

Survey of Medicare's DMEPOS Accreditation and Competitive Bidding Requirements and Policies

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Health Care Reform

- Today's Agenda:
  1. Competitive Bidding for DME
  2. Implementation Schedule
  3. Health Reform

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Competitive Bidding for DME

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## Competitive Bidding Program Established in MMA

- The Medicare Modernization Act of 2003 (MMA) established requirements for a competitive bidding program for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
- Intent is to improve the effectiveness of Medicare methodology for setting DMEPOS amounts, which will reduce beneficiary costs and save Medicare money while ensuring beneficiary access to quality items and services
  - Competitive bidding program replaces DMEPOS fee schedule methodology for certain DMEPOS items in competitive bidding areas
  - MMA mandated the program Round 1 competition to occur in 10 of the largest Metropolitan Statistical Areas (MSAs) in 2007; 80 of the largest MSAs in 2009; and additional areas after 2009

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## Changes to Competitive Bidding in MIPPA

- Program was originally launched July 1, 2008, but was halted two weeks later
- Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) made changes to the competitive bidding program
  - Delayed Round 1: Re-bid to occur in 2009
  - Excludes from Round 1:
    - Puerto Rico as an area;
    - Negative pressure wound therapy (NPWT) as an item;
    - Group 3 or higher complex rehabilitative wheelchairs from all rounds of competition; and
    - Certain DME furnished by a hospital to the hospital's own patients during an admission or on the date of discharge
  - Established a process for supplier feedback on missing financial documents
  - Required contract suppliers to notify CMS of subcontracting relationships and that subcontractors meet accreditation requirements

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## Overview of Program Operations

- Competition among suppliers who operate in a particular Competitive Bidding Area (CBA) is conducted
- Suppliers are required to submit a bid for selected products
  - Not all products or items are subject to competitive bidding
- Bids are evaluated based on the supplier's eligibility, financial stability, and bid price
- Contracts are awarded to Medicare suppliers who offer the best price and meet quality and financial standards
- Contract suppliers must agree to accept assignment on all claims for bid items and will be paid the bid price amount
  - Bid price amount derived from the median of all winning bids for an item

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## Program Advisory and Oversight Committee

- The MMA creates a Program Advisory and Oversight Committee (PAOC) to provide advice on the development and implementation of the program
- The PAOC is to advise on the following:
  - Implementation of the program
  - Establishment of financial standards that take into account the needs of small providers
  - Establishment of requirements for collection of data for the efficient management
  - Development of proposals for efficient interaction among manufacturers, providers of services, suppliers, and individuals
  - Establishment of quality standards

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## Competitive Bidding Areas for Round 1 Re-Bid

- Within Competitive Bidding Areas (CBAs), only contract suppliers may furnish certain DMEPOS items to beneficiaries
- CBAs designated for Round 1 Re-bid\*:
  - Cincinnati – Middletown (Ohio, Kentucky, and Indiana)
  - Cleveland – Elyria – Mentor (Ohio)
  - Charlotte – Gastonia – Concord (North Carolina and South Carolina)
  - Dallas – Fort Worth – Arlington (Texas)
  - Kansas City (Missouri and Kansas)
  - Miami – Fort Lauderdale – Miami Beach (Florida)
  - Orlando (Florida)
  - Pittsburgh (Pennsylvania)
  - Riverside – San Bernadino – Ontario (California)

\*These are the same MSAs designated by the MMA, with the exception of Puerto Rico, which was excluded under MIPPA

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## Product Categories for Round 1 Re-Bid

- The Round 1 Re-bid will include the following product categories\*:
  - Oxygen Supplies and Equipment
  - Standard Power Wheelchairs, Scooters, and Related Accessories
  - Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2)
  - Mail-Order Diabetic Supplies
  - Enteral Nutrients, Equipment and Supplies
  - CPAP, RADs, and Related Supplies and Accessories
  - Hospital Beds and Related Accessories
  - Walkers and Related Accessories
  - Support Surfaces (Group 2 mattresses and overlays) in Miami

\*These are the same product categories that were selected for the initial Round 1 in 2007, except for negative pressure wound therapy (NPWT), which is excluded from the Round 1 Re-bid, and group 3 complex rehabilitative wheelchairs, which are excluded from the Round 1 Re-bid and all subsequent rounds

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## Implementation Timeline

- Bidding Timeline for the DMEPOS Competitive Bidding Program Round 1 Rebid
- **8/3/2009**  
The Centers for Medicare & Medicaid Services (CMS) announces timeline/schedule of education events, begins bidder education campaign
- **8/17/2009\***  
Registration for user IDs and passwords begins.
- **9/30/2009**  
Last day for DMEPOS suppliers to get accredited
- **10/2/2009**  
DMEPOS supplier surety bond deadline

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## Implementation Timeline (continued)

- **10/21/2009\***  
CMS opens 60-day bid window for Round 1 Rebid
- **11/21/2009\***  
Covered Document Review Date for bidders to submit financial documents
- **12/21/2009\***  
60-day bid window closes

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## Implementation Timeline (continued)

- **June 2010**  
CMS announces single payment amounts, begins contracting process
- **September 2010**  
CMS announces contract suppliers, begins contract supplier education campaign
- **Early Fall 2010**  
CMS begins supplier, referral agent, and beneficiary education campaign
- **1/1/2011**  
New program begins!

