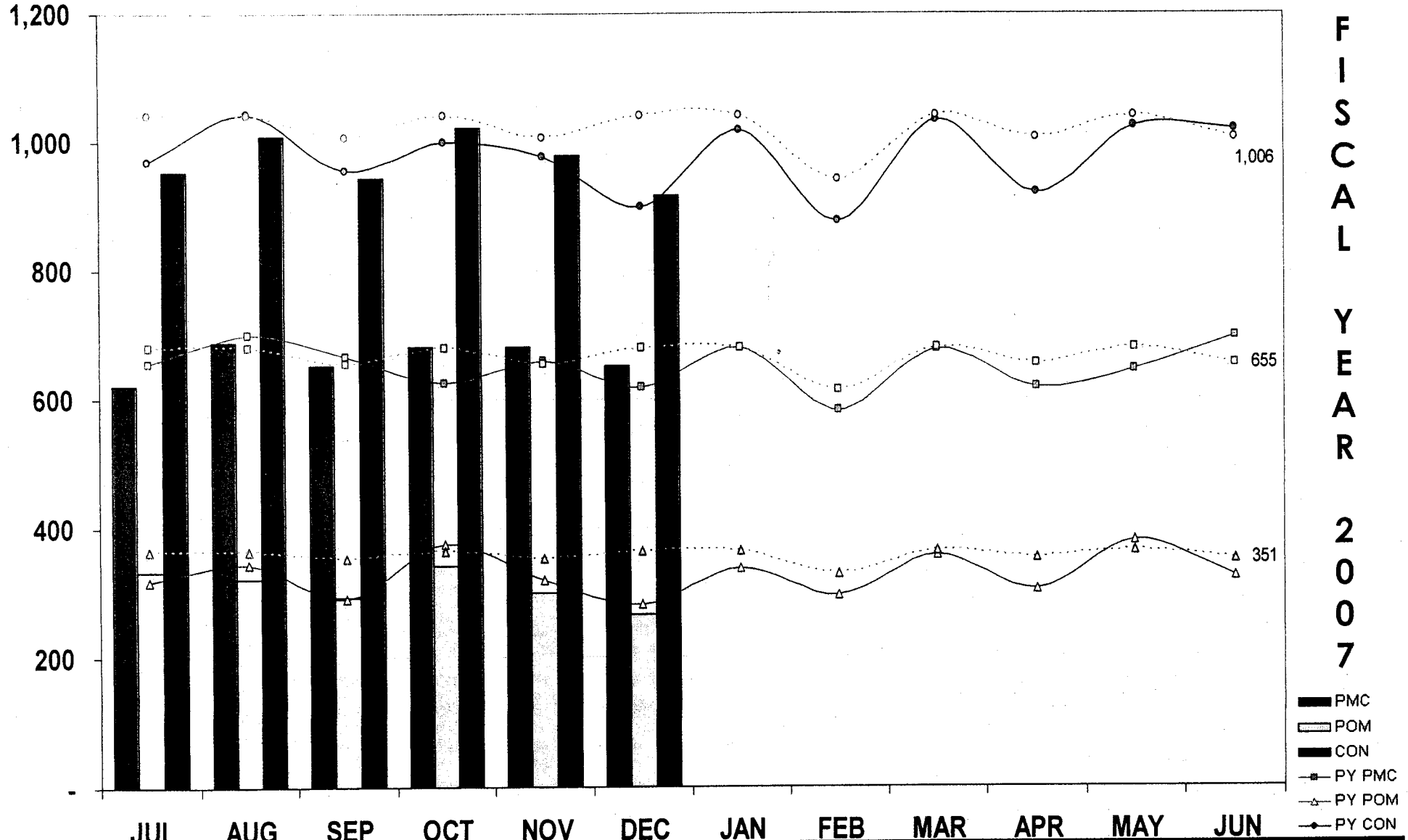

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	621	688	651	682	682	651	-	-	-	-	-	-	3,975	4,022
POM	332	321	293	341	298	265	-	-	-	-	-	-	1,850	2,156
CON	953	1,009	944	1,023	980	916	-	-	-	-	-	-	5,825	6,178

Outpatient Registration

PALOMAR POMERADO HEALTH
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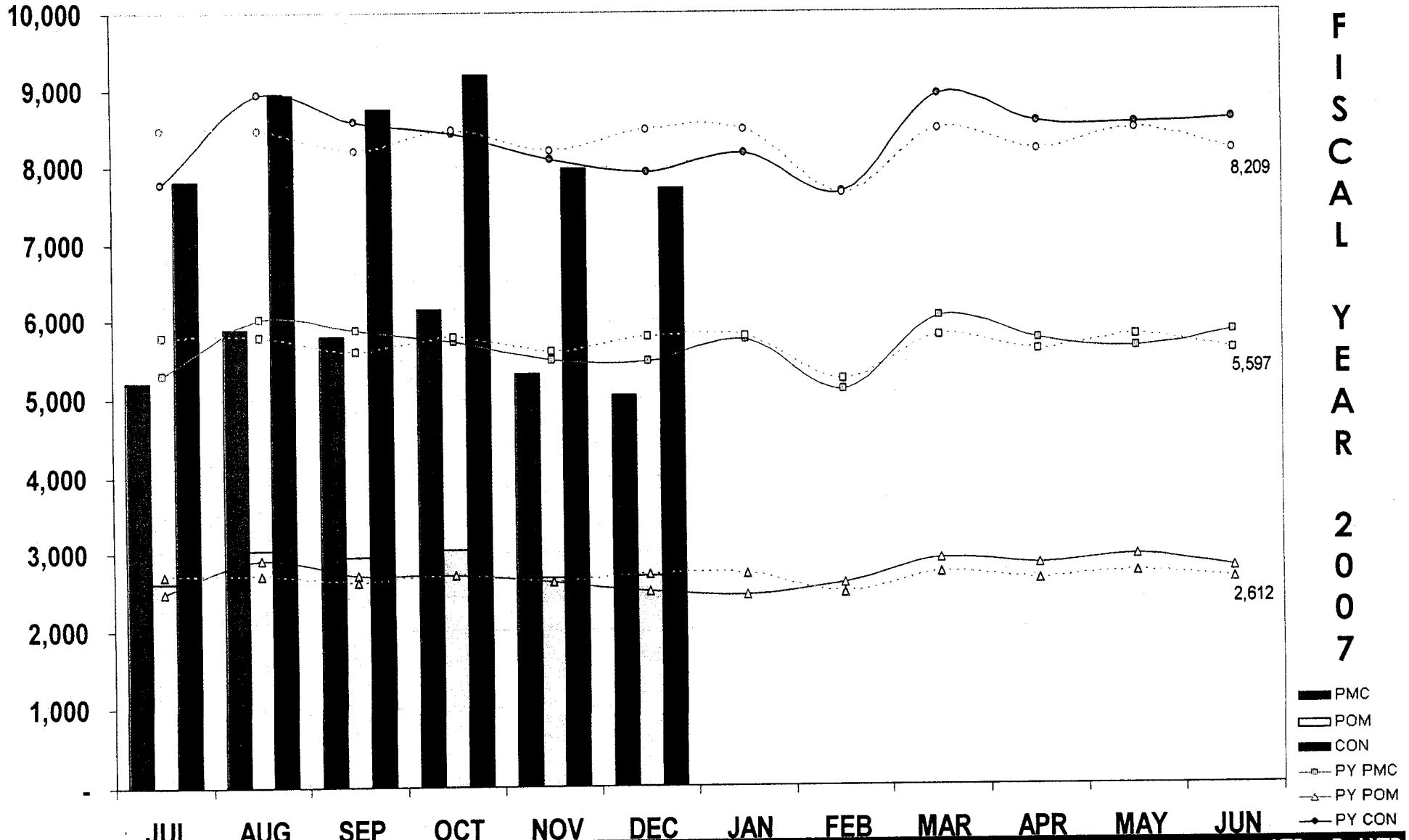

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	5,204	5,900	5,800	6,158	5,326	5,030	-	-	-	-	-	-	33,418	34,308
POM	2,615	3,044	2,944	3,033	2,659	2,690	-	-	-	-	-	-	16,985	16,008
CON	7,819	8,944	8,744	9,191	7,985	7,720	-	-	-	-	-	-	50,403	50,316

ER Visits includes Trauma

PALOMAR POMERADO HEALTH
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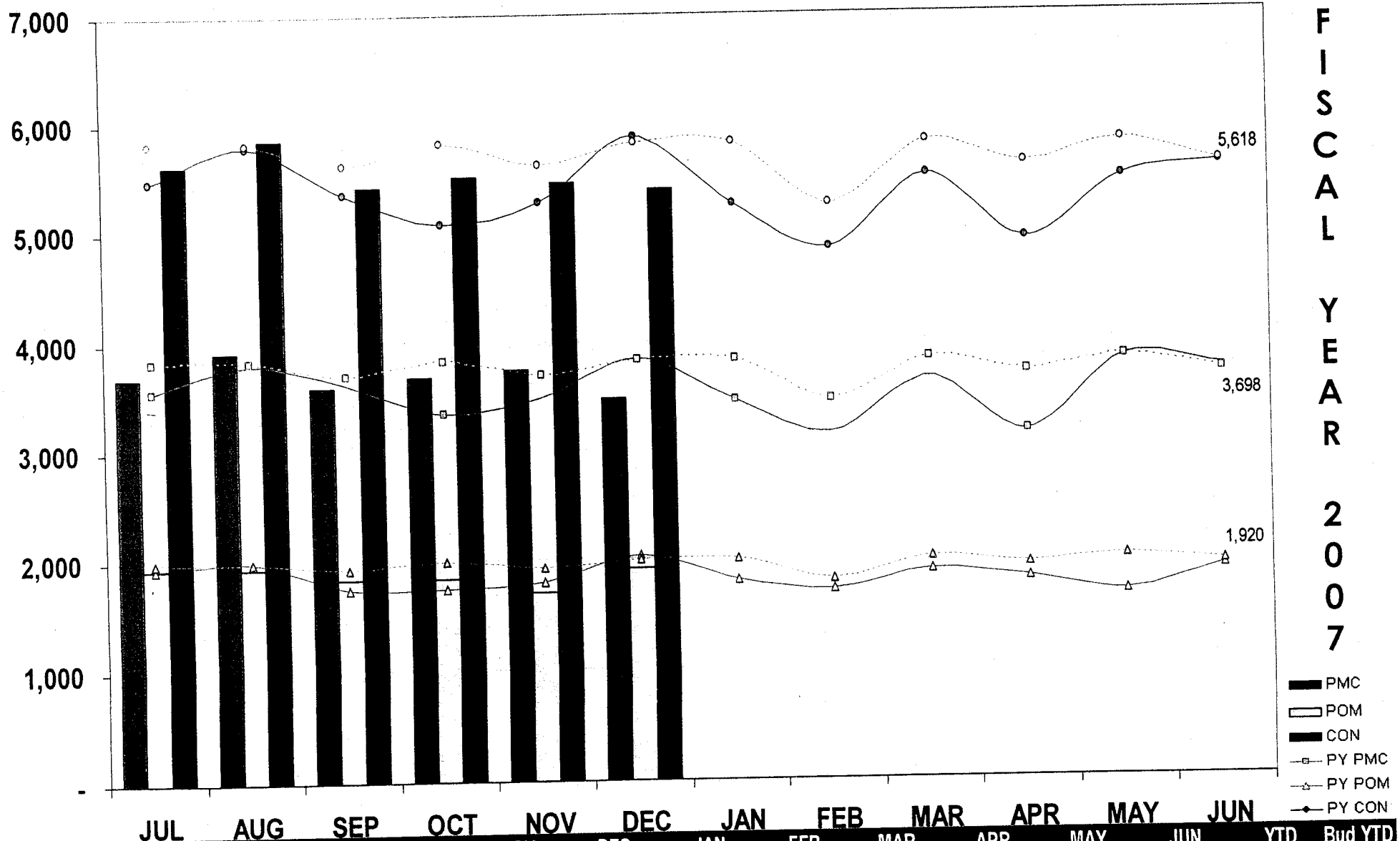

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	3,685	3,916	3,589	3,686	3,751	3,478	-	-	-	-	-	-	22,105	22,704
POM	1,930	1,930	1,828	1,828	1,703	1,910	-	-	-	-	-	-	11,129	11,766
CON	5,615	5,846	5,417	5,514	5,454	5,388	-	-	-	-	-	-	33,234	34,470

Trauma Cases (PMC)

PALOMAR POMERADO HEALTH
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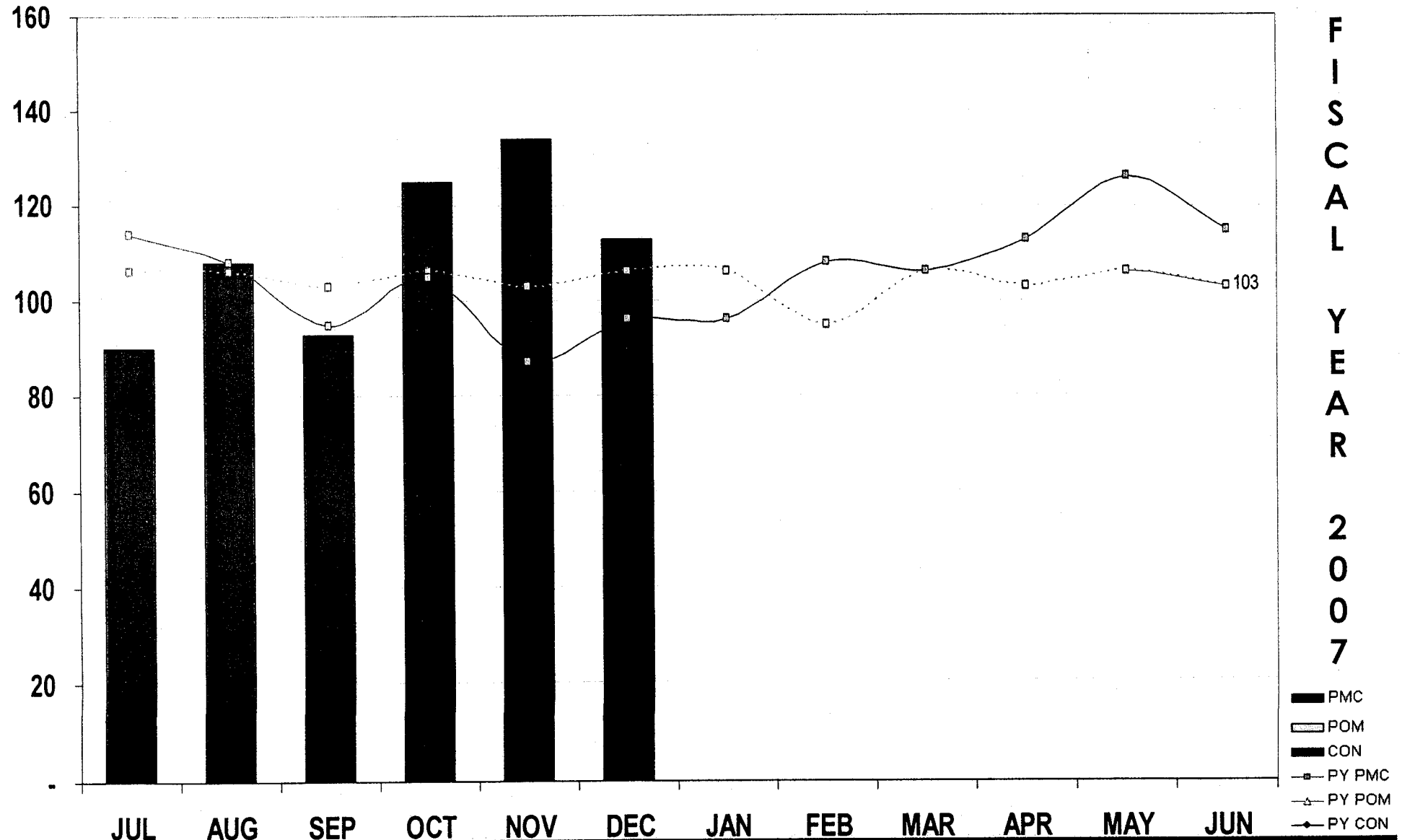

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	90	108	93	125	134	113	-	-	-	-	-	-	663	630

Trauma Admissions (PMC)

PALOMAR POMERADO HEALTH
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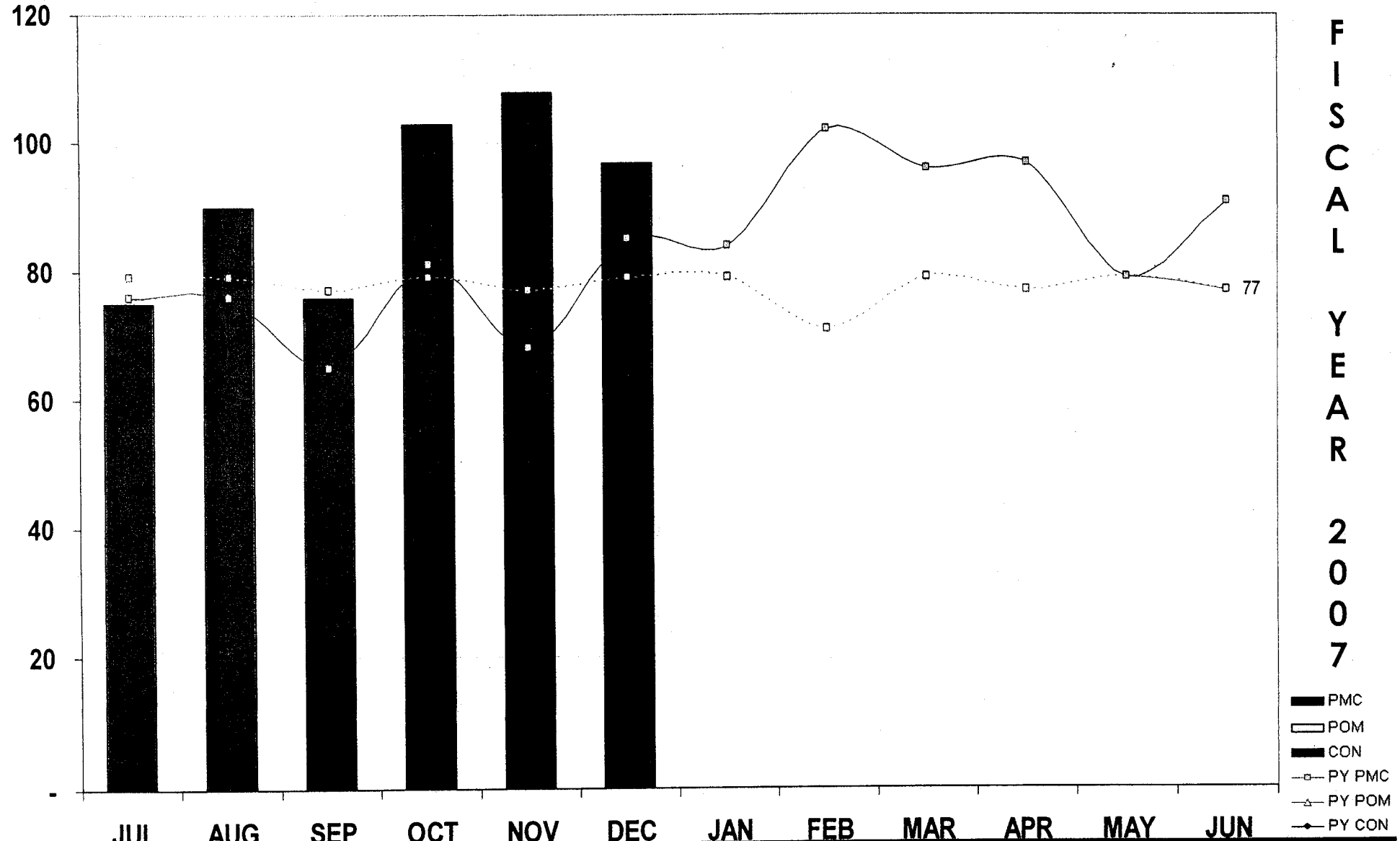

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	75	90	76	103	108	97	-	-	-	-	-	-	549	470

Deliveries

PALOMAR POMERADO HEALTH
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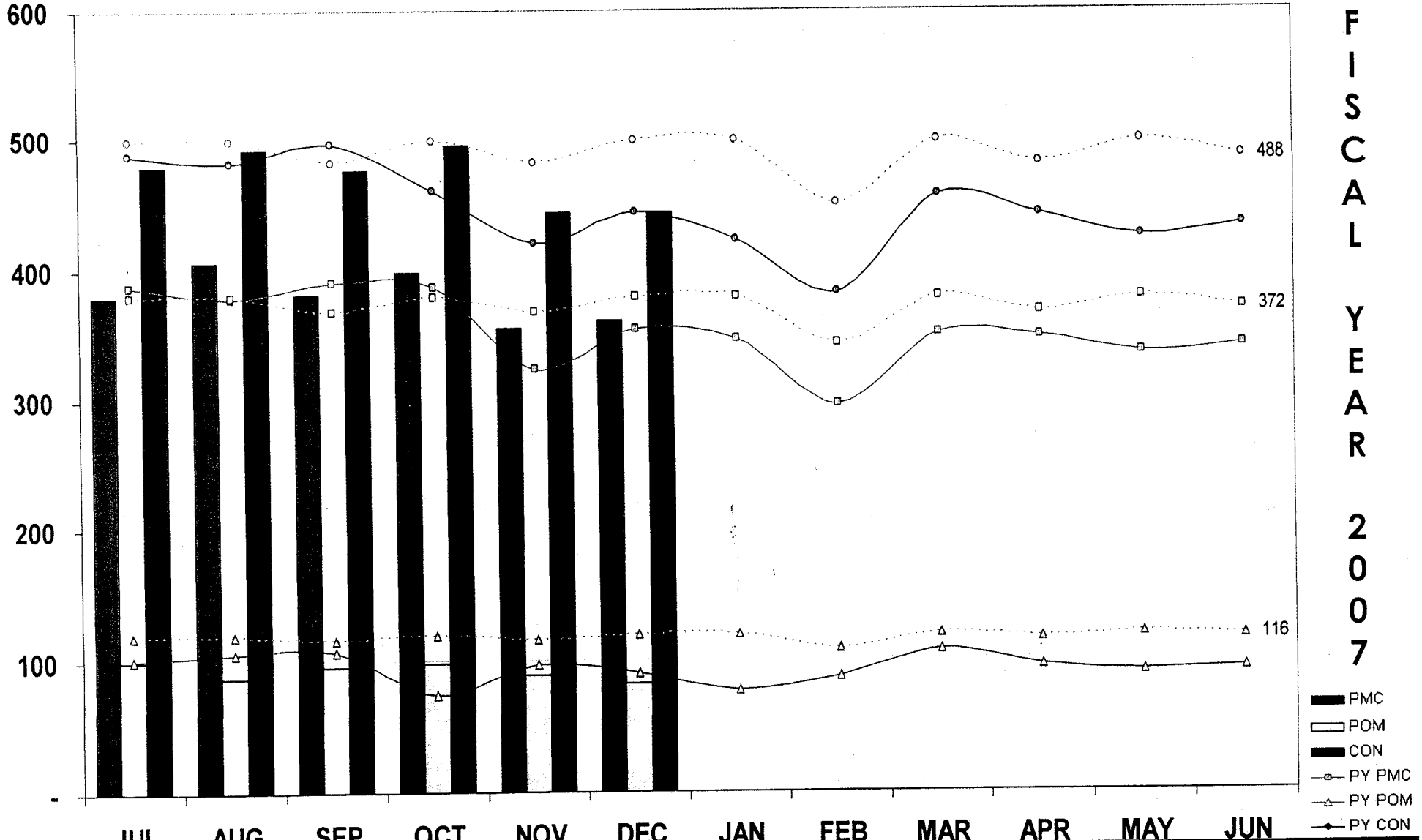
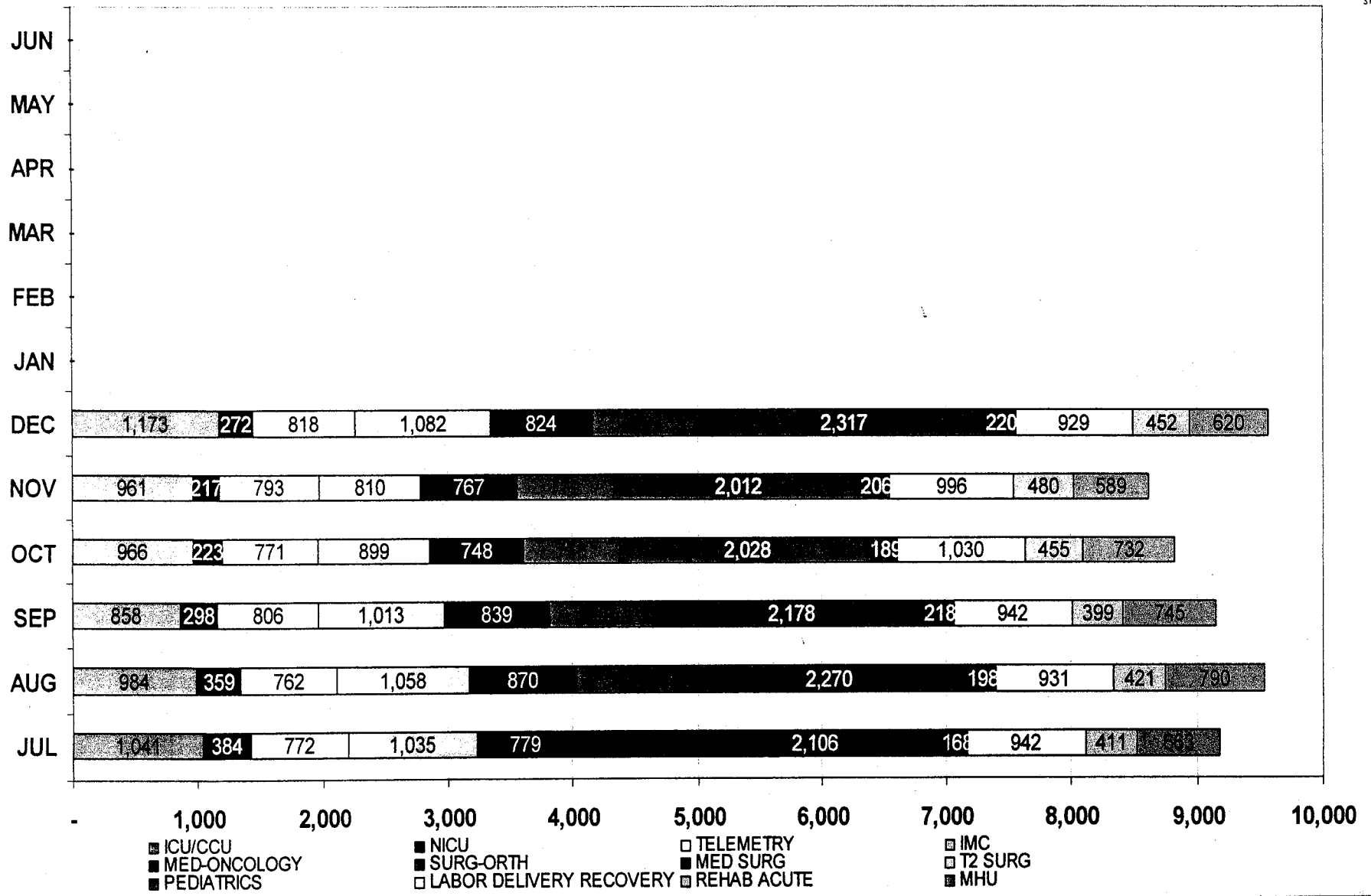


	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	379	406	382	399	356	362	-	-	-	-	-	-	2,284	2,256
POM	100	87	95	97	88	82	-	-	-	-	-	-	549	706
CON	479	493	477	496	444	444	-	-	-	-	-	-	2,833	2,962

Patient Days

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

FISCAL YEAR 2007



	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	6,919	7,102	6,822	6,547	6,607	7,153	-	-	-	-	-	-	41,150	43,898
POM	2,261	2,433	2,329	2,272	2,003	2,406	-	-	-	-	-	-	13,704	14,994
CON	9,180	9,535	9,151	8,819	8,610	9,559	-	-	-	-	-	-	54,854	58,892

PALOMAR POMERDO HEALTH
SUMMARY OF KEY INDICATORS AND RESULTS
FYTD December 2006

	ACTUAL	BUDGET	VARIANCE	FY 2006
ADMISSIONS - Acute:				
Palomar Medical Center	11,120	11,040	80	10,818
Pomerado Hospital	3,356	3,942	(586)	3,428
Total:	14,476	14,982	(506)	14,246
ADMISSIONS - SNF:				
Palomar Medical Center	314	390	(76)	316
Pomerado Hospital	269	316	(47)	293
Total:	583	706	(123)	609
PATIENT DAYS - Acute:				
Palomar Medical Center	41,150	43,898	(2,748)	42,481
Pomerado Hospital	13,704	14,994	(1,290)	13,448
Total:	54,854	58,892	(4,038)	55,929
PATIENT DAYS- SNF:				
Palomar Medical Center	16,084	16,304	(220)	15,542
Pomerado Hospital	22,747	22,816	(69)	22,766
Total:	38,831	39,120	(289)	38,308

PALOMAR POMERDO HEALTH
SUMMARY OF KEY INDICATORS AND RESULTS
FYTD December 2006

	ACTUAL	BUDGET	VARIANCE	FY 2006
WEIGHTED PATIENT DAYS:				
Palomar Medical Center	52,207	54,625	(2,418)	52,893
Pomerado Hospital	21,852	22,655	(803)	20,663
Other Activities	1,477	1,853	(376)	1,112
Total:	75,536	79,133	(3,597)	74,668
AVERAGE LENGTH OF STAY- Acute:				
Palomar Medical Center	3.69	4.02	(0.33)	4.00
Pomerado Hospital	4.06	3.96	0.10	3.89
Total:	3.77	4.00	(0.23)	3.98
AVERAGE LENGTH OF STAY - SNF:				
Palomar Medical Center	52.39	40.56	11.83	47.82
Pomerado Hospital	84.56	73.60	10.96	79.32
Total:	67.41	54.94	12.47	62.59

