

Preparing Ourselves to Leverage Health Care Legislation Directly Impacting the Future of Home Infusion Therapy Success

December 5, 2012

12:00 – 1:30PM Eastern Time

Talk Infusion

The NHIA Membership Forum





Presenters

- Mary Ann Cope, RPh., Pres./CEO, HomeChoice Partners, NHIA Board Chair
- Kendall Van Pool, NHIA VP of Legislative Affairs
- Bill Noyes, NHIA VP of Health Information Policy
- Alan Parver, Esq., Polsinelli Shughart, NHIA Legal Counsel



Call Overview

- Discuss The Medicare Home Infusion Therapy Coverage Act
- Learn about NHIA's grassroots strategies and advocacy efforts
- Discuss NHIA's efforts with regard to Competitive Bidding
- Review competitive bidding legislation and compounding pharmacy developments



Ken Van Pool

Vice President of Legislative Affairs
A Personal Introduction



The Current Legislative Landscape

- **Fiscal Cliff Negotiations Ongoing**
 - **Some proposals on Medicare and Medicaid**
 - Major benefit changes unlikely
 - Medicare premiums and eligibility age
 - Doc fix unlikely
 - Competitive bidding replace bill being pushed (Alan will discuss further)
- **The 113th Congress**
 - Doc fix bill
 - Structural changes to entitlement programs



Resetting the Playing Field by Changing the Game

- **NHIA is looking forward to the 113th Congress with excitement**
- **NHIA is working on a new bill that will also bring a new approach to home infusion coverage**
- **Budget savings or neutrality will be key in the 113th Congress**



The Current Home Infusion Therapy Coverage Act Hurdles to Passage

- Budget score – never released, but noted by Chairman Baucus as high
- Split Part B and D benefit hard to administer
- Viewed as a “new” benefit rather than an extension of a current Part A benefit



Avalere Study

- **NHIA has hired the prestigious health policy firm, Avalere, to propose alternative strategies for home infusion coverage**
- **Avalere is a policy firm that is often cited by leading experts in the health care field and is viewed as a credible resource on the Hill and with the Administration**



Avalere Study Cont.

- **Avalere has been tasked to propose a new regulatory and legislative framework that will be at least budget neutral or, even better, budget saving**
- **NHIA has been working to ensure Avalere has the resources they need to make the best policy arguments for a home infusion benefit**
 - **Data on the home infusion industry**
 - **Visits to home infusion pharmacies**
- **Final study and policy options will be available in early 2013**



A New Medicare Home Infusion Therapy Coverage Act

- With the new policy options from Avalere NHIA will introduce a new and different home infusion benefit bill
- NHIA will be working to educate Members of Congress on the new approach and dispose of the myths that coverage will cost the federal government
- NHIA will also be working to find new champions in this effort
 - Snowe retirement means a new Senate Republican lead will be needed
- You can be part of this process!



A Bill's Life Cycle and Corresponding Grassroots Efforts

- **General Member Education**
 - Constituent letters and calls
 - Member of Congress personal connections to the issue
 - Requests for cosponsorship
 - New forms of advocacy to leverage
 - NHIA will be working with our advocacy vendor to roll out a new advanced advocacy system this year



A Bill's Life Cycle and Corresponding Grassroots Efforts

- **Elevation of Policy as a Priority**
 - **Microtargeting certain Members of Congress that are in positions of influence**
 - **District meetings**
 - **Site Visits**
 - **District press and patient stories**



A Bill's Life Cycle and Corresponding Grassroots Efforts

- **Passage opportunities**
 - Identifying legislative vehicles
 - Timing our grassroots efforts around opportunities for passage
 - Call storms and Twitter storms (proper timing is key)
- **Your involvement is key (passion = passage)**



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Round 1 Re-Compete of Competitive Bidding

Presented by Bill Noyes



Agenda

- Round 1 Re-Compete of Competitive Bidding
 - Competitive Bidding Areas (CBA's)
 - Timeline
 - Product categories
 - NHIA efforts
 - Resources



Round 1 Re-Compete CBA's

- Charlotte-Gastonia-Rock Hill (North Carolina and South Carolina)
- Cincinnati-Middletown (Ohio, Kentucky and Indiana)
- Cleveland-Elyria-Mentor (Ohio)
- Dallas-Fort Worth-Arlington (Texas)
- Kansas City (Missouri and Kansas)
- Miami-Fort Lauderdale-Pompano Beach (Florida)
- Orlando-Kissimmee-Sanford (Florida)
- Pittsburgh (Pennsylvania)
- Riverside-San Bernardino-Ontario (California)



