What May Self-Insured Employers do to Impact Specialty Pharmaceuticals Benefit, Cost and Trend?

January 31, 2014
Specialty Therapies – A Forum for Payers, Las Vegas, NV

Elan Rubinstein, Pharm.D., MPH
EB Rubinstein Associates
www.ebrubinsteinassociates.com
**Introduction to EBRA**

<table>
<thead>
<tr>
<th>CHANNELS</th>
<th>PAYERS</th>
<th>ASSOCIATIONS</th>
<th>MANUFACTURERS</th>
<th>CONSULTANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Group purchasing organization</td>
<td>- Purchasing coalition</td>
<td>- Academy of Managed Care Pharmacy</td>
<td>- 1798 Consultants</td>
<td></td>
</tr>
<tr>
<td>- Pharmacy chain</td>
<td>- Self-insured employer</td>
<td>- National Renal Administers Association</td>
<td>- Bentelligence</td>
<td></td>
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<tr>
<td>- Specialty pharmacy</td>
<td>- CCIIO</td>
<td>- National Business Coalition on Health</td>
<td>- Logistics Management Institute</td>
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<tr>
<td><strong>Serving:</strong></td>
<td><strong>Payers:</strong></td>
<td><strong>Associations:</strong></td>
<td><strong>Consultants:</strong></td>
<td><strong>Startups:</strong></td>
</tr>
<tr>
<td>Product positioning</td>
<td>Claims analysis</td>
<td>Market research/analysis</td>
<td>Pharmacy benefits</td>
<td>Advisory board facilitation</td>
</tr>
<tr>
<td>Market modeling</td>
<td>Pharmacy coverage policy</td>
<td>Program development</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Topics

1. Employer concern & knowledge about SPRx
2. Employer approaches to managing SPRx
3. Reference pricing possible for SPRx?
4. Role of community pharmacy in supporting SPRx?
5. NBCH eValue8 PBM/SPRx module to drive best-of-breed solutions
6. Will ACOs manage pharmaceuticals & SPRx?
7. Employers migrate towards designs at 60% of Minimum Value
8. Benefit consultant private HIXs consolidate purchasing power
9. Consumerism response to higher SPRx cost share
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How impactful will SPRx be on total PB + MB Rx spend?

Abbreviations:
MB = medical benefit
PB = pharmacy benefit
Rx = pharmaceutical
SPRx = specialty pharmaceutical

Source: Company reports, Barclays Research

Elan Rubinstein, Pharm.D., MPH 013014
Payers may find SPRx use hard to manage

<table>
<thead>
<tr>
<th>Factors</th>
<th>Past and Present</th>
<th>Future</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Market Drivers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increasing Diagnosis</td>
<td>HCV infection is under diagnosed</td>
<td>CDC recommending HCV screening for baby boomers</td>
</tr>
<tr>
<td>Increasing Treatment Rate</td>
<td>Only reserved for patients who have liver damage</td>
<td>Expand to potentially infected individuals under care</td>
</tr>
<tr>
<td>Expanding Access</td>
<td>Many chronically infected people do not have access to care</td>
<td>Access to care is expected to broaden with ongoing reform</td>
</tr>
<tr>
<td>Revolutionizing Therapies</td>
<td></td>
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</tr>
<tr>
<td>Cure rates</td>
<td>30-70%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Safety</td>
<td>Flu-like symptoms, anemia, etc</td>
<td>Well tolerated</td>
</tr>
<tr>
<td>Convenience</td>
<td>IFN injection plus BID pills</td>
<td>Oral pills (OD or BID)</td>
</tr>
<tr>
<td>Duration</td>
<td>6 mos - 1 yr</td>
<td>2 - 3 mos</td>
</tr>
</tbody>
</table>

Source: Barclays Research

Abbreviation: HCV = Hepatitis C
Most large employers are watching specialty pharmacy.
Large employers may not fully understand specialty pharmacy.

