

State of Vermont
Office of Vermont Health Access
312 Hurricane Lane, Suite 201
Williston VT 05495-2807
www.ovha.vermont.gov

[Phone] 802-879-5900
[Fax] 802-879-5651

Agency of Human Services

MEMORANDUM

To: Senate Committees on Appropriations and Health and Welfare
House Committees on Appropriations and Human Services

CC: Robert D. Hofmann, Secretary, Agency of Human Services

From: Susan Besio, Director, Office of Vermont Health Access

Date: February 25, 2010

Re: Study on Medicaid Cost Containment for Medical Devices and Biologics per 2009 Special Session Act 1, Section.309.11

- (a) The Office of Vermont Health Access shall determine the feasibility of creating a preferred list of or entering into agreements with other states for purchasing medical devices and biologics to maximize the ability of the Medicaid program to ensure high quality products while negotiating favorable prices and containing costs.
- (b) No later than January 15, 2010*, the office shall report its analysis on the feasibility, including potential benefits and harms, to the senate committees on appropriations and on health and welfare, and the house committees on appropriations and on human services.

* An extension until February 28 was granted, per request in memorandum dated December 10, 2009 from Susan W. Besio to Senators Susan Bartlett and Doug Racine, and Representatives Martha Heath and Ann Pugh, Chairs of the above committees.

EXECUTIVE SUMMARY

The enclosed report summarizes a review of possible measures to contain costs in the Medicaid program, including establishing preferred lists and/or joining with other states for purchasing medical devices and biologics to obtain lower pricing. This review also includes cost containment efforts that have been pursued and/or are currently utilized by OVHA.

The Office of Vermont Health Access (OVHA) looked for opportunities that may exist for cost containment and found that cost savings might exist in the following areas:

- 1) Contracting with ICORE Healthcare at a possible 3:1 return on investment (ROI) on their estimated annual gross savings of \$391,089 on provider administered injectables;
- 2) Investigating single source contracts;
- 3) Examining DME and supplies limits;
- 4) Investigating opportunities for entering into agreements with other states for purchasing and contracting practices;
- 5) Monitoring the CMS competitive bid;
- 6) Investigating alternative Prior Authorization (PA) management systems

The OVHA will continue to pursue opportunities to reduce Medicaid reimbursement costs for durable medical equipment (DME), biologics and all goods and services, while taking into consideration possible harmful or negative effects that may be related directly or indirectly.

INTRODUCTION

The processes used to determine the feasibility of a preferred list or agreements with other states for purchasing medical devices and biologics for this report included:

- 1) Analyzing DME data to determine highest expenditure/ highest use;
- 2) Utilizing Pharmacy Benefit Management (PBM) program resources to review biologics pricing in the Pharmacy Benefit;
- 3) Partnering with the PBM program to access a contractor for analysis of physician-administered injectables in the Medical Benefits program;*
- 4) Researching what other states are doing;
- 5) Reviewing and monitoring the Centers for Medicare and Medicaid Services (CMS) competitive bid process;
- 6) Consideration of possible repercussions and ramifications (benefits and harms) of the above;
- 7) Partnering with the New England States Consortium Systems Organization (NESCSO)

*NOTE: Pharmaceuticals may be reimbursed via the Pharmacy Benefit or the Medical Benefit. The Pharmacy Benefit covers pharmaceuticals when a prescription is dispensed and billed by a retail pharmacy. The Medical Benefit covers pharmaceuticals that are purchased, administered and billed by a physician. The same prior authorization (PA) criteria are used for select pharmaceuticals in both programs.

Reimbursement for Durable Medical Equipment (DME) and Pharmaceuticals

The OVHA reimburses Medicaid providers in the Medical Benefit for claims submitted for services, DME, and supplies according to established fee schedules. The fee schedule lists procedure codes (CPT, HCPCS, etc.), restrictions and reimbursement rates.

The Pharmacy Benefit reimburses at the lower of average wholesale price (AWP) minus 14.2% plus a dispensing fee, or Usual and Customary Charge submitted by the pharmacy. The net cost to the OVHA is reduced by CMS rebates and supplemental rebates (if applicable). The OVHA, through its PBM contractor, MedMetrics Health Partners, also utilizes a contract with Megallan Health Services/ICORE Healthcare (ICORE) for specialty pharmacy.

CONSIDERATIONS, BENEFITS AND HARMS

Cost containment is an important consideration for healthcare and the Vermont Medicaid program at any time, and this has never been truer than in the current economic climate. It is agreed that it is essential that any efforts to control costs take into consideration benefits as well as harms that may result from cost containment methods. Some considerations of benefits and harms considered by OVHA when exploring new cost containment opportunities are outlined below.

Quality:

Price reductions provide disincentives to suppliers to offer high quality devices. Some providers may curtail quality of items they provide.

- Lower quality products may be provided under any contract.
- An extremely limited range of product varieties could have a negative clinical impact.

Service:

Loss of face-to-face provider support, teaching, product service, repair and follow up for beneficiaries could result from too low prices or if a contractor is located outside of Vermont. Similarly, a single source contractor may not have the time or the incentive to adequately service under the contract.

- There is a significant service component with many of these devices/suppliers that adds complexity to contract purchasing methods. Consideration must be given to related costs of the service needed for some DME items, such as delivery, setup, fitting and servicing of wheel chairs, beds, oxygen, etc.
- This may lead to use of subcontractors and additional contract management issues and time by the OVHA.

