Key issues in establishing a Home Dialysis Program

May 15, 2014, Chicago
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Course Objectives

• Discuss merit and logistics of a Home Program (P.D. & H.H.D.).
• Updated Medicare rule for Home.
• Discuss how to establish a Home Program.
• Discuss Financials (Detailed Revenue Stream, and Expense incurred).
• Discuss Wholly Own/Independent vs. Joint Venture Opportunities.
• Discuss barriers of a successful Home Program.

****** Innovate. Adapt. Lead *******
Reality of ESRD program in U.S.

- **THE UGLY** — infection, CV death, CVC, Admission rate, Readmission rate, Mortality rate, the cost. And core measures not relevant enough.

- **THE BAD** — better RRT are available, but unable to enroll more although we all want to.

- **THE GOOD** — home, working, satisfaction, green, save $$.
Peritoneal dialysis cheaper than HD worldwide

- **Cost:** HD is 1.25~2.35 of PD in 5 developing counties and 17 developed counties. In US, HD:PD is 1.29:1, while 1.9:1 in Canada, 2.35:1 in Hong Kong where “PD First” is on.

- **Enrolled rate:** In Japan and Taiwan, PD 488.5/mil. HD 2107/mil; In US, PD 87/mil, HD is 1157/mil.

- USRDS 2012—HD $87500 while PD $66750

- PD remote monitor I Pad to reduce infection

- Only 7% in US is enrolled with PD, if at average of 12% (worldwide), an additional 18,000 would have been on PD and lead to annual of nearly $360 million saving to US economy.

  - Nephrology Dialysis Transplant 2013
2012 USRDS Annual Data Report
General ESRD Costs (Macroeconomic)

• $47.5 billion: Total cost per year for ESRD patient care
• $32.9 billion: Medicare spending on ESRD
• $14.6 billion: Non-Medicare spending on ESRD
• $87,561: Cost of hemodialysis per patient
• $66,761: Cost of peritoneal dialysis per patient
• $32,914: Cost of transplant patient
## Nephrologists Surveyed over Years:

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>% of Pt should be on:</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S./LDO2*</td>
<td>2012</td>
<td>HHD:51 PD:46</td>
<td>600+</td>
</tr>
<tr>
<td>U.S./LDO1*</td>
<td>2012</td>
<td>HHD:50 PD:44</td>
<td>400+</td>
</tr>
<tr>
<td>U.S./LDO1*</td>
<td>2009</td>
<td>HHD:51 PD:46</td>
<td>143</td>
</tr>
<tr>
<td>USA¹</td>
<td>2006</td>
<td>PD:29%</td>
<td>59</td>
</tr>
<tr>
<td>USA²</td>
<td>2001</td>
<td>PD:33%</td>
<td>240</td>
</tr>
<tr>
<td>Canada³</td>
<td>1999</td>
<td>PD:37%</td>
<td>192</td>
</tr>
<tr>
<td>British Isles⁴</td>
<td>2002</td>
<td>PD:38%</td>
<td>108</td>
</tr>
</tbody>
</table>


* Survey during medical director meeting.
With across the board payment reduction trend..
Are there any exceptions CMS actually pays more?

• (A) - Yes.
• (B) - No.
• (C) - Never, you must be kidding!
SO, what are the EXCEPTIONS?

1) **Home dialysis (PD)** — under bundle 2011, PD paid as HD despite of less expense (i.e. high profit margin).

2) **HHD** - mostly will pay for more than 3/wk. treatments (usually 4-5/week)

3) **Home Dialysis Facility Training fee** — increased from $20 to $33.44 to $50.16 to per session.

4) **CKD visit and Code** — pay more than doc visit if document well. Allows 6 visits yearly for CKD IV, V. (CKD visit or Option Education—*the money is on the table, take it or leave it!*)

5) **G code** — under HD, a visit is one visit; home program, one visit is counted as 2-3 visits.

6) **Supervision for Training fee**--$500

7) “Medicare Administrative Contractors may occasionally waive a monthly face-to-face visit for the home dialysis MCP on a case-by-case basis. This might happen, for example, when the nephrologist's notes indicate that he/she actively and adequately managed the care of the patient throughout the month”. ([Medicare Claims Processing Manual](/medicare-claims-processing-manual) §140.1.1. )

1,2,3 are for facility. 4, 5,6,7 are for Nephrologist.
“Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we are proposing an ESRD PPS which does not rely on separate payment rates based on modality. By establishing prospective payment rates that are higher for PD patients than they otherwise would be if separate payments were established based on modality, we believe home dialysis will be encouraged for patients able to use PD.” (2010)

“WE ARE CONFIDENT THAT OUR FINAL POLICIES WILL CONTINUE TO IMPROVE THE QUALITY OF CARE WHILE ENSURING THAT OUR FINAL PAYMENT RATES BETTER REFLECT THE COST OF CARE”.