50% said MB/all SPRx ≤6%
But ratio of MB/all SPRx is actuarially much higher than 6% = 54% MB

**Figure 1: Specialty-Tier Drug Spending Compared to Other Categories of Healthcare Spending, 2012 (commercial population)**

<table>
<thead>
<tr>
<th>Service Category</th>
<th>Estimated 2012 PMPM Gross Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DRUG SPENDING:</strong></td>
<td></td>
</tr>
<tr>
<td>• Non-specialty drugs</td>
<td>$67.11</td>
</tr>
<tr>
<td>• Specialty drugs covered under pharmacy benefit</td>
<td>9.44</td>
</tr>
<tr>
<td>• Specialty drugs covered under medical benefit</td>
<td>10.96</td>
</tr>
<tr>
<td><strong>OTHER SPENDING:</strong></td>
<td></td>
</tr>
<tr>
<td>• Hospital inpatient</td>
<td>$136.00</td>
</tr>
<tr>
<td>• Hospital outpatient</td>
<td>77.00</td>
</tr>
<tr>
<td>• Physician</td>
<td>138.00</td>
</tr>
<tr>
<td>• Other</td>
<td>17.00</td>
</tr>
</tbody>
</table>

*Source: 2012 Milliman Health Cost Guidelines™ and 2012 Milliman Medical Index™. The above figures do not include plan administrative costs and are before member cost-sharing.*
Employers’ top SPRx concerns

- Utilization
- Cost
- Compliance
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Employers’ top SPRx management strategies

- PA
- DM
- SPRx network
- Formulary
- Steps
- Quantity limit
- Move MB ⇒ PB

Abbreviations:
PA = prior authorization
DM = disease management
Steps = must-use-first therapy
Most large employers find DM effective - Expect more evidence-based SPRx management

### Exhibit 14.1
Among Firms Offering Health Benefits, Distribution of Firms’ Opinions on the Effectiveness of the Following Strategies to Contain Health Insurance Costs, by Firm Size, 2013

<table>
<thead>
<tr>
<th></th>
<th>Very Effective</th>
<th>Somewhat Effective</th>
<th>Not Too Effective</th>
<th>Not At All Effective</th>
<th>Don’t Know</th>
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</thead>
<tbody>
<tr>
<td><strong>Wellness Programs</strong></td>
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<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>35%</td>
<td>32%</td>
<td>24%</td>
<td>9%</td>
<td>1%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>36%</td>
<td>40%</td>
<td>17%</td>
<td>6%</td>
<td>1%</td>
</tr>
<tr>
<td>ALL FIRMS</td>
<td>35%</td>
<td>32%</td>
<td>24%</td>
<td>9%</td>
<td>1%</td>
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<tr>
<td><strong>Tighter Managed Care Restrictions</strong></td>
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<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>7%</td>
<td>37%</td>
<td>27%</td>
<td>25%</td>
<td>5%</td>
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<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>15%</td>
<td>40%</td>
<td>28%</td>
<td>14%</td>
<td>3%</td>
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<tr>
<td>ALL FIRMS</td>
<td>8%</td>
<td>37%</td>
<td>27%</td>
<td>24%</td>
<td>4%</td>
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<td><strong>Consumer-Driven Health Plans</strong></td>
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<td>(Ex: High-Deductible Plan Combined with a Health Savings Account)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>20%</td>
<td>42%</td>
<td>21%</td>
<td>14%</td>
<td>4%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>31%</td>
<td>37%</td>
<td>19%</td>
<td>11%</td>
<td>2%</td>
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<tr>
<td>ALL FIRMS</td>
<td>26%</td>
<td>41%</td>
<td>21%</td>
<td>14%</td>
<td>4%</td>
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<tr>
<td><strong>Higher Employee Cost Sharing</strong></td>
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<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>17%</td>
<td>33%</td>
<td>26%</td>
<td>21%</td>
<td>4%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>16%</td>
<td>43%</td>
<td>26%</td>
<td>13%</td>
<td>1%</td>
</tr>
<tr>
<td>ALL FIRMS</td>
<td>17%</td>
<td>33%</td>
<td>26%</td>
<td>20%</td>
<td>4%</td>
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<tr>
<td><strong>Disease Management Programs</strong></td>
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<tr>
<td>All Small Firms (3-199 Workers)</td>
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<td>32%</td>
<td>29%</td>
<td>16%</td>
<td>2%</td>
</tr>
<tr>
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<td>36%</td>
<td>38%</td>
<td>18%</td>
<td>5%</td>
<td>2%</td>
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<td>22%</td>
<td>32%</td>
<td>29%</td>
<td>15%</td>
<td>2%</td>
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</tbody>
</table>

* Distributions are statistically different between All Small Firms and All Large Firms within category (p<.05).

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Reference pricing for SPRx?

• No example of reference price (aka target price) for SPRx, although several for non-SPRx.

