



Specialty Infusion Pharmacy and its impact on Patient Care

Michael Rigas, Pharm.D
Chief Clinical Officer
KabaFusion, LLC
February 2013

Our Mission...

We are guided by our commitment to successful <u>clinical outcomes</u> and dedicated to working proactively with patients, physicians and payors to provide <u>comprehensive support before, during and after</u> infusion therapy.



Company Profile

- Founded in 2010, KabaFusion is privately held and operates infusion pharmacies in CA, TX and NJ. Lunching a new location in PA in March 2013
- Corporate offices in Cerritos, CA, Waltham, MA
- Covers 21 states including all of California
- Nursing Capabilities: 30 specialized infusion nurses across California
- Projected to close 2013 with approximately 150 employees
- > 24/7 capability to service patients
- KabaFusion is contracted with all major health plans in CA, TX and NJ



Service Overview

KabaFusion is a full service infusion pharmacy that manages patients' therapy at home and in ambulatory infusion sites

- > Acute Therapies:
 - > Antibiotics
 - Total Parenteral Nutrition
 - > Enteral
 - Chemotherapy
 - Hydration
 - Pain Management
- > Chronic Therapies:
 - > IV and SQ Immune Globulin
 - Remicade, Tysabri and other DSM's



KabaFusion's Business Model

- Specialty Infusion clinical management and distribution to the Alternate site setting
- Employ Pharmacists, Nurses, Technicians, billing and supportive staff in 3 states
- > Servicing patients in 25 states
- **▶** Buy direct and from several wholesalers via several GPOs
- > Challenges matching supply and demand with reasonable:
 - > cogs
 - Payment Terms
 - Just in time availability
 - Product selection
- Processes could be improved by aligning interests of:
 - Maker
 - **►** MD
 - Patient
 - Payor



Impact of Health Care Reform on KabaFusion's Business Model

- Alternate Site infusion is poised to dramatically help HCR by avoiding and/or lowering inpatient costs
- Hospitals and ACOs are aggressively exploring ambulatory Infusion and home infusion offerings
- Choosing the site of Care is fraught with Peril
- Challenges in reimbursement, regulation and access remain the biggest hurdles
- ➤ Basic knowledge of how Alternate site infusion industry works is a significant barrier
- Pharmacy benefit vs Medical benefit is a significant barrier



Health Care Reform is Forcing Development of New Strategies to Manage Infused and Biologic Therapies

- Hospitals and Physicians face challenges ordering acute and High Cost Biologic drug therapy for their pts in the alternate site setting;
 - > Payor authorization issues
 - Extreme variance in rates of reimbursement for High Cost Biologic therapies by Govt and third party payors causes significant impact on MD office staff
 - > Available Infusion center issues
 - Poor Persistence and Compliance issues due to pts inability to pay their out of pocket costs
 - ➤ Lack of Physician reimbursement for their efforts to order and oversee alternate site infused therapies
- ➤ This Challenges result in increased LOS, increased rates of Readmission, and use of out pt MD services

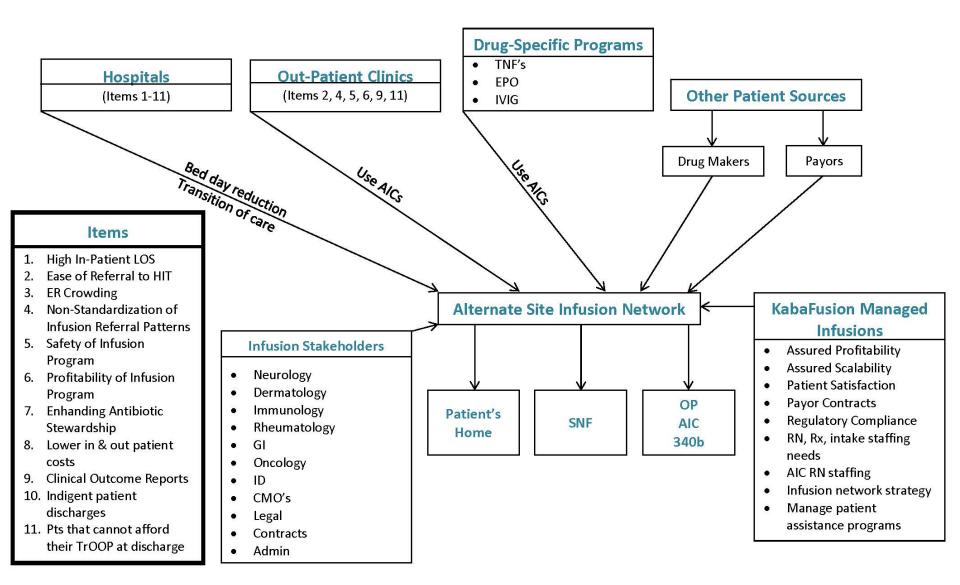


Health Care Reform Hits California Hospitals

- ➤ Several Southern California Hospitals received deductions in MediCare Reimbursement for Higher than expected Rates of Readmission from 2008 to 2011
 - Grossmont Hospital = 0.38% = \$306,000
 - UCSD Med Center = 0.21% = \$287,000
 - Brotman Med Center = 0.55%
 - \rightarrow UCLA = 0.19%
 - > Santa Monica UCLA = 0.35%
 - > LLUMC = 0.25%
- Penalty is Percentage deduction from CMS payments for FY2013
- Nationwide 2217 hospitals (64% of the total) received penalties for their 30 day readmission rates
- > 307 hospitals received the maximum 1% penalty
- > Total Penalties for 2012 are \$280mm = 0.3% of CMS budget
- > In 2103 max rate doubles to 2%