JONATHAN BLUM CMS PRINCIPAL DEPUTY ADMINISTRATOR 2013

- Centers for Medicare and Medicaid Services
Medicare and Home Dialysis update

• Same 1.51 Bundle weight adjustment for Incident Dialysis for first 4 months.
• Medicare, PPO, HMO not an issue.
• Uninsured, or MediCaid/MediCal (but Medicare eligible)...

Started with ICHD:
1) Uninsured--start ICHD, MediCaid eligible on day 1, then Medicare eligible on 91th day.
2) MediCaid—ICHĐ, remains same coverage, then Medicare eligible on 91th day.

Started with Home Dialysis (HHD or PD)
1) Uninsured--Medicare eligible on Day one.
2) MediCaid—Medicare eligible on Day one (M/M)
The effective date of ESRD Medicare is dependent upon the type of treatment

a) **Hemodialysis**--Medicare is effective the fourth month of treatment, i.e. if hemodialysis is begun in May, Medicare becomes effective August 1 (90 day rule).

b) **Home/Self Dialysis**--Medicare is effective the first month of treatment if:

I. The individual takes part in a training program through a Medicare certified training facility,

II. Home/Self training is begun within the first three months of treatment and

III. The individual is expected to finish home training and self-dialyze at home
Why Home Program?
---Cheaper, Faster and Better---

- Easy set **up**—no water treatment, much less equipment/machine, small space, less T.I. Much less initial capital outlay/working capital needed. (~250K vs. ~5 M. for ~200 patient capacity ***)
- CMS pays PD same rate as HD despite of less cost.
- Advantage of **payor mix and Bundle weight** if direct CKD clinic referral.
- Medicare 90 days waiver allowed, and easier training.
- Much easier training for PD, but longer training for HHD.
- Prevailed data showing saving life, reduce cost, better outcome and satisfaction.
- $500 training fee, G code advantage.
- Can address the increasing patient load with minimal investment

**only serve as an example for discussion, may not fit into every reality!**
Under the Bundle:

- Some financial incentives may encourage starting incident patients on home dialysis, either home hemodialysis or peritoneal dialysis.
- Administration of injectable medications such as vitamin D and iron, which are no longer separately billable, may require providers to consider oral equivalents or slightly different dosing patterns.
- Treatment of anemia with erythropoiesis-stimulating agents will also require careful consideration, as will use of oral medications when they are added to the bundle at later year.
- Payment for PD is same as for HD despite of less cost.
- Onset of dialysis <=4 months, adjustment factor for Bundle is 1.51

By Craig A. Solid, PhD, and Allan J. Collins, MD
Medicare requirement to start a Home Program (when Certificate Of Need is not required).

- Site requirement--Fire Marshal clearance, COO, ......>Licensing.
- Fill out a **CMS 855A form**, send it to the Medicare contractor your clinic bills for in-center claims (Medicare Fiscal Intermediary). Medicare Federal Health Care Provider/Supplier Enrollment Application
- The contractor will review the form and if all OK, within 60 days, notify your **State Survey Agency** when the request is approved.
- Your clinic will need to notify the that you are ready for a survey.
- State Survey Agency will add your clinic to its list. When the survey is done and any deficiencies corrected. (This may take long months.)
- State Survey Agency will recommend that CMS add the service of home training and support services for HD and/or PD.
- Must meet all of the relevant requirements in the *Conditions for Coverage*. The Condition for *Care at Home* describes the requirements for training, staffing, equipment and supply maintenance, water and dialysate quality for home HD, medical records, emergency call, etc.
- Download the April 2008 **Federal Register ESRD regulations**.
- Download the October 2008 **Interpretive Guidance**.
Further Steps:

• Your local State Survey Agency will provide you with any additional forms you need and information they require (License, CON, etc.), and help you if you want to apply for Medicaid enrollment. You will need to fill out a CMS-3427 form: the End Stage Renal Disease Application and Survey and Certification Report.

• If you pass the state survey, the local CMS regional office will contact you about issuance of a formal signed agreement. Upon completion of the agreement, you will be given a Centers for Medicare & Medicaid Certification Number (CCN, formerly provider number) and allowed to submit billings.

• You need to run a few patients and wait for State Survey Agency to come back for another survey before full operation can be implemented.