• Payers may differentiate SPRx using the below terms, with higher cost-share applied for drugs classified under terms in 2nd column:

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-preferred</th>
<th>P &amp; NP are on-benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty tier 1</td>
<td>Specialty tier 2</td>
<td>Tier 1 &amp; Tier 2 are on-benefit</td>
</tr>
<tr>
<td>Formulary</td>
<td>Non-formulary</td>
<td>NF may mean on- or off-benefit</td>
</tr>
</tbody>
</table>

• NP, T2 and NF cost-share is limited by Maximum Out-Of-Pocket (MOOP)

• If RP: Patients using non-referenced but on-benefit SPRx more likely to exceed MOOP, after which patients’ cost-share is zero
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Community pharmacy as SPRx provider?

• Walgreens, CVSCaremark and others have local pharmacy programs supported by owned/contract SP systems, purchasing contracts, personnel and expertise

• J Visaria, SG Frazee (ESI), AJMC, 2/7/13
  • “Primary objective of this study was to determine whether there are differences in hepatitis C regimen adherence between specialty & retail pharmacy patients.”
  • “…after adjusting for a number of known confounders, patients who used a single SP exclusively had on average 8.6% higher regimen adherence and 15 fewer gap days than patients who used retail pharmacy exclusively.”
  • “…patients using SP had nearly 60% higher odds of achieving SVR than patients using retail pharmacy.” (Abbreviation: SVR = Sustained Virologic Response)
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As health care costs continue to increase, you want evidence that you are purchasing quality health care, administrative excellence and consumer satisfaction at cost-effective prices. eValue8 makes it possible to both define vendor performance expectations and to evaluate their performance. With eValue8, purchasers can provide true health care value: health care that integrates leading-edge evidence-based practices at a fair cost.

Source: www.nbch.org/evalu8
NBCH eValue8 encourages health plans to adopt best-of-breed solutions.

<table>
<thead>
<tr>
<th>Aetna, Kaiser Permanente and UnitedHealthcare receive 2013 eValue8™ Innovations Awards</th>
</tr>
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<tbody>
<tr>
<td>WASHINGTON - December 6, 2013 - The National Business Coalition on Health (NBCH), a non-profit organization of purchaser-led business and health coalitions, honored Aetna, Kaiser Permanente in California and UnitedHealthcare with the 2013 eValue8™ Innovations Awards at its annual conference. The awards recognize the innovative work of plans to develop programs that address critical health care issues.</td>
</tr>
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<table>
<thead>
<tr>
<th>Aetna’s Member Payment Estimator</th>
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<tr>
<td>Aetna received the award for the Member Payment Estimator (MPE), which improves transparency</td>
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</table>

<table>
<thead>
<tr>
<th>Kaiser Permanente’s Exercise as a Vital Sign</th>
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<tbody>
<tr>
<td>Kaiser Permanente in California was selected for the Exercise as a Vital Sign program. Developed by Kaiser Permanente Southern California to consistently capture information on a member’s exercise habits, Kaiser Northern California added support tools such as the Rooming Tool that</td>
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<table>
<thead>
<tr>
<th>UnitedHealthcare’s Health4Me</th>
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<tbody>
<tr>
<td>UnitedHealthcare won for its flagship mobile smartphone application, Health4Me, which engages members and helps improve consumers’ lives by putting their health and health plan information</td>
</tr>
</tbody>
</table>
Coalitions

use eValue8
to
encourage
best-of-breed vendor programs & results

The coalition demonstrated leadership particularly in the areas of making quality and cost data transparent to consumers in order to move their market. LVBCCH’s signature vendor management RFQ, eValue8™, to select their 2013 health plan partners. Building on that activity, they distributed their first Health Plan Score Card to members to help them understand how health plans are performing and find the best quality of care and services possible.
So... Anticipate that eValue8 PBM/SP will encourage best-of-breed SPRx solutions

- “Please describe any programs you initiated in 2013 to meet unique needs of ACOs”
- “Please provide estimates of the percent spend on SPs (vs overall), self-administered medications, and percent reimbursed through the medical benefit”
- “Describe the plan’s current strategy, activities and programs to manage SP and biologics in 2013; and outline any changes planned for 2014”
So... Anticipate that eValue8 PBM/SP will encourage best-of-breed SPRx solutions

SPRx module requests information re the following tools & programs:

- Prior authorization
- NDC lock
- Quantity edits/limits
- Limits on off-label use
- Split fill
- Genomic tests
- Channel management
- Reimbursement reductions (i.e., fixed fee schedule)
- Disease management & adherence for specific diseases
- SPRx delivery to MD
- Waste management
- Plans for biosimilars mgmt.
- Quality measures

eValue8 PBM/SP module, private communication, Foong-Khwan Siew, NBCH, 011314
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ACO Rx management is a work in progress