Selection:

Product choice or limited selection could negatively impact beneficiaries. One major concern, for example, was found concerning ostomy supplies (collection pouches and products used after surgical procedures involving the bowel or bladder) while researching other states. There are many different brands and not all brands work for all people, so the options of multiple brands to purchase is essential for beneficiaries to get a product that works for them. This is a cost efficiency issue: if the supply doesn't work, the beneficiary may need to use more products or potentially seek more frequent medical care.

Accessibility:

Disruption in supply and less access to healthcare providers is often a concern. Cost savings tactics could limit the number of suppliers in the market. Additionally, consideration must be given to Vermont's rural population.

Medicaid's most vulnerable beneficiaries:

Advocates for Medicaid beneficiaries with disabilities and chronic conditions may suggest that this will negatively impact the most vulnerable beneficiaries.

- Supplier selection may limit related services to evaluate, fit, adjust, repair and/or program devices
- Supplier selection may affect timeliness of repairs
- Access to suppliers may burden beneficiary with restricted ability to physically access provider
- Forced substitution in brand could impact functional level/health of beneficiary.

Vermont businesses / local economy:

Vermont businesses may be negatively impacted if outcome directs business away from Vermont.

- Outsourcing to an organization that supplies the items that are determined to be high use could potentially add cost for the management of the program within the OVHA, and take business away from Vermont businesses.

Reduced Reimbursement:

Reduced reimbursement rates or single sourcing/limiting number of providers could result in loss of providers.

- Single sourcing with one provider would harm loyal Medicaid providers while creating a huge windfall for one provider.
- There is the possibility that smaller providers if receiving a larger share of business would not be able to serve Medicaid beneficiaries.

Time to implement reduces savings:

- It can take up to a year to implement bidding and contracting and time impacts savings, as Michigan showed, and therefore no immediate cost savings would be achieved.
- Multiple bid processes to evaluate savings in various high expenditure DME groups could take longer than one year, and results may indicate that savings are not attainable within the group of DME.

Limited Staff Resources:

With recent staffing reductions of 23%, resources are limited to adequately research, write specifications, issue an RFP for a competitive bid process or RFI to obtain information, and manage the bid process. Management of any resulting contracts may require additional staffing resources.

- Increased staffing may be necessary to handle the bid process, manage contracts, resulting subcontracts and indirectly related issues.
- Additional Prior Authorization (PA) requests due to increased PA requirements could require more staff.

DME suppliers are not regulated:

The State of Vermont, Secretary of State, Office of Professional Regulation does not regulate DME providers, other than hearing aid dispensers. This may be an issue particularly if out-of-state provider participation and enrollment in Vermont Medicaid is encouraged by the bid process.

Other considerations and options:

- Partnering with additional groups, such as the National Association of State Medical Directors, may reveal new opportunities.
- Provider accreditation, when possible, and quality standards and specifications must be included in the RFP, competitive bid process and any resulting contract.

SUMMARY OF CURRENT EFFORTS TO CONTROL COSTS

Some methods currently used and/or explored by OVHA in the effort to control costs for both Durable Medical Equipment (DME) and Pharmaceuticals include:

1. Preferred products
2. Single source contracts
3. Multi-state purchasing efforts
4. Competitive bidding
5. Process and procedure for reimbursement
6. Rebates for drugs

The following sections review these strategies separately for DME and pharmacy/biologics.

DURABLE MEDICAL EQUIPMENT (DME) AND SUPPLIES

Data were collected from the MMIS Medicaid claims system in order to identify the high use / high expenditure groups of items for DME and supplies. The category of DME had a total expenditure of \$8,009,175 for SFY '09. The eight categories that comprised the majority of these expenditures were Oxygen and Related Respiratory Equipment; Orthotics; Home Infusion Therapy; Enteral and Parenteral Nutrition; Hearing aids and supplies; Wheelchairs & Accessories; Eyeglasses & Associated Fees; and Transcutaneous and/or Neuromuscular Electrical Nerve Stimulator.

Recent OVHA Activities to Control Costs

- A. NESCSO: The OVHA is currently a partner with the New England States Consortium Systems Organization (NESCSO). In May 2007, the New England states established a workgroup to collaboratively review DME policies, best practices, product quality comparisons, specification standardization, and the potential for regional purchasing of certain commodities to reduce costs.
- February 2008: A request for Information (RFI) for DME was issued by Vermont to gather information from DME vendors to assist the OVHA in the consideration and development of future Requests for Proposal (RFP).
 - April 2008: Responses to the RFI were received from interested parties.
 - October 2008: A notice was posted to manufacturers of incontinence supplies to request samples for preferred product procurement for Medicaid Programs on behalf of the State of Vermont and other interested state Medicaid programs. A description of products required by beneficiaries was included along with the performance expectations and the testing requirements. Samples were evaluated and rated.

- September - December 2008: Vermont and Maine released a statement that stated they were “interested in opening negotiations for exclusive product relationships for incontinence supplies”.
- October 2008: Vermont hosted a call with incontinence suppliers.
- December 2008: A Request for Proposal (RFP) for incontinent supplies was issued by Maine and Vermont.
- September 2009: The OVHA chose to not issue a contract with a single source incontinent supplies provider when analysis of pricing found it to not be cost effective.
- Currently, NESCSO is collecting and analyzing DME data for the participating States that want to be included.

