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Excerpts from an Audit Risk Assessment

Department of Human Resources Oversight of Pharmacy Benefit Manager (Express Scripts, Inc.) contract

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Assessing Auditor: Tanya Morehouse
Evaluation: SAO met with Harold Schwartz, Director of Administrative Services, Nicole Wilson, Benefits Director, and Jerry Fry, Benefits Administrator, from the Department of Human Resources (DHR) to discuss the state's $130 million contract with Express Scripts, Inc. (ESI). ESI, the state's pharmacy benefit manager (PBM), processes and adjudicates prescription drug claims and provides other services. A second meeting was held with Nicole Wilson and Jerry Fry. SAO reviewed the terms of the current Express Scripts contract (expiring 12/31/13) and the scope of work for audits conducted by CGI of the pharmacy benefit manager's 2009 – 2011 prescription drug claims, discounts and rebates. With regard to the contract terms, SAO held discussions with DHR's general counsel, Steve Collier. SAO reviewed CGI's audit report and held discussions with Pat Gagne, Claims Technology Inc.[1], to better understand the audit conducted by CGI and to obtain information about whether CGI had difficulty obtaining data from ESI. SAO also reviewed Milliman's analysis of pricing models proposed by various PBM's in response to the state's RFP conducted in 2008 and held a discussion with Milliman consultants regarding the analysis and to obtain additional information about the PBM industry.

Background:

Industry
The structure of the services provided by PBM's and the pricing models utilized to charge plan sponsors (e.g. employers providing healthcare benefits) for prescription drug claims and PBM services is complicated. The industry has been subject to litigation and some states have passed laws providing for some regulation of the industry.[2] Additionally, PBM's have closely guarded access to their data and contractual arrangements with pharmaceutical manufacturers and retail pharmacies.

[1] CTI is the primary contractor for the state's audits of its healthcare and pharmacy benefit claims administrators. CTI subcontracts the pharmacy benefit claims audits to other entities, such as CGI, that specialize in this area.
[2] Vermont's law is 18 V.S.A. §9472

PBM's adjudicate drug claims, contract pharmacy networks, develop formulary or drug lists of covered therapies, provide benefit design consultation, manage cost utilization trends and contract for manufacturer rebates. The business model used by the majority of PBM involves complicated revenue streams and there is potential for conflicts of interest when the PBM has significant control over multiple aspects of pharmacy benefit management. Revenue streams include administrative fees from plan sponsors (e.g. the State of Vermont), drug pricing rebates[3] and other program fees from pharmaceutical manufacturers, pharmacy network spread (difference between amount PBM pays retail pharmacy vs. the amount the plan sponsor pays the PBM for prescriptions) and dispensing fees, and mark-up on drug pricing for scripts dispensed by mail-service and specialty pharmacy.

The retention by PBM's of 1) some or all of the rebates obtained from pharmaceutical manufacturers and 2) the pharmacy network spread has become increasingly controversial. In particular, in some PBM arrangements, the PBM develops and manages the formulary (i.e. the preferred drug list) which may be of concern if the PBM's selection of drugs for placement on the formulary is influenced by the amount of manufacturer rebates received. With regard to the pharmacy network spread, PBM's charge plans for prescription drugs based upon average wholesale price (AWP),[4] but negotiate discounts with the pharmacies using a different benchmark, maximum allowable cost (MAC list). PBMs may retain the spread between these two benchmarks rather than pass savings through to the plan.

PBMs and other entities involved in the pharmacy benefit industry have been the subject of multiple lawsuits around the lack of clarity on pricing strategies and tactics used by the PBMs. In May 2008, the Vermont attorney general announced a settlement against ESI.[5] Vermont's share of the $9.3 million settlement was $372,000. In 2009, First Data Bank, the vendor ESI contracts with for AWP a key pricing benchmark for the financial terms of the state's PBM contract, settled a lawsuit that resulted in a reduced markup to this benchmark.

In 2007, the General Assembly passed legislation, 18 V.S.A. §9472, requiring certain practices for pharmacy benefit managers operating in Vermont, including providing all financial and utilization information to plan sponsors. However, the law allows for exemption from these requirements if the PBM contract provides otherwise.

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[3] According to Milliman consultants interviewed by SAO, PBM's negotiate a base rebate and supplemental rebate plus a data transfer fee with the drug manufacturers. Currently, only the base rebate is passed through to plan sponsors.