• If you have already submitted an application and have a problem with the FI, contact the CMS regional office in the state where the FI is located. The regional office has responsibility for monitoring the FI’s performance, and will be glad to assist you.
What does Medicare expect in a Home Program?

- Kidney disease and how to manage it
- How to use the supplies and equipment correctly to remove as many wastes and excess fluid as possible
- How to manage anemia, using the drugs the doctor prescribes
- How to detect, report, and manage problems that might occur, including machine and water treatment problems
- How to reach help when needed
- How to keep track, report, and record the patient's health status
- How to handle medical and non-medical emergencies
- How to avoid infections
- How to get, store, and get rid of medical waste
## Bundle Elements

<table>
<thead>
<tr>
<th>Elements</th>
<th>Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Volume</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;3000 treatments/year for three years</td>
<td>1.202</td>
</tr>
<tr>
<td><strong>Incident Dialysis Status</strong></td>
<td></td>
</tr>
<tr>
<td>Onset of dialysis ≤ 4 months</td>
<td>1.51</td>
</tr>
<tr>
<td><strong>Acute: current M + 3 months</strong></td>
<td></td>
</tr>
<tr>
<td>Pericarditis</td>
<td>1.114</td>
</tr>
<tr>
<td>Bacterial Pneumonia</td>
<td>1.135</td>
</tr>
<tr>
<td>Acute GIB with Hemorrhage</td>
<td>1.183</td>
</tr>
<tr>
<td><strong>Chronic: Add on current M till death or Transplant</strong></td>
<td></td>
</tr>
<tr>
<td>Hereditary Hemolytic or Sickle Cell Anemia</td>
<td>1.072</td>
</tr>
<tr>
<td>Myelodysplastic Syndrome</td>
<td>1.099</td>
</tr>
<tr>
<td>Monoclonal Gammanopathy</td>
<td>1.024</td>
</tr>
</tbody>
</table>
Home Hemodialysis

- Same application processes. Best to include HHD when apply PD Home Program from the start, but separate programs.
- Need to justify the number of treatments/wk. for HHD when bill.
- Training a HHD patient cost $5,000. (RN : Pt 1:1-2, for 6 weeks)
- More barriers and limitation to be overcome to grow a program.
- Space design.
- Hire to grow.
- Patient recruitment—different pools of referral, different processes involved. Best from PD program or in center HD. Great if directly office referral (NHD competes with HHD?).
- Button Hole to facilitate the training for HHD.
- Conquer fear of blood, needle and machine—”meet and play”, “mentoring program”
How does a clinic bill for home dialysis?

- **0821** Hemodialysis/Composite or other rate - HEMO/COMPOSITE
- **0841** CAPD/Composite or other rate - CAPD/COMPOSITE
- **0851** CCPD/Composite or other rate - CCPD/COMPOSITE

(Chapter 8 of the Medicare Claims Processing Manual §50 and §80)

- If a patient starts training but fails to complete it, $50.16 per training session; if complete the training, then based on 25 sessions for HHD and 15 sessions for PD at $50.16/session ....) (§150. ).

- A **nephrologist** can bill Medicare $500 for supervising training of a home dialysis patient (PD or home HD), *plus* the monthly capitation payment (or MCP).
Billing

• **For CAPD**, Medicare allows up to 15 training sessions based on 5–6 sessions a week with each session lasting up to 8 hours.

• **For CCPD**, Medicare allows up to 15 training sessions based on up to 5 exchanges per day 5–6 days a week.

• **For home hemodialysis**, Medicare routinely pays up to 25 training sessions.

• If more training sessions are needed, there must be **medical justification**.

• Need to have agreement with all insurers.

• Each training session is billable at $33.44 → 50.16.
Medicare Bundled Dialysis Prospective Payment System (PPS): PD & HHD by facility

- National Average Base Rate:
  a) Use Medicare HD equivalent sessions of CY2007, adjusted for CY2011 prices = $251.60 per treatment
  b) Reduce by 5.94% to account for average case-mix adjustment = $236.68 per treatment
  c) Reduce by 1% to create outlier payment pool = $234.31 per treatment
  d) Reduce by 2% per MIPPA for budget neutrality = $229.63 per treatment

2013 Bundled Payment –CY2013 $ 240.36 (UP 2.4%)
  a) The ESRD bundle market basket increase is 2.9 %. multi-factor productivity adjustment is 0.6 %, final bundle market basket update equal to 2.3 %. budget-neutrality adjustment-0.1 % adjustment.
  b) Average Medicare payments for dialysis in 2014 and 2015 will remain relatively unchanged.
• HD equivalent rate for PD = $229.63
• PD daily base rate = ($229.63 x 3)/7 = $98.41
• Adjusters
  ➢ Age adjuster
  ➢ Bundle Weight adjuster
• Home dialysis Training sessions (initial training or re-training) -- $50.16 per session if incomplete training. $50.16 if retraining with justification. (see Chapter 8, §150 of the Medicare Claims Processing Manual.)
When Medicare WILL pay for retraining ...