In May of 2009, NESCSO issued a report titled Durable Medical Equipment Procurement for Medicaid for the New England States: An Overview, to summarize the progress of the New England states workgroup. This included the progress of the group following the spring of 2007 formation, to review the potential for regional purchasing of selected DME. See Addendum B for this report in its entirety.

The OVHA Clinical Operation Unit will participate in the regional workgroup meetings and teleconferences/web-casts that will be utilized to facilitate discussions and recommendations and continue to collaborate with NESCSO on future projects.

- B. The OVHA is looking at high cost DME and the impact on members who are both Medicaid and Medicare beneficiaries (dual eligible) as it relates to Medicare/Medicaid reimbursement policy and access to DME. CMS procedures influence providers' willingness to provide high cost specialty DME, since CMS has advance determination only on uniquely constructed or substantially modified DME; as such, there is no guarantee of Medicare reimbursement for the majority of items that have no advance determination by Medicare. Medicare procedures affect Medicaid process and reimbursement. Vermont Medicaid may pay all or more than our share, although Medicaid is the payer of last resort. Power wheelchairs and specialty hospital beds have been a particular area of concern. A conference call on February 12 with representatives of the CMS, including both Medicare and Medicaid representatives, initiated discussion about process, policy and procedure. This resulted in formation of a workgroup represented by members of CMS (i.e., Medicare), OVHA, Department of Disabilities, Aging and Independent Living (DAIL), Vermont Legal Aid, and perhaps DMERC (regional Medicare contractor). This group will better define the issues and pursue a pilot under Medicare to test the problems and possible solutions. The OVHA will involve New England Medical Equipment Dealers (NEMED) and other interested groups while reviewing this process.
- C. McKesson InterQual - In November of 2008, the OVHA purchased an evidence based clinical criteria program. The criteria are utilized for DME equipment that requires a prior authorization. This contract was renewed for another year, beginning November 2009. This process helps ensure consistent and appropriate dispensing

of DME. Vermont Medicaid Rules are referenced for prior authorizations in determining medical necessity and other requirements.

- D. Single source bidding efforts have resulted in the following varied results.
1. Eyeglasses: The OVHA currently contracts with a single source provider for eyeglasses. This method has proved successful for a number of years, although an RFP was issued last year to be compliant with state contracting requirements.
 - March 2009: The OVHA issued an RFP with specifications for eyeglasses to secure pricing.
 - July 1, 2009: Contract started. It was determined through the process that the single source is cost effective and allows control of quality and availability of eyeglasses provided to Medicaid beneficiaries. The OVHA will continue to review this process when the contract approaches its end date of June 30, 2011.
 2. Incontinence Supplies: As stated earlier, the OVHA found that single sourcing incontinence supplies would not accomplish cost savings.
- E. CMS Competitive Bidding Program: The OVHA is monitoring the CMS Competitive Bidding Program mandated by Congress requiring that Medicare replace the current fee schedule payment methodology for selected DME with a competitive bid process. The intent is to improve the effectiveness of the Medicare methodology for setting payment amounts to reduce beneficiary out-of-pocket expenses and to save the Medicare program money while ensuring beneficiary access to quality items and service.
- July 2008: Initial regional competitive bid process initiated and later cancelled due to the numerous problems encountered.
 - August 2009: CMS reinstates the program as “Round 1 Rebid” with improvements, such as early bidder education and increased oversight of bidders that are new to product categories or competitive bidding areas. The bid is limited to specific regions and certain specified DME items.
 - December 21, 2009: Bids were due to the CMS contractor handling the process.
 - As of the date of this report, no results are publicly available. On February 23, 2010, CMS will be hosting a meeting with the Program Advisory and Oversight Committee (PAOC) to discuss the Round 1 Rebid and upcoming Rounds of the Medicare DMEPOS Competitive Bidding Program.
 - January 1, 2011: The scheduled implementation date for CMS contracts with selected providers for certain bid items and pricing resulting from this bid.

The OVHA will continue to monitor this program. Upon implementation, the OVHA may be able to utilize relevant components. However, feasibility for savings would need to be considered on a case-by-case basis for each DME category. At this time, the OVHA does not have adequate staff to implement a program of this magnitude on its own.

What other states are doing

Due to the current fiscal environment, cost containment is a top priority. Unfortunately, research has found little information from other states, although it was found that Michigan Department of Community Health examined their Medicaid program in 2007 in an attempt to find savings associated with the creation of a preferred provider program or an alternative program for DME, prosthetics, and orthotics. They concluded that the creation of a preferred or alternative DME program would create unintended consequences in quality and accessibility.

In addition, MaineCare, Maine's Medicaid program, is proposing changes to its coverage and reimbursement methodology for DME/Medical Supplies. These include implementing quantity limits, adding prior authorization to select procedures, and discontinuing coverage on selected items (e.g., non-sterile wipes). Vermont's practice already contains most of these features.