The Grand Infusion Vision



The Patient is at the Eye of the Outpatient Pharmacoregulatory Storm

Federal Government

CMS (Medicare, competitive bidding and pricing, regulatory compliance, regulations) 340 B
Fraud and Abuse
FDA
Healthcare Reform
Readmission Rate fines

Hospital

ACOs

Length of stay concerns \ Clinician coordination \ Antimicrobial Stewardship

Case management
Referral processes
Variance in approach
to infusion mgmt
Difficulty in coming
to agreement on
Approach to infusion

State Government

Medicaid coverage for IV Board of Pharmacy Regs DEA

Department of Health issues

Manufacturer

Product lifecycle focus Product financial goals

FDA controlled communication

Payer

Increase ROI
QOL concerns questionable
Medical loss ratio
Multiple payers (Medicare,
managed care
Contracts needed to bill
RX vs Medical Benefit

KabaFusion Patient-Focused Infusion Therapy

Physician

Increase ROI
Decrease hassle
Legal exposure
Time (see many
representatives per week)
Lack of Infusion set up

awareness

Pharmacy Industry

Oral vs IV vs Hospital RX
Coordination/transitioning
of care
Right drug, right dose, right
patient, right time

Patient

Increase ROI
Decrease TROOP
Speed of service
Entitlement
Low attention to details
Lack of awareness
regarding system
Ability to afford TrOOP

Selection of Site of Care for Alternate Site IV Patient is Complex and Fraught with Peril

- > KabaFusion Pt site of selection algorithm
 - > Pt dx
 - Drug ordered
 - **Comorbidities**
 - > Payor coverages and patients TrOOP
 - Desired outcomes
- Possible Site of Care Options
 - > AIC
 - > Home
 - > SNF
 - > Stay inpt
 - Convert to Oral Therapy





Coverage for IV ABX at home is Highly Variable

- > Medicare
 - **≻Part A**
 - **≻Part B**
 - >Part C
 - >Part D
- ➤ Medicaid (>15 kinds in CA)
- > Managed care
 - **>PPO**
 - >HMO





Antagonistic Payor Strategies

- **Medicare**
 - >Part A
 - **≻Part B**
 - **≻Part C**
 - **≻Part D**
- **Medicaid**
- > Managed care
 - >PPO
 - >HMO
- > Drug Reimbursement Methods
 - **>AWP**
 - **>ASP**
 - >WAC
 - >MAC
- > Pharmacy Benefit vs Medical Benefit





Patient True Out of Pocket (TrOOP) Costs

- > Copay
- > Deductible
- Part D donut hole
- > Catastrophic
- > Variance in TrOOP over life of the RX
- > Payor Inclusion Criteria
 - Widely variable between payors
 - Not always evidence based
 - Challenging to produce data to meet all criteria
 - Compromises MD/RX relationship





Financial Assistance Programs Impact Patient Access to Care

- > Drug Manufacturer Programs
 - **➢Over 450 programs covering 2000+ drugs**
 - > Each has unique rules and forms
 - > Cannot be used for Medicare/Medicaid pts
- >501c(3) Foundation based Programs
 - **▶** Disease specific
 - > Funded by drug maker, limited \$\$ per year
 - ➤ More than 50 unique programs
- **►** Infusion provider programs
 - **≻Vary widely**
 - **≻**Most not regulatory compliant





Patient Assistance Fraud and Abuse Pitfalls

- >Government Pay patients
- > Managed Care patients
- >Indigent Patients
- > Underinsured Patients
- > Regulatory Paperwork Requirements
 - **Enrollment forms**
 - >Tax records
 - >Approval process
 - >Annual reapplication
 - >Privacy issues
- ➤ Impact on Referral Source relationship and FWA risk





The End Result of the Pharmacoregulatory Storm

- > Patients Suffer while payor profits rise
 - Complexity of strategy to obtain Auth
 - > Disease progression while waiting for auth
 - > Patents that need > 30 days to get Auth
 - > Percentage of pts that actually start Tx
 - >Impact on persistence and compliance
 - ➤ Impact on Medical Care system and Re-Hospitalization