- The patient changes to a different home modality
- The home dialysis equipment changes
- The setting where the home dialysis occurs changes
- The dialysis partner changes
- The patient has a change in medical status that would not keep him or her from doing home dialysis—but would require additional training (examples in the Medicare Claims Processing Manual include memory loss due to stroke, and physical impairment) -- Chapter 8, §50.8 in the Medicare Claims Processing Manual.

- "Support services" is not "Retraining"
Operational Financial

**Operational Revenue/Tx.**

**Operational Expense/Tx.**

**Fixed Expense**

***Labor/Treatment***

**Variable Expense**

***Pharmacy/Treatment***

***Dialysis Supply/Treatment***

***Center expense/Treatment***

Depreciation & Amortization

Margin/Treatment

Management Fee % .... %

EBITA ....
## LABOR COST

..only rough estimate., may not be valid in all circumstance

<table>
<thead>
<tr>
<th>Modality</th>
<th>Hour/Tx</th>
<th>SWB/Tx</th>
<th>Hour rate/Tx</th>
<th>RN:PT ratio</th>
<th>PCT needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICHD</td>
<td>2.5</td>
<td>100</td>
<td>25</td>
<td>1:12</td>
<td>3</td>
</tr>
<tr>
<td>PD</td>
<td>1.5</td>
<td>70</td>
<td>46</td>
<td>1:20</td>
<td>0.1</td>
</tr>
<tr>
<td>HHD</td>
<td></td>
<td></td>
<td></td>
<td>1:20</td>
<td>1</td>
</tr>
</tbody>
</table>
Expense Analysis

- Average hourly cost = total labor $$ / total hours.
- Total labor cost/day = total labor $$ / 365 * number of patients.
- Supply: pharmacy + dialysis supplies.
- Capital equipment and Depreciation.
- General Administration.
- PD cost ~ 20-30% less than ICHD.
Revenues Streams guidelines for PD program.

• Training fee.
• 1.51 x adjusters for the first of 4 months after onset of ESRD.
• Re-training fee if justified.
• PD Maintenance fee. Allows 2013 Bundle Single-Base Rate System.
• With this unique advantage per CMS—
  a) **Uninsured, Medicare eligible** patients starting HD would only receive one month of the onset of dialysis adjuster due to 90 day waiting period.
  b) While patient enters PD center as the chosen **initial modality of ESRD treatment** during any date of the month, Medicare becomes retroactive to the beginning of the month. This will serve hospital, surgeon and other consultants with advantage.
**Revenue** (Billable items, PD/HHD) with impact of “adjusters” and Training ($401.41 max/*HD equivalent*)

<table>
<thead>
<tr>
<th>Description</th>
<th>Reimbursement Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD Reimbursement for training during onset of ESRD period</td>
<td>$ 229.63</td>
</tr>
<tr>
<td>National Average Base Rate</td>
<td></td>
</tr>
<tr>
<td>Age 54 yr. = Index of 1.3% =</td>
<td>$ 2.99</td>
</tr>
<tr>
<td>Reimbursement Add-On</td>
<td></td>
</tr>
<tr>
<td>Time of therapy less than 4 months = Index of 51%</td>
<td>$ 118.63</td>
</tr>
<tr>
<td>Home Dialysis Training $50.16 per session (HHD up to 25, PD up to 15)</td>
<td>$ 50.16</td>
</tr>
</tbody>
</table>
Impact of “adjusters” added into PD daily rate

PD reimbursement for first four months

Daily PD reimbursement rate

National Average Base Rate

(229.63 x 3)/7 = 98.41

Age 54 yr. = Index of 1.3% = 
Reimbursement Add-On

Time of therapy less than 4 months = Index of 51%

Total

$ 150.56 ( $351.31 for each HD equivalent at x 3 sessions/week)
PD First year Reimbursement
(Incident dialysis patient chooses PD)