Future OVHA Efforts to Control Costs

- Investigate opportunities for entering into agreements with other states through purchasing and contracting practices that might include issuing of RFI and RFPs to gather information and/or establish prices.
- Continue to monitor the CMS competitive Bidding Program.
- Investigate single source contracting or multistate contracting for the following areas:
 - Oxygen and supplies, including CPAP
 - Hearing aids and supplies
 - Wheelchairs and supplies
 - Enteral and parenteral nutrition
 - Orthotics
 - Home infusion therapy
 - Transcutaneous electrical nerve stimulation (TENS)

Investigating the feasibility for each of these items is extremely labor intensive with unclear return on investment, as evidenced by the incontinence supply effort described previously. As such, OVHA will continue to collaborate with NESCO and CMS to identify potential high return areas.

- Investigate supply limits. The OVHA will review DME and supplies to ensure the limits allowed are appropriate. For example, the OVHA recently researched ancillary supply limits for continuous positive airway pressure (CPAP) and will be changing our limits based on the research found.
- Examine DME items that do not need prior authorization (PA). The OVHA has determined that some DME items were being properly requested by providers and did not need a prior authorization. However, all items need to be periodically reviewed to ensure items are still being prescribed appropriately. If any aberrant practices seem to be occurring, the item can be returned to needing a prior authorization. This is currently being done for CPAPs.

- Investigate purchasing a DME PA utilization management system with HP Enterprise Services, our fiscal agent. The new system will help in the efficient processing of PAs. Additionally, the clinical staff can concentrate on other priorities, such as procedure PAs and other system edits, audits and criteria.
- Utilize an external vendor to review pricing methodology for fee schedules for DME.

BIOLOGICS - PHARMACY

Biologics include a variety of products used in medicine. However, in most cases the term is used to refer to a class of medications that are produced by a biological process.

The Pharmacy Benefit program, represented by the OVHA's MedMetrics contractor, assisted in efforts to review policies and procedures regarding this report. It was determined that the Pharmacy Benefit has many cost control strategies in place, which include biologics. These strategies include the following:

- Preferred Drug List (PDL)
- PA requirements
- Drug Utilization Review (DUR) Board
- Supplemental rebates from pharmaceutical companies [Sovereign States Drug Consortium (SSDC) with Iowa, Maine, Vermont, Utah, Wyoming, West Virginia, Oregon]
- Specialty Pharmacy vendors – ICORE Healthcare and Wilcox Home Infusion
- Generic drug requirements
- Maximum Acquisition Cost (MAC) pricing

See Addendum A for more detail about the above processes.

However, opportunities for savings for biologics may exist in the Medical Benefit, specifically for provider-administered injectables.

Management of Provider-Administered Specialty Injectable Drugs

ICORE, a specialty pharmacy vendor for the Pharmacy Benefit, provided a no-cost analysis of OPVHA Medicaid claims data to determine if savings opportunities exist for specialty management of provider-administered injectable drugs. ICORE indicates this is an area of increasing cost, with an inflation rate of 15-25% per year, and provider-administered injectables now represent 20% of the drug expenditures. Chemotherapy and chemotherapy-support drugs may comprise 70% of the expenditures in this category and is fueling much of this growth

The following initiatives were offered as possible cost containment strategies in this area:

- Rationalizing reimbursement by aligning incentives for physicians using ICORE's variable fee schedule (avoiding the pitfalls of either AWP-based or ASP-based methods), shifting use to generic drugs and drug administration

and a disincentive to shift service to the more costly hospital setting, thus lowering costs;

- Operational improvements by mitigating inappropriate use of chemotherapy and chemotherapy-support agents utilizing claims edits and processing rules for maximum unit dosing, and migrating prescribing behavior towards less costly off-label use within selected therapeutic classes;
- Utilization management through prior authorizations, eligible diagnoses, duration of therapy, etc.

The above practices would be implemented in a manner that minimized provider dissatisfaction and network disruption. Prior to implementation, ICORE would review the strategy with a group of key provider oncologists to tailor the approach to our market. In addition, changing utilization to generic drugs under the ICORE fee schedule may allow a positive shift in profit margins for the physicians.

ICORE provided the OVHA with the following estimates of savings, based on annual claims from 07/2008 to 06/2009.

<i>Rationalizing Reimbursement</i>		
Fee Schedule	\$ 54,668.00	3.6%
Generic Shift	\$ 27,390.00	1.8%
Drug Administration	\$ 11,000.00	0.7%
<i>Operational Improvements</i>		
Max Unit Edits	\$ 124,813.00	8.3%
Off-label Use	\$ 127,647.00	8.4%
<i>Utilization Management</i>		
Prior Authorization	\$ 45,571.00	3.0%
Totals	\$ 391,089.00	25.8%

ICORE estimates the state will realize a 3 to 1 net ROI. The OVHA has the opportunity to request customizing of this proposal. If the decision were made to move forward with these strategies, it would require an estimated at 90 to 120 days due to ICORE implementation and notifying Vermont Medicaid providers of this new program.

CONCLUSION

The OVHA has been, and will continue to be, proactive in identifying and implementing cost containment strategies for Durable Medical Devices and Biologics while continuously weighing the possible negative effects that may occur as a result of such activities.

For pharmacy biologics, a new cost containment opportunity has been identified within the provider-administered specialty injectable drugs medical benefit that could yield an estimated annual gross savings of \$391,089.

Additionally, regarding DME and supplies, the OVHA will continue to:

- Further analyze and prioritize areas of high cost and high utilization DME and supplies for opportunities to pursue and contain costs by appropriate and effective means, such as single source contracting.
- Work with NESCSCO and other organizations or states with sole source initiatives and cost containment strategies.
- Monitor the outcome of the CMS Competitive Bid process.
- Further analyze DME supply limits and use of prior authorizations, including Investigating alternative PA management systems.