PALOMAR POMERDO HEALTH
SUMMARY OF KEY INDICATORS AND RESULTS
FYTD December 2006

	ACTUAL	BUDGET	VARIANCE	FY 2006
EMERGENCY ROOM VISITS & TRAUMA CASES:				
Palomar Medical Center	22,105	22,704	(599)	21,621
Pomerado Hospital	11,129	11,766	(637)	11,206
Total:	33,234	34,470	(1,236)	32,827
EMERGENCY & TRAUMA ADMISSIONS:				
Palomar Medical Center	5,441	5,720	(279)	5,446
Pomerado Hospital	1,928	2,060	(132)	1,962
Total:	7,369	7,780	(411)	7,408
SURGERIES:				
Palomar Medical Center	3,975	4,022	(47)	3,921
Pomerado Hospital	1,850	2,156	(306)	1,923
Total:	5,825	6,178	(353)	5,844
BIRTHS:				
Palomar Medical Center	2,284	2,256	28	2,223
Pomerado Hospital	549	706	(157)	571
Total:	2,833	2,962	(129)	2,794

Salaries per Weighted Patient Days

PALOMAR POMERADO HEALTH
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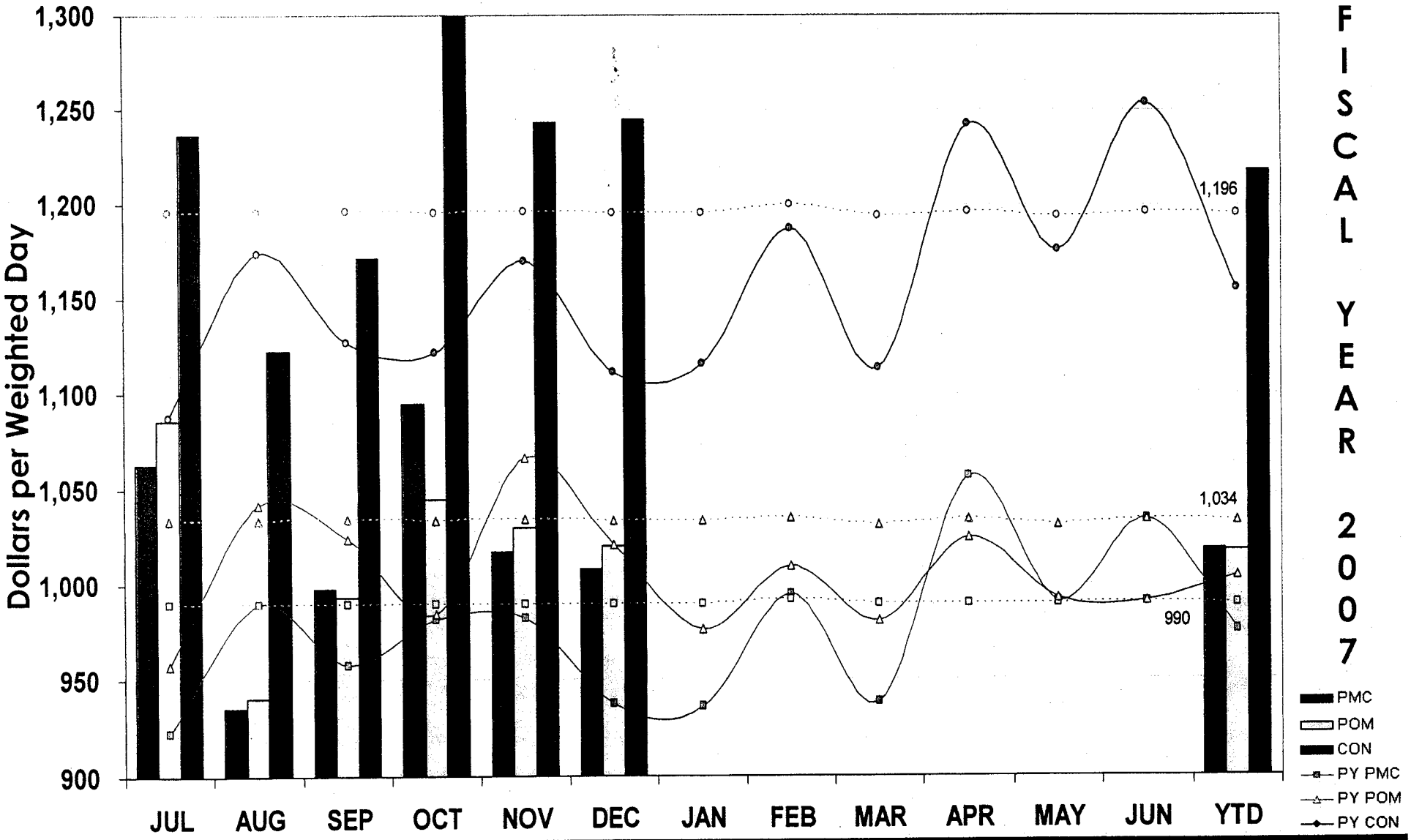
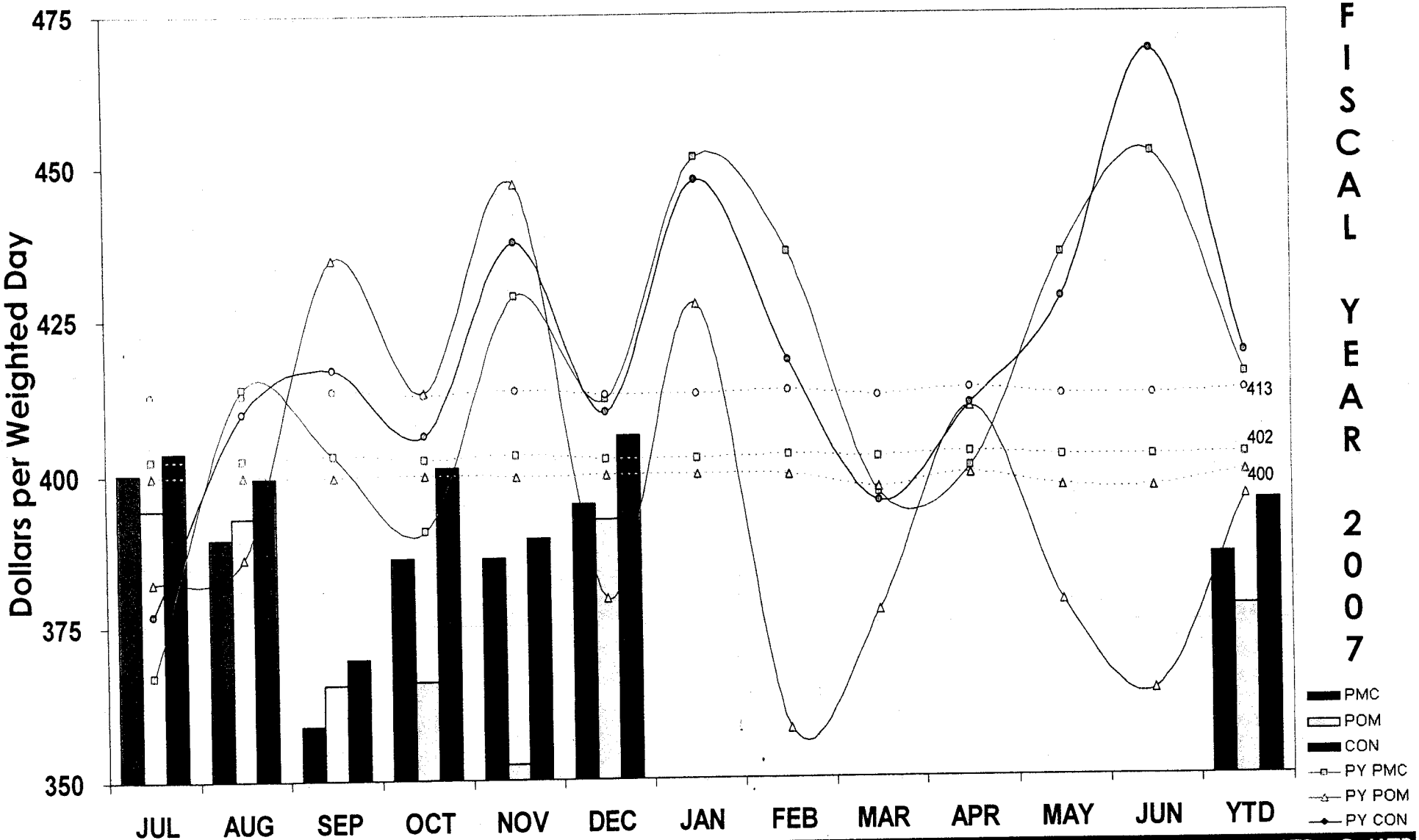


	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	1,063	935	998	1,095	1,017	1,008	-	-	-	-	-	-	1,018	990
POM	1,086	940	993	1,045	1,030	1,020	-	-	-	-	-	-	1,018	1,034
CON	1,236	1,122	1,172	1,299	1,243	1,244	-	-	-	-	-	-	1,218	1,196

Supplies per Weighted Patient Days

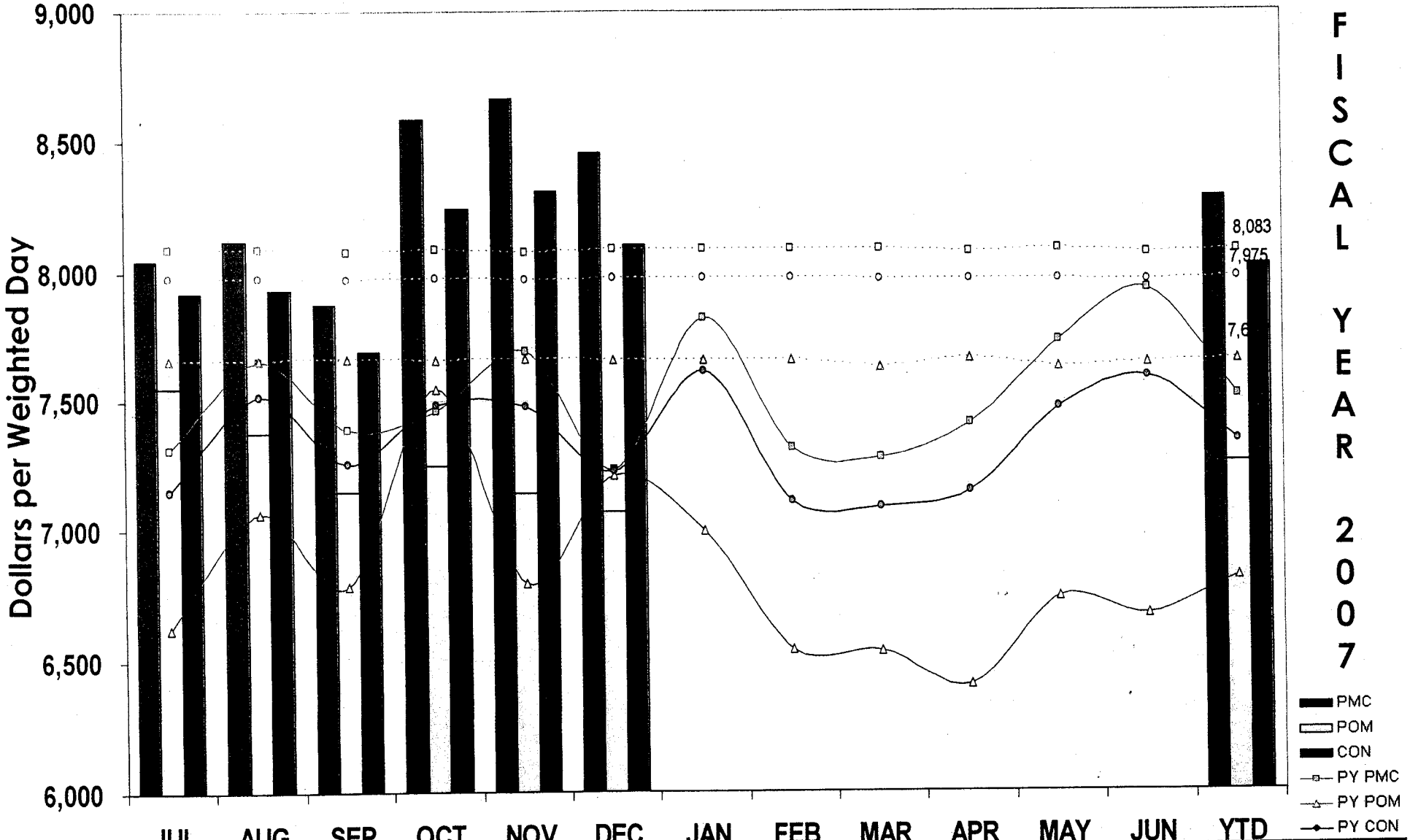
PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU



	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	400	389	359	386	386	395	-	-	-	-	-	-	386	402
POM	394	393	365	366	353	392	-	-	-	-	-	-	378	400
CON	404	399	370	401	389	406	-	-	-	-	-	-	395	413

Gross Patient Revenue per Weighted Patient Days

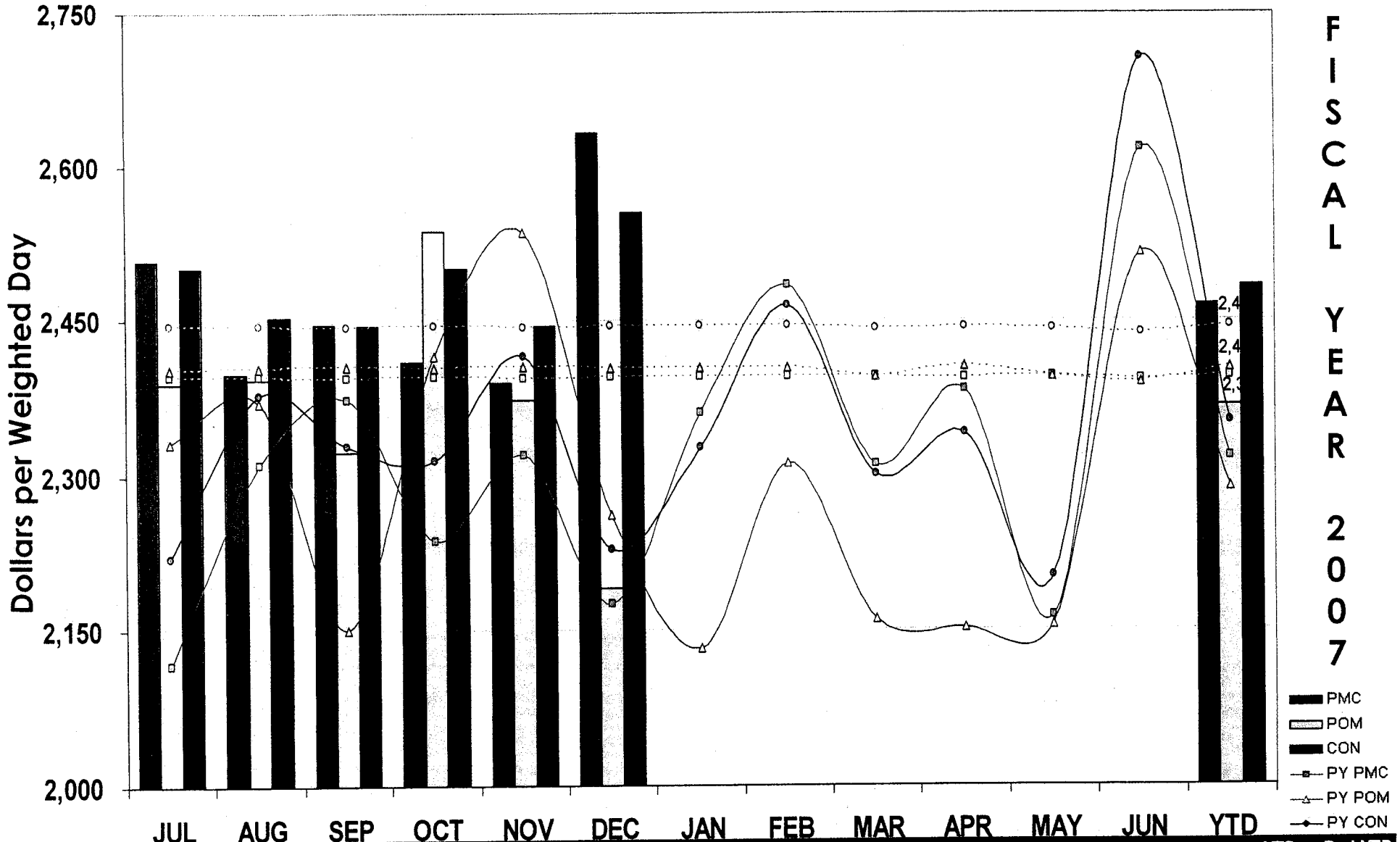
PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU



	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	8,041	8,120	7,875	8,587	8,665	8,455	-	-	-	-	-	-	8,287	8,083
POM	7,552	7,379	7,149	7,247	7,142	7,068	-	-	-	-	-	-	7,257	7,658
CON	7,921	7,932	7,690	8,242	8,311	8,106	-	-	-	-	-	-	8,029	7,975

Net Patient Revenue per Weighted Patient Days

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU



	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	2,508	2,398	2,446	2,410	2,391	2,634	-	-	-	-	-	-	2,465	2,396
POM	2,389	2,393	2,323	2,537	2,373	2,191	-	-	-	-	-	-	2,368	2,404
CON	2,500	2,453	2,445	2,500	2,445	2,556	-	-	-	-	-	-	2,483	2,444

Total Expenses per Weighted Patient Days

PALOMAR POMERADO HEALTH
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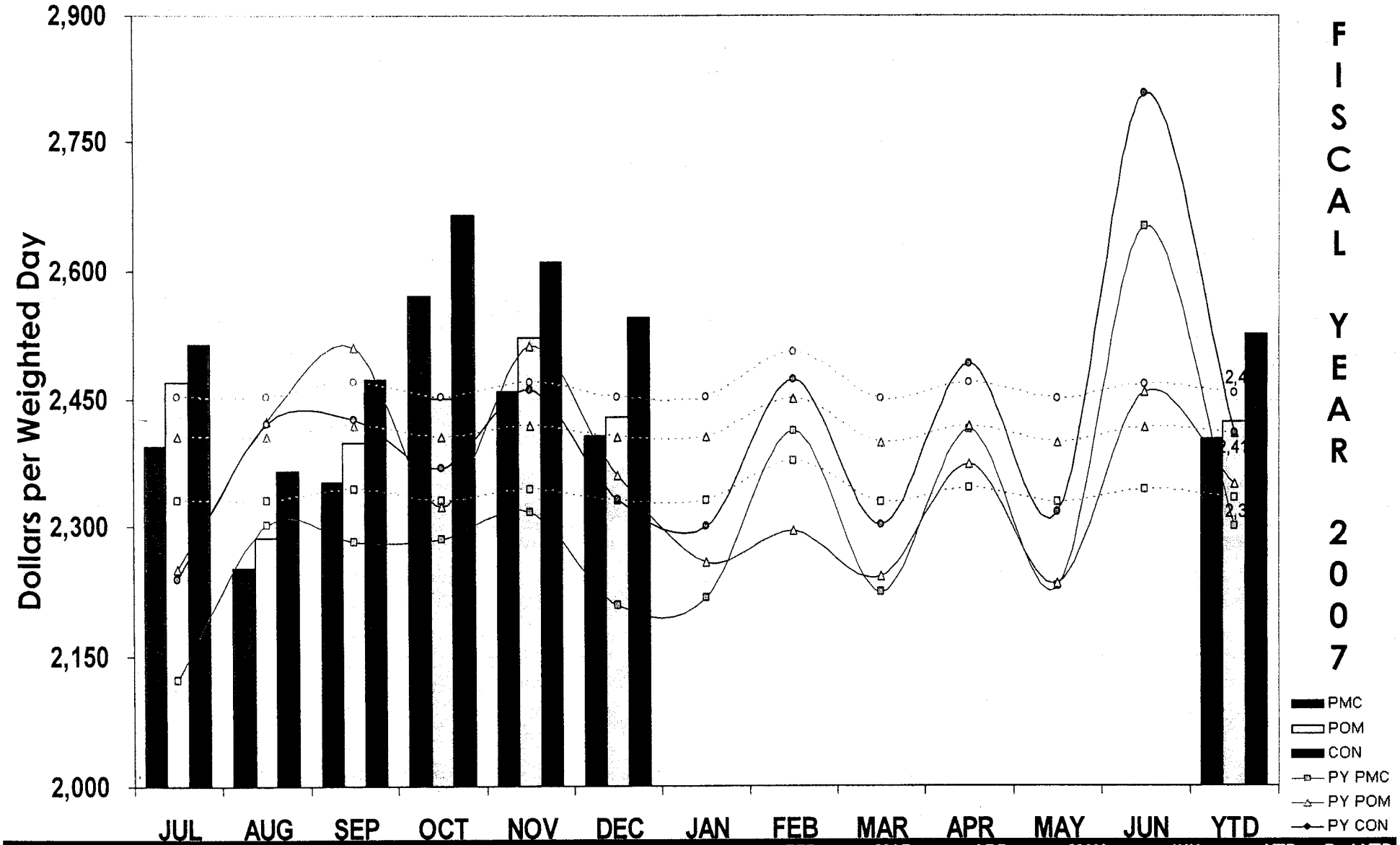
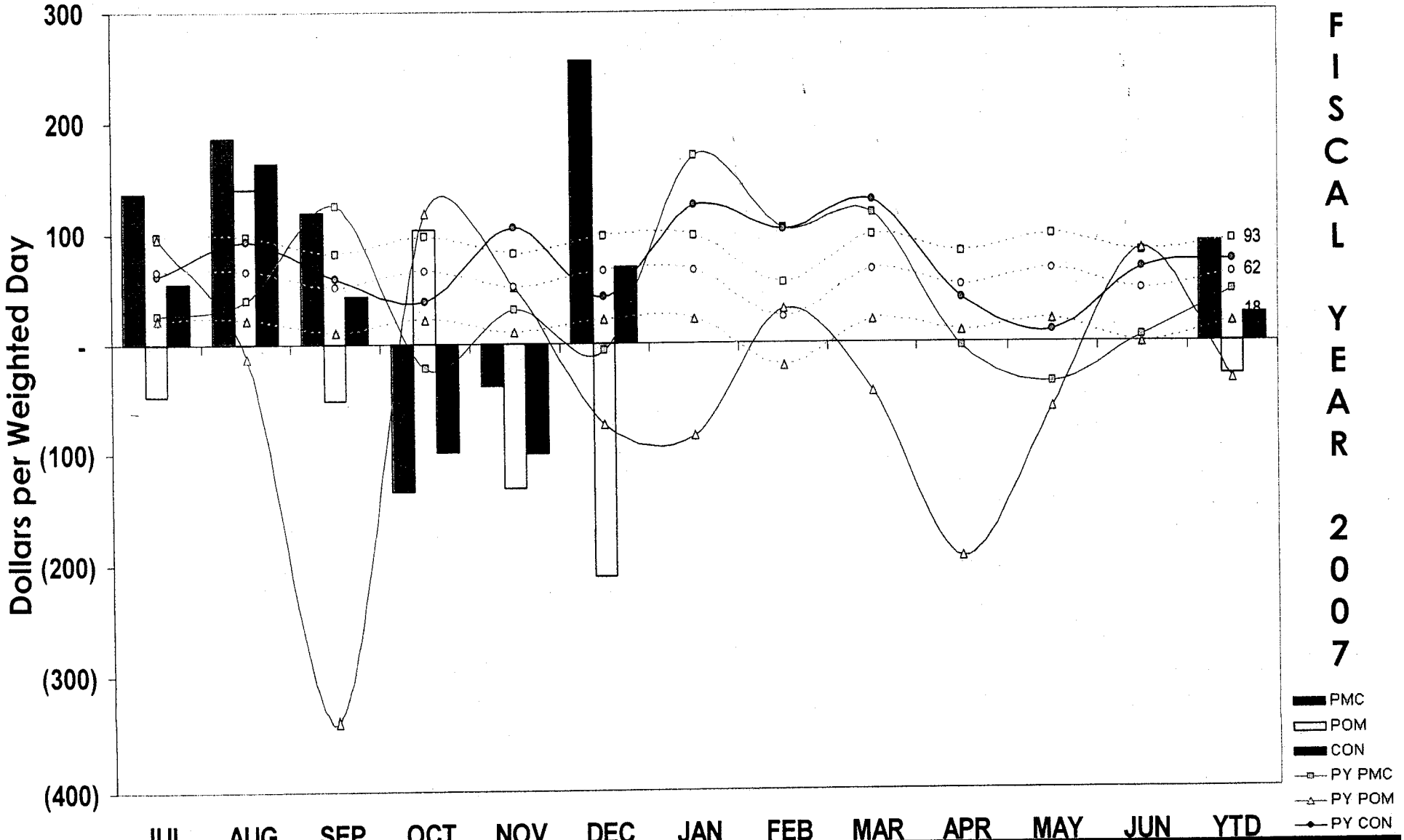


	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	2,395	2,252	2,352	2,571	2,459	2,408	-	-	-	-	-	-	2,404	2,335
POM	2,469	2,287	2,400	2,451	2,522	2,430	-	-	-	-	-	-	2,424	2,411
CON	2,514	2,367	2,473	2,665	2,610	2,546	-	-	-	-	-	-	2,527	2,459

Net Operating Income per Weighted Patient Days

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU



	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	YTD	Bud YTD
PMC	137	186	120	(133)	(39)	255	-	-	-	-	-	-	91	93
POM	(48)	140	(52)	105	(132)	(211)	-	-	-	-	-	-	(30)	18
CON	56	164	45	(98)	(100)	71	-	-	-	-	-	-	25	62

PALOMAR POMERADO HEALTH
Key Variance Explanations for December 2006

	Actual	Budget	Variance
Weighted Patient Days	**12,813**	**13,331**	**(518)**
Gross Patient Revenue:	**103,866,051**	**106,338,260**	**(2,472,209)**
Due to lower volumes			
Contractuals:	**71,591,160**	**73,812,302**	**2,221,142**
Due to lower-than-budgeted revenues			
Net Capitation:	**475,206**	**63,927**	**411,279**
Other Operating Revenue:	**777,515**	**1,007,597**	**(230,082)**
Health Development			(58,085)
PPH Foundation			(72,011)
Welcome Home Baby			(13,796)
Home Health Outreach			(19,051)
PMC Auxiliary			(15,000)

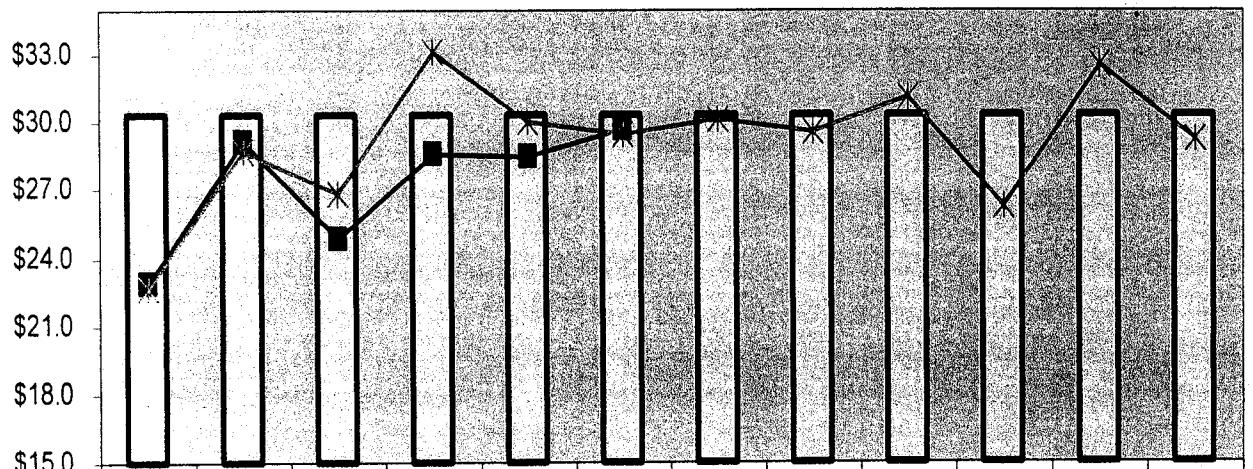
PALOMAR POMERADO HEALTH
Key Variance Explanations for December 2006 (Cont'd)

Salaries & Wages:	**15,274,497**	**15,256,595**	**(17,902)**
Volume variance and due to staff flexing			619,202
Longevity/retros/other discretionary bonus adjustments			(567,860)
Benefits:	**3,995,671**	**3,774,533**	**(221,138)**
Pension and Deferred Comp			(192,935)
Contract Labor:	**671,107**	**678,883**	**7,776**
Professional Fees:	**1,876,093**	**1,815,681**	**(60,412)**
Legal fees			(112,311)
Pomerado ED calls			(50,142)
Information System consulting fees			(29,560)
Physician Recruitment Program			60,583
Affiliates physician fees			49,408

PALOMAR POMERADO HEALTH
Key Variance Explanations for December 2006 (Cont'd)

Supplies:	**5,203,199**	**5,503,090**	**299,891**
Due to lower than budgeted volumes			213,832
Purchased Services:	**2,288,897**	**2,164,495**	**(124,402)**
Aramark for holiday meals			(73,395)
Xerox late invoices			(65,174)
Depreciation:	**1,680,349**	**1,568,084**	**(112,265)**
Additional CIP's			(65,231)
Escondido Surgery Center			(35,232)
Other Direct Expenses:	**1,632,347**	**1,949,209**	**316,862**
Marketing / Recruiting			356,500
Net Income From Operations	**$905,452**	**$886,912**	**$18,540**

PBS Monthly Collections
in Millions



	July	Aug.	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.	March	April	May	June
FY07 Goal	$30.3	$30.3	$30.3	$30.3	$30.3	$30.3	$30.3	$30.3	$30.3	$30.3	$30.3	$30.3
Pr. Yr Actual	$22.6	$28.7	$26.8	$33.1	$30.1	$29.5	$30.2	$29.6	$31.2	$26.2	$32.6	$29.2
Curr. Yr Actual	$22.8	$29.1	$24.9	$28.6	$28.5	$29.7						