• ACO self-assessment survey fielded in late 2012 concluded: “...for most of the surveyed ACOs significant improvements are needed if these organizations are to optimize medication use and improve patient outcomes” (J Manag Care Pharm. 2014; 20(1):17-21)

• “With our ACO, which began January 1, 2013, as a partnership with Walgreens, we are targeting improvements in the care of patients with high blood pressure, chronic obstructive pulmonary disease and congestive heart failure.” (Scott&White Hospital Llano 2013 Implementation Strategy)
ACO SPRRx management also a work in progress

• University HealthSystem Consortium (UHC) is an alliance of >100 academic medical centers and nearly 250 of their affiliate hospitals
  • UHC will launch an SPRRx program to provide patients with access to the SPRRx they need at the hospitals where they are treated.
  • The program will help members succeed in an ACO environment by coordinating care and services among inpatient settings, outpatient settings, infusion clinics, and pharmacies.
  • The program will use a data repository based on medical record data to track patient outcomes to promote the best therapeutic regimens and identify patients who have not responded to therapy.

UHC news release: 090913
Medical oncology, for example

Integrated Payer/Provider Initiatives

- Nearly half of MCOs reported pursuing **new integrated payer/provider initiatives** with oncologists to improve cancer care, such as
  - Forming an oncology accountable care organization (ACO)
  - New risk-sharing arrangements/payment models
- The percentage of oncology practice revenue tied to **global payment arrangements** has been increasing steadily over the past 3 study periods, as has the percentage of practices negotiating such an arrangement

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage of Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>7.4%</td>
</tr>
<tr>
<td>2011</td>
<td>38.0%</td>
</tr>
<tr>
<td>2012</td>
<td>50.0%</td>
</tr>
</tbody>
</table>

**THE 2013 GENENTECH ONCOLOGY TREND REPORT**
Medical oncology, for example

- **Cancer drug acquisition costs** accounted for an average of 41.1% of oncology practices’ total expenses in 2011
  - More than half of community-based OPMs expect this percentage to rise by the end of 2012

- On average, practices buy and bill more than half (55.8%) of their cancer drugs, another 27.5% are purchased/supplied by hospitals, and 16.7% come from SPPs
  - One-fifth of practices purchase oral cancer drugs and dispense them directly to patients; another 13.2% plan to do so in 2013
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Employers likely to migrate towards IRS ‘safe harbor’ benefit designs at 60% MV

• ACA does not require large self-insured employers to cover all EHBs
• EHBs included must provide a Minimum Value of 60% of total cost, or ER can meet ‘safe harbor’ designs (Internal Revenue Bulletin, 6/3/13)
  • A plan with a $3,500 integrated medical and drug deductible, 80% plan cost sharing, and a $6,000 maximum out-of-pocket limit for employee cost sharing.
  • A plan with a $4,500 integrated medical and drug deductible, 70% plan cost sharing, a $6,400 maximum out-of-pocket limit, and a $500 employer contribution to an HSA.
  • A plan with a $3,500 medical deductible, $0 drug deductible, 60% plan medical expense cost sharing, 75% plan drug cost sharing, a $6,400 maximum out-of-pocket limit, and drug copays of $10/$20/$50 for the first/second/third prescription drug tiers, with 75% coinsurance for specialty drugs.
Percent of Employers Offering/Likely to Offer CDHP.

<table>
<thead>
<tr>
<th>Number of employees</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small employers</td>
<td>9%</td>
<td>15%</td>
<td>16%</td>
<td>20%</td>
<td>22%</td>
<td>23%</td>
</tr>
<tr>
<td>(10-499 employees)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All large employers</td>
<td>20%</td>
<td>20%</td>
<td>23%</td>
<td>32%</td>
<td>36%</td>
<td>39%</td>
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<tr>
<td>(500+ employees)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employers with 5,000 or more employees</td>
<td>35%</td>
<td>41%</td>
<td>42%</td>
<td>45%</td>
<td>51%</td>
<td>55%</td>
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<tr>
<td>Very likely to offer in 2016</td>
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<tr>
<td>Small employers</td>
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<tr>
<td>(10-499 employees)</td>
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<td>(500+ employees)</td>
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<tr>
<td>Employers with 5,000 or more employees</td>
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</table>

Source: Mercer’s National Survey of Employer Sponsored Health Plans, 2013

Abbreviation: CDHP = consumer-directed health plan (high deductible health plan w/health savings account)
In 2013, ~23% of employer drug formularies had ≥4 tiers
Employers likely to increase use of co-insurance for $\geq 4^{th}$ tiers