Round 1 Re-Compete Timeline

8/16/2012

The Centers for Medicare & Medicaid Services (CMS) announces bidding timeline, begins bidder education program

8/20/2012

Registration for user IDs and passwords begins

9/7/2012

Authorized Officials are strongly encouraged to register no later than this date

9/28/2012

Backup Authorized Officials are strongly encouraged to register no later than this date

10/15/2012

CMS opens 60-day bid window for Round 1 Re-Compete

10/19/2012

Registration closes

11/14/2012

Covered document review date for bidders to submit financial documents

Bill Noyes

12/5/2012



Round 1 Re-Compete Timeline (cont.)

12/14/2012

60-day bid window closes

Spring 2013*

CMS announces single payment amounts, begins contracting process

Fall 2013*

CMS announces contract suppliers, begins contract supplier education campaign.

Fall 2013*

CMS begins supplier, referral agent, and beneficiary education campaign

January 1, 2014*

Implementation of Round 1 Re-Compete contracts and prices

** Dates listed are target dates. Actual dates will be announced through listserv notice.*



Product Categories

- Respiratory Equipment and Related Supplies and Accessories
 - includes oxygen, oxygen equipment, and supplies; continuous positive airway pressure (CPAP) devices and respiratory assist devices (RADs) and related supplies and accessories; and standard nebulizers
- Standard Mobility Equipment and Related Accessories
 - includes walkers, standard power and manual wheelchairs, scooters, and related accessories
- General Home Equipment and Related Supplies and Accessories
 - includes hospital beds and related accessories, group 1 and 2 support surfaces, transcutaneous electrical nerve stimulation (TENS) devices, commode chairs, patient lifts, and seat lifts
- Enteral Nutrients, Equipment and Supplies
- Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories
- **External Infusion Pumps and Supplies (EIP)**



External Infusion Pumps and Supplies

A4221	Supplies For Maintenance Of Drug Infusion Catheter, Per Week (List Drug Separately)
A4222	Infusion Supplies For External Drug Infusion Pump, Per Cassette Or Bag (List Drugs Separately)
E0776	IV Pole
E0779	Ambulatory Infusion Pump, Mechanical, Reusable, For Infusion 8 Hours Or Greater
E0780	Ambulatory Infusion Pump, Mechanical, Reusable, For Infusion Less Than 8 Hours
E0781	Ambulatory Infusion Pump, Single Or Multiple Channels, Electric Or Battery Operated, With Administrative Equipment, Worn By Patient
E0784	External Ambulatory Infusion Pump, Insulin
E0791	Parenteral Infusion Pump, Stationary, Single Or Multi-Channel
K0552	Supplies For External Drug Infusion Pump, Syringe Type Cartridge, Sterile, Each
K0601	Replacement Battery For External Infusion Pump Owned By Patient, Silver Oxide, 1.5 Volt, Each
K0602	Replacement Battery For External Infusion Pump Owned By Patient, Silver Oxide, 3 Volt, Each
K0603	Replacement Battery For External Infusion Pump Owned By Patient, Alkaline, 1.5 Volt, Each
K0604	Replacement Battery For External Infusion Pump Owned By Patient, Lithium, 3.6 Volt, Each
K0605	Replacement Battery For External Infusion Pump Owned By Patient, Lithium, 4.5 Volt, Each

Bill Noyes



NHIA Efforts

NHIA has communicated its serious patient safety concerns regarding the Inclusion of EIP in Competitive Bidding to...

- Centers for Medicare & Medicaid Services (CMS)
- Competitive Bidding Implementation Contractor (CBIC)
- National Supplier Clearinghouse (NSC)
 - National Supplier Clearinghouse Advisory Committee (NSCAC)



Many unanswered questions remain

- Bifurcated or Split Benefit – General DME Supplier
 - Who will provide the drugs?
 - Who will select the pump and supplies?
 - Who will program the pump?
 - Who will train the patient on the use of the pump?
 - Who will field equipment related calls after hours?