Palomar Pomerado Health
Consolidated Balance Sheet
As of December 31, 2006

	Current Month	Prior Month	Prior Fiscal Year End
Assets			
Current Assets			
Cash on Hand	$9,466,896	$7,770,645	$2,001,279
Cash Marketable Securities	93,801,600	93,081,237	110,035,151
Total Cash & Cash Equivalents	103,268,496	100,851,882	112,036,430
Patient Accounts Receivable	180,168,464	175,866,695	149,045,009
Allowance on Accounts	-90,047,561	-88,250,372	-78,078,378
Net Accounts Receivable	90,120,903	87,616,323	70,966,631
Inventories	6,845,712	6,917,224	6,937,645
Prepaid Expenses	2,003,952	2,195,042	2,293,992
Other	11,047,582	18,609,499	3,868,903
Total Current Assets	213,286,645	216,189,970	196,103,601
Non-Current Assets			
Restricted Assets	43,771,163	41,638,758	66,734,609
Restricted by Donor	292,686	291,911	288,265
Board Designated	908,525	6,272,728	9,267,526
Total Restricted Assets	44,972,374	48,203,397	76,290,400
Property Plant & Equipment	337,296,249	338,383,583	343,335,572
Accumulated Depreciation	-221,875,604	-221,570,793	-220,455,460
Construction in Process	115,795,783	111,728,404	85,858,842
Net Property Plant & Equipment	231,216,428	228,541,194	208,738,954
Investment in Related Compani	1,437,209	1,429,441	268,203
Deferred Financing Costs	4,074,620	3,701,869	3,354,469
Other Non-Current Assets	2,514,807	2,528,363	2,594,765
Total Non-Current Assets	284,215,438	284,404,264	291,246,791
Total Assets	$497,502,083	$500,594,234	$487,350,392

	Current Month	Prior Month	Prior Fiscal Year End
Liabilities			
Current Liabilities			
Accounts Payable	$20,061,931	$23,076,507	$23,154,953
Accrued Payroll	17,073,781	18,672,405	13,504,395
Accrued PTO	11,566,244	11,442,299	11,133,368
Accrued Interest Payable	2,045,907	1,426,621	2,265,274
Current Portion of Bonds	12,305,000	12,305,000	12,745,000
Est Third Party Settlements	-1,310,255	-89,339	-995,051
Other Current Liabilities	17,465,564	17,969,841	9,482,924
Total Current Liabilities	79,208,172	84,803,334	71,290,863
Long Term Liabilities			
Bonds & Contracts Payable	139,142,626	139,130,105	151,347,395
General Fund Balance			
Unrestricted	277,950,073	270,096,156	255,156,342
Restricted for Other Purpose	292,686	291,911	288,265
Board Designated	908,525	6,272,728	9,267,526
Total Fund Balance	279,151,284	276,660,795	264,712,133
Total Liabilities / Fund Balance	$497,502,083	$500,594,234	$487,350,392

PALOMAR POMERADO HEALTH
CONSOLIDATED
Year-to-Date as of December FY 2007

	Month Activity			Variance		$/Wtg Pt Day		
	Actual	Budget	Variance	Volume	Rate/Eff	Actual	Budget	Variance
Statistics:								
Admissions - Acute	14,476	14,982	(506)					
Admissions - SNF	583	706	(123)					
Patient Days - Acute	54,854	58,892	(4,038)					
Patient Days - SNF	38,831	39,120	(289)					
ALOS - Acute	3.77	4.00	(0.23)					
ALOS - SNF	67.41	54.94	12.47					
Weighted Pt Days	75,536	79,133	(3,597)					
Revenue:								
Gross Revenue	$ 606,493,620	$ 631,115,017	$ (24,621,397) U	$ (28,687,409)	$ 4,066,012	$ 8,029.20	$ 7,975.37	$ 53.83
Deductions from Rev	(418,941,063)	(437,695,532)	18,754,469 F	19,895,503	(1,141,034)	(5,546.24)	(5,531.14)	(15.11)
Net Patient Revenue	187,552,556	193,419,485	(5,866,928) U	(8,791,906)	2,924,978	2,482.96	2,444.23	38.72
Other Oper Revenue	5,218,772	6,045,582	(826,810) U	(274,803)	(552,007)	69.09	76.40	(7.31)
Total Net Revenue	192,771,328	199,465,067	(6,693,738) U	(9,066,709)	2,372,971	2,552.05	2,520.63	31.42
Expenses:								
Salaries, Wages & Contr Labor	92,018,168	94,615,352	2,597,184 F	4,300,752	(1,703,568)	1,218.20	1,195.65	(22.55)
Benefits	22,920,634	22,509,448	(411,186) U	1,023,170	(1,434,356)	303.44	284.45	(18.99)
Supplies	29,829,599	32,680,942	2,851,343 F	1,485,516	1,365,827	394.91	412.99	18.08
Prof Fees & Purch Svc	25,385,507	23,726,044	(1,659,463) U	1,078,470	(2,737,933)	336.07	299.82	(36.25)
Depreciation	9,992,076	9,408,504	(583,572) U	427,665	(1,011,237)	132.28	118.89	(13.39)
Other	10,718,349	11,635,522	917,173 F	528,894	388,279	141.90	147.04	5.14
Total Expenses	190,864,333	194,575,812	3,711,479 F	8,844,467	(5,132,988)	2,526.80	2,458.85	(67.95)
Net Inc Before Non-Oper Income	1,906,995	4,889,255	(2,982,259) U	(222,242)	(2,760,017)	25.25	61.79	(36.54)
Property Tax Revenue	6,324,996	6,324,996	- -	(287,503)	287,503	83.73	79.93	3.81
Non-Operating Income	1,536,323	438,348	1,097,975 F	(19,925)	1,117,900	20.34	5.54	14.80
Net Income (Loss)	$ 9,768,314	$ 11,652,599	$ (1,884,284) U	$ (529,670)	$ (1,354,614)	$ 129.32	$ 147.25	$ (17.93)
Net Income Margin	4.7%	5.6%	-0.9%					
OEBITDA Margin w/o Prop Tax	5.8%	6.8%	-1.0%					
OEBITDA Margin with Prop Tax	8.8%	9.8%	-1.0%					

F= Favorable variance
U= Unfavorable variance

PALOMAR POMERADO HEALTH

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

PALOMAR POMERADO HEALTH
CONSOLIDATED
Month-to-Date as of December FY 2007

	Month Activity			Variance		$/Wtg Pt Day		
	Actual	Budget	Variance	Volume	Rate/Eff	Actual	Budget	Variance
Statistics:								
Admissions - Acute	2,460	2,524	(64)					
Admissions - SNF	99	119	(20)					
Patient Days - Acute	9,559	9,922	(363)					
Patient Days - SNF	6,503	6,591	(88)					
ALOS - Acute	3.88	4.00	(0.12)					
ALOS - SNF	71.46	54.93	16.53					
Weighted Pt Days	12,813	13,331	(518)					
Revenue:								
Gross Revenue	$ 103,866,051	$ 106,338,260	$ (2,472,209) U	$ (4,131,964)	$ 1,659,755	$ 8,106.30	$ 7,976.77	$ 129.54
Deductions from Rev	(71,115,954)	(73,748,375)	2,632,421 F	2,865,626	(233,205)	(5,550.30)	(5,532.10)	(18.20)
Net Patient Revenue	32,750,097	32,589,885	160,212 F	(1,266,339)	1,426,551	2,556.01	2,444.67	111.34
Other Oper Revenue	777,515	1,007,597	(230,082) U	(39,152)	(190,930)	60.68	75.58	(14.90)
Total Net Revenue	33,527,612	33,597,482	(69,870) U	(1,305,491)	1,235,621	2,616.69	2,520.25	96.43
Expenses:								
Salaries, Wages & Contr Labor	15,945,604	15,935,478	(10,126) U	619,202	(629,328)	1,244.49	1,195.37	(49.12)
Benefits	3,995,671	3,774,533	(221,138) U	146,666	(367,804)	311.85	283.14	(28.71)
Supplies	5,203,199	5,503,090	299,891 F	213,832	86,059	406.09	412.80	6.72
Prof Fees & Purch Svc	4,164,990	3,980,176	(184,814) U	154,657	(339,471)	325.06	298.57	(26.49)
Depreciation	1,680,349	1,568,084	(112,265) U	60,931	(173,196)	131.14	117.63	(13.52)
Other	1,632,347	1,949,209	316,862 F	75,740	241,122	127.40	146.22	18.82
Total Expenses	32,622,160	32,710,570	88,410 F	1,271,028	(1,182,618)	2,546.02	2,453.72	(92.30)
Net Inc Before Non-Oper Income	905,452	886,912	18,540 F	(34,463)	53,003	70.67	66.53	4.14
Property Tax Revenue	1,054,166	1,054,166	- -	(40,962)	40,962	82.27	79.08	3.20
Non-Operating Income	(223,879)	73,058	(296,937) U	(2,839)	(294,098)	(17.47)	5.48	(22.95)
Net Income (Loss)	$ 1,735,739	$ 2,014,136	$ (278,397) U	$ (78,263)	$ (200,134)	$ 135.47	$ 151.09	$ (15.62)
Net Income Margin	4.8%	5.7%	-0.9%					
OEBITDA Margin w/o Prop Tax	7.1%	7.0%	0.1%					
OEBITDA Margin with Prop Tax	10.0%	9.9%	0.1%					

F= Favorable variance
U= Unfavorable variance

PALOMAR POMERADO HEALTH
CONSOLIDATED
MONTHLY TREND - FY 2007

	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06	FYTD
Statistics:							
Admissions - Acute	2,402	2,464	2,443	2,384	2,323	2,460	14,476
Admissions - SNF	104	99	90	104	87	99	583
Patient Days - Acute	9,180	9,535	9,151	8,819	8,610	9,559	54,854
Patient Days - SNF	6,635	6,517	6,308	6,590	6,278	6,503	38,831
LOS - Acute	3.86	3.82	3.70	3.64	3.74	3.88	3.77
LOS - SNF	72.12	63.27	64.37	69.37	64.72	71.46	67.41
Weighted Pt Days	12,517	13,150	12,568	12,431	12,042	12,813	75,536
Revenue:							
Gross Revenue	$ 99,141,914	$ 104,303,733	$ 96,648,451	$ 102,455,908	$ 100,077,561	$ 103,866,051	$ 606,493,620
Deductions from Rev	(67,846,129)	(72,046,060)	(65,925,304)	(71,374,464)	(70,633,148)	(71,115,954)	(418,941,063)
Net Patient Revenue	31,295,785	32,257,673	30,723,147	31,081,444	29,444,413	32,750,097	187,552,556
Other Oper Revenue	872,741	1,024,339	917,501	836,197	790,479	777,515	5,218,772
Total Net Revenue	32,168,526	33,282,012	31,640,648	31,917,641	30,234,892	33,527,612	192,771,328
Expenses:							
Salaries, Wages & Contr Labor	15,474,327	14,754,829	14,727,754	16,146,815	14,968,840	15,945,604	92,018,168
Benefits	3,710,570	3,719,161	3,639,220	4,022,437	3,833,574	3,995,671	22,920,634
Supplies	5,053,134	5,252,262	4,645,918	4,986,864	4,688,222	5,203,199	29,829,599
Prof Fees & Purch Svc	3,957,885	4,023,887	4,535,289	4,491,200	4,212,258	4,164,990	25,385,507
Depreciation	1,647,188	1,661,866	1,661,093	1,668,606	1,672,974	1,680,349	9,992,076
Other	1,626,284	1,709,799	1,872,046	1,818,374	2,059,500	1,632,347	10,718,349
Total Expenses	31,469,388	31,121,804	31,081,320	33,134,296	31,435,368	32,622,160	190,864,333
Net Inc Before Non-Oper Income	699,138	2,160,208	559,328	(1,216,655)	(1,200,476)	905,452	1,906,995
Property Tax Revenue	1,054,166	1,054,166	1,054,166	1,054,166	1,054,166	1,054,166	6,324,996
Non-Operating Income	427,875	505,503	338,114	190,429	298,286	(223,879)	1,536,323
Net Income (Loss)	$ 2,181,179	$ 3,719,874	$ 1,951,605	$ 27,940	$ 151,976	$ 1,735,739	$ 9,768,314
Net Income Margin	6.5%	10.0%	6.1%	0.1%	0.5%	4.8%	4.7%
OEBITDA Margin w/o Prop Tax	6.9%	10.3%	6.9%	1.3%	1.4%	7.1%	5.8%
OEBITDA Margin with Prop Tax	10.1%	13.2%	10.2%	4.4%	4.6%	10.0%	8.8%

F= Favorable variance
U= Unfavorable variance

Palomar Pomerado Health
STATEMENTS OF CASH FLOWS
Fiscal Year 2007

	December	YTD
CASH FLOWS FROM OPERATING ACTIVITIES:		
Income (Loss from operations)	905,452	1,906,495
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation Expense	1,680,349	9,992,077
Provision for bad debts	3,632,968	18,695,205
Changes in operating assets and liabilities:		
Patient accounts receivable	(6,137,548)	(37,791,128)
Property Tax and other receivables	(913,592)	(3,004,839)
Inventories	71,512	91,933
Prepaid expenses and Other Non-Current assets	231,236	(831,052)
Accounts payable	(3,014,576)	(10,562,717)
Accrued comp	(1,474,569)	1,912,943
Estimated settlement amounts due third-party payors	(1,220,916)	(245,158)
Other current liabilities	554,145	4,210,050
Net cash provided by operating activities	(5,685,539)	(15,626,191)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net (purchases) sales on investments	2,510,660	47,551,577
Interest (Loss) received on investments	278,868	3,985,117
Investment in affiliates	64,955	893,171
Net cash used in investing activities	2,854,483	52,429,865
CASH FLOWS FROM NON CAPITAL FINANCING ACTIVITIES:		
Receipt of G.O. Bond Taxes	3,915,345	4,674,678
Receipt of District Taxes	4,460,851	5,470,042
Net cash used in activities	8,376,196	10,144,720
CASH FLOWS FROM CAPITAL AND RELATED FINANCING ACTIVITIES:		
Acquisition of property plant and equipment	(3,860,289)	(30,551,383)
Proceeds from sale of asset	11,400	11,400
G.O. Bond Interest paid	0	(1,838,488)
Revenue Bond Interest paid	0	(2,068,283)
Proceeds from issuance of debt	0	0
Payments of LT Debt	0	(12,745,000)
Net cash used in activities	(3,848,889)	(47,191,754)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,696,251	(243,360)
CASH AND CASH EQUIVALENTS - Beginning of period	7,770,645	9,710,258
CASH AND CASH EQUIVALENTS - End of period	9,466,896	9,466,896

PALOMAR POMERADO HEALTH
BOND COVENANT RATIOS

CUSHION RATIO	Jun-05	Jun-06	Dec-06
Cash and Cash Equivalents	109,043,208	112,036,430	103,268,496
Board Designated Reserves	22,388,648	9,267,526	908,525
Trustee-held Funds	12,026,055	12,170,183	8,722,818
Total	143,457,911	133,474,139	112,899,839
Divided by:			
Max Annual Debt Service (Bond Year 2012)	10,697,594	10,697,594	10,697,594
CUSHION RATIO	**13.4**	**12.5**	**10.6**
REQUIREMENT	1.5	1.5	1.5
	Achieved	**Achieved**	**Achieved**

DAYS CASH ON HAND	Jun-05	Jun-06	Dec-06
Cash and Cash Equivalents	109,043,208	112,036,430	103,268,496
Board Designated Reserves	22,388,648	9,267,526	908,525
Total	131,431,856	121,303,956	104,177,021
Divide Total by Average Adjusted Expenses per Day			
Total Expenses	340,338,156	364,120,335	190,864,333
Less: Depreciation	16,394,985	18,737,467	9,992,076
Adjusted Expenses	323,943,171	345,382,868	180,872,257
Number of days in period	365	365	184
Average Adjusted Expenses per Day	887,516	946,254	983,001
DAYS CASH ON HAND	**148**	**128**	**106**
REQUIREMENT	90	90	90
	Achieved	**Achieved**	**Achieved**

Net Income Available for Debt Service	Jun-05	Jun-06	Dec-06
Excess of revenue over expenses Cur Mo.	1,490,930	1,315,850	1,735,739
Excess of revenues over expenses YTD (General Funds)	17,052,649	11,558,633	9,768,314
ADD:			
Depreciation and Amortization	16,394,985	18,737,467	9,992,076
Interest Expense	5,272,031	4,405,929	2,383,005
Net Income Available for Debt Service	38,719,665	34,702,029	22,143,395
Aggregate Debt Service			
1993 Insured Refunding Revenue Bonds	6,020,301	3,639,772	1,223,002
1999 Insured Refunding Revenue Bonds	4,356,844	6,950,508	4,124,474
Aggregate Debt Service	10,377,145	10,590,280	5,347,476
Net Income Available for Debt Service	**3.73**	**3.28**	**4.14**
Required Coverage	1.15	1.15	1.15
	Achieved	**Achieved**	**Achieved**

PALOMAR POMERADO HEALTH
A California Health Care District
Investment Fund Balances
Quarterly Report

Investment Account:	Interest Payable	Interest Rate	Maturity Date	Dec. 31, 2006
Fidelity-Institutional Portfolio Treasury Fund	Monthly	4.97%	Demand	$ 942,137
State Treasurer Local Agency Investment Fund	Quarterly	5.11%	Demand	561,798
Salomon Brothers	Various	Various	Various	32,208,974
Pacific Income Advisors, Inc.	Various	Various	Various	31,035,134
Morgan Stanley & Co.	Various	Various	Various	30,328,349
TOTAL INVESTMENTS AT CURRENT FAIR MARKET VALUE				$ 95,076,392
ACCRUED INTEREST INCOME RECEIVABLE				868,554
Bank of America - Cash in Checking/COR Acct.				166,522
TOTAL VALUE OF INVESTMENT PORTFOLIO				$ 96,111,468

INVESTMENTS COMPARATIVE

12/06	$ 95,076,392
12/05	$132,022,711
12/04	$142,752,906
12/03	$155,822,700
12/02	$123,111,473

SUMMARY OF INVESTMENT PORTFOLIO BY FUND

Palomar Pomerado Unrestricted Fund	$ 95,818,782
Palomar Pomerado Restricted Fund	292,686
	$ 96,111,468

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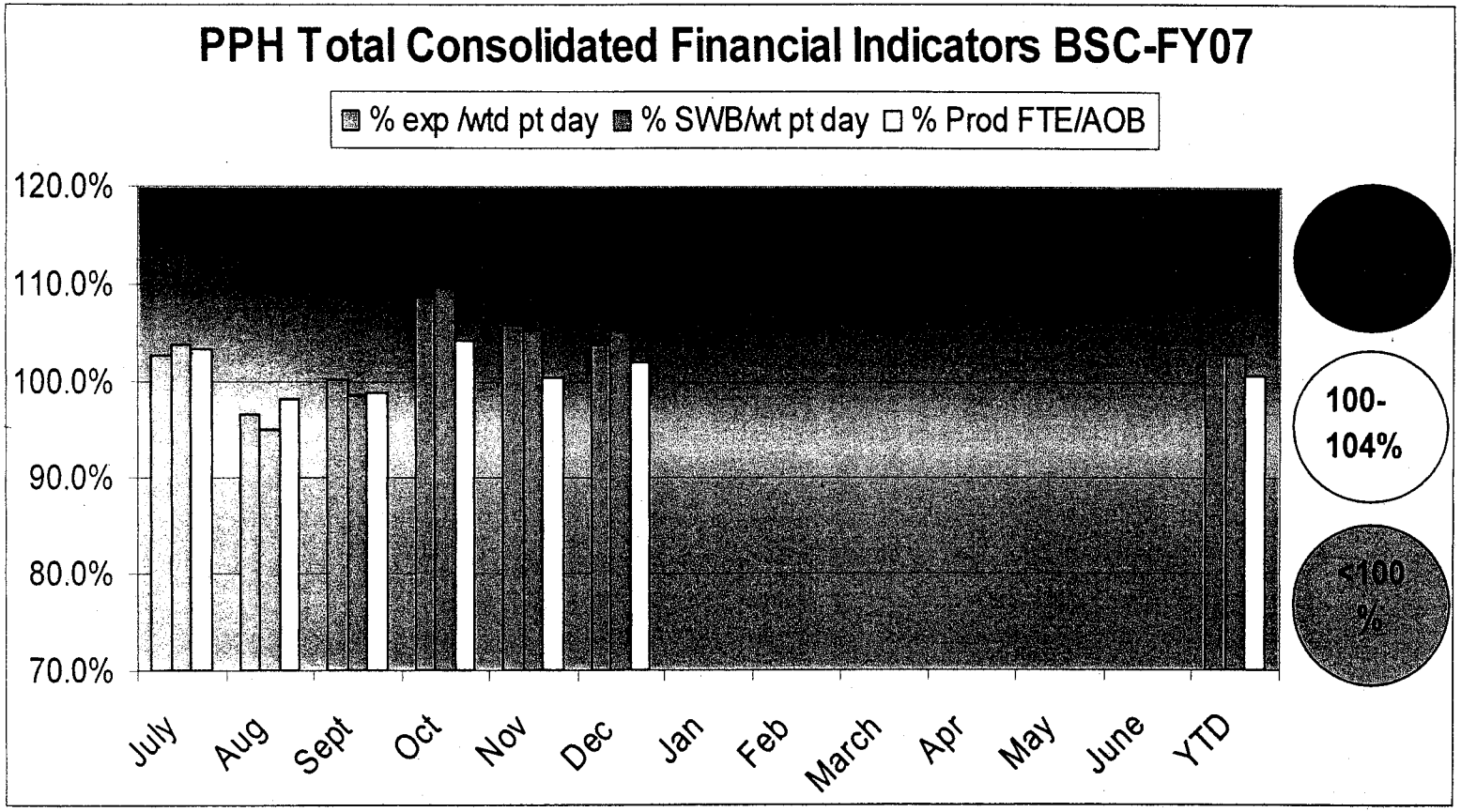
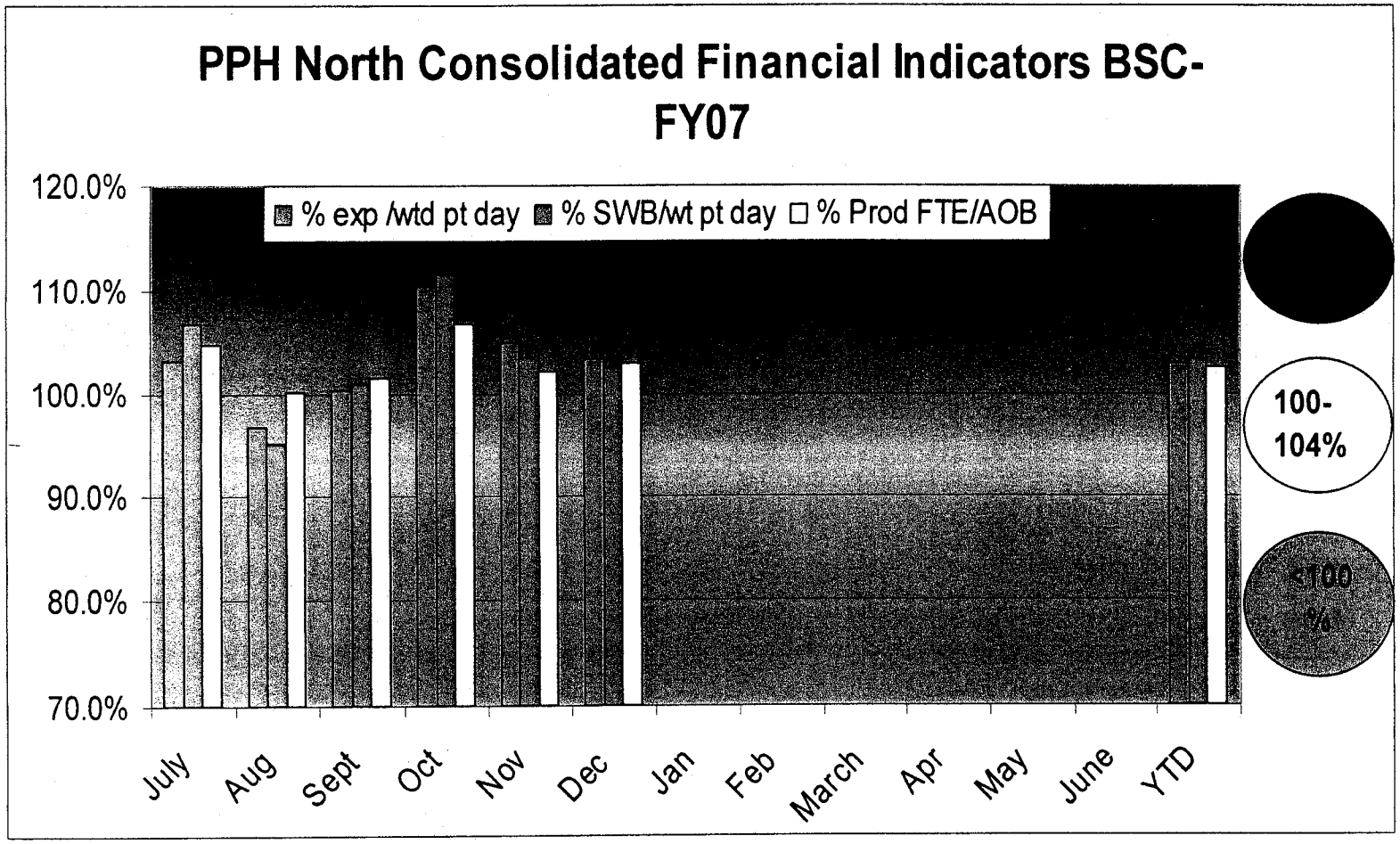
PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