... subject to cost-share minimum or maximum or both
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8. **Benefit consultant private HIXs consolidate purchasing power**
9. Consumerism response to higher SPRx cost share
Employers’ options to control employee health benefit expense

Source: Health systems strategy at the tipping point. Advisory Board Co. 2013
**Will Group Employer Health Plans Become Extinct?**

**Three factors that threaten the employer-based system:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>New Federal Premium Subsidy creates substantial potential for savings to employers/plan sponsors in lower wage industries (retail, food, etc.)</td>
</tr>
<tr>
<td>2</td>
<td>Guaranteed Issue (elimination of pre-existing condition exclusions)</td>
</tr>
<tr>
<td>3</td>
<td>Highly regulated underwriting rules for insurers in the public exchanges</td>
</tr>
</tbody>
</table>

- Private and Public Exchanges offer the potential for plan sponsors to eliminate risk of medical trends
  - Shift burden of medical trends to individual, federal government and insurers

Large benefit consulting groups have set up private health insurance exchanges.

Projected enrollment in public and private exchanges, 2014E-2019E

Source: CBO, Goldman Sachs Global Investment Research
“Several large benefit consulting firms have predicted that within five years more than 45 percent of group health insurance policies will be purchased via private exchanges.”

“A strong positive sign of growth is that, at the beginning of Q4 in 2013, we are more than two-thirds of the way to exceeding most projected estimates for uptake in 2014.”

- Michael Levitt, former secretary of US Dept HHS
Rx & SPRx impact of private exchanges

- Consolidated purchasing power of the big benefit consulting houses (e.g., Mercer, TowersWatson, AON, Buck)
- Less variability in medical & pharmaceutical benefit designs
- More lives under common control, subject to smaller number of and more consistently applied...
  - Drug formularies, including increasing number of tiers including SPRx
  - Pharma manufacturer contracting for discounts, access & programs
  - Prior authorization requirements
  - Evidence-based disease management standards & programs
  - Retail, mail order and specialty pharmacy provider networks
  - “Big data” to identify high cost, non-responder, non-adherent patient

EBRA and private communication: Peter Hayes, former director health & wellness, Hannaford Bros. Co.
Topics

1. Employer concern & knowledge about SPRx
2. Employer approaches to managing SPRx
3. Reference pricing possible for SPRx?
4. Role of community pharmacy in supporting SPRx?
5. NBCH eValue8 PBM/SPRx module to drive best-of-breed solutions
6. Will ACOs manage pharmaceuticals & SPRx?
7. Employers migrate towards designs at 60% of Minimum Value
8. Benefit consultant private HIXs consolidate purchasing power
9. Consumerism response to higher SPRx cost share
Expect increased SPRx consumerism in response to higher OOP cost share.

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**Cost-Conscious Decision Making, by Type of Health Plan, 2013**

(Percentage of Privately Insured Adults Ages 21–64 Who Received Health Care in Past 12 Months)

<table>
<thead>
<tr>
<th>Decision Making Activity</th>
<th>Traditional</th>
<th>HDHP</th>
<th>CDHP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checked whether plan would cover care</td>
<td>39%</td>
<td>49%</td>
<td>57%</td>
</tr>
<tr>
<td>Asked for generic drug instead of brand name drug</td>
<td>37%</td>
<td>47%</td>
<td>50%</td>
</tr>
<tr>
<td>Talked to doctor about prescription options and costs</td>
<td>26%</td>
<td>34%</td>
<td>40%</td>
</tr>
<tr>
<td>Talked to doctor about treatment options and costs</td>
<td>26%</td>
<td>33%</td>
<td>36%</td>
</tr>
<tr>
<td>Asked doctor to recommend less costly prescription drug</td>
<td>27%</td>
<td>36%</td>
<td>38%</td>
</tr>
<tr>
<td>Developed budget to manage health care expenses</td>
<td>15%</td>
<td>17%</td>
<td>28%</td>
</tr>
<tr>
<td>Checked price of service before getting care</td>
<td>26%</td>
<td>33%</td>
<td>39%</td>
</tr>
<tr>
<td>Used online cost-tracking tool provided by health plan</td>
<td>12%</td>
<td>13%</td>
<td>25%</td>
</tr>
</tbody>
</table>


- Traditional = health plan with no deductible or <$1,000 (individual), <$2,000 (family).
- HDHP = High-deductible health plan with deductible $1,000+ (individual), $2,000+ (family), no account.
- CDHP = Consumer-driven health plan with deductible $1,000+ (individual), $2,000+ (family), with account.
- Difference between HDHP/CDHP and Traditional is statistically significant at p ≤ 0.05 or better.