Unanswered questions

- How will the CBIC determine the right mix of providers to meet the projected needs of Part B beneficiaries for all covered infusion drugs?
- The pump (E0781) and kit (A4222) are used to bill for a wide range of therapies. Not all suppliers provide the full spectrum of drugs (example: Chemotherapy)



Insulin Pumps

- You must place a bid for ALL HPCPS
- Must be accredited to provide Insulin Pumps
- Update your CMS-855
- Bid capacity may affect bid acceptance



Bidding on Kit Codes A4222 and A4221

- “When bidding on kits, suppliers should enter the manufacturing information of the 'prominent' item within the kit whether it is tubing, dressings, flush or diluting solutions, etc. It is up to the supplier to determine the 'prominent' item.”



Resources

- National Home Infusion Association
Competitive Bidding Resource Center
 - http://www.nhia.org/members/bidding/bidding_program.cfm
 - You can view all competitive bidding related correspondence and Q&A's



<http://www.dmecompetitivebid.com>

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DMEPOS Competitive Bidding Program

[CBIC HOME](#) [ABOUT US](#) [FIND A CBA](#) [E-MAIL UPDATES](#) [CONTACT US](#) Search

Round 1 Recompete
Round 2 & National Mail-Order
Round 1 Rebid
Non-Contract Suppliers
Referral Providers
Helpful Links

STAY CONNECTED
Keep up with the latest information about the DMEPOS Competitive Bidding Program by taking advantage of the Internet's connectivity.

E-MAIL UPDATES
 CONTACT US

ABOUT THE PROGRAM
The DMEPOS Competitive Bidding Program was mandated by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The statute requires that Medicare replace the current fee schedule payment methodology for selected Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items with a competitive bid process. [More info...](#)

Use our interactive map to view Competitive Bidding Areas (CBAs).

PEOPLE WITH MEDICARE
For more information, please visit the Medicare website at www.medicare.gov or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

[PRIVACY POLICY](#) | [SITE MAP](#) | [SITE HELP](#) | [REDESIGN OVERVIEW](#)



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Market Pricing Program and Compounding Pharmacy Legislative Action

Presented by Alan Parver



Market Pricing Program

- H.R. 6490 (Tom Price (R-GA), 64 co-sponsors)
- Concept supported by much of DMEPOS industry
- Based largely on Professor Peter Crampton's criticisms of current competitive bidding system
- Major sea change for industry
 - Shift from full repeal to modify current program
 - Acceptance of competitive bidding mechanism



Market Pricing Program

- **Would bring DMEPOS competitive bidding in line with other government-run competitive bidding programs**
- **No “winning” bidder would have to accept less than its bid**
 - **More reflective of the market**
- **Limit program to two product categories per competitive bidding area**
- **Other products in competitive bidding area would have prices adjusted based on competitive bidding in other comparable areas**



Market Pricing Program

- Bids would be binding
- Competitive bidding contracts would be for 2 years
- Managed by Market Manager and Auction Expert
- Issues can be resolved at design conferences with stakeholders?
- Begin 2013
 - CMS says it is not implementable that quickly



Market Pricing Program

- **No CBO score yet**
- **Congress will not consider H.R. 6490 without a CBO score that saves money or is budget neutral**
- **May not be considered in lame duck session in December**



Compounding

- Issue of proper regulation of compounding pharmacies raised by meningitis outbreak
 - New England Compounding Center
 - Appeared to compound drugs in large bulks
 - Per individual prescriptions?
- Congress exploring roles of FDA and state pharmacy boards
 - Compounding traditionally regulated by states, not FDA
 - FDA does regulate drug manufacturing



Compounding

- **The Verifying Authority and Legality in Drug Compounding Act (VALID) of 2012 (H.R. 6584) introduced by Rep. Markey**
- **VALID Act would exempt compounding from FDA manufacturer regulations if certain conditions are met**
 - **Drug compounded for an identified patient with a valid prescription**
 - **Drug must be compounded with safe and approved ingredients**
 - **Drug cannot be a copy of a commercially-available drug**
 - **FDA (not state) could grant waivers to enable pharmacies to compound before receipt of valid prescription**
 - **Other waivers possible to protect public health or to deal with drug shortages**



Prospects for H.R. 6584

- Congress looking at FDA's failure to act
- Did FDA have requisite authority to close NECC?
- Where is the line between manufacturing and compounding?
- Some reluctance to add to regulation before answering these questions and thus determine if further regulation is necessary



Talk Infusion

The NHIA Membership Forum



Alan K. Parver, Esq.

Alan Parver

12/5/2012



Wrap-Up – Call to Action!

Question/Answer Session

- To ask a question:
- Press “7” on your touch tone phone

- *As a reminder, this call is being recorded



Thank You!