ADDENDUM A

Current Pharmacy Benefit Management (PBM) Practices for Cost Control in the Biologic Drug Class and/or Supply Categories

The OVHA PBM program assures the availability of clinically appropriate services at the most reasonable cost possible. Various methods are in use to manage costs.

Preferred Drug List (PDL)

The PBM program utilizes a Preferred Drug List (PDL) as a key feature in the program. The PDL identifies drugs that meet specific clinical criteria and are clinically effective, but less costly. The PDL features clinically appropriate, lower-cost options for biologics including:

- lower-cost brands
- brands where manufacturers pay a level of federal Medicaid rebates that make net cost of the drug comparative to other products in the drug's therapeutic class
- brands where manufacturers pay Vermont rebates supplemental to required Federal Medicaid rebates to make their products more affordable.

In addition to the preferred products listing, the clinical criteria manual lists the clinical criteria that must be met in order to gain prior approval for many of the biologics. Thus, biologics are often preferred after clinical criteria are met which may include a trial of less costly non-biologic therapy. In addition, the following methods are employed to manage costs:

- requirement for trials of less costly non-biologic therapies
- quantity limits that reflect FDA approved and widely accepted appropriate prescribing
- approved diagnoses
- limiting drug choices maximizes rebates.

In March of 2002, the first version of the PDL was completed. Additional classes were systematically implemented. By 2003, the foundation of the PDL was established. Since that time, the PDL has been modified to reflect changes in clinical approaches, prescribing practices, product availability, and supplemental rebate opportunities. Since January 1, 2006, the PDL has been expanded by almost 60%, from 79 drug classes to over 140 drug classes. Automated step-therapy protocols and over 100 new product-specific dispensing limits have also been instituted.

For other drug categories, other PDL features employed to encourage lower cost prescribing include the encouragement of over-the-counter or generic products. The options are not currently available within the biologic drug and supply classes addressed in this report.

Specialty Pharmacy Services

In 2005, it was proposed that the PBM program require the purchase of selected pharmacy products using mail order options, with the intention to assure that when beneficiaries received drug treatments for complex medical conditions those treatments were obtained in the most economical way possible. The Legislature approved this requirement (V.S.A. 33 §1998a) allowing the use of the mail order services of specialty pharmacies. In 2007, the OVHA sought bids from specialty pharmacies to provide this additional tool in chronic care management. In 2008, two specialty pharmacies were selected to serve Medicaid beneficiaries: Wilcox Medical dba Wilcox Home Infusion and ICORE Healthcare, LLC, partnering with our pharmacy benefits manager, MedMetrics Health Partners. Wilcox Medical is the specialty pharmacy for respiratory syncytial virus (RSV) and ICORE Healthcare/MedMetrics is the specialty pharmacy for all other conditions. Dispensing of identified specialty medications is limited to these pharmacies for Medicaid beneficiaries where Medicaid is the primary insurer.

Both providers were selected based on a combination of the quality and the value of the services they offered and the price of the products involved. Operating in Rutland, Wilcox Medical represents the pharmacy that served the majority of Medicaid RSV patients in the last two RSV seasons. They came with local clinical recommendations including the physician who has been the primary prescriber for most Medicaid RSV patients. In addition, this physician is the Medical Director of the Neonatal Medical Follow-up Clinic at Fletcher Allen Health Care. MedMetrics Health Partners of Worcester, Massachusetts has been OVHA's pharmacy benefit manager for the last three years. ICORE is their specialty pharmacy partner and is located in Plantation, Florida. ICORE is a wholly owned subsidiary of Magellan Health Services, Inc. and provides specialty pharmacy services for 35 managed care contracts covering 60 million subscribers. The partnership of MedMetrics and ICORE assures the coordination of our pharmacy benefit management initiatives with our specialty pharmacy approach.

As of October 1, 2008 Wilcox Medical began providing services for Synagis[®], the drug used to prevent respiratory syncytial virus (RSV). As of November 3, 2008 ICORE Healthcare, LLC, with MedMetrics Health Partners, began providing services for hemophilia factors, growth hormones, multiple sclerosis self-injectables, hepatitis C (ribavirin and injectables) treatments, and Elaprase[®] (for Hunter's Syndrome). On February 15, 2009, self-injectables for rheumatoid arthritis, psoriatic arthritis, juvenile arthritis, psoriasis, Crohn's Disease and ankylosing spondylitis were added to the program. Additionally, Pulmozyme[®] and Tobi[®] for cystic fibrosis patients were added to the program on April 1, 2009.

In the first year of the Specialty Drug Program (November 2008 through October 2009), annual savings was \$796,833 compared to what would have been paid to traditional retail pharmacies. Of note, additional market share has been moved to OVHA's preferred products that have a lower net cost. These additional savings are not reflected in the annual savings figure noted above. The majority of self-injectable biologics available through the pharmacy benefit are now managed through the specialty pharmacy program.