CASE STUDY #1: Pt HP

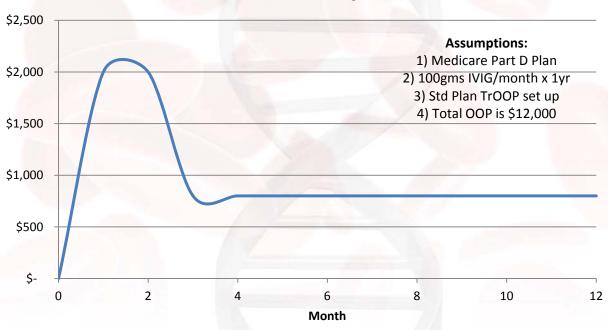
- ➤ Medicare A, B, D and supplement vs access to IVIG at home/MD office
 - > Pt is 72yo with CIDP; IVIG 150 grams per month x 12
 - Not covered at home by Medicare B
 - Covered by D but TrOOP is > \$15,000 just for IVIG
 - Supplement does not apply
 - > Covered under B in MD office, but at ASP+6%
 - Supplement pays pts 20% copay
 - Onc MD willing to do favor as long as does not loose money
 - > Took > 20 hours over 60 days to set up
 - Pt Improved dramatically with IVIG





CASE STUDY #1: Pt HP TrOOP

Patient OOP Cost/Month







CASE STUDY #2; Pt JR

- ➤ Immune deficient pt turns 65 and converts to Medicare A, B and D
 - ▶ Pt gets SQIG 50 grams QM was Managed care at AWP-20% now going to ASP+6%
 - ➢ Been with IV provider and managed care for 5 years now must go Medicare Primary
 - Part B covers 6 of 150 PIDD DXs/FDA approved
 - Part D does not cover if covered by B
 - > The other 144 would be covered under D
 - > SQIG COGS is \$76 per gram
 - > ASP+6% is \$75 per gram
 - How to manage this catastrophic situation



CASE STUDY #3; Pt JH

- > Pt On IVIG, looses job/insurance needs assistance
 - Pt gets 200 grams QM for CIDP, uses Gammagard for last 12 months with insurance
 - > Apply to Gammassist credit based program
 - Takes 30 days to approve once sent in paperwork
 - **▶** Life time cap is 720 grams
 - Pt misses 2 months of therapy
 - > Pt uses all 720 grams allocated
 - > Pt gains state based Risk pool Insurance
 - Kaba must contract with Risk pool
 - > Pt restarts after missing 2 more months of Tx
 - > Pt able to work after 6 more months of Tx



CASE STUDY #4; Pt FF

- Pt is 40 year old woman with MS, failed steroids and DMARDs self injected drugs
 - > Order is for Tysabri 300mg IV q month
 - Must apply for Managed Care Payor for Auth
 - Must apply to TOUCH (REMS) program for Tysabri
 - > TOUCH program takes 60 days to complete for MD, RN, Pharmacy and Pharm.D
 - Payor takes 30 days to Authorize
 - > Drug must be shipped to MD office but billed to Managing Pharmacy. No diluent included
 - Pt starts therapy and improves in 2 doses KabaFusion Patient-Focused Infusion Therapy

CASE STUDY #5; Pt MK

- > Pt is 60 yo on IVIG for CIDP with Managed Care Payor
- **Payors Criteria included Drug Dosage Optimization yearly**
 - > Pt is getting 50 grams 3 x Days every 3 weeks
 - Payor demands dose Optimization before next re-auth
 - > MD calls to ask Rx how to optimize
 - > Less grams or less frequently
 - What happens if breakthrough symptoms
 - How to tell pt that has improved dramatically and is stable on current regimen
 - > Request comes at calendar year end, effects holidays
 - > Pharm.D develops plan for MD, gets auth for emergent back up doses, counsels worried pt through holiday KabaFusion Patient-Focused Infusion Therapy



$\overline{\parallel}$

CASE STUDY #6; Pt EB

- ▶ Pt is 50 yo Dx is CIDP. New orders for IVIG 200 gm q Month, Auth is complex with Managed Care payor
 - Managed care payor uses the published ICE trial (paper that lead to FDA approval for IVIG for CIDP in 2008)
 - **▶** MDs order is for IVIG 50 grams per week x 12 months
 - Payor says ICE trial dosage regimen is dosed only every three weeks, so not approved due to frequent dosing
 - Pharmacist and Intake spent over 10 hours in 2 weeks to gain payor approval
 - > All other documentation acceptable
 - Would not budge on dosage frequency
 - ➤ Called ICE paper author to verify q 3 weeks was picked as average dosage period of the 10 authors
 - Finally got auth for 150 grams over 3 days q 3 weeks x 12 months
 - All parties thoroughly frustrated by whole process which took 4 weeks KabaFusion Patient-Focused Infusion Therapy



CASE STUDY #7 PharmacoRegulatory Excess

- Sales rep tracking systems
 - RepTrax
 - Vendor mate
- Vendor Contracting excesses
 - **Fed Buz Opps**
 - Prime therapeutics requests for productivity data
 - **ECIN:** electronic referral system



Thank You And Discussion