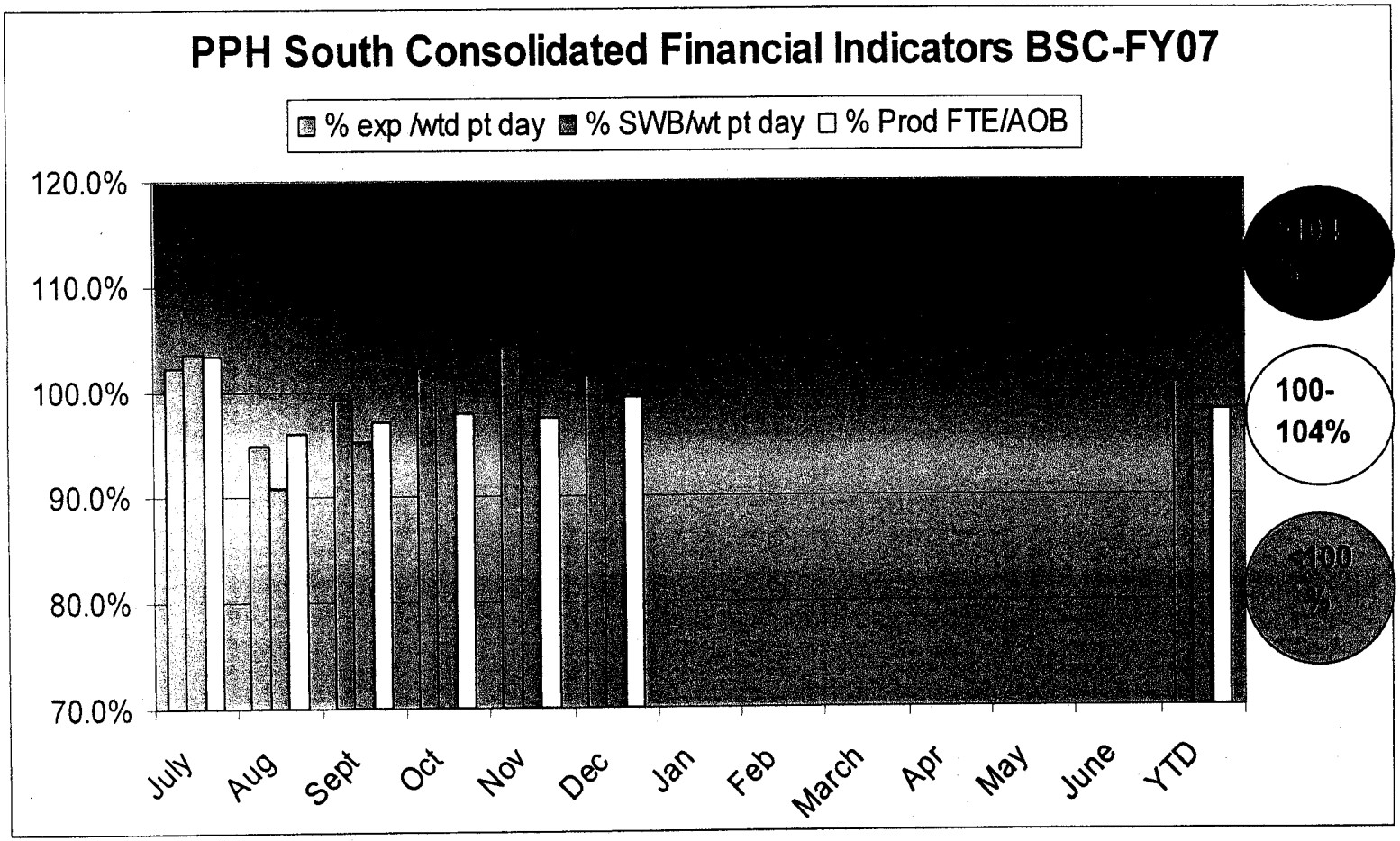


PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU



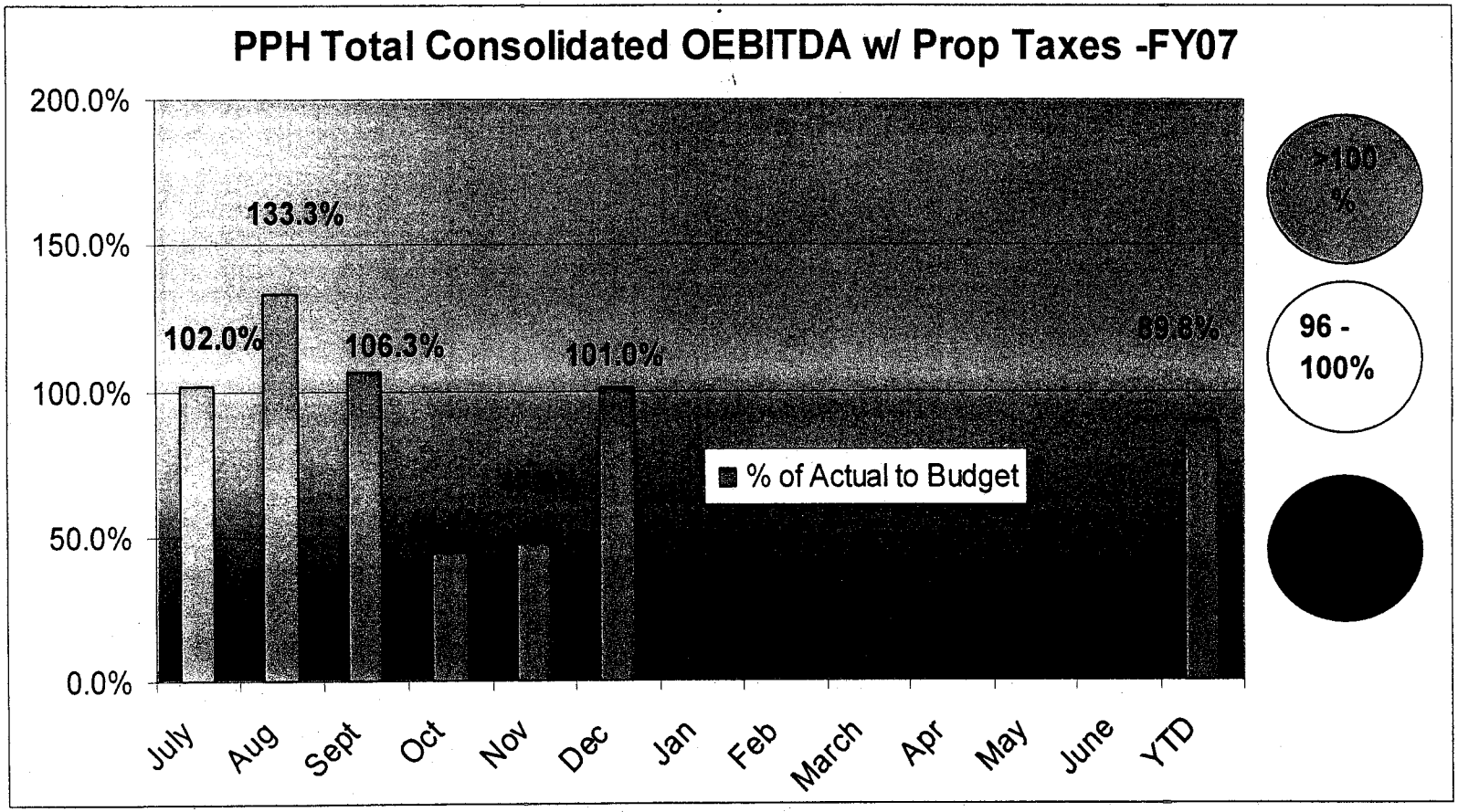
PALOMAR POMERADO HEALTH

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU



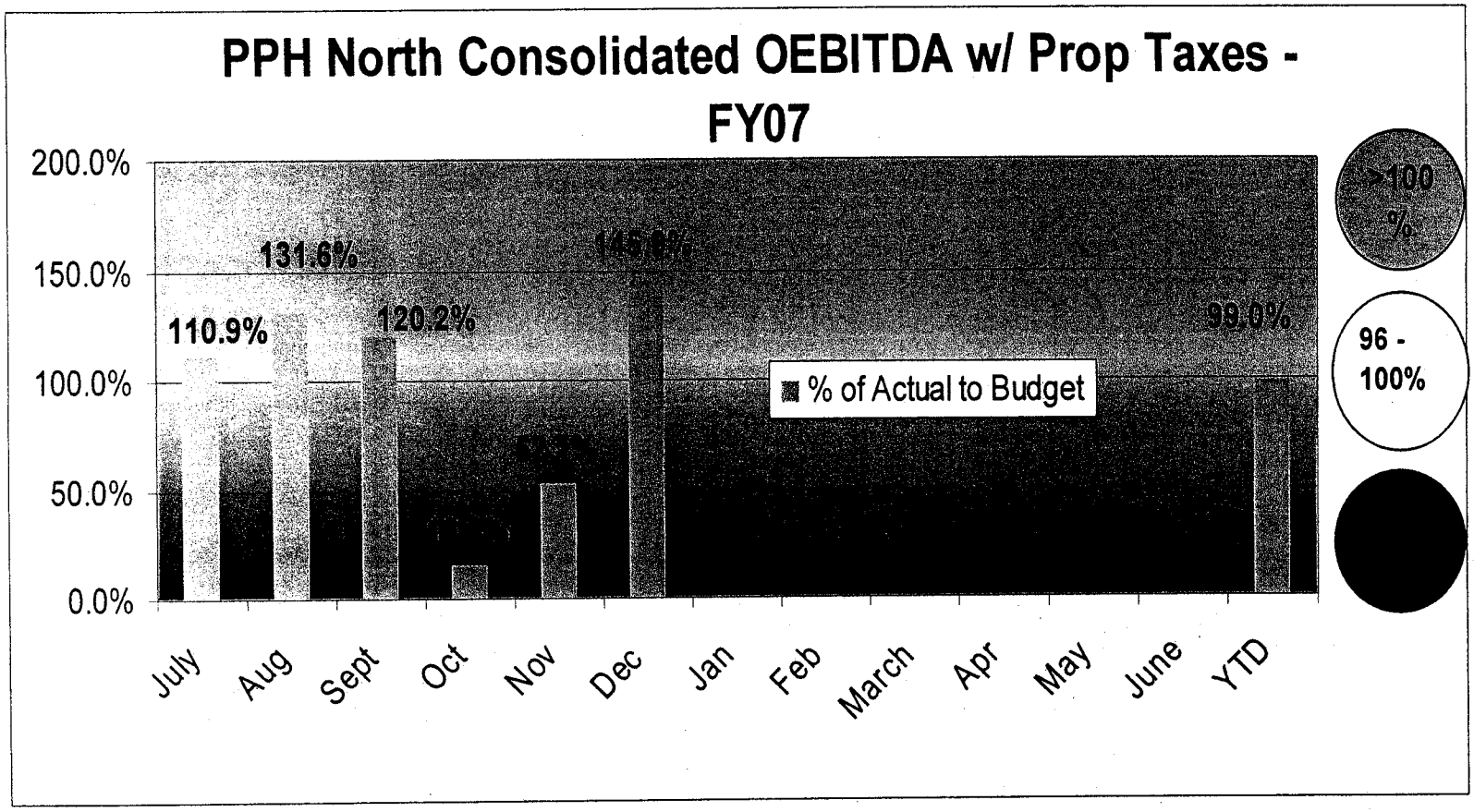
PALOMAR POMERADO HEALTH

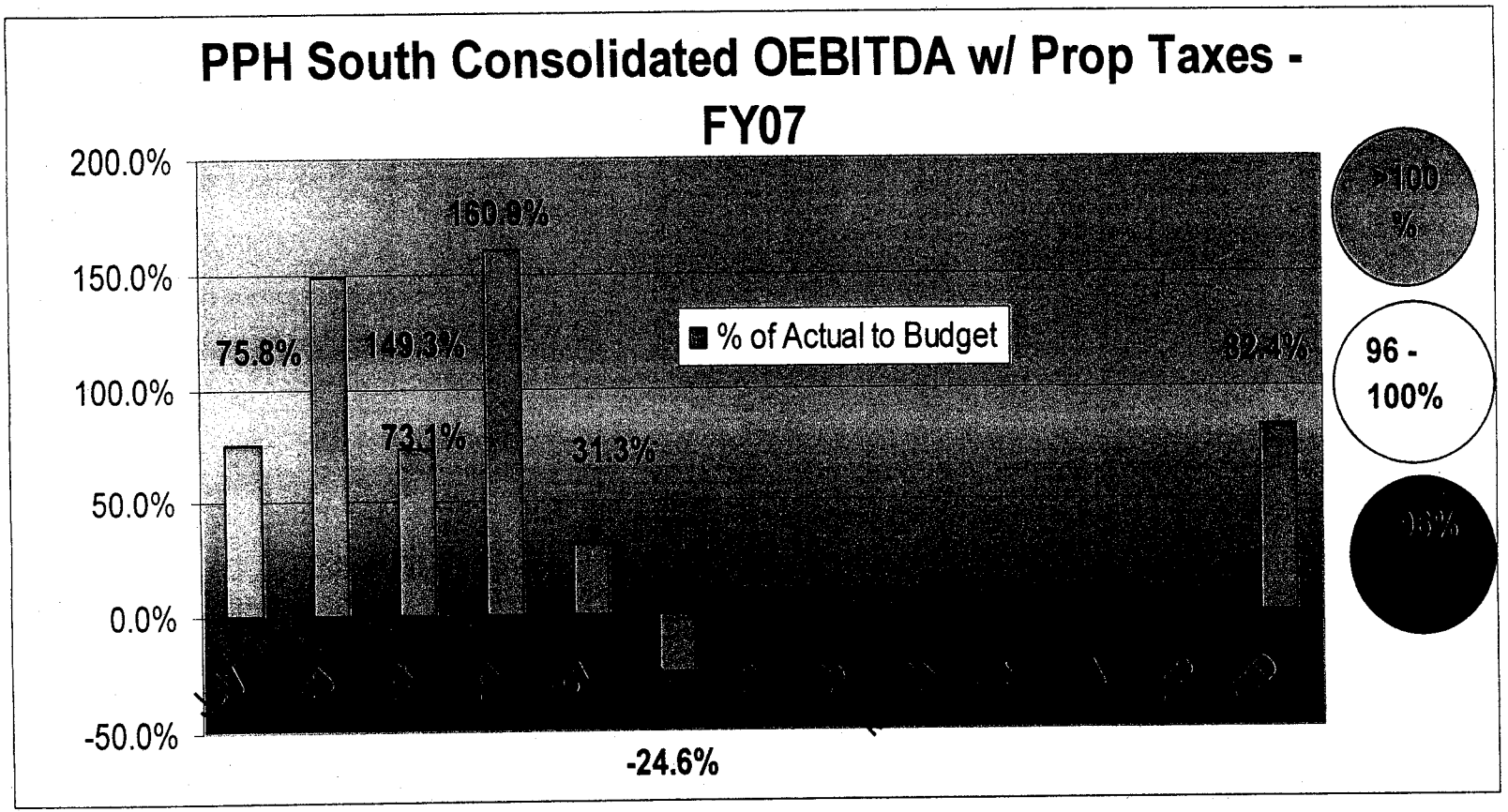
PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU



PALOMAR POMERADO HEALTH

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU


PPH North Consolidated OEBITDA w/ Prop Taxes - FY07
200.0%
150.0%
100.0%
50.0%
0.0%
110.9%
131.6%
120.2%
99.0%
% of Actual to Budget
>100 %
96 - 100%
July
Aug
Sept
Oct
Nov
Dec
Jan
Feb
March
Apr
May
June
YTD



PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

PPH Weekly Flash Report

January 2007	Dec 29-Jan 4	Jan 5 - 11	MTD Total	MTD Budget	% Variance
ADC (Acute)	309	331	320	320	0.02
PMC	233	250	242	239	1.25
POM	76	81	79	81	(3.57)
PCCC	90	92	91	89	2.29
VP	120	123	121	124	(2.07)
Patient Days (Acute)	2163	2319	4,482	4,481	0.02
PMC	1629	1753	3,382	3,340	1.25
POM	534	566	1,100	1,141	(3.57)
PCCC	627	642	1,269	1,241	2.29
VP	837	863	1,700	1,736	(2.07)
Discharges	509	542	1,051	1,140	(7.80)
PMC	387	418	805	840	(4.17)
POM	122	124	246	300	(17.96)
Number of Surgeries	168	222	390	470	(17.04)
PMC	109	162	271	306	(11.49)
POM	59	60	119	164	(27.41)
Number of Births	99	108	207	225	(8.14)
PMC	80	82	162	172	(5.60)
POM	19	26	45	54	(16.27)
Outpatient Visits (inc. Lab)	1651	1658	3,309	3,828	(13.57)
PMC	1136	1029	2,165	2,610	(17.06)
POM	515	629	1,144	1,218	(6.08)
ER Visits	1862	1696	3,558	3,215	10.68
PMC	1243	1193	2,436	2,163	12.63
POM	619	503	1,122	1,052	6.67
Trauma Visits	24	22	46	48	(3.91)
IP	21	17	38	36	6.51
OP	3	5	8	12	(34.39)

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PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

PPH Weekly Flash Report

January 2007	Dec 29-Jan 4	Jan 5 - 11	MTD Total	MTD Budget	% Variance
Gross IP Revenue	19,059,940	20,203,367	39,263,307	37,456,773	4.82
Gross OP Revenue	4,366,231	5,284,666	9,650,897	10,565,667	(8.66)
Cash Collection	3,519,441	5,617,406	9,136,847	11,382,898	(19.73)
Days cash on hand	98	104	104	80	
Productive Hrs (PP14)		181,875	181,875	202,184	10.04
PMC - North		110,071	110,071	119,535	7.92
POM - South		48,282	48,282	51,718	6.64
Others		23,522	23,522	30,931	23.95
Productive $ (PP14)		5,627,595	5,627,595	6,109,504	7.89
PMC - North		3,459,415	3,459,415	3,613,736	4.27
POM - South		1,437,887	1,437,887	1,510,644	4.82
Others		730,293	730,293	985,124	25.87

Note: There are only 3 days for cash collection since PBS was closed on January 1 & 2.

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PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

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PPH Weekly Flash Report

January 2007	Dec 29-Jan 4	Jan 5 - 11	Jan 12-18	MTD Total	MTD Budget	% Variance
ADC (Acute)	309	331	329	323	320	0.98
PMC	233	250	243	242	239	1.49
POM	76	81	86	81	81	(0.54)
PCCC	90	92	92	91	89	2.75
VP	120	123	123	122	124	(1.54)
Patient Days (Acute)	2163	2319	2305	6,787	6,721	0.98
PMC	1629	1753	1703	5,085	5,010	1.49
POM	534	566	602	1,702	1,711	(0.54)
PCCC	627	642	643	1,912	1,861	2.75
VP	837	863	864	2,564	2,604	(1.54)
Discharges	509	542	537	1,588	1,710	(7.12)
PMC	387	418	405	1,210	1,260	(3.97)
POM	122	124	132	378	450	(15.96)
Number of Surgeries	168	222	222	612	705	(13.22)
PMC	109	162	151	422	459	(8.12)
POM	59	60	71	190	246	(22.73)
Number of Births	99	108	111	318	338	(5.93)
PMC	80	82	87	249	257	(3.27)
POM	19	26	24	69	81	(14.41)
Outpatient Visits (inc. Lab)	1651	1658	1917	5,226	5,742	(8.99)
PMC	1136	1029	1274	3,439	3,915	(12.17)
POM	515	629	643	1,787	1,827	(2.19)
ER Visits	1862	1696	1695	5,253	4,822	8.94
PMC	1243	1193	1157	3,593	3,244	10.75
POM	619	503	538	1,660	1,578	5.22
Trauma Visits	24	22	21	67	72	(6.69)
IP	21	17	16	54	54	0.90
OP	3	5	5	13	18	(28.92)

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PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

PPH Weekly Flash Report

January 2007	Dec 29-Jan 4	Jan 5 - 11	Jan 12-18		MTD Total	MTD Budget	% Variance
Gross IP Revenue	19,059,940	20,203,367	19,757,438		59,020,745	56,185,159	5.05
Gross OP Revenue	4,366,231	5,284,666	5,414,560		15,065,457	15,848,500	(4.94)
Cash Collection	3,519,441	5,617,406	7,660,340		16,797,187	18,497,209	(9.19)
Days cash on hand	98	104	100		104	80	
Productive Hrs (PP14)		181,875			181,875	202,184	10.04
PMC - North		110,071			110,071	119,535	7.92
POM - South		48,282			48,282	51,718	6.64
Others		23,522			23,522	30,931	23.95
Productive $ (PP14)		5,627,595			5,627,595	6,109,504	7.89
PMC - North		3,459,415			3,459,415	3,613,736	4.27
POM - South		1,437,887			1,437,887	1,510,644	4.82
Others		730,293			730,293	985,124	25.87

Note: There are only 3 days for cash collection since PBS was closed on January 1 & 2.

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PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

VARIANCE TO BUDGET EXPLANATIONS
FOR PROFESSIONAL FEES & PURCHASED SERVICE
YTD as of December 2006

	YTD Variance to budget Fav/(Unfav)
Professional Fees	**$ (821,323)**
Legal fees Administration	(682,802)
Rehabcare Group therapists	(298,437)
North Co Emergency Med Assoc physician fees for ER	(250,154)
Gustavson & Associates consulting fees	(115,029)
Pediatrics physician fees	(109,477)
Surgery perfusion fees	34,961
North Co Emergency Med Assoc physician fees for Trauma	52,502
Information System consulting feees	64,834
North Co Emergency Med Assoc physician fees for L&D	84,598
Parkway and Gateway Radiology physician fees	161,089
Physician recruitment	195,017
	$ (862,898)

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PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

VARIANCE TO BUDGET EXPLANATIONS
FOR PROFESSIONAL FEES & PURCHASED SERVICE
YTD as of December 2006

Purchased Services	**$**	**(838,140)**
Patient Accounting recovery fees		(676,394)
Gateway/Parkway outside contracted services		(482,238)
Billing collection fees		(180,946)
Medical Surgical Special Care Hospital management fees		(125,304)
Laundry & Linen purchased services		(111,492)
Clinical Utilization		87,714
Dialysis purchased services		93,918
Health Source		104,265
Human Resources		110,560
Patient Transportation ambulance services		129,233
Plant Operations for repairs & maintenance		170,492
	$	**(880,192)**

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PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

MEDICAL STAFF SERVICES

PALOMAR POMERADO HEALTH

January 23, 2007

TO: Board of Directors

BOARD MEETING DATE: February 12, 2007

FROM: Robert D. Trifunovic, M.D., Chief of Staff
PMC Medical Staff Executive Committee

SUBJECT: Medical Staff Credentialing Recommendations

PALOMAR MEDICAL CENTER

I. Provisional Appointment (02/12/2007 – 01/31/2009)
Adil Abbasi, M.D., Internal Medicine (includes PCCC)
Delois J. Bean, M.D., Orthopaedic Surgery
Luis Esquenazi, M.D., Family Practice
George W. Moore, M.D., Internal Medicine
Sarah A. Russell, M.D., Family Practice
Reza Shirazi, M.D., Radiation Oncology
Robert J. Vallone, D.P.M., Podiatry
Marcus M. Van, M.D., Diagnostic Radiology (Teleradiology)

II. Advance from Provisional to Active Status
Julie J. Chuan, M.D., Family Practice (02/12/2007 – 06/30/2008) (Includes PCCC)
Yasser E. Farrag, M.D., Internal Medicine (02/12/2007 – 12/31/2008)
Peggy L. Shoval, M.D., Family Practice (02/12/2007 – 01/31/2008)
Steven M. Sorenson, M.D., Diagnostic Radiology (02/12/2007 – 02/29/2008)

III. Advance from Provisional to Associate Status
Steven A. LaFond, M.D., Family Practice/Geriatric Medicine (02/12/2007 – 06/30/2007) (Includes PCCC)

IV. Change from Associate to Courtesy Status
Colin A. Scher, M.D., Pediatric Ophthalmology

V. Additional Privileges
Marianna Siksay, M.D., Family Practice
- Cervical Biopsy and Cautery; Colposcopy
- Biopsy, Skin
- Repair of Simple Lacerations (excluding tendon and nerve)
- Removal of Ingrown Toenail
- Infant Circumcision
- Excision of Presumably Benign Skin and Subcutaneous Lesion (no skin graft)
- Treatment of Sprain, Strain, Chip Fractures
- Arthrocentesis – Aspiration and Steroid Injection – including Bursa
- Immobilization of Uncomplicated, Undisplaced Fractures
- Uncomplicated Dislocations of Fingers and Toes
- Epistaxis Control (Consult with Posterior Pack)
- Foreign Body Removal – Eye (Superficial), Ear, Nose, Vagina, Rectum
- Surgery Assist

☑ PALOMAR MEDICAL CENTER
555 East Valley Parkway
Escondido, CA 92025
Tel 760.739.3140
Fax 760.739.2926

☐ POMERADO HOSPITAL
15615 Pomerado Road
Poway, CA 92064
Tel 858.613.4664
Fax 858.613.4217

☐ ESCONDIDO SURGERY CENTER
343 East Second Avenue
Escondido, CA 92025
Tel 760.480.6606
Fax 760.480.1288

Additional Privileges – Marianna Siksay, M.D. continued
For Palomar Continuing Care Center:

- Skin Biopsy
- Splinting & Casting
- Nasal Packing
- Minor Suturing

VI. Leave of Absence

Christine Q. Phan, D.O., Family Practice (12/31/2006 – 11/30/2008)

VII. Allied Health Professional Withdrawal

Keira K. Dillon, N.P., Family Nurse Practitioner (Effective 12/28/2006)
Lori D. Echeverria-Ring, Assistant (Effective 12/27/2006)
Nancy J. Horton, LVN, CRC, Clinical Research Coordinator (Effective 01/15/2007)

VIII. Reappointments Effective 03/01/2007 – 02/28/2009

Mark M. Boiskin, M.D.	Nephrology	Dept of Medicine	Associate
Stephen M. Capon, M.D. (Includes PCCC)	Internal Medicine	Dept of Medicine	Active
Christopher D. Costanza, M.D.	Gastroenterology	Dept of Medicine	Courtesy
Douglas C. Dechairo, M.D.	Pediatrics	Dept of Pediatrics	Active
Richard C. Engel, M.D.	Anesthesiology	Dept of Anesthesia	Active
P. Eva Fadul, M.D.	Anesthesiology	Dept of Anesthesia	Active
Nabil I. Fatayerji, M.D.	Neonatal-Perinatal Med	Dept of Pediatrics	Active
Corinne H. Giesemann, M.D.	Family Practice	Dept of Family Practice	Active
Benjamin Kanter, M.D. (Includes PCCC)	Pulmonary Disease	Dept of Medicine	Active
Howard N. Kaye, M.D.	Rheumatology	Dept of Medicine	Consulting
Michael A. LaRocque, M.D.	Urology	Dept of Surgery	Active
Thomas J. Marcisz, M.D.	Neurosurgery	Dept of Surgery	Active
Mark P. Nespeca, M.D.	Pediatric Neurology	Dept of Pediatrics	Courtesy
Julie M. Phillips, M.D.	Internal Medicine	Dept of Medicine	Active
Gina Rosenfeld, M.D.	Pediatrics	Dept of Pediatrics	Active
Maria G. Sebiane, M.D.	Pediatrics	Dept of Pediatrics	Active
Stephen F. Signer, M.D. (Includes PCCC)	Psychiatry	Dept of Medicine	Active
Jeffrey M. Smith, M.D.	Orthopaedic Surgery	Dept of Ortho/Rehab	Active
Carol L. Young, M.D.	Rheumatology	Dept of Medicine	Active

IX. Allied Health Professional Reappointment Effective 03/01/2007 – 02/28/2009

Regina R. McFadden-Moehling, N.P., Geriatric Nurse Practitioner; Sponsors: Kaiser Continuing Care Physicians (Includes PCCC)
Ellen S. Petersen, N.P., Corporate Health Nurse Practitioner; Sponsors: Drs. Esmaeili and Herip.
Glen T. Pugh, N.P., Corporate Health Nurse Practitioner; Sponsors: Drs. Esmaeili and Herip.

Certification by and Recommendation of Chief of Staff:

As Chief of Staff of Palomar Medical Center, I certify that the procedures described in the Medical Staff Bylaws for appointment, reappointment or alteration of staff membership or the granting of privileges and that the policy of the Palomar Pomerado Health System's Board of Directors regarding such practices have been properly followed. I recommend that the action requested in each case be taken by the Board of Directors.

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Adil A. Abbasi, M.D.
PPHS Facilities	Pomerado Hospital (Villa Pomerado) Palomar Medical Center (Palomar Continuing Care Center)

SPECIALTIES/BOARD CERTIFICATION

Specialties	Geriatric Medicine: Certified 1992; Expired 2002 Internal Medicine: Certified 1988

ORGANIZATIONAL NAME

Name	Adil A. Abbasi, M.D.

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	University of Karachi, Pakistan To: 01/13/1981 Doctor of Medicine Degree
Internship Information	N/A
Residency Information	Chicago Medical School, North Chicago, IL Internal Medicine From: 07/01/1985 To: 06/30/1988
Fellowship Information	LAC/University of Southern Calif. Medical Center, Los Angeles, CA Medical Oncology From: 07/01/1988 To: 06/30/1989 Medical College of Wisconsin, Milwaukee, WI Geriatric Medicine From: 07/01/1989 To: 06/30/1991
Current Affiliation Information	Scripps Memorial Hospital, Encinitas Scripps Memorial Hospital, La Jolla

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PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Delois J. Bean, M.D.
PPHS Facilities	Escondido Surgery Center Palomar Medical Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Orthopaedic Surgery - Certified: 1994/2005 Surgery, Hand – Certified: 1997/2005

ORGANIZATIONAL NAME

Name	Kaiser Permanente

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	Stanford University School of Medicine, Palo Alto, CA From: 09/01/1976 TO: 06/15/1980 Doctor of Medicine Degree
Internship Information	N/A
Residency Information	Vanderbilt University Hospital, Nashville, TN General Surgery From: 06/24/1980 To: 06/24/1982 University of California, San Diego Orthopaedic Surgery From: 07/01/1985 To: 06/30/1989
Fellowship Information	Vanderbilt University Hospital, Nashville, TN Surgery Research From: 06/24/1982 To: 09/30/1983 University of California, San Diego Orthopaedic Research From: 07/01/1983 To: 06/30/1984 Scripps Clinic and Research Foundation, La Jolla, CA Hand Surgery From: 08/01/1989 To: 12/31/1989 University of California, San Diego Hand Surgery and Microsurgery From: 01/01/1990 To: 12/31/1990
Current Affiliation Information	Pomerado Hospital Kaiser Permanente, San Diego University of California, San Diego

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Luis Esquenazi, M.D.
PPHS Facilities	Palomar Medical Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Family Practice – Certified: 1990/2003

ORGANIZATIONAL NAME

Name	Kaiser Permanente

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	University of Southern California, Los Angeles, CA FROM: 09/01/1983 TO: 05/08/1987 Doctor of Medicine Degree
Internship Information	LAC/University of Southern Calif. Medical Center, Los Angeles, CA Family Practice From: 06/24/1987 To: 06/24/1988
Residency Information	Presbyterian Intercommunity Hospital/USC, Los Angeles, CA Family Practice From: 07/01/1987 To: 06/30/1990
Fellowship Information	N/A
Current Affiliation Information	Kaiser Permanente, San Diego Tri-City Medical Center

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Patrick S. Giesemann, M.D.
PPHS Facilities	Pomerado Hospital

SPECIALTIES/BOARD CERTIFICATION

Specialties	Family Practice - Certified: 2001 Geriatric Medicine – Certified: 2002

ORGANIZATIONAL NAME

Name	Neighborhood Healthcare

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	Albany Medical College of Union University, Albany, NY FROM: 09/01/1993 TO: 05/22/1997 Doctor of Medicine Degree
Internship Information	Harbor/UCLA Medical Center, Torrance, CA General Surgery From: 06/24/1997 To: 06/23/1998
Residency Information	Harbor/UCLA Medical Center, Torrance, CA Family Practice From: 06/24/1998 To: 06/30/2001
Fellowship Information	University of California, Los Angeles Geriatric Medicine From: 07/01/2001 To: 06/30/2002
Current Affiliation Information	Palomar Medical Center

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	George W. Moore, M.D.
PPHS Facilities	Palomar Medical Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Internal Medicine – Certified: 2001

ORGANIZATIONAL NAME

Name	Kaiser Permanente

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	University of Michigan, Ann Arbor, MI FROM: 08/01/1994 TO: 06/01/1998 Doctor of Medicine Degree
Internship Information	University of California, San Diego Internal Medicine From: 06/24/1998 To: 06/27/1999
Residency Information	University of California, San Diego Internal Medicine From: 07/01/1999 To: 06/30/2001
Fellowship Information	N/A
Current Affiliation Information	Kaiser Permanente, San Diego

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Michael S. Rafii, M.D.
PPHS Facilities	Pomerado Hospital

SPECIALTIES/BOARD CERTIFICATION

Specialties	Neurology – Not Board Certified

ORGANIZATIONAL NAME

Name	Southwest Neurology Med Group

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	Brown University School of Medicine, Providence, RI FROM: 08/01/1995 TO: 06/30/2002 Doctor of Medicine Degree
Internship Information	Johns Hopkins Hospital, Baltimore, MD Internal Medicine From: 06/23/2002 To: 06/22/2003
Residency Information	Johns Hopkins Hospital, Baltimore, MD Adult Clinical Neurology From: 07/01/2003 To: 06/30/2006
Fellowship Information	N/A
Current Affiliation Information	Palomar Medical Center University of California, San Diego Veterans Administration, San Diego

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Sarah A. Russell, M.D.
PPHS Facilities	Palomar Medical Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Family Practice – Certified: 2005

ORGANIZATIONAL NAME

Name	Neighborhood Healthcare

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	UCSD School of Medicine, La Jolla, CA FROM: 06/01/1998 TO: 06/09/2002 Doctor of Medicine Degree
Internship Information	Scripps Mercy Hospital, Chula Vista Family Practice From: 06/24/2002 To: 06/30/2003
Residency Information	Scripps Mercy Hospital, Chula Vista Family Practice From: 07/01/2003 To: 06/23/2005
Fellowship Information	N/A
Current Affiliation Information	None

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Reza Shirazi, M.D.
PPHS Facilities	Pomerado Hospital Palomar Medical Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Radiation Oncology – Not Board Certified

ORGANIZATIONAL NAME

Name	Radiation Medical Group, Inc.

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	Chicago Medical School, North Chicago, IL FROM: 07/21/1996 TO: 06/08/2001 Doctor of Medicine Degree
Internship Information	Loyola University, Chicago, IL Internal Medicine From: 06/22/2001 To: 06/21/2002
Residency Information	University of Cincinnati Medical Center, Cincinnati, OH Radiation Oncology From: 07/01/2002 To: 06/30/2006 07/01/05-06/30/06: Chief Resident
Fellowship Information	N/A
Current Affiliation Information	Scripps Mercy Hospital, San Diego

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Marianna Siksay, M.D.
PPHS Facilities	Escondido Surgery Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Family Practice – Certified: 2006

ORGANIZATIONAL NAME

Name	Graybill Medical Group

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	Uzhgorod State University, Ukraine FROM: 09/01/1987 TO: 06/18/1993 Doctor of Medicine Degree
Internship Information	N/A
Residency Information	University of Wisconsin-Madison Family Practice From: 06/30/2003 To: 06/30/2006
Fellowship Information	University of California, San Diego Research – Ophthalmology From: 04/01/2001 To: 06/30/2002
Current Affiliation Information	Palomar Medical Center

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Robert J. Vallone, D.P.M.
PPHS Facilities	Escondido Surgery Center Palomar Medical Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Podiatry – Certified: 1993/2003

ORGANIZATIONAL NAME

Name	Robert J. Vallone, D.P.M., Inc.