Diabetic Testing Supplies

In 2005 when the Administration proposed managing specialty pharmacy services, diabetic testing supplies were identified as a target area. However, the use of such supplies generally does not require any specialty disease management services, so the OVHA opted to address this by limiting the product choices available in local pharmacies while seeking additional rebates from preferred manufacturers. This began with a partnership between the states of Maine, Utah, North Dakota, and Vermont. Diabetic supply manufacturers were approached in the summer of 2007 and offered preferred status for their products in exchange for rebates against states' utilization in their Medicaid programs. Rebate amounts for Diabetic Supplies, originally estimated to be approximately \$700,000 annually, exceeded \$1 million for SFY 2009.

Supplemental Rebates

A preferred drug list may "prefer" clinically appropriate products because they are singularly clinically appropriate; when multiple products are clinically appropriate, products may be preferred because they are inherently cost effective or because the manufacturer has offered to make them cost effective. Beginning in October 2002, Vermont started securing Vermont-only supplemental rebate agreements. From April 2003 until December 2005, Vermont was a member of the National Medicaid Pooling Initiative (NMPI) with eight other states.

In the fall 2005, Vermont committed to the Sovereign States Drug Consortium (SSDC), the first in the nation state-administered Medicaid pooling initiative for supplemental rebates, with member states of Iowa, Maine, and Vermont. Membership has grown to include Utah, Wyoming, West Virginia and Oregon. The states pool their collective lives, state staff and pharmacy benefit management contractor resources to negotiate supplemental rebate agreements with drug manufacturers. Many of the preferred biologics available through the pharmacy benefit offer supplemental rebate.

Supplemental rebates collected in SFY 2009 totaled \$ 6,489,711, representing a 22% increase from the prior year. This increase is due to an improvement in rebate contracting on a variety of drug products as well as increases in utilization. In some cases, the Sovereign States Drug Consortium (SSDC) aggressively negotiated more substantial supplemental rebates. For other drugs, new drug categories were added to the Preferred Drug List for drug management in order to be able to accept and realize the supplemental rebates being offered.

ADDENDUM B

NESCSO Durable Medical Equipment Procurement for Medicaid for the New England States: An Overview.



Durable Medical Equipment

Procurement for Medicaid

for the

New England States:

An Overview

May, 2009

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1. Executive Summary

The intent of this white paper is to summarize the progress of the New England states workgroup focused on Durable Medical Equipment (DME) issues that was facilitated by NESCSO between April 2007 to the present. The goal of this exercise is to take the project to a higher level culminating in the development of a strategic plan to implement a collaborative approach for the procurement of DME by the New England states. In support of this goal, this paper defines DME, provides a local snapshot of the New England states' activities, outlines some of the key challenges in the procurement, improvement of quality and related procedures of DME identified by the New England Medical Equipment Dealers Association (NEMED) and continues to identify and prioritize key DME areas where maximum quality and cost savings can be realized by states.

An important issue that should be noted is the fact that the importance of addressing DME procurement issues has been validated. NESCSO staff has contacted states outside of New England and we have found these states are concerned with the same issues as discussed in this paper. Additionally, the NESCSO DME workgroup has provided a forum for a comprehensive discussion related to DME in the Medicaid environment. The discussions have not only focused on potential cost saving measures for the States but also on the importance of quality standards for DME. Vermont has developed quality standards using ISO Test Method 11948-1:1996 rating incontinence products on absorbent capacity, rate of acquisition test (ROA) and rewet test. These quality measures were included in the recent Maine and Vermont RFP for incontinence supplies which has made the concept of joint procurement of DME a reality. Although it is too early to measure the success of this activity, this potential model of joint DME procurement merits monitoring and review. Finally, the information identified through this strategic planning process can be the basis of discussion to address coding issues with CMS.

2. Background

In the spring of 2007, the New England Health and Human Services Commissioners requested assistance from NESCSO to review the potential of regional purchasing of selected durable medical equipment (DME) commodities. In response, NESCSO established a workgroup to collaboratively review DME policies, best practices, product quality comparisons, specification standardization, and the potential for regional purchasing (including rebates) of certain commodities to reduce costs.

NESCSO facilitated this workgroup by setting up a project on its web-based project-reporting tool, ONTRAK, and provided all members with contact information for the group. Additionally, NESCSO organized several teleconferences with the New England states to discuss potential next steps for regional collaboration. With assistance from New Hampshire, NESCSO prepared and distributed a survey to all of the New England

states related to current pricing for oxygen, enteral supplies and incontinence supplies. The survey revealed wide variation in calculating expenditures and coding practices.

Vermont and New Hampshire have been the most active states in the region pursuing DME purchasing alternatives through the use of the traditional RFP process. One of the notable events to take place in this process was a meeting held in White River Junction, Vermont with DME vendors and representatives of the New England Medical Equipment Dealer's Association (NEMED) in response to Vermont's September 15, 2008 letter to Manufacturers and Suppliers of incontinence products (Appendix A) to pursue a joint purchasing arrangement with Maine and potentially other states.. The meeting provided the opportunity to hear issues from the vendor community that were of high importance in the DME arena. New Hampshire also issued an RFP (Appendix B) for incontinence supplies in September of 2008.

Vermont and Maine issued a joint RFP (Appendix C) for incontinence supplies in December of 2008. The goal of the RFP is to identify distributors for certain incontinence care supplies for the MaineCare and Vermont Medicaid programs. The States prefer a Distributor that can:

- Assure access to high quality cost effective products and services
- Offer prices through arrangements with participating Medicaid providers that save the States money without compromising quality. The approach is unique in that four suppliers were identified as preferred. Distributors were asked to provide pricing for those preferred products. Maine and Vermont will contract separately with the successful bidder but pricing will be based on a total number of covered lives for both states.