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# Health Reform

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## Health Care Reform and Average Manufacturer Price (AMP)

- AMP changes included in:
  - House Tri-Committee bill
  - “Fair Medicaid Drug Payment Act of 2007” introduced by Sen. Baucus and Rep. Pallone
- Currently no AMP changes in the Senate Health, Education, Labor & Pensions (HELP) Committee bill
- AMP changes expected in Senate Finance Committee bill

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## Key AMP-Related Provisions in Health Reform Proposals

- Calculation of the Federal Upper Limit (FUL)
  - DRA required FULs for multiple-source drugs to be based on 250% of the AMP for the least costly therapeutically-equivalent drug
  - MIPPA delayed implementation of AMP-based FULs
  - Baucus/Pallone bill would increase FUL to at least 300% of weighted average of the most recent AMPs for generic drugs available for purchase by retail community pharmacies on a nationwide basis
  - House bill would set FULs at 130% of the weighted average of monthly AMPs (with weighted average determined on basis of manufacturer Medicaid utilization)

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## Key AMP-Related Provisions in Health Reform Proposals (continued)

- Definition of AMP:
  - Proposals would modify definition of AMP by excluding additional types of payment, which could ultimately affect FUL if AMP-based
- Public Disclosure of AMP:
  - Current law permits the Secretary to disclose AMPs on a publicly-accessible website, but CMS is currently prohibited by court order and statute from publicly disclosing AMP data
  - Under Baucus/ Pallone bill, AMP data would be available to states, but not published on a public website
  - House bill would permit disclosure of only weighted AMPs

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## Key AMP-Related Provisions in Health Reform Proposals (continued)

- Definition of Multiple-Source Drug:
  - Baucus/Pallone bill would reduce the number of drugs subject to the FUL by restoring the pre-DRA definition (which required that there be at least 2 *other* pharmaceutically and therapeutically equivalent drug products)
- Definition of Pharmacy Benefit Manager (PBM):
  - Not currently defined
  - Major proposals do not include definitions

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## Key AMP-Related Provisions in Health Reform Proposals (continued)

- Pharmacy Reimbursement:
  - House bill would extend MIPPA provision so that FUL calculation methodology based on 150% of lowest published price would continue to apply to payments made by a state for multiple-source drugs under a state Medicaid plan through December 31, 2010
- Manufacturer Reporting:
  - House bill would require manufacturers to report to Secretary, within 30 days of the last day of each month of a rebate period, the total number of units used to calculate the monthly AMP for each covered outpatient drug
- AMP and FUL Regulations:
  - House bill would give the Secretary authority to promulgate expedited regulations to clarify requirements for FULs and calculating AMP

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# Manufacturer Rebates



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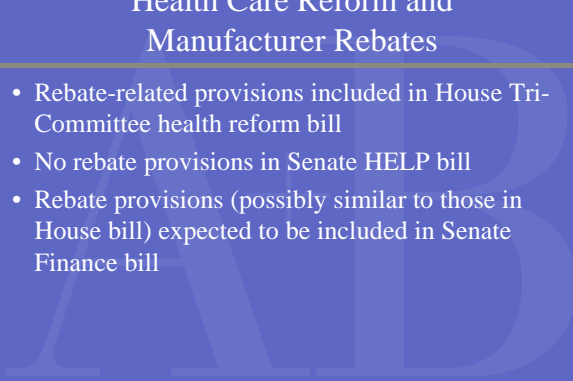
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## Health Care Reform and Manufacturer Rebates

- Rebate-related provisions included in House Tri-Committee health reform bill
- No rebate provisions in Senate HELP bill
- Rebate provisions (possibly similar to those in House bill) expected to be included in Senate Finance bill



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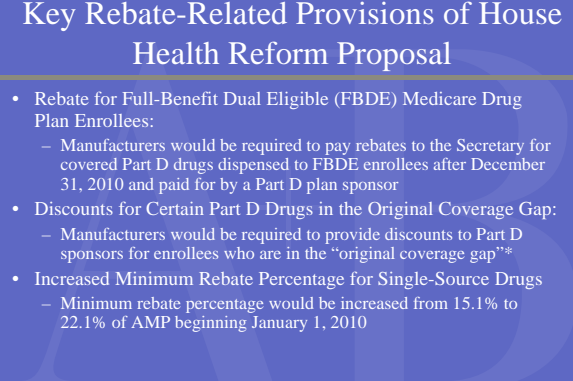
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## Key Rebate-Related Provisions of House Health Reform Proposal

- Rebate for Full-Benefit Dual Eligible (FBDE) Medicare Drug Plan Enrollees:
  - Manufacturers would be required to pay rebates to the Secretary for covered Part D drugs dispensed to FBDE enrollees after December 31, 2010 and paid for by a Part D plan sponsor
- Discounts for Certain Part D Drugs in the Original Coverage Gap:
  - Manufacturers would be required to provide discounts to Part D sponsors for enrollees who are in the "original coverage gap"\*\*\*
- Increased Minimum Rebate Percentage for Single-Source Drugs
  - Minimum rebate percentage would be increased from 15.1% to 22.1% of AMP beginning January 1, 2010

\*\*\*Original coverage gap" and "actual gap of coverage" are defined in the bill as the House proposal would eliminate the coverage gap.



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Thank You

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