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	New York College of Podiatric Medicine, New York, NY FROM: 09/01/1976 TO: 06/10/1980 Doctor of Podiatric Medicine Degree
Internship Information	N/A
Residency Information	Bon Secours Hospital, Baltimore, MD Podiatric Medicine & Foot Surgery From: 07/01/1980 To: 06/30/1981
Fellowship Information	N/A
Current Affiliation Information	Pomerado Hospital Scripps Mercy Hospital, San Diego

PALOMAR POMERADO HEALTH SYSTEM
PROVISIONAL APPOINTMENT
February, 2007

PERSONAL INFORMATION

Provider Name & Title	Marcus M. Van, M.D.
PPHS Facilities	Pomerado Hospital Palomar Medical Center

SPECIALTIES/BOARD CERTIFICATION

Specialties	Diagnostic Radiology – Certified: 2006

ORGANIZATIONAL NAME

Name	Stat Radiology Medical Corp.

EDUCATION/AFFILIATION INFORMATION

Medical Education Information	Virginia Commonwealth University, Richmond, VA FROM: 08/01/1997 TO: 05/19/2001 Doctor of Medicine Degree
Internship Information	Mayo Clinic College of Medicine, Jacksonville, FL Transitional From: 07/01/2001 To: 06/28/2002
Residency Information	University of California, Los Angeles Radiology, Diagnostic Imaging From: 07/01/2002 To: 06/30/2006
Fellowship Information	University of California, San Diego Magnetic Resonance Imaging From: 07/01/2006 To: Present Expected Date of Completion: 06/30/2007
Current Affiliation Information	University of California, San Diego

PALOMAR POMERADO HEALTH
ALLIED HEALTH PROFESSIONAL
APPOINTMENTS
FOR FEBRUARY 2007

NAME:	**Elisabeth C. Herrera, RNFA**	
SPECIALTY:	Registered Nurse First Assistant	
SERVICES:	Registered Nurse First Assistant	
TRAINING:	Palomar College, San Marcos, CA	
	Associate Degree in Nursing	08/01/96-01/17/01
	University of California, Los Angeles Extension program	
	RNFA Training Program- Completed 12/03/2006	04/21/06-04/23/06
		05/12/06-05/14/06
PRACTICE:	RN/RNFA, Coastal Plastic Surgeons, San Diego, CA	02/01/06-Present
	R.N./O.R. R.N. Mark Mofid, M. D., San Diego, CA	07/01/05-02/01/06
	R.N., The Oaks Surgery Center, Murrieta, CA	02/01/04-06/30/05
	R.N.,perdiem, Center for Surgery of Encinitas, Encinitas, CA	11/18/04-05/09/05
	R.N., Tri-City Medical Center, Oceanside, CA	11/01/02-03/02/05
	R.N. , Scripps Ambulatory Surgery Center, Encinitas, CA	10/01/01-08/12/03
	R.N./CRC, Reproductive Science Center of the San Francisco BayArea	04/01/01-09/30/01
SPONSORS:	Munish Batra, M.D. and Abhay Gupta, M.D.	
CERTIFICATION:	Competency&Credentialing Institute, CNOR	2006
FACILITY:	Pomerado Hospital	

02/12/07

MEDICAL STAFF SERVICES

PALOMAR
POMERADO
HEALTH

January 30, 2007

TO: Palomar Pomerado Health Board of Directors

MEETING DATE: February 12, 2007

FROM: Ben Kanter, M.D., Chief of Staff
Pomerado Medical Staff Executive Committee
Robert Trifunovic, M.D., Chief of Staff
PMC Medical Staff Executive Committee

SUBJECT: Investigational Review Committee Policies and Procedures

I. At the Executive Committee meetings held January 22, 2007 at Palomar Medical Center and January 30, 2007 at Pomerado Hospital, the attached PPH Investigational Review Committee Policies and Procedures were approved for submission to the Board of Directors.

Attachment

☑ PALOMAR MEDICAL CENTER
555 East Valley Parkway
Escondido, CA 92025
Tel 760.739.3140
Fax 760.739.2926

☑ POMERADO HOSPITAL
15615 Pomerado Road
Poway, CA 92064
Tel 858.613.4664
Fax 858.613.4217

☐ ESCONDIDO SURGERY CENTER
343 East Second Avenue
Escondido, CA 92025
Tel 760.480.6606
Fax 760.480.1288

Palomar Pomerado Health

Investigational Review Committee

Policies and Procedures

Approved:

PPH Investigational Review Committee 12/14/06
Executive Committee - Palomar Medical Center _____
Executive Committee - Pomerado Hospital _____
PPH Board of Directors _____

Palomar Pomerado Health
Investigational Review Committee
Policies and Procedures

I. Introduction

Palomar Pomerado Health ["PPH"], by its constituent members, Palomar Medical Center and Pomerado Hospital, establishes these policies and procedures to govern the conduct of research involving human subjects and all other activities which even in part involve such research, regardless of sponsorship. The Palomar Pomerado Institutional Review Committee (PPH IRC) was created to comply with federal regulations and state laws for the protection of the rights and welfare of human research subjects. The Palomar Pomerado Health constituent members have designated the PPH IRC as their IRC of record.

The purpose of the IRC is to protect the rights and welfare of human subjects of research and to assure that clinical research is conducted according to corresponding federal regulations, state law, and IRC policies.

Ethical Principles

The PPH IRC applies the Belmont Principles to its deliberations and decision-making in its goal to protect the rights and welfare of human subjects of research along with applicable federal regulations and state laws to human research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral, and published in 1979 delineates the ethical principles for the conduct of human research upon which the federal regulations are based. Those principles are:

Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Justice requires that the benefits and burdens of research be distributed fairly.

Palomar Pomerado Health
Investigational Review Committee
Policies and Procedures

II. Scope of Authority

Scope of Authority Defined
All research or clinical investigations involving human subjects in which PPH, its staff, its Medical Staff members or its patients are involved may be subject to the authority of the IRC, regardless of funding source or other regulatory requirements.

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 46.102 (d)]

For FDA-regulated research, clinical investigation is defined as any experiment that involves a test article and one or more human subjects and that is either subject to requirements for prior submission to the FDA, or the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. [21 CFR 50.3(c)]

Human subject is defined as a living individual about whom a researcher obtains data through intervention or interaction with the individual, or identifiable private information about the individual [45 CFR 46.102(f)] or an individual who is or becomes a subject (either a healthy human or a patient) in research, either as a recipient of the test article or as a control [21 CFR 50.3(g)].

The IRC has the authority to:

a. Approve, require modifications in (to secure approval), or disapprove all research activities involving patients and/or clinical activity.
b. Conduct continuing review of the research not less than once a year and require progress reports from study investigators.
c. Oversee the conduct of the research, including observation of the consent process.
d. Suspend or terminate IRC approval of research that is not being conducted in accordance with the IRC's requirements, or that has been associated with unexpected serious harm to subjects or any unanticipated problems involving risks to human subjects or others.

Statutory Basis for IRC Authority / Regulatory Agencies
The PPH IRC is subject to regulation and inspection by all governmental regulatory agencies, including the Food and Drug Administration and the Department of Health and Human Services' Office of Human Research Protection. In addition, the laws of the State of California also apply.

Federal Regulatory Authority for Institutional Review Board operations and human research standards:
Food and Drug Administration (FDA) regulations pertaining to rights and welfare of subjects participating in research involving products regulated by the FDA, including drugs, medical devices and biological products. [21 CFR Parts 50 and 56]

Department of Health and Human Services (DHH) regulations pertaining to rights and welfare of subjects participating in research supported with federal funding. [45 CFR Part 46 (Federal Policy for the Protection of Human Subjects)].

State Statutory and Regulatory Authority for Institutional Review Boards: California Health and Safety Code: Section 24170-24179.5 (Human Experimentation), Section 24170 (Minimum Statutory Protection for the Citizens), Section 24815-24187 (Human Cloning), Section 111515-111545 (Experimental Use of Drugs), Section 121075-121125 [Acquired Immune Defieciency Syndrome (AIDS) Research Confidentiality Act], Section 123445

(Abortion), Section 124980 (Heredity Disorders Act), Section 124320-125300 (Embryo Registry); California Legislative Information (California Laws Regarding Research with Human Subjects – searchable); Research Advisory Panel of California; Welfare and Institutions Code 15601 (Elder Abuse and Dependent Adult Civil Protection Act); California Senate Bill 71 (California Comprehensive Sexual Health and HIV/AIDS Prevention Education Act); California Education Code 51513 (Parental Consent for Children to Participate in Research); California Penal Code, Section 3500 (Biomedical and Behavioral Research), Section 3521-3523 (Prisoners Rights as Research Subjects), Section 1165 (Child Abuse and Neglect Reporting Act), Section 1160 (Reports of Injuries), California SB 253, 2002; SB 322, 2003 (Human Embryonic Stem Cell Research), California Code of Regulations, Title 17, Section 2500 (Reporting of Positive Results of Communicable Disease Testing); and other California statutory and regulatory requirements not otherwise referenced.

Organizational Structure

The PPH IRC reports to the Executive Committees of Palomar Medical Center and Pomerado Hospital. Although the IRC reports to the Executive Committees, it retains autonomy in decision-making. IRC disapprovals, restrictions, or conditions cannot be rescinded or removed except by the action of the IRC.

The IRC reports to the Executive Committee by providing the Committees with a copy of the minutes of all IRC meetings.

Human research that has been approved by the IRC may be subject to further review and approval or disapproval by other PPH officials or committees or by officials of entities that rely on the PPH IRC. However, PPH researchers may only conduct human research that has been approved by the IRC.

IRC Jurisdiction

The IRC reviews all research in which a PPH constituent or entity relying on the PPH IRC is engaged in research, including without limitation when the following apply:

(a) research is sponsored by PPH
(b) research is conducted by or under the direction of any employee, staff member, agent, or student in connection with his or her PPH responsibilities
(c) research is conducted by or under the direction of any employee, staff member, agent, or student uses any property or facility of PPH
(d) research involves any patients of PPH
(e) research involves the use of PPH's non-public information to identify or contact human research subjects or prospective subjects.

See generally, Engagement of Institutions in Research (January 26, 1999) (OPRR Guidance)

Multi-Institutional Research

For research conducted at PPH and concurrently at another institution, the PPH IRC requires review and approval of the full protocol (including recruitment documents) and consent forms. In general, the IRC can waive PPH standard language or formatting elements if subjects are not recruited at or PPH has no subject contact. PPH IRC will also review amendments, serious adverse events, and protocol deviations. Each IRC that reviewed the protocol must be notified of any protocol changes, serious adverse events or other reportable events occurring at any site. Continuing Review is to be conducted in accordance with 45 CFR 46.109 and 21 CFR 56.109.

The PPH IRC is responsible for the protection of the rights and welfare of human subjects at Palomar Medical Center or Pomerado Hospital, as well as research conducted at other locations by PPH faculty and staff. There are standing cooperative agreements with other institutions whereby the PPH IRC has the authority over, and is responsible for, research at those institutions. The PPH IRC may function as the IRC of record for another investigator and/or institution but the other institution must apply for and receive a Federalwide Assurance (FWA) of Protection for Human Subjects that designates PPH as the IRC on record filed at the Office of Human Research Protection (OHRP). In addition, an Authorization Agreement must be signed, and a copy of the approved FWA must be submitted to the PPH IRC. The FWA must be renewed every three years.

Palomar Pomerado Health
Investigational Review Committee
Policies and Procedures

III. Structure of the PPH Institutional Review Committee

Panels

The PPH Institutional Review Committee is currently made up of one active review Panel. The IRC panel is comprised of members from multiple professions, multiple cultural backgrounds, and both genders, with knowledge of institutional commitments and requirements, local research, local context, and experience with vulnerable subjects. The panel is constituted with both scientific and non-scientific members in order to ensure diversity on each panel. At least one member on the panel has no affiliation with Palomar Pomerado Health other than his/her membership on the IRC.

A list of IRC members identified by name, earned degrees, representative capacity, and employment or other relationship to the institution is submitted to the Office of Human Research Protections in the PPH IRC Registration.

It is the policy of the Palomar Pomerado Health Investigational Review Committee not to release the names of the members of the IRC, except as required by law or regulation.

Trainees may serve as an IRC reviewer, under the mentorship of an experienced IRC member. These trainees are not members of the IRC and do not vote on approval of protocols.

IRC members

Selection and Appointment

IRC Chairs determine the types of expertise required for review of research conducted at PPH. PPH Department Chairs, IRC administrative staff and others may nominate IRC members. The potential member's name is forwarded to the Chiefs of Staff of Palomar Medical Center and Pomerado Hospital, who are responsible for appointment of all members.

Length of Term/Service

There is no set term limit for the member's appointment, although appointments are made annually for a one-year term.

Duties

PPH IRC Panel members are responsible for ensuring that the rights and welfare of research subjects are protected by reviewing and approving human research in a manner consistent with federal regulations, state and local laws, and institutional guidelines and policies.

Attendance Requirements; Alternate Members

Members are required to attend at least 50% of the meetings each year. Attendance at each meeting is noted for the minutes. Certain members may be designated alternate members, as submitted to the Office of Human Research Protections in the IRC Registration. An alternate member may only substitute for his/her designated member if that member is not available to vote (e.g.; absent, recused for conflict of interest). If more than one alternate member is present at a meeting where the member is not present, only one alternate may vote.

Removal/replacement
IRC members may be removed or replaced by the Chairman of the Committee or the Chiefs of Staff of Palomar Medical Center and Pomerado Hospital.

Leadership
Chair(s)
Selection and Appointment
The Chiefs of Staff of Palomar Medical Center and Pomerado Hospital appoint the Chair(s) to the IRB. The Chairs' names and credentials are submitted to the Office of Human Research Protections in the IRB Registration.

Length of Term
There is no set term duration for the Chair's appointment.

Duties
The Chairs direct the Panel's proceedings in accordance with institutional and federal requirements, as well as parliamentary procedure. They work closely with Panel members, IRB administrator, institutional officials, and investigators to ensure that the rights and welfare of research subjects are protected. They are the principal signatory officials for IRB correspondence but they may designate as appropriate, the IRB Administrator, and any designated IRB members to review selected IRB documents and materials. Each Panel Chair is responsible for approving the IRB minutes, reviewing serious adverse events, reviewing minor amendments and conducting expedited reviews.

Removal/Replacement
Chairs may be removed or replaced by the Chiefs of Staff of Palomar Medical Center or Pomerado Hospital.

Training of IRB Chairs and members
Orientation
The IRB Chairs and members are provided with educational training materials. These materials include, but are not limited to, the Belmont Report, Department of Health and Human Services Protection of Human Services regulations 45 CFR 46, Food and Drug Administration regulations 21 CFR 50 and 56, PPH IRC Policies and Procedures, and additional resource materials.

Continuing Education
Educational materials are provided regularly to the Panel members and discussed at IRB meetings. These materials cover both general topics and panel-specific issues. The December meeting each year is devoted to educational topics and discussions of issues of concern to the Panel.

Reference materials (IRB library)
Reference materials may be found in the PPH Medical library, the IRB office, the OHRP website, and the FDA website.

Compensation of IRB Members
Members are not compensated for their work on the IRB.

Liability Coverage for IRB Members
IRB member liability is covered by the Palomar Pomerado Health insurance policies.

Use of Consultants
IRB panels are encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be Palomar Medical Center or Pomerado Hospital medical staff, or may be unaffiliated with PPH. The consultants may present their assessments in writing or in person.

IRB Member Conflict of Interest Policy

Reviews of applications will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IRC on actions concerning projects or activities in which they have an active role or conflict of interest. Knowing failure to abide by these provisions may be cause for removal of a member from the IRC. IRC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol. The IRC member must make any conflict of interest known to the IRC Chair and recuse him/herself from the meeting during discussion and voting on this protocol. The member may provide information to the IRC if requested. The fact that a protocol is submitted by another investigator from an IRC member's Department or Section does not, in and of itself, constitute a conflict of interest.

Secretarial support and resources

The Palomar Medical Center Medical Staff Services Office provides administrative support for the IRC panel (the IRC office). The IRB Administrator serves as communication link between investigators and IRC panel. The Administrator's responsibilities include but are not limited to: recording the minutes, distribution of meeting materials to the panel, transcribing minutes, reviewing submissions to the panel, and generating letters to investigators. PPH provides the IRC office with appropriate office space, equipment and other support to perform its functions. The files that contain the active protocols are located in a locked file room in the IRC office. Inactive protocols may be stored in the locked file room in the IRC office or in an off-site secure facility.

Palomar Pomerado Health
Investigational Review Committee
Policies and Procedures

IV. IRC Office

Responsibilities
The primary responsibility of the PPH Office of the IRC is to support the IRC Panel and Chair(s) as they fulfill their review and other regulatory responsibilities.

The general responsibilities of the Office of the IRC include, but are not limited to:

- Receipt and tracking of IRC applications
- Preliminary screening of protocols and other IRC submissions to determine if they are complete and ready for IRC review
- Initial determination as to whether a protocol qualifies for expedited review or requires review by a full (convened) panel
- Preparation of agendas for IRC meetings; distribution of agendas and review materials prior to meetings to Panel members and Chairs
- Preparation of the minutes of each IRC meeting
- Submission of the minutes to the Executive Committees of Palomar Medical Center and Pomerado Hospital
- Prompt notification of the PI of the outcome of IRC meetings and any actions taken related to his/her protocol
- Receipt and review of all correspondence (including amendments, modifications, protocols deviations, AEs, SAEs, etc.) related to existing protocols. Distribution of these materials to the Chairs and Panel members and communication with the PI regarding these materials.
- Notification of PIs regarding the due date for submitting Continuing Review Reports
- Receipt and processing of Continuing Review Reports. Notification of PIs regarding the outcome of Continuing Reviews.
- Maintenance of complete, organized, and easily assessable IRC records, with particular attention to the integrity and security of the IRC records.
- Communication with the IRC and Investigators regarding any subject complaints received by the Office
- Provision of education and assistance to investigators regarding IRC related issues
- Facilitation of communication among IRC Chairs, IRC Panel members and Investigators

IRC Administrator
The IRC Administrator is responsible for the day to day operations of the Office of the IRC. The IRC Administrator directly reports to the Manager of the Medical Staff Services office at Palomar Medical Center and is accountable to the IRC Chairs and the Manager of the Medical Staff Services office for the timeliness and accuracy of administrative tasks completed for the IRC. The IRC Administrator processes and reviews IRC submissions according to the procedures described in this document. Exceptions to these procedures must be approved by the Administrator or the Chairman of the IRC. The Administrator provides ongoing oversight and evaluation of the administrative processes in the Office including but not limited to

- Status of the study files (organization and completeness)
- Adequacy and completeness of the minutes and agendas
- Timeliness of continuing reviews
- Timeliness and accuracy of letters to investigators
- Timeliness and accuracy of processing protocols and other IRC submissions (i.e. amendments, AEs, etc.)

The Administrator recommends changes to internal processes as required to ensure that the Office is compliant with regulations and PPH policies and procedures.

The IRC Administrator of the IRC office reviews all IRC submissions for completeness. The PI is contacted promptly if required materials are missing or incomplete. The materials and information required by the IRC are necessary to enable a thorough review of research to ensure that it conforms to applicable regulations and federal guidance. The IRC Administrator does not place protocols or submissions on the IRC meeting agenda or send them for expedited review until they are complete and contain all required signatures. Exceptions are made only with the approval of the Administrator or Chairman of the PPH IRC.

IRC Records

The Office of the IRC maintains IRC records in a confidential manner either in the Office of the IRC or in a secure off-site records management facility. Original study files are not removed from the Office of the IRC without the permission of the Administrator or Manager of the Medical Staff Services office. The records are available for inspection and copying by the Food and Drug Administration (FDA), federal or state government agencies, hospital accrediting agencies, or others, as appropriate. The IRC Administrator is responsible for the IRC records. The Office of the IRC maintains IRC records, including but not limited to the following:

- **IRC Membership Roster** The IRC Roster includes names of members, alternate members, ex officio (non-voting) members' names; earned degrees; specialty and relationship to Palomar Pomerado Health. The IRC membership roster is submitted with the IRC Registration to OHRP. A copy of that registration is kept on file at the Office of the IRC.
- **Written Procedures and Guidelines**
  FDA (21 CFR 56) and DHHS (45 CFR 46) require that an IRC operate according to written Policies and Procedures to ensure protection of the rights and welfare of individuals involved as subjects in research. These Policies and Procedures are approved by the Executive Committees of Palomar Medical Center, Pomerado Hospital and the PPH Board of Directors, reviewed annually, and updated as needed. Any person wishing to suggest a new policy or revision to a current policy must submit the suggestion in writing to the IRC Administrator along with the rationale for the change/addition. The Administrator will review the proposal and present it to the PPH IRC and the Executive Committees of Palomar Medical Center and Pomerado Hospital for consideration.
- **IRC Records, including Protocols Reviewed, Approved Informed Consent Forms, and Correspondence**
  While active, IRC records are maintained in the IRC office. After study closure, records are retained in the IRC office or at an off-site secure storage facility for a minimum of seven years, or longer if required for a particular study.
- **Proceedings of all IRC meetings and Executive Committee Meetings** This includes agenda, minutes, primary/secondary review sheets, and educational materials provided during IRC meetings. Copies of minutes signed by the Chair(s) are stored in the IRC office and are not removed from the IRC office without the permission of the Administrator or Manager of the Medical Staff Services office.
- **Communications to and from the IRC**
  All formal communications to and from the IRC are written and filed in the IRC's study file. Electronic communications (email) are printed and retained as hard copies. Records of these communications are maintained with the complete study file.
- **IRC Documentation of Review of Adverse Event Reports** All serious adverse event reports are reviewed by the Panel Chair or an experienced IRC member designated by the Chair. These reviews are documented on the Agenda. Reviews are then documented in the Committee minutes and filed in the IRC's study file. All reports from Data Monitoring Committees and reports of non-serious adverse events are maintained in the appropriate study files.
- **Record of Continuing Review** Requirements for Continuing Review are provided to the Principal Investigator with the IRC Approval Letter. Deliberations and approvals of Continuing Reviews are documented in the minutes and filed in the IRC's study file. The IRC notifies investigators of the need to submit Continuing Reviews at least 30 days in advance of expiration of their studies.

Records of these courtesy notifications are maintained in the IRC office as photocopies of courtesy letters or emails placed in the study files.

- **Emergency Use Reports** Instances of emergency use of a drug, device or biologic agent must be carefully documented in writing by the physician and must be received by the IRC within 5 working days of use of an emergency article. Reviews of emergency use are documented in Committee minutes and filed in the IRC's study file, or in a separate emergency use file if there is no study file.
- **Statements of Significant New Findings Provided to Subjects** The requirement to provide information to subjects regarding significant new findings is included in the consent form template provided to investigators as deemed necessary by the IRC. The Committee verifies that this statement is included in the approved consent form. The method and urgency of conveyance of new findings will vary depending on the nature of new information to be provided. For example, if a study medication is harmful, then all patients will be notified immediately. In less urgent cases, written notification may be appropriate. In addition, a telephone call may be necessary. A revised consent form with or without the re-consenting of all affected subjects may be necessary. Verification of these notifications may be required by the IRC, will be maintained in the PI's study files, and will be made available for audit
- **Other materials related to the operations of the Office of the IRC** Records related to the orientation and training of IRC office staff and internal processes/ SOPs are maintained in the Administrator's office.
- **Administrative forms used by the Office of the IRC** The Administrator of the IRC is responsible for the management of forms used by the Office. New forms must be approved by the Administrator. Any person wishing to suggest a new form or revision of a current form must submit the suggestion in writing to the Administrator along with a description of the rationale for the change.

Palomar Pomerado Health
Investigational Review Committee
Policies and Procedures

V. **IRC Meetings**

Location
IRC meetings are held in a suitable conference room at Palomar Medical Center and videoconferenced at either Pomerado Hospital or the PPH corporate offices, as necessary.

Scheduling of Meetings
IRC typically meets on the second Thursday of each month at 12:15 p.m. as noted in the schedule set at the beginning of the calendar year by the Panel Chairs and the Administrator of the Office of the IRC. A schedule of the dates and locations of meetings is available through the IRC office and provided to each Panel member prior to the beginning of each calendar year. Scheduled meetings may be canceled or rescheduled for holidays, a lack of quorum, or if Palomar Medical Center is closed for any reason. Meetings are cancelled or rescheduled by the action of the Panel Chair(s) in conjunction with the Administrator of the Office of the IRC.

Meeting Attendance
IRC Panel members are required under the Medical Staff Bylaws to attend a minimum of 50% of the scheduled meetings in each calendar year. The failure to meet the foregoing attendance requirement during the medical staff year shall be grounds for sanctions as stated in the Medical Staff Bylaws of Palomar Medical Center (Section 8.3.5). The Chairman shall report all such failures to the appropriate Executive Committee for action.

Visitors
Visitors are allowed to attend IRC meetings with the permission of the Panel Chair(s). Visitors may request permission to attend IRC meetings by contacting the Administrator of the Office of the IRC. Visitors must agree to sign a statement of confidentiality prior to attending any IRC meeting. Visitors may not remove any written materials that are distributed during the meeting from the meeting (agendas, minutes, study protocols) with the exception of educational materials. If during an IRC meeting the Chair moves the meeting to Executive Session then any visitors will be asked to leave the room until the Executive Session has ended.

Quorum / Voting Procedures:
After discussion, the IRC members vote their decision, which can include approval, conditional approval (conditions that require simple concurrence), deferral, and disapproval. The number of votes (for, against, abstain), those recused, and the attendance are recorded in the minutes. The IRC observes the following regulations in its voting:

(1) A Quorum Required to Transact Business - One half of the total number of Panel members plus one must be present to achieve a quorum.
(2) Diversity Requirements of Quorum - At least one member whose concerns are non-scientific must be present.
(3) Percent needed to approve or disapprove study - Approvals, conditional approval, deferral, and disapproval must be by a majority of the members present.
(4) Full voting rights of all members - Each member has one vote. If the member is unable to vote (absent or recused), then one designated alternate member may vote in place of the member. Ex-officio members are non-voting members. IRC Office staff are non-voting members.
(5) Proxy votes (written or telephone) - No proxy votes (written or telephone) are allowed.

(6) Prohibition against conflict-of-interest voting - Members who have a conflict of interest may be present to answer question about the protocol but then must leave the room and recuse themselves from deliberations and voting. The presence of a conflict and the recusal are recorded in the minutes.

Minutes and Agendas
Meeting agendas and minutes are prepared for each convened IRC meeting. The IRC reviews and approves the minutes of its previous meetings during subsequent convened IRC meetings.

The PPH IRC minutes document separate deliberations, actions, and votes for each protocol reviewed by the convened panel. Additionally, educational materials distributed, audits discussed and protocol deviations submitted are also noted in the minutes.

All IRC minutes are confidential. Minutes contain, at a minimum

1. The date, time and location of the meeting
2. Documentation of voting and non-voting members present, absent, and excused and any alternate members replacing absent or excused members
3. Any loss of quorum during the meeting
4. Attendance of staff, ex-officio members and guests
5. Educational material distributed
6. Actions taken by the IRC at the meeting on any of the following:

    i. initial and continuing reviews
    ii. amendments
    iii. serious adverse events
    iv. resubmitted protocols
    v. safety or investigational brochure updates
    vi. expedited reviews of protocols
    vii. final approvals for protocols conditionally approved at a previous meeting
    viii. protocol deviations
    ix. any non-compliance issues

7. All votes on actions, including number of members voting for, against, those recusing themselves from voting (and discussion) and those abstaining from voting on actions
8. Administrative issues
9. Summary of discussion of issues pertaining to protocol reviews, particularly controversial issues
10. The basis for requiring changes in or disapproval of research, and any subsequent resolution of those requirements or disapproval
11. Any determinations regarding waiver of the requirement for informed consent, for informed consent documentation, or for particular elements of informed consent.
12. Any determinations regarding regulatory categories and justifications for research involving pregnant women, fetuses, prisoners, or children
13. The results and issues pertaining to audits of research conducted by the IRC

Notification of IRC Actions to the Executive Committee(s)
The PPH IRC Administrator is responsible for sending copies of the minutes of each IRC panel meeting to the Executive Committees of Palomar Medical Center and Pomerado Hospital.

Communication with Investigators Conveying the Outcome of IRC Meetings
IRC actions that occur during IRC meetings are promptly conveyed to the Principal Investigator in writing. Communications include conditional approval and its conditions, or deferral or disapproval including the reasons for non-approval. Letters and minutes may suggest changes to the protocol and/or consent form that are required before the protocol will be reconsidered by the Panel. An IRC member may volunteer or may be assigned to work with the Principal Investigator to address the IRC's concerns.

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VI. Principal Investigators, Co-investigators and Other Research Personnel

Qualifications to Perform Human Research
The PPH IRC decides who can perform clinical research at PPH. Prior to approving any study the IRB is required to assure that the PI, any co-investigators, and the research staff possess appropriate professional qualifications and resources to conduct the research project and to assure that the rights and welfare of subjects are protected.

Requirements for Principal Investigators
The PPH IRC requires that Principal Investigators (PIs) have the appropriate background and training to conduct the research required for each study. PIs must also be a member of the medical staff with admitting privileges at the institution(s) at which the study will take place. All research staff, including employees of PPH, must also obtain and maintain privilege on the Allied Health Professionals staff of the appropriate facility prior to performing any functions related to any study.

The Principal Investigator of record must be consistent across research documents, including the IRC application and informed consent form.

Communication between IRB and Investigators
The PPH IRC communicates with the PI of record for each project. The Principal Investigator has the ultimate responsibility for oversight of all research he/she is conducting and is ultimately responsible for all communication with the IRC (via the Office of the IRC) regarding that research. All official IRC correspondence is directed to the PI. The PI may request that another member of the research staff also receive communication from the IRC; however in the eyes of the IRC it is the Principal Investigator who is responsible for all aspects of the research protocol.

The PI must provide the office of the IRC with current contact information including mailing address, telephone number, fax number and email address. The PI must promptly inform the office whenever there is a change in this information.

The IRC may request additional information from the Principal Investigator or the sponsor to enable appropriate review of research applications. Communications to the investigators will be in writing, by e-mail or by telephone, with written documentation of the action. Documentation of communication between investigators and the IRB is maintained in the office of the IRB. Investigators are expected to maintain their own study records containing appropriate documentation relevant to their research.

Training of Investigators
All principal investigators and their research staff complete the National Institutes of Health internet based training on Protecting Human Subjects for Researchers and Research Staff. The certificate of completion must be provided to the IRC at the time of protocol submission for approval. Additional training may be required. The PPH IRC will notify the PI of any additional training requirements.

Conflict of Interest for Investigators
Investigators must report to the PPH IRC office any financial conflict of interest related to proposed research at the time of protocol submission.

PI Responsibilities when Conducting Research at PPH
PI is required to follow the regulations and conduct research in an ethically and morally correct manner.