**First Month**
($351.31+$50.16) x 12
(training)

**Revenue**
$4,817.64

**NOTE**
Assume 12 training sessions needed after onset of dialysis.

**Subsequent 3 Months**
$150.54 x 90

**Revenue**
$13,548.6

**2nd, 3rd and 4th month reimbursement**

**Remaining 8 Months**
$98.41 x 240

**Revenue**
$23,618

**Rest of the year.**

**Total**
$41,783.6

Incident PD enrollment, the revenue of the first year!
HHD First year Reimbursement
(Incident dialysis patient choses HHD)

<table>
<thead>
<tr>
<th>First Two Months</th>
<th>Revenue</th>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>$(351.25+50.16) x 25</td>
<td>$10,036.75</td>
<td>Assume 25 training sessions needed after onset of dialysis.</td>
</tr>
<tr>
<td>(training in 1.5 Months)</td>
<td></td>
<td></td>
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<tr>
<td>$351.25 x 7 sessions</td>
<td>$2458.75</td>
<td>Rest of 2 weeks of home dialysis after training completed</td>
</tr>
<tr>
<td>for remaining 2 wks of second month</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Subsequent 2 Months</th>
<th>Revenue</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$351.25 x 32</td>
<td>$11,240</td>
<td>3rd and 4th month at x4/wk. session.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remaining 8 Months</th>
<th>Revenue</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$ 232.62 x 16 x 8</td>
<td>$29,775.36</td>
<td>Rest of the year.</td>
</tr>
</tbody>
</table>

| Total                       | $53,091.36   | Incident HHD enrollment, first year revenue!  |
To Be Successful .....  
(Financially)

- Number of patients to break even: 10-12 each for PD and also for HHD program.
- Payor Mix-more nongovernmental payers is favorable.
- Incident dialysis patient recruit—1.51 x Bundle weight –help financial success.
Independent vs. Joint Venture

...Attributes to the decision making...

Of course! Independent program is a better choice *if you are ready, capable and prepared*......

• Management: Need to assemble a motivated and experienced team, Billing and Collection, Supply and Inventory management, Medical/Quality support, Education and Training.........
• Standing alone Home program not under QIP.
• Patient Growth and Retention remains a big challenge. Need to have a centralized program to do well (>70-80)
• But Legal constraint/Restriction —MDA, MSA, JV agreement (Geographic and time limitation/tails), joinder clause unless....
• Minority share vs. Majority share.
• Purchase of existing equity to merge into a large program—pay market price vs. Internal price.
• LDO divesture of existing unit to nephrologist as JV—not allowed due to recent ruling. Reverse circumstance is allowed.
Independent vs. Joint Venture continue

- Management fee-% of collection. % varies among LDOs and consulting firm.
- Group Purchasing power—national contract, Cost of med, supply...pass through cost...
- Expense (COS--cost of pharmaceuticals and supply).
- Training and education for home nurse. Quality program and IT support.
- To establish a large Home Program requires innovative approach esp. dealing with a competitive environment among nephrologists in the community and unintended division by LDOs thru its legal restriction.
Barriers to Independent Home Program

• Medical Director agreement.
• Joint Venture agreement.
• Joinder clause.
• MSA-nondisclosure, confidential information..
• Reality of “Local competitors” among potential partners. How to get over this barrier?
The Challenges for a PD program:

- When to preemptively prepare for HHD with AVF creation?
- PD patient is a natural candidate for HHD and allow avoidance of CVC. How to encourage PD patient exit into HHD needs process in place.
- Select proper PD patient to avoid “churn”.
- Acute start PD—acute initiation of PD in hospital and urgent start PD.
- Decision of “Independently Own” vs. “Joint Venture”.
- How to group all nephrologists in the community.
- During Bundle era, how to reduce expense for drugs—ESA, BMD.....how to survive among pharmacy in the bundle.
-H.E.O.R. of a PD Program-

• Triple Aims—Improve individual health, Improve population health, Reduce cost.

• < 3-4 % 90 day mortality. < 9% mortality yearly.

• Crash landing 11.5% during transitioning to PD.

• Peritonitis Rate: 1/~100 months.

• Hospitalization rate: 1 per patient per year.

• Working class: 35-38%.
## Crude mortality and Hospitalization Rate

<table>
<thead>
<tr>
<th>Year</th>
<th>Crude Mortality (yearly)</th>
<th>Hospitalization rate (USRDS 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>8.5%</td>
<td>HD 1.8</td>
</tr>
<tr>
<td>2010</td>
<td>9%</td>
<td>PD 1.6</td>
</tr>
<tr>
<td>2011</td>
<td>8.8%</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>8.8%</td>
<td>1.0</td>
</tr>
<tr>
<td>2013</td>
<td>8.9%</td>
<td>1.0</td>
</tr>
</tbody>
</table>