In December, 2008, NESCSO assigned a project coordinator to function as a point of contact, to track progress and provide a starting point for discussion through the distribution of a white paper on DME procurement in New England.

3. DME Summary

A. Global Overview of DME

The Durable Medical Equipment industry provides quality equipment and services to customers (patients) in the home environment. The DME supplier plays a vital role in the healthcare system by providing the equipment, delivery and setup, and supporting services.

The applications of DME products and services are wide ranging and include addressing acute and chronic medical conditions, maximizing independence and function, assuring safety and comfort, and providing solutions to the challenges of customers, caregivers and families. Insurance companies and other third party payers use these items to obtain cost effective short-term and long-term health care solutions.

Reducing the necessity and length of hospital stays, decreasing the need for nursing care, preventing and controlling medical conditions, and reducing health care costs are some of the many benefits stemming from DME products and services.

A DME supplier typically derives substantially all of its revenues from third-party payers. These payers include governmental programs such as the federal Medicare program and the state Medicaid program. Other payers include private insurance organizations such as traditional health insurance companies and health maintenance organizations. Individual customers are normally responsible for co-payments, deductibles and non-covered charges.

The DME Marketplace

Health & aging trends affecting the U. S. population and home healthcare have created an environment that will continue to produce an increasing demand for the products and services provided by DME companies. The average age of Americans is increasing and as a person ages, more healthcare services may be required. In addition, the well-documented and dramatic changes in the healthcare delivery system have moved more services into the home and out of institutions.

To put DME expenses into perspective, DME for the homecare sector represents less than two percent of the total \$400 billion-plus Medicare budget. DME is also the slowest growing sector: 2.3 percent DME spending growth from 2005 to 2006. Total Medicare spending grew 19 percent during that same period.¹

Product Categories

Although it is common to group all of our medical supplies under the generic term Durable Medical Equipment (DME), these products can be grouped in five primary areas: Respiratory Therapy, Durable Medical Equipment (traditional), Rehab Technology, Infusion Therapy and Soft Goods (Incontinence Supplies). The following is a brief summary of the products offered:²

Respiratory Therapy:

- Oxygen Concentrators
- Liquid Oxygen Systems
- Oxygen Cylinders
- Continuous Positive Airway Pressure (CPAP) Devices
- Noninvasive Positive Pressure Ventilators (NPPV)
- Ventilators
- Apnea Monitors
- Nebulizers
- Respiratory Medications

¹ (American Association for Homecare, 2008)

² (New England Medical Equipment Dealers Association, 2008)

Durable Medical Equipment (Basic):
Hospital Beds
Wheelchairs
Patient Lifters. Ambulatory Aids
Bathing & Toileting Products

Rehab Technology:
Mobility Products
Seating & Positioning Products
Repair and Maintenance Products
Home Accessibility Products
Other Specialized Products

Infusion Therapy:
Antibiotic Therapy
Total Parenteral Nutrition (TPN) Therapy
Enteral Nutrition Therapy
Pain Management Therapy
Chemotherapy
Diabetic Supplies

Soft Goods:
Incontinence Supplies
Diapers, Liners, non-sterile gloves

D. DME Supply Chain

Most DME items are purchased directly from the manufacturer. For example, in the case of wheelchairs, whether manual or powered, the DME provider orders a basic chassis then provides various add-ons depending on the patient's needs. Because of this customization aspect, DME of this nature is ordered directly. Expendable or soft type DME items are purchased through a distributor. These items are generic in nature and may be stored for a period of months. Incontinence supplies and related items fall into this category. The supply source must be considered when considering procurement options and developing an RFP. Earlier in the DME review process, the State of Vermont investigated the possibility of reducing costs by qualifying for manufacturers' rebates. In a meeting with DME suppliers, state representatives were asked to reconsider the concept of rebates for incontinence supplies as the procurement process was not similar to prescription drug purchasing where rebates are very common for Medicaid programs. In an interview with an individual from the State of Washington, NESCSO learned that Washington also attempted to negotiate rebated contracts with incontinence manufacturers who had a presence in the state. These contracts were based on similar contracts for diabetic supplies and the contracts faced legal challenges.³

³ (McMullen, 2009)

E. New England Industry View

On January 20, 2008, NESCO staff had the opportunity to have a conference call with Karyn Estrella, Executive Director – New England Medical Equipment Dealers Association (NEMED), and several of NEMED’S Executive Board members.⁴ This section reflects NEMED’s views on the DME industry.

- 1) The DME industry is primarily a service industry that provides equipment. Items such as hospital beds, wheelchairs and respirators require special set-up and periodic maintenance. This component is sometimes overlooked when incontinence supplies and other soft items are rolled into the general category of DME.
- 2) Internet pricing for DME is sometimes misleading because the price does not include equipment maintenance and/or the typical DME cost of doing business.
- 3) The pre-approval process, especially for basic DME, can be very time consuming. In the meantime, clients end up spending additional time in the hospital.
- 4) Group purchasing: NEMED stated this is very feasible for disposable items. It’s important that the RFP focus on a category of DME, instead of including multiple categories.
- 5) Universal coding issues: NEMED, as well as other sources, expressed frustration over coding issues. A common complaint was the inconsistent use of state defined modifiers and the lack of keeping up with coding changes. This is a universal problem, in part, due to the timing of coding updates by CMS.