Continuing Review
The IRC must continually review ongoing research projects. Requirements for Continuing Review are provided to the Principal Investigator with the IRC approval letter. The PI is responsible for providing a Continuing Review Report and an updated Informed Consent Form to the IRC for review and approval prior to expiration of the study. Some research projects (e.g. those with higher risks) may require that reviews occur more frequently than annually. The frequency of review will be clearly spelled out in the IRC approval letter.

Continuing review must be substantive and meaningful. The IRC applies the same criteria for approval of continuing review applications as it does for initial applications. For this reason the IRC must receive enough information to ensure continued protection of human subjects.

The Continuing Review Form contains the following information: IRC protocol information, PI, protocol status (pending/no accrual, active, closed to accrual, completed), protocol information, accrual information, accrual categories, adverse event information, subject complaints, amendment information, protocol deviations and protocol findings information. In addition, any additional information concerning the state of knowledge about the study question (particularly other information that might change the assessment of clinical equipoise or the risk: benefit assessment) must be presented. Any presentations or publications of study findings must be included with the continuing review application.

The office of the IRC notifies the PI that the research protocol is due to expire at least 30 days prior to the expiration date. It is the responsibility of the PI to ensure that the research protocol does not expire. Failure of the PI to receive the renewal notice does not excuse the PI from his/her responsibility for submitting continuing review reports.

The continuation of research after expiration of IRC approval is a violation of the federal regulations. If the IRC has not received and approved continuation of a research study by the study's current expiration date, research activities must stop. No new subjects may be enrolled in the study, no research procedures can be performed, and no research data can be collected. A notice of study expiration is sent to the PI and to the department chair by the office of the IRC. A new, complete application must then be submitted to and approved by the IRC prior to continuation of an expired study.

If there is a lapse in approval due to late Continuing Review

The IRC and investigators must plan ahead to meet required Continuing Review dates. If a PI has failed to provide Continuing Review information to the IRC or the IRC has not reviewed and approved a research study by the approval expiration date specified by the IRC, the research must stop, unless the IRC finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur.

When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRC, IRC approval expires automatically. Such expiration of IRC approval does not need to be reported to OHRP as a suspension of IRC approval under HHS regulations.

Reporting of Adverse Events (AEs) and Serious Adverse Events (SAEs)
Adverse Events (AE) are defined as "unanticipated problems involving risks to subjects or others". An Unexpected Adverse Drug Experience (for FDA regulated studies) is defined as "any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure or the general investigational plan". In addition, certain protocols may define in advance certain events as Adverse Events to be reported, e.g., discontinuation of a study medication. Alternatively, an event which would otherwise meet the definition of Adverse Event may be specified in advance as a study end point: e.g., readmission to the hospital. All definitions should be used to define adverse events that must be reported to the IRC. Note that problems involving risks to subjects or others include not only biomedical risks, but also risks of breach of confidentiality. Thus an event, such as the theft of a computer containing research data including subject identifiers, would qualify as an adverse event. In addition, problems with study procedures; subject or family complaints regarding recruitment, confidentiality concerns, or conduct of the study; expressions of fear or emotional upset; and theft or loss of study data are also considered adverse events.

Serious Adverse Event (SAE) includes any event that results in any of the following outcomes:

- ☐ Death
- ☐ A life-threatening adverse event
- ☐ Inpatient hospitalization or prolongation of existing hospitalization
- ☐ A persistent or significant disability/incapacity
- ☐ A congenital anomaly/birth defect.
- ☐ An event that requires medical or surgical intervention to prevent one of the outcomes above

Serious adverse events that occur at the local research site (rather than those that occur at other sites in a multi-center study) that are unexpected or unanticipated and are potentially related to the research must be reported by telephone, fax, or email to the IRC office within 24 hours of the occurrence of the event or of the investigator being notified of the adverse event. A written report must be submitted to the IRC within 10 working days. If the adverse event necessitates a change in the informed consent, a copy of the proposed revised informed consent form must be included with the report.

Serious adverse events that are either expected (stated in the risk section of the informed consent form or in the investigator's brochure) or are unrelated to the research must be reported to the IRC promptly.

In addition to reporting to the PPH IRC, serious adverse events must be reported to the study sponsor and/or appropriate federal agency, when appropriate.

- ☐ If the study involves an FDA regulated test article (IND or IDE held by the sponsor) investigators must notify the study sponsor. Investigators should check

study protocol and procedure manual for details on what needs to be reported, how soon, and to whom.

☐ If the study involves an FDA regulated test article (IND or IDE held by the investigator), the investigator must notify the FDA directly. He/she may also need to notify the entity that holds the original IND for the investigational product being tested.

☐ For NIH-funded research, investigators are instructed to consult their Project Officers (different Institutes have different reporting requirements).

When SAEs are reviewed by the IRC Chair, he/she will determine within 2 working days whether the study should be suspended. If the study is suspended, IRB Director will notify the Institution and the PI within 2 working days. The IRC Chair will notify the sponsor, OHRP, and, if appropriate, FDA that the study has been suspended. This notification will occur within 5 working days.

Different types of unanticipated problems require different types of further investigation by the IRC. For unanticipated problems that are not adverse drug or device events, investigation appropriate to the problem will be conducted. After investigation, if the unanticipated problem warrants, the IRB Chair will send a final report to the Institution. The final report shall describe the IRC's action in response to the unanticipated problem including study suspension or termination, consent form or protocol modifications, any corrective action plan, or IRC intensive monitoring plan. The IRC Chair will send the final report to the PI, the Sponsor/Grantor, OHRP, and, if appropriate, FDA. This notification will occur no later than 5 working days after receipt of the final report. The notification shall include the final report describing the IRC's action in response to the unanticipated problem including study suspension or termination, consent form or protocol modifications, any corrective action plan, or IRC intensive monitoring plan.

Adverse events (non-serious) are reported to the IRC at the time of the Continuing Review reporting.

If adverse events have occurred between the time of the most recent Continuing Review Report and the time the protocol is closed, a list of adverse events must be included in the Final Report of a protocol to the IRC. The Continuing Review Form is to be completed as the Final Report of a protocol to the IRC.

Adverse events must continue to be reported for a minimum of 30 days following completion of subject's participation. However, if the protocol requires an extended reporting period, the investigator must also forward the reporting findings to the IRC. If follow-up information is available for an adverse event it must also be forwarded to the IRC. If subjects are to be notified of an adverse event, a copy of the proposed notification letter must be included in the submission to the IRC.

All information regarding adverse events (AEs and SAEs) that is reported to the sponsor and/or to the FDA must also be reported to the IRC.

Requesting IRC Approval for Amendments and Modifications to Protocols

Investigators are notified in their IRC approval letter that all changes that are not necessary to eliminate apparent immediate hazards must not be initiated without prior IRC review and approval. Study changes cannot be initiated without approval by the IRC.

PIs must promptly request from the IRC approval for proposed changes in research activity by written communication. This written communication should include complete and detailed documentation as to what changes or modifications are being proposed and the justification, as well as an assessment of the impact of the changes on the risks to subjects. These changes must be approved by the IRC prior to implementation. All amendments, advertisements or other changes (including minor consent form changes) are reviewed, findings are documented in IRC minutes and written notification of the IRC decision is provided to the PI. Audits may be conducted by the IRC if there is reason to suspect a change in protocol has occurred without IRC approval. The IRC Chair will appoint a Committee member to be responsible for these audits. A report of the audit findings will be presented to the IRC upon completion.

Reporting Protocol Deviations
Protocol deviations must be promptly reported to the IRC when the PI becomes aware that they have occurred. A summary of protocol deviations is completed by the PI on the continuing review report.

Frequent or serious protocol deviations can be a reason for the IRB to institute an audit of a research protocol.

Submitting a Final Report
Investigators are required to notify the IRC when their studies are completed using the Continuing Review form. The PI is required to check the appropriate box and provide the necessary information on the final form. Any presentations or publications of study findings must be included with the final report.

Maintaining Research Records
It is the responsibility of the PI to maintain all study related records according to federal requirements. All signed informed consent forms must be retained after the end of the study for a period of three years by the Principal Investigator.

The IRC retains the right to inspect any and all research records at any time during the active stage of the study, during follow-up and after the study has been closed. The IRC may conduct unannounced audits of research at any time. Failure to allow an audit by the IRC could result in termination or suspension of the research project by the IRC.

Transferring a Protocol to Another Investigator
If a PI leaves PPH or does not renew his/her medical staff membership all of his / her approved research studies must be transferred to another medical staff member with admitting privileges at the appropriate facility or closed.

When an investigator chooses to transfer his status as PI on an approved protocol to another investigator, the IRC must be notified. The new investigator must be eligible to serves as a PPH Principal Investigator (PI). To effect this transfer, an Amendment letter that includes a statement that the protocol should be transferred to another investigator who will take over responsibility for the research, must be submitted to the IRC. This letter is co-signed by the existing PI and the new PI. Appropriate changes to consent forms, recruitment materials, etc. must also be submitted to the IRC when transferring a protocol. The Office of the IRC will notify the existing PI and the new PI in writing when the amendment is approved.

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VII. Research Protocols

Preparing a Protocol for Submission to the IRB
All protocols must be submitted to the PPH IRC by following the PPH IRC Submittal Guidelines which may be obtained by contacting the IRC office in the Medical Staff Services office at Palomar Medical Center.

Protocol Submission
Following the instructions in the PPH IRC Submittal Guidelines, investigators must submit (as appropriate for the study) the indicated number of copies of the following to the PPH IRC office (located in the Medical Staff Services office at Palomar Medical Center):

- Protocol Abstract
- Study Protocol
- Consent Form(s)
- Investigator's Brochure and/or Device Manual
- Form 1572
- Disclosure of Position/Affiliation/Financial Interest form
- Study Contact Information form
- Reference Materials for Nursing Units form
- Clinical Research Coordinator Credentialing sheet (if applicable)
- Clinical Research Coordinator Confidentiality Agreement (if applicable)
- Curriculum Vitae of Principal Investigator
- IRC Submittal Fee
- Medication Summary Sheet
- Clinical Investigation Agreement for PPH
- List of Study Specific Tests/Procedures/Medications
- HIPAA Security and Privacy Rules Confirmation Statement
- Recruitment Materials and Advertisements – to include any advertising or publicity information such as recruitment letters, flyers, posters, public service announcements, newspaper, radio and television advertisements and internet content seeking subjects for research
- Questionnaires, interview scripts, subject diaries – any document that will be used by subjects or by research staff to obtain information from subjects
- Documentation of completion of the National Institutes of Health computer based training on Protecting Human Subjects for Researchers and Research Staff

The PPH IRC staff will review the submission for completeness and ask the PI to submit any missing elements, if applicable. The packet will then be referred to the Chairman of the Committee for determination whether the subsequent review should be full-board or expedited. For full-board reviews, submissions are scheduled for the next regularly scheduled meeting of the Committee and sent to each member of the Committee prior to the meeting.

The following elements must be included with the PPH IRC application:

- Title of the study
- Purpose of the study
- Funding sponsor of the study
- Study protocol containing a complete study protocol. If the protocol is submitted for review and the panel members believe that there is insufficient information to enable an appropriate review, a request for additional information may be made to the PI.
- Results of previous research
- Subject inclusion/exclusion criteria

- Justification for use of any special/vulnerable subject populations and/or justification for exclusion of any particular groups
- Study design, including justification for the proposed sample size
- Description of procedures to be performed and identification of which ones are being done for research purposes only
- The methods of identifying and contacting potential subjects
- The processes for obtaining informed consent, including setting, subject autonomy concerns, language interpretation issues and vulnerable populations issues
- The procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses, waiver of consent, translation of forms and informed consent form storage
- Compensation to subjects for their participation, and justification
- Compensation for research-related injury
- Provisions for the protection of subject's privacy and confidentiality of data
- Extra costs to the subjects for their participation in the study
- Extra costs to third party payers because of subject's participation
- A clear statement that this is research and not treatment
- A statement about the purpose of the research
- The eligibility criteria (summary form)
- Time commitments and other commitments for subjects
- The location of the research
- The name, telephone number, address and email address of a contact person or office

Signatures Required
All IRB applications require the signature of the Primary Investigator. Rubber stamped and proxy signatures on the application are not accepted.

Other Reviews Required
Following review and approval by the PPH IRC, all protocols are required to be reviewed and approved by the Executive Committee(s) of the appropriate facility where the research will be conducted. The Executive Committee(s) will forward their findings to the IRC office and may approve, require modification or disapprove proposals. In addition, an administrative review process will be conducted to ensure that appropriate resources are available to conduct the study at PPH. Studies which may have a financial and/or resource impact on PPH facilities and departments may not proceed until after administrative approval is obtained. Principal Investigators should prepare a statement of financial and resource impact of the study for presentation with any study related materials to the Medical Staff Services office. Administrative review shall include the establishment of an institutional billing account for billing of any study specific charges for lab, imaging and other services along with the completion of in-service education for at least 90% of the affected staff prior to implementation of any protocol.

Clinical Research Coordinators and other study staff who will have contact with patients within Palomar Medical Center and/or Pomerado Hospital must be credentialed as Allied Health Professionals through the Medical Staff Services credentialing process. The credentialing process will take approximately 90 days to complete, once the complete application has been received by the Medical Staff Services office. Applications for this process may be obtained from the Medical Staff Services office at Palomar Medical Center.

Approval by the Executive Committee(s) or completion of Administrative Review does not constitute IRC approval and all proposals must be reviewed by the IRC. Additionally, any modifications that are required or recommended by either the Executive Committee(s) or under the Administrative Review process must go through the IRC review procedure for further approval of the modifications.

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VIII. Informed Consents

Federal Regulations regarding Informed Consent
Federal regulations require that no investigator may involve a human being as a subject in a research project without obtaining legally effective informed consent of the person or the person's legally authorized representative (LAR). The investigator must provide the prospective subject or the LAR sufficient opportunity to consider whether or not to participate and must minimize the possibility to coercion or undue influence. The information that is given to the subject or LAR shall be in language understandable to the subject or LAR.

21 CFR 50.25(a) and 45 CFR 45.116 require that the elements of informed consent criteria be met. A checklist of elements required elements is available from the PPH IRC office.

Elements of Informed Consent
The following are required elements in an informed consent form (ICF):

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

☐ A description of any reasonably foreseeable risks or discomforts to the subject.

☐ A description of any benefits to the subject or to others that may reasonably be expected from the research.

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.

☐ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the IRB, the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, the sponsor (and others, as appropriate) may inspect the records.

☐ For research involving more than minimal risk, an explanation as to whether any compensation and/or an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

☐ An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

☐ A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

☐ When appropriate, a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

☐ When appropriate, anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

☐ When appropriate, any additional costs to the subject that may result from participation in the research.

☐ " When appropriate, the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

☐ When appropriate, a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

☐ When appropriate, the approximate number of subjects involved in the study.

The IRB review focuses on the informed consent form and assures inclusion of required elements. All consent forms must be in the format that the IRC dictates.

Review of Informed Consent
The IRC reviewers review the informed consent form using the Informed Consent checklist of required and optional elements (45 CFR 46.116 and 21 CFR) (See Appendix "C"). Changes are marked on the informed consent form and returned to the Principal Investigator for revision. Once the informed consent form is modified and approved, the PI is sent a validated copy, stamped with the date of the IRB approval. All signed informed consent forms must be retained after the end of the study for a period of three years by the Principal Investigator.

Informed Consent Categories

Written Consent
Informed consent must be documented on a stamped PPH IRC approved consent form unless these requirements are specifically waived or modified by the IRC. The consent form (ICF) must be signed and dated by the subject or his/her legally authorized representative. The expiration date on the ICF is the last day of the current IRC approval. The date of the subject's signature on the ICF must be prior to the expiration date stamped on the ICF.

Waiver of Documentation of Consent
Federal regulations permit an IRC to waive the requirement for the PI to obtain a signed consent form for some or all subjects if the IRC finds and documents in the minutes either

☐ That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach in confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subjects' wishes will govern;
or

☐ That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Waiver of documentation of consent is granted by the PPH IRC on a case-by-case basis. It is not permitted except in those rare instances in which the above criteria apply and in which the research could not practicably be carried out without the waiver. In cases in which the documentation requirement is waived, the IRC may require that the PI provide subjects with a written statement regarding the research. The rationale for requesting the waiver of documentation of consent must be justified in the IRC submission.

Waiver of Consent in Non-Emergency Research

The PPH IRC can approve a request for waiver of the informed consent procedure either by the expedited or convened full board process. In order to qualify for waiver of informed consent the research study must fulfill all of the following (four) criteria

- ☐ The research must present no more than minimal risk of harm to subjects (see Appendix C for definition of minimal risk);
- ☐ The waiver will not adversely affect the rights and welfare of the subjects
- ☐ The research could not practicably be carried out without the waiver
- ☐ Whenever appropriate, the subjects will be provided with any additional pertinent information after participation.

Waiver of consent is allowed by the IRC on a case-by-case basis. IRC review (whether expedited or full board) must ensure that each protocol satisfies each of the above criteria. In instances where consent is waived, it is still essential that appropriate procedures for maintenance of confidentiality be described in the protocol.

Informed Consent for Non-English Speakers

Special issues arise in situations when the research subjects do no speak or read English. Federal regulations require that informed consent be presented "in language understandable to the subject" and be documented in writing. Whenever possible, the documentation must be in the form of an informed consent written in a language understandable to the subject that embodies all of the elements of informed consent. The Principal Investigator must translate the consent form if subjects expected to be enrolled are not fluent in written English. A completely translated copy of the informed consent and a complete translation done by a certified translators must be submitted to the IRC before the translated ICF is approved. Expedited review of these versions is done if the protocol and the full English language ICF have already been approved. The PI must provide in writing to the IRC the qualifications of the persons who completed the translation of the documents.

Short Form Consent

In accordance with 45 CFR 46.117 (b)(2) and 21 CFR 50.27(b)(2), the PPH IRC allows the use of a short form written consent document. Short form consents, for use with non-English speaking subjects or illiterate (non-English reading) subjects may only be used with specific IRC approval. Use of the written short form consent must include documentation stating that the required elements of informed consent have been presented orally to the subject or his/her legally authorized representative (LAR) in their language. Expedited review of the short form is allowed if the protocol, the full English language version of the ICF, and the English version of the short form document have already been approved by the IRB. The IRB must approve a written summary of what will be said to the subject or the LAR. The short form is signed by the subject or LAR and the person who provided the oral translation. A copy of the summary along with a copy of the short form must be given to the subject or LAR.

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IX. Special Populations

Special Populations

Federal regulations require that special consideration be given to protecting the welfare of particularly vulnerable subjects. In general the regulations allow approval of research that is of minimal risk or that will benefit these subjects directly. However, the regulations require special safeguards, particularly with respect to obtaining informed consent.

Children

Children are defined as persons "who have not attained the legal age for consent to treatments or procedures involved in the research". The PPH IRC generally considers all subjects under the age of 18 as children. All studies that involve, or will potentially involve children must be identified by the PI at the time of submission of a protocol to the IRC. If children are to be added as study subjects after initial IRC approval, then the PI must submit an amendment describing how the children will be involved in the research and the potential risks to these subjects. In all protocols involving children as subjects, the research must be classified into one of the four following categories. For those studies approved by full convened board, the minutes must reflect the category under which the protocol was approved together with the protocol specific findings which justify application of that category. The four categories of research involving children are based on degree of risk and benefit to the individual subjects:

- **Category 1:** Research involves no greater than **minimal risk**. (see Appendix C for definition of minimal risk)
- **Category 2:** Research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects. Category 2 can only be approved if (1) the risk is justified by the anticipated benefit to the subjects **and** (2) the relation of the anticipated benefits to the risk is at least as favorable to the subjects as that presented by available alternative approaches
- **Category 3:** Research involves greater than minimal risk with no prospect of direct benefit to individual subjects. Category 3 research can only be approved if (1) the risk represents a minor increase over minimal risk; (2) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; **and** (3) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding of the subject's condition
- **Category 4:** Research that does not fall into one of the three above categories, but which the IRC determines presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research in this category cannot be approved by the IRC without the approval of the Secretary of HHS.

Only research in Category 1 can be approved by the Expedited Review process since research must present no more than minimal risk to qualify for Expedited Review.

Assent and Permission

For research involving children as subjects the IRC must ensure that the study includes procedure for obtaining the assent of the child, if appropriate, as well as the permission of the parent(s) or legal guardian(s).

Assent refers to the child's agreement and must be solicited if the child is aged seven years or older when the IRC determines the children are capable of providing assent. To determine this, the IRC takes into account the ages, maturity, and psychological state of the children involved. If the IRC determines that the

capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition of proceeding with the research. Even where the IRC determines that the subjects are capable of assenting, the IRC may still waive the assent requirement under circumstances in which consent may be waived.
To elicit assent the child must be provided with a fair explanation of what participation will involve. Children with reading skills sufficient to understand the consent form may be invited to sign the form. The child may sign a signature line next to the parent(s) signature, or the IRC may require a separate assent form. The IRC must determine the extent to which consent is required. In some instances a minor legally may be considered an "emancipated minor" (e.g. a pregnant minor) and can consent on his/her own behalf without parental involvement. It is the responsibility of the IRC to determine whether this is allowed.

Permission
After review of the research the IRC must determine whether the permission of one parent or two parents (or legal guardians) is required. For Categories 1 & 2, the permission of one parent is usually sufficient (although the IRC may, at its discretion, require the signature of both parents). For Categories 3 & 4 the permission of two parents is required (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child).

Prisoners
Federal regulations (45 CFR 46 Subpart C) require that an IRC must be constituted with at least one member who participates in reviews who is a prisoner or prisoner representative in order for the IRC to review research involving prisoners as subjects. The PPH IRC does not currently have a member who is a prisoner or prisoner representative and therefore does not currently review research involving prisoners as subjects.

Pregnant Women, Fetuses, or Neonates
Approval Criteria
Review of research involving pregnant women, human fetuses, or neonates must include the following:

- Where scientifically appropriate, preclinical studies (including animal studies or non-pregnant women studies) to provide risk assessment data for pregnant women and fetuses
- Prospect of benefit:

  1. the sole cause of fetal risk is intervention or procedures that hold out prospect of direct benefit for the woman or the fetus
  2. If no prospect of benefit than the risk to the fetus must not be greater than minimal AND the purpose is development of important biomedical knowledge which cannot be obtained by any other means
  3. any risk is the least possible for achieving the objectives of the research

Informed Consent
Maternal Consent

- Research holds out prospect of direct benefit for the woman or the fetus
- Research holds out prospect of direct benefit for both woman and fetus
- No prospect of direct benefit to either woman or fetus; risk to fetus is not greater than minimal; purpose of the research is development of important biomedcal knowledge that coannot be obtained by any other means

Maternal AND Paternal Consent

- Research holds out prospect of benefit solely to the fetus

- Paternal consent not required if father unable to consent because of unavailability, incompetence, temporary incapacity or pregnancy resulted from rape or incest

Pregnant Children

- Permission and assent is required as in Subpart D (Children's Regulations)

Other Informed Consent Requirements

- No inducements, monetary or otherwise may be offered to terminate the pregnancy.
- Individuals engaged in research must have no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.
- Individuals involved in the research must have no part in determining the viability of a neonate.

Research Involving Neonates
Neonates of Uncertain Viability and Nonviable Neonates : Approval Criteria

- Where appropriate, preclinical studies (including animal studies or non-pregnant women studies) to provide risk assessment data for neonates
- Consenting individual is fully informed about reasonably foreseeable impact of research on the neonate
- Individuals engaged in research have no part in viability determination
- Following additional rules applicable to each viability category

Neonates of Uncertain Viability
The conditions for research prior to viability determination are that the IRC must find

- That the research holds out prospect of enhancing probability of survival to viability with least possible risk to achieve that objective OR
- The purpose of research is development of important biomedical knowledge not obtainable by other means and there is no added risk to the neonate
- The informed consent is obtained from either parent or parent's legally authorized representative (with rape/incest exception)

Nonviable Neonates
The conditions for research in nonviable neonates are

- Vital functions are not artificially maintained
- Research will not terminate heartbeat or respiration
- No added risk to the neonate results from research
- The purpose is to develop important biomedical knowledge not obtainable by other means
- The informed consent is obtained from both parents except if one parent is unavailable, incompetent, or temporarily incapacitated; the father's consent is not required for pregnancy from rape/incest; 46.116 © and (d) waiver/ alteration is NOT applicable; legally authorized representative of either or both parents is NOT sufficient

After Delivery Research on Placenta, Dead Fetus, or Fetal Material

- Other Federal, State, or local laws

- Research subjects: individuals identifiable through information associated with after delivery placenta, dead fetus, or fetal material, directly or indirectly through linkers.

Decisionally Impaired Persons

The use of decisionally impaired persons as research subjects presents a risk that their disability may compromise their capacity to understand the information presented during the consent process and their ability to make a sound decision as to whether to participate in the research. For this reason the PPH IRC may make additional requirements to ensure protection of these subjects.

Employees

The PPH IRC aims to ensure that a subject's decision to participate in research is truly **voluntary** and that there is no coercion for persons to participate in research. Employees may be vulnerable to "subtle inducements to participate" in research by such methods as promises of academic rewards, professional achievement, vacation time, etc. Therefore, the PPH IRC requires that additional protections be in place in research studies where these persons will be recruited as subjects. Generally, PIs who intend to recruit employees as subjects are required to clearly define the subjects to be enrolled, the rationale for their participation and the proposed method for their recruitment. Employees should not be the sole recruitment target unless the research objective is to study this population. The Director from the applicable department must be notified of the proposed research use of the employees as subjects and must provide written approval to the IRC. Employees directly employed by the PI or co-PIs may not be used as subjects without the expressed permission of the IRC. Due to the increased risk of loss of confidentiality, the PI must also explain in the protocol the methods to be used to protect these subjects' identities in the research data.

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X. IRB Procedures for the Review of Protocols and Amendments

Conducting Initial and Continuing Review
The PPH IRC, through its review of new protocols and its oversight of ongoing protocols, protects the safety of human research subjects by ensuring that:

☐ The protocol is scientifically appropriate and the degree of risk to the human subjects is justifiable.

☐ Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risks, and whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

☐ The risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects, the general public, and science, and the importance of the knowledge that may reasonably be expected to result. (In evaluating risks and benefits, the PPH IRC will consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.)

☐ Selection of subjects is equitable.

☐ Legally effective informed consent will be obtained from research subjects or legally authorized representative(s) and will be documented in accordance with applicable regulations.

☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

☐ Vulnerable populations are protected and that they are not being coerced, or otherwise taken advantage of. Vulnerable populations include those identified in 45 CFR 46.111 and 21 CFR 56.111, as well as any groups of subjects identified through knowledge of local research context.

☐ All changes to approved research protocols are promptly reported to the IRC and that all new procedures are not initiated without review and approval from the IRC except to eliminate apparent immediate hazard to human subjects under the existing protocol.

☐ The safety of research subjects is maximized.

☐ Continuing review be scheduled at an interval based upon degree of risk and the risk/benefit analysis. The Continuing Review intervals are documented in the minutes, approval letter and PPH IRC files.

☐ " Serious Adverse Events or Unanticipated Problems involving risk to human subjects or others are reported to the IRC, and if applicable, to the sponsor, FDA, OHRP, or other appropriate regulatory agencies. The IRC will also promptly report serious or continuing noncompliance with IRC requirements or federal regulations and any suspension or

termination of research privileges to the Institutional Official and to the sponsor, FDA, OHRP or other appropriate regulatory agencies.

Types of Review

Full Board Review
All protocols not eligible for expedited approval are responsible for review of all protocols submitted to the PPH IRC. The review will include at least the following (as appropriate for the study):

- IRB application including a protocol summary in lay language and supplemental materials as needed. Information contained herein must be sufficient to address all of the criteria for approval of research [45 CFR 46.111 and 21 CFR 56.111]
- A proposed informed consent form
- All recruitment materials and scripts
- All survey instruments, questionnaires and interview scripts
- A complete research protocol
- Any relevant federal grant application or federal contract proposals
- Any relevant Investigator Brochures for investigational drugs, medical devices, or biologic agents
- Any additional relevant information required to address criteria of approval
- Additionally, if the research is a clinical trial that is being conducted as an HHS-supported multi-center trial, the IRC receives and reviews a copy of the HHS-approved sample informed consent document and the complete HHS-approved protocol, if they exist

For **continuing reviews and amendments**, all members of the Committee receive the Continuing Review Progress Report (protocol information, accrual information, accrual categories, adverse event information, subject complaints, amendment information, protocol deviations, a summary of unexpected events and protocol findings information), initial application including recruitment materials, research protocol, informed consent document, amendment descriptions and approval letter(s). The investigator attends the meeting and presents a summary of the information to the Panel for discussion and vote during a regularly convened meeting.

All Committee members shall receive all relevant documentation necessary to make the determinations required in 45 CFR 46.111 and 21 CFR 56.111.

Expedited Review
An Expedited Review may be conducted at the discretion of a panel Chair by a Chair, or experienced Panel member, in accordance with the criteria defined in the Federal Register Vol. 63 November 9, 1998 (See Appendix A for complete text.). Applications are eligible for an expedited review if they involve no more than minimal risk and the only involvement of human subjects is in one or more of the categories authorized in 45 CFR 46.110 and 21 CFR 56.110. In addition, research that is defined as exempt from federal regulation in 45 CFR 46 101(b) will be reviewed by the expedited procedure.

The person performing the expedited review exercises full IRC authority except may not disapprove the research. The expedited review process may not be used to circumvent the normal review process. IRC members are informed of research that was approved by Expedited Review through listings of these approvals in the IRC meeting agendas and documentation in the minutes.

Continuing reviews may be conducted using the expedited review process if the protocol was originally reviewed using expedited review; if the protocol has not yet enrolled any subjects and no additional risks have been identified; if subject accrual is permanently closed, intervention is complete, and the remaining research is limited to long-term follow-up; or if remaining research activities are limited to data review and analysis.

When conducting an expedited continuing review, the IRC Chair or designee will receive and review a full protocol including any modifications previously approved by the IRB, informed consent form, a status report on the progress of the study, including the number of subjects recruited, summary of any adverse events, unanticipated problems, withdrawals and complaints since the last review.

The PPH IRC does not routinely use subcommittees for reviews. Special-expertise subcommittees may be convened if necessary.

Exempt from review
The PPH IRC does not recognize as exempt from IRC review those categories of research defined as exempt from federal regulation as defined in 45 CFR 46.101((b). Research fitting those categories must be reviewed and approved by the IRC.

Review of Informed Consent Forms
The Committee members review the informed consent form using the Informed Consent checklist of required and optional elements (45 CFR 46.116 and 21 CFR). Changes are marked on the informed consent form and returned to the Principal Investigator for revision. Once the informed consent form is modified and approved, the PI is sent a validated copy, IRC approval date ("valid from").

Review Decisions
The IRB may vote to approve, conditionally approve, defer, or disapprove all research activities.

> **Approval** indicates that the submission has been approved as submitted requiring no changes, additions, or modifications.
>
> **Conditional Approval** indicates that only minor clarifications are required in the submission and revisions require only simple concurrence by the investigator. The IRC Chair or the Chair's designee may subsequently approve on behalf of the IRC under an expedited process a research protocol that has been revised in response to a conditional approval (i.e., where revisions require only simple concurrence by the investigator and the investigator concurs). With a conditional approval, the PI must respond in writing specifically to each IRC comment point by point. If the revisions requested by the IRC are not received within 90 days after the date of the IRC notification, then a warning letter will be sent to the PI. The warning letter will notify the PI that he has 15 business days to respond in writing with the revisions or the proposal will be removed from consideration. In extenuating circumstances, the PI may submit a written appeal to the IRC Chair for an extension to the 90-day submission deadline for revisions to conditional approvals.
>
> **Deferral** indicates that the IRC panel has requested substantive clarifications or modifications regarding the protocol or informed consent documents that are directly related to the requirements under 45 CFR 46.111. A subsequent review by the convened IRC of the revised material is necessary to determine approval. If an IRC application is deferred, the revised submission must be submitted for full board review. With a deferral, the PI must respond in writing specifically to each IRC comment point by point. If the revisions requested by the IRC are not received within 90 days after the date of the IRC notification, then a warning letter will be sent to the PI. The warning letter will notify the PI that he has 15 business days to respond in writing with the revisions or the proposal will be removed from consideration. In extenuating circumstances, the PI may submit a written appeal to the IRC Panel Chair for an extension to the 90-day submission deadline for revisions to conditional approvals.
>
> **Disapproval** indicates that the IRC has found major flaws in the design of the research, or other problems so great, that they determine that the study must be redesigned to address the issues. In this case, a new application must be submitted with the re-designed study. Protocols can not be disapproved by the expedited process; they must be reviewed by a convened full board. Investigators whose protocols are disapproved may appeal this decision by responding in writing, and may request an opportunity to appear before the IRC.

Determining Studies That Require Review More Often Than Annually

The IRC conducts review of research at intervals appropriate to the degree of risk, but not less than once a year. Continuing Review is required as long as the research remains active for long-term follow-up of subjects. Continuing Review is also required when the remaining research activities are limited to data analysis.
The IRC may determine that certain studies must be reviewed more often than once a year based upon the initial review or continuing review (e.g. 3 months, 6 months, 9 months, or 12 months). Additionally, the IRC may require review after a predetermined number of subjects have been enrolled into the protocol. The IRC minutes will document the specific review interval, as will the IRC approval letter. Studies that might be considered for review intervals of less than one year include, but are not limited to:

☐ The use of vulnerable populations, including those identified in 45 CFR 46.111(b) and 21 CFR 56.111(b) as well as cognitively impaired persons or others determined to be vulnerable by the IRC

☐ The withdrawal of standard treatment or therapy regardless of replacement by experimental treatment, when there is a high risk of mortality or morbidity

☐ Significant risks or potential serious impairment to the subject

☐ Risk when there is no potential clinical benefit to the subject

☐ Invasive surgical procedures

☐ Gene transfer research

☐ Phase I studies

☐ Research by investigators who have required corrective action in previous studies

Notification of Investigators
The IRC promptly reports all findings and actions in writing to the Principal Investigator and, if required, to a sponsor or regulatory agency. These include written communication from the IRC to the Principal Investigator for additional information, for conveying IRC findings and for acknowledgment of notifications received. IRC records and communications are maintained in permanent study files located in the IRC office. After the close of the study, files are maintained for a minimum of three years, or longer if required for a particular study.

The IRC Approval Letter includes the following information about approval and conditions of approval:

1. Study protocol name (with version number and/or date)
2. Notice of approval
3. Date of approval
4. Duration of Approval (not more than one year)
5. A statement that no modifications are to be made without prior IRC approval
6. A statement that the IRC must review all recruitment materials before they can be used
7. The requirements to report all adverse reactions, amendments/modifications to the protocol, protocol deviations, or study termination to the IRC in a timely manner.
8. Continuing review requirements
9. Notice that the protocol may be audited at any time
10. Requirement to retain study-related documents (including informed consent forms and protocol) for at least 3 years after the completion of the study.

Approval letters are sent to the Principal Investigator and a copy is sent to the study coordinator, as appropriate.

Investigator's Right to Appeal
If an IRC application is disapproved, the reasons for disapproval will be conveyed to the investigator in writing. The investigator may request the IRC to reconsider by responding in writing, and may request an opportunity to appear before the IRC.

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XI. Compliance Oversight of Research

Quality Assurance Audits of Research

The IRC has the responsibility to oversee the conduct of research that it approves. Consistent with this responsibility, the IRC may audit research studies at PPH or studies in which faculty and/or staff of PPH are engaged in research outside the institution. The Director of Corporate Compliance is responsible conducting audits at PPH. The Director of Corporate Compliance reports administratively to the Chairman of the IRC and has accountability to the Chairman for the research audits.

Situations that may warrant audit include, but are not limited to:

- ☐ A study conducted by an investigator who previously failed to comply with federal regulations or IRC policies
- ☐ Randomly selected projects
- ☐ Complex projects involving unusual levels or types of risk to subjects
- ☐ Projects where continuing review information suggests that possible material changes occurred without IRC approval
- ☐ Studies not otherwise monitored (e.g.; single center, investigator initiated, unfunded, etc)
- ☐ Locally manufactured drug, biologic, or device
- ☐ Investigator-held IND or IDE
- ☐ Gene transfer research
- ☐ Investigator or research staff financial conflict of interest
- ☐ Institutional financial conflict of interest

During the course of an IRC audit information may be gathered from multiple sources including, but not limited to;

- ☐ Incident reports
- ☐ Radiation safety or source documents
- ☐ Families of research subjects
- ☐ Research staff
- ☐ Research subjects

- ☐ Research subject surrogates
- ☐ Sponsors

Non-Compliance
As a result of an IRC audit, or in the course of routine IRC business, incidents of noncompliance by investigators with federal regulations or PPH IRC policies may be identified. When these situations occur they are brought to the attention of the PPH IRC Chairman. The incidents of non-compliance are then reviewed and managed in one of several ways depending on the severity of the non-compliance and the determination as to the willfulness of the investigator. For each incident of non-compliance that is identified a plan of correction is documented. Further audit may be required. In order to assess subject risk, the IRC may also seek additional expertise or supervision.

Protocol Deviations
Investigators are required to report protocol deviations to the IRC as soon as they occur or as soon as the investigator becomes aware that they occurred. Protocol deviations are also to be summarized by investigators on the Continuing Review Report. Protocol deviations that are submitted to the IRC office are sent to the Chair for review. They may also be reviewed by the IRC as a whole.

At the time of review the protocol deviation is determined to present either minimal risk or greater than minimal risk to subjects. Minimal risk protocol deviations are reviewed by the Expedited Process. Greater than minimal risk protocol deviations are brought to the full convened board for review.

Discrepancies in Application of Policies or Regulations
The Executive Committee plays a central role in reconciling non-willful discrepancies in the application of policies or regulations. When such discrepancies are discovered, an inquiry into the situation is initiated. This inquiry is reviewed by the Chair. The inquiry may include a meeting with the investigator. A corrective action plan is developed and presented to the IRC for discussion and ratification. Revisions to the plan are made as needed. The final plan is then presented and approved by the IRC prior to allowing the investigator to apply the corrective action plan.

Serious or Continuing Noncompliance
Serious or continuing noncompliance refers specifically to compliance with 45 CFR part 46, 21 CFR parts 50 and 56 or the requirements of the IRC. The IRC may become aware of possible serious or continuing noncompliance in several ways, including

- ☐ as a result of a self-report by an investigator
- ☐ a complaint from a subject or subject's family
- ☐ through an audit (either by IRC auditor or by an auditor representing a sponsor or agency)
- ☐ or from a "whistleblower."

In categorizing noncompliance as serious or continuing, the IRC uses the guidelines outlined in Appendix B. When incidents of potential serious or continuing non-compliance are identified, it is the decision of the IRC Chair to

- ☐ Decide whether the study should be suspended, **AND**

☐ Refer the matter to the IRC to investigate the evidence as to whether serious or continuing noncompliance has occurred. Evidence can include, but is not limited to, study records and data, interviews with the PI, research team, and study subjects.

☐ If at any point during the investigation the weight of evidence indicates that serious or continuing noncompliance is likely and/or that study subjects are at risk if the study were to continue, the IRC may suspend the study until the end of the investigation.

The Director of Corporate Compliance audits research protocols suspected of noncompliance and reports his/her findings to the IRC Chair. The Principal Investigator is notified in writing of IRC concerns, and is expected to respond, point by point to the concerns in writing. At the conclusion of a sufficient investigation, the IRC Chair reports the findings of the IRC to the Institutional Official, specifying whether noncompliance had occurred, and if it did, the nature of that noncompliance. The Institutional Official provides to the PI and Sponsor/Grantor, OHRP, and, if appropriate, the FDA the results of the investigation. The notice describes the IRC action in response to the finding including dismissal of the concern or allegation, study suspension or study termination; any corrective action plan; or IRC intensive monitoring plan for preventing future noncompliance.

Suspension or Termination of IRB Approval

The IRC may vote to restrict, suspend or terminate an investigator's privilege to conduct research at Palomar Pomerado Health facilities if it finds that research activities are continually (either purposefully or through careless disregard) not being conducted in accordance with federal regulations, state law, or institutional policies governing human research. Any suspension or termination of approval to conduct research at PPH will be conveyed to the Principal Investigator in writing and will include a statement of the reasons for the action.

If the study is suspended or terminated, IRC Chairman notifies the Institutional Official, and the PI within 2 working days of the decision. The suspension or termination notice includes a statement of the reasons for the action. The Institutional Official sends a preliminary notification to Sponsor/Grantor, OHRP, and, if appropriate, FDA that the study has been suspended or terminated. This notification occurs within 5 working days.

When a study is suspended pending further investigation (e.g., of an unanticipated problem or noncompliance), a final report is prepared by the IRC Chairman summarizing the basis for its conclusions, consent form or protocol modifications, and any corrective action plan or IRC intensive monitoring plan. The final report is forwarded to Institutional Official and the PI. The Institutional Official forwards the final report to Sponsor/Grantor, OHRP, and, if appropriate, the FDA.

Any allegations of misconduct in research are referred to the Chairman of the appropriate Department and the Chief of Staff.

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XII . Special Topics

Investigational New Drug (IND)
Any research involving a drug, whether FDA approved or not, requires IRC approval. Drugs or drug combinations which have not been approved require an IND number from the FDA. The IND number must be clearly indicated on the IRB application. Approved drugs being studied for unapproved indications require either an IND or a waiver of the IND. Studies that use an approved drug for an unapproved indication that request a waiver of the IND must meet all of the following criteria of 21 CRF 312.2:

(i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
(ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
(iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
(iv) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
(v) The investigation is conducted in compliance with the requirements of Sec. 312.7.

Investigational Device Exemption (IDE)
Investigational Device Assessment: Significant vs. Nonsignificant Devices: A significant risk (SR) device means an investigational device that presents a potential for serious risk to the health, safety, or welfare of a subject and

1. is intended as an implant, or
2. is used in supporting or sustaining life, or
3. is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health, or
4. otherwise presents a potential for serious risk to the health, safety or welfare of a subject.

If, upon review of the device, and its proposed use in the research, the IRC determines that the device does not meet these criteria for a significant risk device, it shall be classified as a nonsignificant (NSR) risk device. IRC approval must be obtained prior to conducting any clinical research using either a SR or NSR device. Continuing review is required as determined by the IRC.

Emergency Use Notification and Reporting
Drugs and Biologics: The emergency use of an investigational drug or biologic agent with a patient in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRC approval may occur if it is the medical judgment of a physician that it is in the subject's best interest. Any subsequent use of this test article is subject to IRC review and approval.

The physician must notify the IRC Chair prior to this emergency use, but this notification is not to be construed as IRC approval. The patient, or legally authorized representative in accordance with FDA regulations, must sign a consent form. This patient is not considered a research subject and data from this patient may not be included in any report of the research. The physician must submit a written report of this emergency use to the IRB within 5 working days.
Medical Devices: The emergency use of a medical device may occur if the patient is in a life-threatening condition that needs immediate treatment; there is no generally acceptable alternative for treating the patient and there is reason to believe that the medical device will provide a benefit; and because of the immediate need to use the device, there is no time to obtain IRB approval. The physician must notify the IRC Chair and FDA's Center for Devices and Radiologic Health prior to use of the device. These notifications are not to be construed as IRC approval. The patient, or legally authorized representative in accordance with FDA regulations, must sign a consent form. This patient is not considered a research subject and data from this patient may not be included in any report of the research. The physician must submit a written report of this emergency use to the IRC within 5 working days. Any subsequent use of this device is subject to IRC review and approval. A medical device fitting the above procedure includes a device that does not yet have an IDE, or if the proposed use is not approved under an existing IDE, or if the physician or institution is not approved to use this device under an existing IDE.

Humanitarian Device Exemptions
Regulatory Background
The purpose of the HDE law and its implementing regulations (21 C.F.R. Part 814) "is, to the extent consistent with the protection of the public health and safety and with ethical standards, to encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States." [21 C.F.R. §360j(m)(1)] The law prescribes a method that permits a manufacturer to lawfully market a device without meeting the efficacy standards generally required for FDA pre-market approval of devices. After a manufacturer applies for an HDE, meets the regulatory requirements[1] , and obtains FDA approval of HUD status, the HUD may be used in humans. However, the law permits the use of HUDs only in facilities that have a local IRC and provided that the IRC approves the HUD's use in the facility.

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(A)the device is designed to treat or diagnose a disease or condition that effects fewer than 4,000 individuals in the United States,
(B) the device would not be available to a person with a disease or condition referred to in subparagrapg (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and
(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

21 U.S.C.§360j(m)(2)

IRC Responsibilities
The PPH IRC performs initial and continuing review of each HUD. For initial approval of a HUD, full board review is required; however, continuing review may take place under an expedited process. **[Humanitarian Device Exemption (HDE) Regulation, Questions and Answers; Final Guidance for Industry** (July 12, 2001), Food and Drug Administration Center for Devices and Radiological Health]. FDA does not interpret the HDE law to require IRC review and approval for each individual use of the HUD. Thus it states that the law permits "the IRB to approve the use of the device in general, use of the device for groups of patients meeting certain criteria, or use of the device under a treatment protocol." [61 Fed. Reg 33232, 33235 (June 26, 1991)] In addition, if it desires, "an IRB may specify limitations on the

use of the device based upon one or more measures of disease progression, prior use and failure of any alternative treatment modalities, reporting requirements to the IRB or IRB chair, appropriate follow-up precautions and evaluations, or any other criteria it determines to be appropriate." .

Informed Consent
Since the HDE law does not require informed consent and because the FDA has determined that the humanitarian device exemption provides for temporary marketing approval, HUD use does not constitute "research" or an "investigation" which would normally require informed consent [61 Fed. Reg 33232, 33235 (June 26, 1991)]. However, the FDA does not intend for the HUD waiver from 21 C.F.R. Part 56 informed consent requirements to preempt institutional policies that require informed consent.
PPH IRC policy requires written informed consent for the procedure in question unless immediate care is necessary to prevent jeopardy to the patient's life, limb, or mental well being. Importantly, it should be noted that if the manufacturer wants to collect safety and effectiveness data in support of a pre-market approval (PMA) application, the informed consent requirements under Part 56 would apply.

Application of 21 C.F.R. §56.111 Approval Criteria
The PPH IRC may minimize or ignore certain approval criteria when evaluating a HUD at the discretion of the Panel and the Chair(s). Although the requirements of 21 C.F.R. Part 56, including continuing review apply, "an IRB evaluating a HUD retains the discretion to minimize or ignore approval criteria that may be inappropriate in the treatment context (e.g., 'the importance of the knowledge that may be expected to result')." [61 Fed. Reg 33232, 33240]

Emergency Use of a HUD
In an emergency, a physician can use a HUD prior to IRB approval if he or she determines that PPH IRC approval "can not be obtained in time to prevent serious harm or death to a patient." 21 U.S.C. §360j(m)(4)(B). In such a circumstance, the physician shall, after the use of the device, notify the Chairman of the PPH IRC of such use. Such notification shall include;

- ☐ the identification of the patient involved
- ☐ the date on which the device was used,
- ☐ and the reason for the use.

Off-Label Use of a HUD
In an emergency, a HUD may be used off-label, but FDA has stated that the emergency use rules for non-approved devices shall apply to HUDs. Namely, the physician should (if possible) seek prior concurrence of the IRC Chairman, informed consent, and an independent assessment from an uninvolved physician. Prior notice to the HDE holder is required. After the use, the physician must report to the HDE holder and to the IRC if not done previously. [For more information see **Humanitarian Device Exemption (HDE) Regulation, Questions and Answers; Final Guidance for Industry** (July 12, 2001), Food and Drug Administration, Center for Devices and Radiological Health].

User Facility Adverse Event Reporting Requirements
PPH IRC has to report to either or both the FDA and the manufacturer.
Death Reported Directly to FDA: "Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information" it must report both the FDA and the manufacturer. 21 C.F.R. §803.30(a)(1)
Serious Injury Reported to Manufacturer: "Reports of serious injury. Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information" must report to the

manufacturer. 21 C.F.R. §803.30(a)(2) If the manufacturer is unknown, the report shall be made directly to FDA.

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Appendix "A"

Categories of Research That May Be Reviewed by the Investigational Revive Committee (IRC) Through an Expedited Review Procedure

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRC through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRCs are reminded that the standard requirements for informed consent (or its waiver, alteration or exception) apply regardless of the type of review—expedited or convened—utilized by the IRC.

(F) Categoreis one (1) through seven (7) pertain to both initial and continuing IRC review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children[2], considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount

drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by non-invasive means.

   Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or was or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records or speciments) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRC as follows:

a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
b. Where no subjects have been enrolled and no additional risks have been identified; or
c. Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[1] An expedited review procedure consists of review of research involving human subjects by the IRC chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRC in accordance with the requirements set forth in 45 CFR 46.110.
[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of jurisdiction in which the research will be conducted." 45 CFR 46.402(a), Source: 63 FR 60364-60367, November 9, 1998.

Palomar Pomerado Health
Investigational Review Committee
Policies and Procedures
Appendix "B"

Examples of Major and Lesser Deficiencies Considered in Assessing Noncompliance*
The following is not an exhaustive list of examples. It is intended to serve as guidance.

IRC DOCUMENTATION:

Major Deficiencies	Lesser Deficiencies
Failure to comply with IRC approval and reapproval guidelines, including: Protocol never approved Initial IRC approval documentation missing Expedited reapproval inappropriate situations Treatment of research subject prior to IRC approval Continuing review approval expired Missing continuing review approval Serious Adverse Events not reported to IRC Missing documentation of full IRC approval of major amendments to protocol	Delayed continuing review for protocols closed to accrual for which all patients have completed therapy Missing documentation of IRC approval of minor amendments to protocol

CONSENT PROCESS:

Major Deficiencies	Lesser Deficiencies
Failure to document properly obtained consent: Research subject signature missing from the signature page of the consent form Consent dated after treatment of research subject Consent not obtained in language fully understood by research subject Consent obtained with incorrect/invalid version of the consent form	Consent does not have date/witness signature Missing pages from the body of the consent form for an individual case Consent form missing research subject identification on each page within the body of the consent form (if missing from the signature page-major deficiency)

ELIGIBILITY:

Major Deficiencies	Lesser Deficiencies
Review of documentation available at time of audit confirms research subject did not meet all eligibility criteria as specified by protocol Eligibility documentation missing Unable to confirm eligibility	Small variations of criteria with reasonable explanation/approval

EVALUATIONS:

Major Deficiencies	Lesser Deficiencies
Tests of major importance not performed prior to, during, or following therapy, including protocol specified lab tests, physical exams and diagnostic studies Unacceptable frequency of lesser deficiencies	Missing a small number of minor tests prior to, during or following therapy

TREATMENT:

Major Deficiencies	Lesser Deficiencies
Incorrect study drug/device used Inappropriate administration of non-protocol medication Failure to modify dose/device according to protocol, especially where doses/devices are expected to have a major impact on outcome Failure to dose reduce in face of severe toxicity Failure to dose escalate on a dose-intensification study Inappropriate dose reduction on a dose intensity study Repetitive or systemic errors in dosing Repetitive or serious errors in dosing, timing or scheduling Wrong route of administration Failure to document drug administration Error in concomitant medications	Wrong antiemetic given as per protocol Wrong dose with error within 10% Wrong timing of dose (with acceptable explanation of delay)

RESPONSE:

Major Deficiencies	Lesser Deficiencies
Failure to assess disease status according to the required protocol guidelines either pre-therapy or in response to treatment Failure to obtain baseline protocol required scans to document pre-therapy measurements Failure to obtain the required scans/measurements to document response as specified by protocol Claimed response cannot be verified Inaccurate assessment of response	Missing minor measurements Missing one of several measurements used to assess response and scans unavailable for referral

TOXICITY:

Major Deficiencies	Lesser Deficiencies
Failure to obtain the required protocol baseline studies to effectively assess toxicity Failure to obtain necessary follow-up studies to assess toxicity as required by protocol Failure to report a toxicity that would require filing an adverse event report (AER) Grades, types, dates or duration of serious toxicities inaccurately recorded Recurrent under- or over-reporting of toxicities Serious toxicities cannot be sustained	Recorded grade 1 or 2 toxicities cannot be substantiated

DATA COLLECTION:

Major Deficiencies	Lesser Deficiencies
Unacceptable level of missing documentation Missing charts Frequent errors in submitted data Delinquent data submission	Acceptable level of missing documentation with explanation Infrequent errors in submitted data

DRUG/DEVICE ACCOUNTABILITY:

Major Deficiencies	Lesser Deficiencies
Inability to track disposition of supplied investigational agents Subjects identified on DARF are not consented subjects Incorrect storage of agent Each agent not accounted for separately by protocol Multiple non-compliant categories identified	Use of erasers or "white outs" on records Corrections not lined out initialed and dated Inability to track receipts of supplied investigational agent

* Based on quality assurance audit standards of the National Institutes of Health. National Cancer Institute. GUIDELINES FOR MONITORING OF CLINICAL TRIALS FOR COOPERATIVE GROUPS, CCOP RESEARCH BASES, AND THE CANCER TRIALS SUPPORT UNIT (CTSU) (August 2001 Revised)

Palomar Pomerado Health
Investigational Review Committee
Policies and Procedures
Appendix "C"

Checklist for Review of Informed Consent Compliance

Palomar Pomerado Health Investigational Review Committee
CHECK SHEET
HUMAN SUBJECT'S CONSENT FORM

Principal Investigator: _____

Manufacturer: _____

Sponsor or funding source, if any: _____

Will some of the subjects in this investigation be given a placebo? YES NO

Approximate number of subjects in this investigation (if appropriate): _____

Is there a copy of a current form 1572 attached? YES NO

Is there a copy of "California Investigational Subjects' Bill of Rights" attached? YES NO

Date: _____

1. GENERAL PROVISIONS

	Is there a general description, in lay terms, of the nature and purpose of this clinical investigation and procedures to be used?
	Is there a statement that this study may involve risks and discomforts that are currently unforeseeable?
	Is there a description of the study procedures?
	Is there a statement regarding if the subject is a woman of child-bearing age and is or may become pregnant during the study, include and a statement regarding the potential risks, foreseeable and unforeseeable, to an embryo or fetus.
	Is there a statement regarding the potential benefits of this study (describe in detail): to the subject or to humanity?
	Is there a statement regarding new information on the study?
	Is there a statement that the subject understands that all or some of the benefits described above may not occur in their case and that the possibility exits that their condition may be worsened?
	Is there place for the date and subject's signature, or the personal representative's signature and a description of the representative's authority to act for the individual?
	Is there a place for the name of the person explaining the consent?
	Is there a statement regarding payment to the subject for participation in the study by the sponsor?
	Is there a statement regarding payment to the Principal Investigator by the sponsor?

2. PARTICIPATION IS VOLUNTARY

	Is there a statement that the subjects participation in the study is voluntary and that their refusal to participate will involve no penalty or loss of benefits to which they are otherwise entitled?
	Is there a statement that if I the subject decides to participate in this study, they may withdraw at any time without penalty or loss of benefits to which they am otherwise entitled?
	If appropriate, is there a statement regarding the consequences of subject's decision to withdraw and procedures for the orderly termination of participation by the subject?
	If appropriate, is there a comment regarding circumstances under which the subject's participation may be terminated by the investigator, without regard to the subject's consent?

3. ALTERNATIVE TREATMENTS

	Is there a statement that if the subject does not participate in this study, what conventional procedures and treatments are available to them?

4. TREATMENT FOR POSSIBLE PHYSICAL INJURY RESULTING FROM RESEARCH PROCEDURES

	Is there a statement that if the subject suffers any physical injury as a result of their participation in this study, they should immediately contact the principal investigator or the Emergency Department if the investigator is unavailable?
	Is there a statement regarding medical treatment will or will not necessarily be provided free of charge or at subject's expense?
	Is there a statement regarding any additional costs that may result to the subject from participation in this study?
	Is there a statement regarding the availability of medical treatment and compensation for injury suffered as a result of participating in this study may be obtained from (Office at Hospital)?
	Is there a statement regarding the availability of financial compensation for any physical injury the subject might suffer as a result of their participation in this study?

5. CONFIDENTIALITY OF DATA

	Is there a description of the PHI to be used?
	Is there identification of who PHI will use by or disclosure to?
	Is there statement regarding the subjects right to see and copy their medical information?
	Is the purpose of the use or disclosure identified?
	Is there an expiration date for the authorization (may use "end of study" or if the study is establishing a database, may use "none")?
	Is there an expiration that PHI may be subject to re-disclosure or release to a third party

Comments:

MEDICAL STAFF SERVICES

PALOMAR POMERADO HEALTH

DATE: January 23, 2007

MEMO TO: Palomar Pomerado Health
Board of Directors

FROM: Marvin Levenson, M.D.
Medical Director, Escondido Surgery Center

RE: **Medical Staff Recommendations**

The Medical Staff of Palomar Medical Center approved the following credentialing recommendations for Escondido Surgery Center for submission to the Board of Directors:

Appointment:
02/12/2007 – 01/31/2009
- Delois J. Bean, M.D., Orthopaedic Surgery
- Marianna Siksay, M.D., Family Practice
- Robert J. Vallone, D.P.M., Podiatry

Voluntary Resignations/Withdrawals
- Marvin M. Kripps, M.D., Otorhinolaryngology (Effective 01/01/2007)

Allied Health Professional Withdrawal
- Lori D. Echeverria-Ring, Assistant (Effective 12/27/2006)

Reappointment:
03/01/2007 – 02/28/2009
- Richard C. Engel, M.D., Anesthesiology
- P. Eva Fadul, M.D., Anesthesiology
- Michael A. LaRocque, M.D., Urology
- Thomas J. Marcisz, M.D., Neurosurgery

Certification by and Recommendation of Escondido Surgery Center Medical Director:

As Medical Director of Escondido Surgery Center, I certify that the procedures described in the Escondido Surgery Center Bylaws for appointment, reappointment or the granting of privileges and that the policy of the Palomar Pomerado Health Board of Directors regarding such practices have been properly followed. I recommend that the action requested in each case be taken by the Board of Directors.

☐ PALOMAR MEDICAL CENTER
555 East Valley Parkway
Escondido, CA 92025
Tel 760.739.3140
Fax 760.739.2926

☐ POMERADO HOSPITAL
15615 Pomerado Road
Poway, CA 92064
Tel 858.613.4664
Fax 858.613.4217

☑ ESCONDIDO SURGERY CENTER
343 East Second Avenue
Escondido, CA 92025
Tel 760.480.6606
Fax 760.480.1288

PALOMAR
POMERADO
HEALTH

Pomerado Hospital Medical Staff Services
15615 Pomerado Road
Poway, CA 92064
Phone – (858) 613-4664
FAX - (858) 613-4217

DATE: January 31, 2007
TO: Board of Directors - February 12, 2007
FROM: Benjamin Kanter, M.D., Chief of Staff, Pomerado Hospital Medical Staff
SUBJECT: Medical Staff Credentials Recommendations – **January 2007:**

Credentials Recommendations: January 2007

Provisional Appointments: (02/12/2007 – 01/31/2009)
Adil Abbasi, M.D. - Medicine (includes Villa)
Patrick S. Giesemann, M.D. - Medicine (includes Villa)
Michael S. Rafii, M.D. - Medicine
Reza Shirazi, M.D. – Radiology
Marcus M. Van, M.D. - Radiology

Biennial Reappointments: (03/01/2007 – 02/28/2009)
Mark M. Boiskin, M.D. – Courtesy – Medicine
John E. Bokosky, M.D. – Consulting - Surgery
Charles D. Callery, M.D. – Active – Surgery
Richard C. Engel, M.D. – Active – Anesthesiology
P. Eva Fadul, M.D. – Active – Anesthesiology
Nabil I. Fatayerji, M.D. – Active – Pediatrics
James L. Halcomb, M.D. – Courtesy – Anesthesiology
Benjamin Kanter, M.D. – Active – Medicine (includes Villa)
Michael A. LaRocque, M.D.- Courtesy - Surgery
Thomas J. Marcisz, M.D. – Active – Surgery
Stephen F. Signer, M.D. – Courtesy – Medicine (includes Villa)

Advancement to Active Category: (02/12/2007 – 02/29/2008)
Steven M. Sorenson, M.D. – Radiology

Leave of Absence:
Matthew J. Curtis, M.D. (02/12/07 – 02/12/09)

Resignations/Withdrawal of Membership
Corrie D. Broudy, M.D. - Medicine
Walter L. Millar, M.D. - Anesthesiology

Allied Health Professionals Appointments: (02/12/2007 – 01/31/2009)
Elizabeth C. Herrera, RNFA – Sponsors – Dr. Batra & Dr. Gupta

Allied Health Professionals Reappointment (02/12/2007 – 01/31/2009)
Regina R. McFadden-Moehling, N.P. – Sponsors Kaiser Physicians (includes Villa)
Ellen S. Petersen, N.P. – Sponsor Dr. Herip
Glen T. Pugh, N.P. – Sponsor Dr. Herip

AHP Withdrawal of Membership
Keira Dillon, N.P.
Lori D. Echeverria-Ring
Nancy J. Horton, LVN,CRC

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 Certification by and Recommendation of Chief of Staff: As Chief of Staff of Pomerado Hospital, I certify that the procedures described in the Medical Staff Bylaws for appointment, reappointment, or alternation of staff membership or the granting of privileges and the policy of the Palomar Pomerado Health System's Board of Directors regarding such practices have been properly followed. I recommend that the Board of Directors take the action requested in each case.