The New England Medical Equipment Dealers Association (NEMED) has offered to assist us to identify, best practices, product quality comparisons & specification standards, coding & billing issues and DME items with greatest cost saving potential.

F. Other DME Points to Consider

Based on NESCSO staff discussion with several DME subject matter experts, the following points are noted:

Diabetic Supplies: Glucometers are relatively inexpensive, however the test strips to use with this instrument can be very expensive. Monitoring the monthly volume of test strips purchased or setting a monthly limit may result in significant cost savings. It should also be noted that test strips could be purchased either through the DME provider using standard HCPCS codes or through a pharmacy using national pharmaceutical codes. This problem is compounded by the fact a pharmacy can also bill as a DME provider. The possibility exists for inadvertent billing in this area.⁵

⁴ (Estrella, 2009)

⁵ (McMullen, 2009)

Incontinence Supplies: It should be noted that Medicaid covers these supplies, but Medicare does not reimburse for most incontinence supplies. Specific coverage for Medicaid DME is determined by each state.

Group Purchasing: Discussions with other subject matter experts outside of New England identified some past group purchasing efforts that encountered legal hurdles. This may cause a reduction of the number of available vendors because only large vendors can accommodate large volume procurements. Prices may be low at the beginning, but eventually they may rise because of an oligopoly situation. Another issue to consider is potential litigation. In the early nineties, Connecticut attempted to publish an RFP which basically provided for group purchasing of incontinence supplies. Connecticut was put on notice by the DME trade association that such a procurement might be in violation of interstate commerce laws and might also cause a restraint of trade.⁶

Double sales tax for Medicaid/Medicare crossover claims: CMS included sales tax in their reimbursement calculations for DME. Those states that require sales tax be paid on DME, are being forced to pay the full amount of sales tax on those Medicaid/Medicare crossover claims. As a result states that use the Medicare rate are collecting tax twice.

4. Status of New England States

A. A snapshot survey was taken of New England States in January, 2009. The following questions were asked.

- What are the three major categories of DME spending in your State?
- What are the costs associated with these categories, and what is the total cost for DME expenses for the period 7/1/07 to 6/30/08?
- What is the date of the most recent RFP for DME? Please attach a copy of the RFP.
- Has your State participated in any group purchases with another State or organization?
- Has your state started any cost saving initiatives?
- What are the three greatest procurement challenges associated with DME?
- What are the three greatest needs associated with DME?

The results of this survey can be found in Appendix D.

⁶ (Pollard, 2009)

New England Caseload figures: The following is an unduplicated count of the number of members with claims for DME, oxygen and medical supplies for FY 2008:

Connecticut	33,649
Massachusetts	45,000
Maine	35,000
New Hampshire	13,610
Rhode Island	Pending
Vermont	Pending

- B. New England States Medicaid Reimbursement Rates. NESCSO conducted a survey in 2005 (updated 2009) of the New England States' pricing policy for medical equipment (e.g. percentage of Medicare fee, list price minus a certain percentage, acquisition plus a certain percentage). A summary of rates may be found in Appendix E.

5. Recommended Courses of Action

In conclusion, NESCSO has identified the following areas for future discussion related to procurement, quality, coding and reimbursement of DME in New England. State staff will be encouraged to work with NESCSO and UMASS/Commonwealth Medicine to identify opportunities for collaborative projects.

- A. Continue NESCSO DME Workgroup with facilitated meetings (UMASS/Commonwealth Medicine). This will ensure that the dialogue will continue and will present opportunities to compare State purchasing policies and regulations in New England.
- B. Present white paper and progress at May Commissioners' meeting. This will provide baseline information on DME issues. It will also give us the opportunity to address the following:
- What would be the downside to using a percentage of the Medicare fee schedule for all items Medicaid covers?
 - Should a user committee of selected providers be established to assist in developing ideas and strategies for coding issues, cost saving and quality assurance?
 - Should selected procedures for prior approval and post audit be established?
 - Should a multi state manufacturer bid for incontinence supplies and/or other areas be contemplated for the local providers to obtain their supplies?
 - Should a group be established to write specific medical criteria for all codes and should all of the states use the same criteria?
 - Should uniform edits be developed to select transactions for post audit scrutiny on potential errors and abuse? For example, certain items may be billed by a pharmacy using pharmacy codes while the same items may be

- billed by that pharmacy as a DME provider leading to inadvertent duplicate billing.
- Should prosthetics and orthotics be viewed differently and not lumped in with DME?
 - Should additional edits be initiated in states' MMIS to ensure DME item limits; for example, decrementation?
- C. Maintain an open dialog with NEMED. This will enable NESCSO and the states to jointly monitor industry issues and developments and address several items above.
- D. Follow the progress of the Vermont/Maine Procurement and other DME opportunities throughout the country to identify opportunities for further collaboration.
- E. Follow the progress of OIG investigations into the area of DME and developments by CMS in the DME competitive bidding demonstration.
- F. Investigate the value in having UMASS/Commonwealth Medicine look at State purchasing rules.
- G. Discuss the possibility of a New England rate structure for DME.

NESCSO looks forward to working with state staff identified and empowered by the Commissioners to work on some or all courses of action.

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