Informational: Compensation

TO: PPH Board of Directors

MEETING DATE: February 12, 2007

FROM: Nancy Bassett, RN
Chair Human Resources Committee

BACKGROUND: An update on management compensation procedures was provided to the Committee.
Discussion included:

1. Draft for the management compensation program was not received from the consultant in time for M. Covert, W. George and B. Turner to review prior to the HR Committee meeting.
2. A brief overview of the expected content was shared.
3. HR Committee will be included in the discussion process as the development of the management compensation program progresses. Document to be presented at the February HR Committee meeting.

BUDGET IMPACT: Not Applicable

STAFF RECOMMENDATION:

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION:

Motion:

Individual Action:

Information: X

Required Time:

Informational: Annual Review of PPH Bylaws Relating to HR Committee

TO: PPH Board of Directors

MEETING DATE: February 12, 2007

FROM: Human Resources Committee: January 16, 2007

BACKGROUND:

PPH Board Bylaws are reviewed annually. HR Committee met on January 16, 2007, to review section 6.2.3 that relates to the Human Resources Committee.

BUDGET IMPACT: None

COMMITTEE RECOMMENDATION:
The Governance Committee will be asked to review recommended changes to the HR Committee Board Bylaws at their February 20, 2007 meeting.

Change to include the word "special":
(c) Duties. (i) .... Including initiating special studies;

Additions to include a new section:
(d) Meeting requirements. HR Committee to meet a minimum of six (6) times per year: more often if needed.

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION:

Motion:

Individual Action:

Information: *X*

Required Time:

Informational: Quarterly Turnover Report

TO: PPH Board of Directors

MEETING DATE: February 12, 2007

FROM: Nancy Bassett, RN
Chair Human Resources Committee

BACKGROUND: Wallie George, CHRO will provided the HR Committee with a quarterly turnover rate report.

1. W. George electronically presented a look at PPH's turnover rates via information in the Balanced Scorecard Briefing Book.
2. W. George also shared the electronic data in the Work Institute program that provides PPH with information on why PPH employees terminate.
   a. Committee members were provided a brief overview of types of information available through this web site, including: verbatim indicating the reason for leaving PPH employment; termination rates by department, site, as well as the person the individual reported to; voluntary; involuntary; ethical issues; etc.
   b. Information helps assess the need for management education with respect to the hiring process, or the development of tools to assist with the hiring process.
3. B. Turner announced the organization of a Retention Workgroup tasked with 1) evaluating retention issues within the organization and 2) developing a recommendation to reverse the losses.

BUDGET IMPACT: Not Applicable

STAFF RECOMMENDATION:

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION:

Motion:

Individual Action:

Information: X

Required Time:

Update: Van Pool Service

TO: PPH Board of Directors

MEETING DATE: February 12, 2007

FROM: Nancy Bassett, RN
Chair Human Resources Committee

BACKGROUND:

The Human Resources Department has worked with Enterprise to develop a vanpool program that would benefit both the employee and PPH.

1. W. George informed the Committee that the first PPH Vanpool (in partnership with Enterprise) is in operation.
2. This new program will be promoted in the next edition of Momentum. However, interest is already being generated and more vanpools may soon be in operation.

BUDGET IMPACT: Not Applicable

STAFF RECOMMENDATION:

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION:

Motion:

Individual Action:

Information: X

Required Time:

Informational: 2007 HR Committee Meeting Dates

TO: PPH Board of Directors

MEETING DATE: February 12, 2007

FROM: Nancy Bassett, RN
Chair Human Resources Committee

BACKGROUND: Accepted dates for the 2007 HR Committee are as follows:

Time: 1600-1730

February 20.....Innov / Conf Rm D
March 20.....PMC / Admin 1
April 17..... Innov / Conf Rm D
May 15.....Innov / Conf Rm D
June 19..... Innov / Conf Rm D
July 17.....PMC / Admin 1
August 21..... Innov / Conf Rm D
September 18.....PMC / Admin 1
October 16..... Innov / Conf Rm D
November 20.....PMC / Admin 1
December 18..... Innov / Conf Rm

BUDGET IMPACT: Not Applicable

STAFF RECOMMENDATION:

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION:

Motion:

Individual Action:

Information: X

Required Time:

Annual Review of Finance Committee Bylaws

TO: Board of Directors

FROM: Board Finance Committee
Tuesday, January 23, 2007

MEETING DATE: Monday, February 12, 2007

BY: Bob Hemker, CFO

Background: Annually, the Board Finance Committee is required to review the Bylaws of Palomar Pomerado Health as they relate to the Committee *(excerpt attached)* and recommend any necessary revisions.

Budget Impact: None.

Staff Recommendation: At the Board Finance Committee meeting, staff recommended approval of existing Bylaws without revision.

Committee Questions:

COMMITTEE RECOMMENDATION: The Board Finance Committee approved the existing Bylaws without revision.

Motion:

Individual Action:

Information: X

Required Time:

AMENDED AND RESTATED

BYLAWS

OF

PALOMAR POMERADO HEALTH

Revised February 13, 2006

6.2 STANDING COMMITTEES. There shall be the following standing committees of the Board: Finance, Governance, Human Resources, Strategic Planning, Community Relations, Quality Review, Audit Committee, and Facilities and Grounds Committee. Standing committees will be treated as the Board with respect to Article V of these bylaws. All provisions in Article V that apply to Board members shall apply to members of any standing committee.

6.2.1 Finance Committee.

(a) Voting Membership. The Finance Committee shall consist of seven voting members, four members of the Board, the President and Chief Executive Officer and the Chief of Medical Staff from each hospital. One alternate Committee member shall also be appointed by the Chairperson who shall attend Committee meetings and enjoy voting rights on the Committee only when serving as an alternate for a voting Committee member. The Chairperson of the Board may appoint the Treasurer as the chairperson of the Finance Committee.

(b) Non-Voting Membership. The Chief Financial Officer (CFO), the Chief Administrative Officers Palomar Medical Center and Pomerado Hospital and a nurse representative.

(c) Duties. The duties of the Committee shall include but are not limited to:

(i) Review the preliminary, annual operating budgets for the District and Facilities and other entities;

(ii) Develop and recommend to the Board the final, annual, operating budgets;

(iii) Develop and recommend to the Board a three-year, capital expenditure plan that shall be updated at least annually. The capital expenditure plan shall include and identify anticipated sources of financing for and objectives of each proposed capital expenditure in excess of $100,000;

(iv) Review and recommend approval of the monthly financial statements to the Board;

(v) Recommend to the Board cost containment measures and policies;

(vi) Review annually those policies and procedures within its purview and report the results of such review to the Governance Committee. Such reports shall include recommendations regarding the modification of existing or creation of new policies and procedures; and

(vii) Perform such other duties as may be assigned by the Board.

IT Strategic Plan Update

TO: Board of Directors

FROM: Board Finance Committee
Tuesday, January 23, 2007

MEETING DATE: Monday, February 12, 2007

BY: Steven Tanaka, CIO

BACKGROUND: The 2002 Information Technology Strategic Plan was a 2 to 3 year process to replace and update the majority of the information systems at Palomar Pomerado Health. The outcome of this plan was to provide an Information Technology environment that will improve the quality of care, enhance patient safety and facilitate clinical and financial processes and decision support analysis.

Utilizing the attached presentation, a status report on the project's status and information regarding new IT Strategic Planning and IT Governance activities were provided at the Board Finance Committee meeting.

BUDGET IMPACT: None

STAFF RECOMMENDATION: Information only

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION:

Motion:

Individual Action:

Information: X

Required Time:

Information Systems
2002 Strategic Plan Update

Finance Committee

January 23, 2007

PALOMAR
POMERADO
HEALTH

SPECIALIZING IN YOU

2002 IT Strategic Projects

Lawson • Financials •Human Resources •Materials Mgmt	**Avega** • Decision Support •Contract Mgmt •Cost Accounting	**MIDAS** • Quality Management
API • Time & Attendance	**Carex-Vision** • Food and Nutrition	**Long Term Care** •* System Selection
PACS • Cerner	**Website-Intranet**	**Cerner** • Patient Management •Clinical Documentation •Clinical Departmentals

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

2002 IT Strategic Plan
Project Status

Financial Systems (Lawson) - Installed

Phase 1

General Ledger, Accounts Payable,
Fixed Assets, Materials Management
Live- February 2004 (v8.1 Upgrade FY08)

Phase 2

Human Resources, Payroll, Time & Attendance,
Employee/Manager Self Service
Live- August 2004 (v8.1 Upgrade FY08)

PALOMAR
POMERADO
HEALTH
SPECIALIZING IN YOU

2002 IT Strategic Plan
Project Status

Decision Support **(Avega)** Installed

Contract Management, Cost Accounting, Decision Support

Live- April 2004

***Budgeting -SRC**

Quality Management (Midas) Pending

Current Midas implementation revisited

Re-install scheduled post Cerner Upgrade – Calendar Q1 2007

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

2002 IT Strategic Plan
Project Status

Dietary (Carex/Vision) Installed

- User training in process.
- Live- February 2004

PACS Installed

- Cerner ProVision PACS system
- Live- May 2005

Web Site & Intranet Under Construction

- Web network infrastructure installed
- Live- August 2005

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

2002 IT Strategic Plan
Cerner Phase 1Project Status

Enterprise Patient Management Under Construction

Registration, Scheduling, Medical Records, Lab, Pharmacy, Radiology, OR, ER, Clinical Orders, Results & Documentation, Patient Billing, Clinical Reporting

Live- October 2004

Upgrade- Jan. 25, 2007

Cerner Clinical Doc. Optimization- FY07/FY08

* System selection- Long Term Care

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

2002 IT Strategic Plan
Cerner Phase II Projects

- Computerized Physician Order Entry
- Document Imaging
- Medical Transcription
- Initial MD Documentation
- Cardiology Management
- ICU Management
- Anesthesia Management
- Electronic Medical Record (EMR) enhancement

Hold-Pending Cerner Upgrade and Optimization

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

2002 IT Strategic Plan Challenges

- Project Pre-Planning
- Workflow Redesign
- Project Scope
- Project Resourcing
- Shifting/Competing Priorities
- Lack of a Project Management Methodology
- Changing operational environment

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

2002 Projects Budget

- Approved Ten Year Project Budget
  Includes Capital & Operational Costs
- Total 10 year cost $44.5 M
- Capital Costs to Date $30.5 M
- Costs to Date Includes:

  Hardware, software, consulting, training, travel, development teams, supplies, construction

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

Next Steps: Updated IT Strategic Plan and IT Governance

Strategy

Understand the environment

Create the vision

Shape, inform expectations

Create clear IT governance

Weave business and IT strategy together

Service Delivery

Communicate performance

Support the Needs of Today

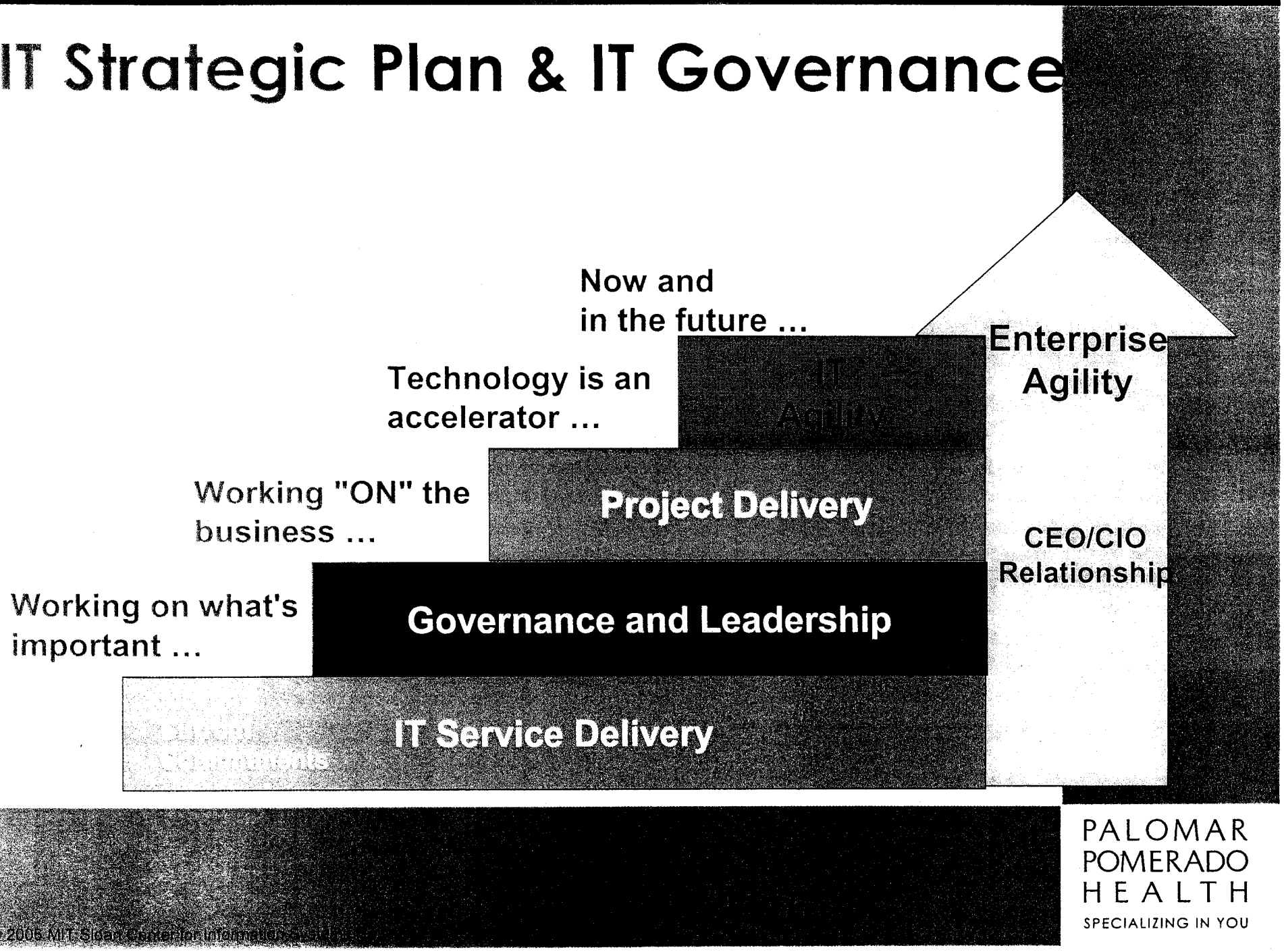
Manage enterprise Initiatives & risks

Develop a high-performing team

Build a new IT organization

PALOMAR POMERADO HEALTH
SPECIALIZING IN YOU

IT Strategic Plan & IT Governance



PALOMAR
POMERADO
HEALTH
SPECIALIZING IN YOU

Skilled Nursing Facilities Update

TO: Board of Directors

FROM: Board Finance Committee]
Tuesday, January 23, 2007

MEETING DATE: Monday, February 12, 2007

BY: Steve Gold, Administrator SNF Services

BACKGROUND: Utilizing the attached presentation, an update on the two Skilled Nursing Facilities (SNFs) – Villa Pomerado and Palomar Continuing Care – was presented at the Board Finance Committee meeting. The presentation included information on financial operations, quality improvements, customer service enhancements and future directions for SNF services.

BUDGET IMPACT: None

STAFF RECOMMENDATION: Information only

COMMITTEE QUESTIONS:

COMMITTEE RECOMMENDATION:

Motion:

Individual Action:

Information: X

Required Time:

Finance Committee-
Skilled Services Update

Palomar Pomerado Health

Palomar Pomerado SNF's

- **Villa Pomerado - Distinct Part**
  - * 129 Beds with 20 Sub-Acute (Vent) Level
  - * 40-50 Admits/Discharges Per month

- **Palomar Continuing Care-Distinct Part**
  - * 96 Bed Free Standing
  - * 50-60 Admits/Discharges Per Month

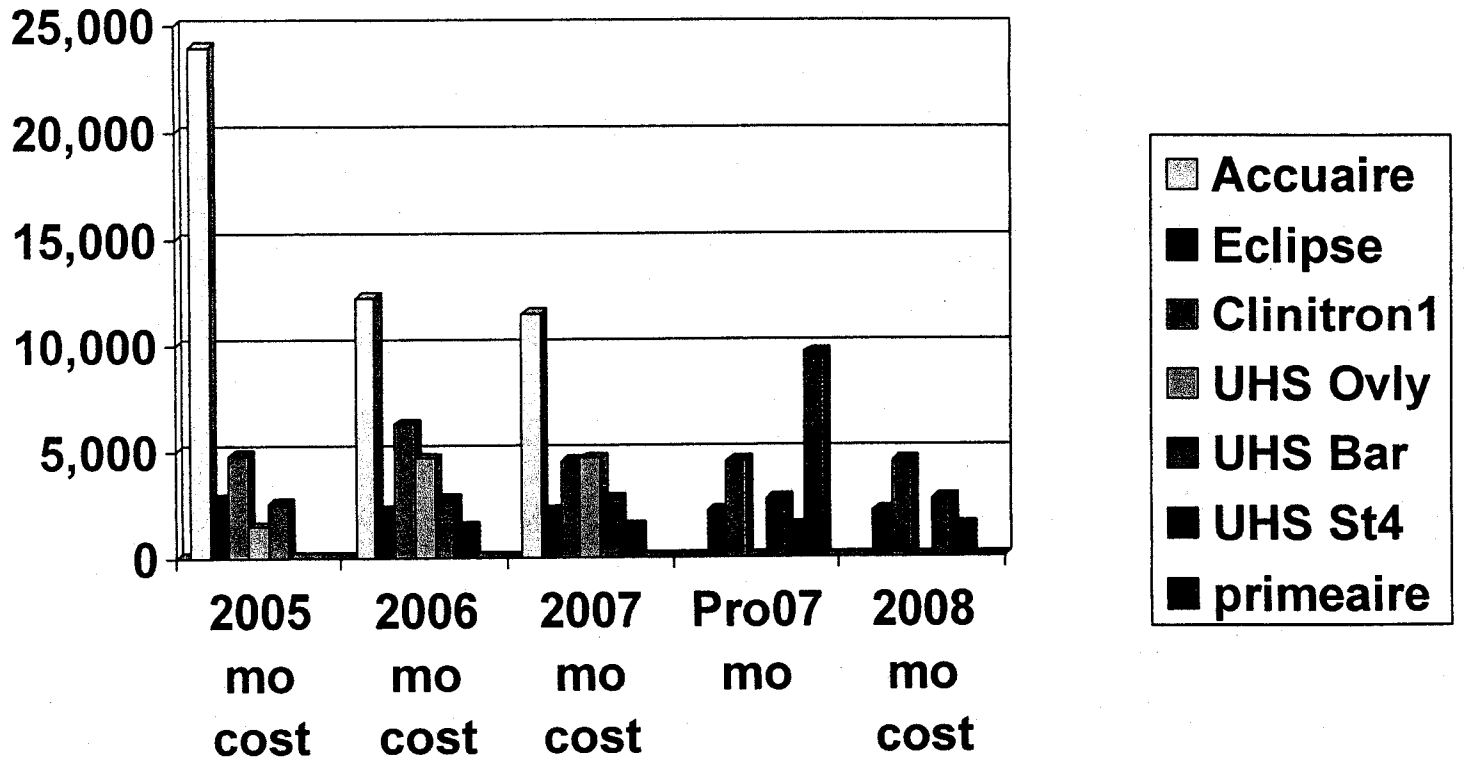
Additional Cash Flows-Fiscal '07

- Medi-Cal Retro Rate Increases to 8/1/06
- PCCC Rate Increase $14 per day
- Villa Pom Rate Increase $10 per day
- Subacute Rate Increase $90 per day
- Projected Annualized Impact $930,388

Year to Date Performance-Nov 06

- Patient Days-PCCC (138) Days YTD but +520 Days Over Prior Year/VP (103) Days YTD/SubAcute (40) Days YTD but +100 Days Over Prior Year
- Net Income based on Zone Reports-VP +$689,000 variance over budget, SubAcute +$275,745 variance over budget,PCCC ($279,960) variance under budget($60,000-Undocumented Care and $253,000-Bad Debts -YTD)
- Productivity-99.8% Combined,OT Monitored
- Changes to Leadership-Villa Pom DON
- Renegotiating Kaiser Rates including Sub-acute Care

Cost Savings Projects Specialty Bed Utilization-Monthly Costs-Lease Purchase of Primeaires to replace Accuaires & UHS Overlays Saves $73,000 year one & $177,000 years 2+ less depreciation (approximately $24,000 per year)



Savings Project-Glucose Test Strips

- POCT Test Strips Supplied by Central Supply
- Facilities use over 2200 boxes (50 Strips bx) each year - **$45,000**
- Medi-Cal will cover the cost of strips for Medi-Cal Patients only Billed Via Pharmacy
- Savings for billing direct To Medi-Cal **$30,000** per year
- Working with Lab, Pharmacy& Compliance on how to implement project to ensure testing & integrity

DHS Survey Licensure Process

SEVERITY/SCOPE	ISOLATED	PATTERN	WIDESPREAD
IMMEDIATE JEOPARDY TO RESIDENT HEALTH AND SAFETY	**J**	**K**	**L**
ACTUAL HARM THAT IS NOT IMMEDIATE JEOPARDY	**G**	**H**	**I**
NO ACTUAL HARM WITH POTENTIAL FOR MORE THAN MINIMAL HARM THAT IS NOT IMMEDIATE JEOPARDY	**D**	**E**	**F**
NO ACTUAL HARM WITH POTENTIAL FOR MORE THAN MINIMAL HARM	**A**	**B**	**C**
SEVERITY/SCOPE	ISOLATED	PATTERN	WIDESPREAD

Changes to Pharmacy Services

- Changed Services to Pharmerica 12-1-06- VP

PCCC changing as of 1/15/07

- Introduce Electronic MAR as of 4-1-07
- Utilize Wireless Laptops on Drug & Treatment Carts-Part of Contract with Pharmerica
- Electronically Document Drug Disposition
- Electronically Reorder Meds
- Updates Resident Records When Order Entered
- Nursing Teams More Productive/Patient Focused

Digital Pens for C N A's

- Contract with ISS in Utah –ISS has Grant with AHRQ
- 24 Nursing Centers- USA
- Contract Pays 60% of Cost
- C N A's Chart w/ digital pens- scan sheets
- Digital Pens Downloaded Daily
- Reports Provide Real Time Care and Interventions for Residents
- Documented Improvements Should come from Decreased Pressure Ulcers and Decreased Costs

Facility Quality Improvement/Quality Management

- There are 34 different Quality Measures
- Reports Display each QI/QM, Facility %, and How Facility Compares State and Nation
- Assists to Identify Possible Areas for Further Emphasis in Improvement Activities or Investigation during the Survey Process

Quality Domains

- Accidents
- Behavior/Emotion Pat.
- Clinical Management
- Cognitive Patterns
- Elimination/Incont.
- Infection Control
- Nutrition/Eating
- Pain Management
- Physical Functioning
- Psychotropic Drug Use
- Quality of Life
- Skin Care
- Post Acute Measures

Facility Quality Improvement/Quality Management

- For Each Selected Measure-Identify Residents who flagged, review clinical records
- Accuracy, review care and documentation
- Draw Conclusions about Quality-decide if isolated or facility wide
- Develop Action Plans and Monitor Future Reports for Effectiveness

Address Issues in Case Management

- Improve MD to MD communication
- Examine electronic referral to replace current faxing system
- Upgrade response to need to specialized equipment for admissions
- Improve utilization of beds at both facilities
- Merge Admit and Billing functions into a Financial Services Rep on Site at Facilities

Renovations Updates
Initiatives for Press -Ganey

- Requesting 5 Nurse Call replacements with Beepers and Nurse Call Monitoring Systems-both nursing homes-Rauland Nurse Followers
- Complete incomplete renovations from last year-nursing stations, carpeting, both facilities
- Upgrade Resident Rooms with new paint, flooring, some replacement furniture
- Continue Training Staff on Press-Ganey Suggested Improvements for Scoring Increases

Future Directions for SNF Services

- Update Strategic Plan for Additional SNF Beds
- PACE-Program for All-Inclusive Care of the Elderly-Evaluation Complete
- 8 Bed Sub-Acute Expansion
- 18 Bed Villa -Pomerado Addition
- Purchase of Other Nursing Homes
- LTACS-Compete with Rehab and SNF Services?
- Old Palomar Campus-Assisted Living &Senior Apartment Complexes

2007 Finance Committee Meeting Dates

TO: Board of Directors

FROM: Board Finance Committee
Tuesday, January 23, 2007

MEETING DATE: Monday, February 12, 2007

BY: Bob Hemker, CFO

Background: Based on key financial dates regarding the monthly closing of financial results, as well as the calendars of the Board members on the Committee, Finance Committee meetings for the 2006 calendar year were held during the last week of the month.

The Board members on the Finance Committee having remained constant for the 2007 calendar year, the last Tuesday evening of the month was presented by staff as the choice for the monthly meetings of the Finance Committee, except for the months of November/December, which have historically been held in a combined meeting on the first Tuesday of December. Alternatives presented were for the meetings to be held on the fourth (4^{th}) Tuesday (3 remaining months have 5 Tuesdays), or as daytime meetings.

After discussion, the Finance Committee agreed to continue to meet on the **last Tuesday of each month, with a combined November/December meeting to be held on the first Tuesday in December.**

The final schedule for Calendar Year 2007—with the meetings rotating between Pomerado Hospital and Palomar Medical Center (as available)—is attached.

Budget Impact: N/A

Staff Recommendation: Meeting schedule as per discussion and Committee consensus.

Committee Questions:

COMMITTEE RECOMMENDATION: The Board Finance Committee agreed to meet on the last Tuesday of each month, with a combined November/December meeting to be held on the first Tuesday in December.

Motion:

Individual Action:

Information: X

Required Time:

PALOMAR POMERADO HEALTH

SPECIALIZING IN YOU

PALOMAR POMERADO HEALTH FINANCE COMMITTEE MEETING SCHEDULE CALENDAR YEAR 2007

Last Tuesday of every month[1]

Meeting start time is 6:00 p.m. for all meetings, preceded by dinner[2] at 5:30 p.m.

DATE		LOCATION OF MEETING
Tuesday January 23, 2007		Administrative Offices Conference Rooms B&C
Tuesday February 27, 2007		Palomar Medical Center Graybill Auditorium
Tuesday March 27, 2007		Pomerado Hospital Conference Room E
Tuesday April 24, 2007		Palomar Medical Center Graybill Auditorium
Tuesday May 29, 2007		Pomerado Hospital Conference Room E
MAY/JUNE 2007	**Budget Workshop & Board Meeting Full Board Attendance**	**Palomar Medical Center Graybill Auditorium**
Tuesday June 26, 2007		Palomar Medical Center Graybill Auditorium
Tuesday July 31, 2007		Pomerado Hospital Conference Room E
Tuesday August 28, 2007		Palomar Medical Center Graybill Auditorium
Tuesday September 25, 2007		Pomerado Hospital Conference Room E
Tuesday October 30, 2007		Palomar Medical Center Graybill Auditorium
Tuesday December 4, 2007		Pomerado Hospital Conference Room E

[1] Exceptions noted in red

[2] **Dinner will be catered at Palomar Medical Center and via the cafeteria line at Pomerado Hospital**

POTENTIAL AMENDMENT OF ESTABLISHED DATE OF REGULAR BOARD MEETING

TO: Board of Directors

DATE: February 12, 2007

FROM: Marcelo R. Rivera, MD., Board Chairman

BY: Christine Meaney, Board Assistant

SUBJECT: **POTENTIAL RESOLUTION TO AMEND ESTABLISHED DATE OF REGULAR BOARD MEETING FOR CALENDAR YEAR 2007**

BACKGROUND: Consistent with legal requirements to establish dates, times and locations of Regular Board Meetings prior to the upcoming calendar year, a resolution was approved at the December 11, 2006 Annual Board Meeting.

Following recent Board Member request, the Chairman has asked that discussion take place for the following 2007 date amendment to be considered for potential Board action under Resolution No. 02.12.07 (01) – 01 attached:

> Amending March 12 to another mutually convenient date in March, or to remain as originally scheduled.

ACTION: Board input/potential action sought.

RESOLUTION NO. 02.12.07 (01) - 01

RESOLUTION OF THE BOARD OF DIRECTORS OF PALOMAR POMERADO HEALTH ESTABLISHING REGULAR BOARD MEETINGS FOR CALENDAR YEAR 2007

WHEREAS, Palomar Pomerado Health is required, pursuant to Section 54954 of the California Government Code and Section 5.2.2 of the PPH Bylaws, to pass a resolution adopting the time, place and location of the regular board meetings;

WHEREAS, the Board of Directors established the dates of regular board meetings for calendar year 2007 by Resolution No. 12.11.06 (02) – 29 at the Annual Meeting of the Board of Directors held on December 11, 2006;

WHEREAS, the Board of Directors wishes to change the date of the regular meeting currently scheduled on March 12 to another convenient date in March;

NOW, THEREFORE, BE IT RESOLVED by the Board of Directors of Palomar Pomerado Health that the following **amended** schedule of regular meetings will apply for calendar year 2007:

2007 BOARD MEETING SCHEDULE

January 8	Pomerado	**July 9**	Pomerado
February 12	**Moved to Pomerado**	**August 13**	PMC
March (12)	Pomerado	**September 10**	Pomerado
April 16	PMC	**October 8**	PMC
May 15	Pomerado	**November 12**	Pomerado
June 11	PMC	**December 10**	PMC

Each meeting will begin at **6:30 p.m.** Those meetings held at Palomar will be in Graybill Auditorium; those at Pomerado will be in the third floor meeting room.

PASSED AND ADOPTED at a regular meeting of the Board of Directors of Palomar Pomerado Health, held on February 12, 2007, by the following vote:

AYES:

NOES:

ABSENT:

ABSTAINING:

DATED: February 12, 2007

APPROVED: ***ATTESTED:***

Marcelo R. Rivera, M.D., Chairman
Board of Directors

Linda C. Greer, R.N., Secretary
Board of Directors