[4] AWP is a pricing benchmark developed by companies such as First Data Bank and is calculated based upon wholesale acquisition cost (WAC) multiplied by a markup.

[5] The settlement agreement asserted that ESI engaged in deceptive business practices by encouraging doctors to switch patients to different brand name prescription drugs and representing that the patients and/or health plans would save money. ESI did not clearly disclose to their client plans that rebates accrued from the drug switching process would be retained by ESI.

State's contract with ESI

The state's contract with Express Scripts runs from 1/1/09 to 12/31/13 totaling $130 million. Per the contract terms, the state's relationship with ESI is consistent with the business model used in the industry. ESI determines eligibility of prescription drug claims and makes claim payments. Other services provided under this contract include pharmacy service (mail service and retail services), program management (general support), formulary management functions and administration of clinical programs (e.g. drug utilization review). With regard to formulary management, ESI develops the state's formulary utilizing ESI's Pharmacy and Therapeutics Committee.[6]

Contract oversight

DHR contracted with CTI for an electronic prescription benefit claims review for 2009 – 2011. CTI subcontracted with CGI. CGI performed multiple analyses, including financial accuracy of claims data, recalculation of discounts and rebates, among others. CGI's report indicated that while there was room for improvement in the financial accuracy of claims payments, overall it found that there was a 99% accuracy rate. With regard to discounts and rebates, CGI detected pricing variances for brand and generic prescriptions for 2010 and reached a preliminary conclusion that ESI owed the state $1,185,000. However, the state determined that a contract amendment changed the agreed upon discounts for brand drugs. Subsequently, CGI re-ran its analysis for brand pricing discounts using the amended discounts and noted insignificant pricing variances for brand drugs, leaving an amount owed of $394,000 for generic pricing discounts. According to the report SAO was provided by DHR, this remains unresolved.

Financial terms

Based on information presented in ESI's 2009 proposal and an analysis conducted by Milliman of all the PBM's that responded to the state's RFP, the state selected ESI as the PBM and elected to use ESI's traditional pricing model. Milliman's analysis estimated that ESI's traditional model would be the least cost option. This model appears to pass through 100% of the manufacturer's base rebate (e.g. not supplemental rebates or other program fees) while allowing ESI to retain the pharmacy network spread. The alternative is the transparent model which seems to be a 100% pass through (all rebates and discounts passed to plan sponsor), but there is an administrative fee charged by the PBM that is not charged under the traditional model.

Per the contract, drug pricing varies by delivery channel (i.e. retail pharmacy vs. mail order pharmacy) and product (i.e. brand, generic or specialty drugs). Pricing may be based on a discount from average wholesale price (AWP), the usual and customary charge[7] (U&C) or the Maximum Reimbursable Amount[8] (MRA). The benchmark to be

[6] Exhibit A-1 Definitions, ESI contract.

[7] U&C is the retail price charged by a participating pharmacy (part of ESI's retail pharmacy network) for the particular drug in a cash transaction on the date the drug is dispensed as reported to ESI by the participating pharmacy.

used is specified in the contract. In addition, each prescription filled at a retail pharmacy has a dispensing fee. The state receives rebates from ESI based upon retrospective rebates paid to ESI pursuant to rebate contracts negotiated with pharmaceutical manufacturers and directly attributable to the utilization of certain pharmaceuticals by plan members (i.e. state employees). The state does not receive any rebates or discounts related to the pharmacy network spread retained by ESI.

Access to records

Access seems to be broadly stated in one section of the contract, but another section specifies restrictions related to ESI's arrangements with participating pharmacies (retail pharmacies).

Section 8 of Attachment C specifies that all evidence pertaining to prescription drug claim data and billing records under the contract are to be available. In addition, this section specifies that contractual information concerning participating pharmacies, pharmaceutical manufacturers and other providers of products and services to ESI is proprietary and confidential but will be disclosed to the state and its auditors subject to such entities entering into a confidentiality agreement acceptable to ESI and the state. Further, ESI is required to make available to the state or its auditors all materials necessary to allow the state or its auditor to re-price claims for prescription drugs and supplies to affirm correct payments and compliance with the plan provisions and the contract.

Section 2(c)(5) of the contract exempts ESI from providing information regarding its compensation arrangement with participating pharmacies except as it relates to a pass through arrangement (n/a for Vermont since DHR elected a traditional model).

The exemption from the requirement to provide information about the pharmacy network spread would limit SAO's ability to analyze whether the traditional model yielded the lowest cost for the state versus the transparent model. Without information regarding the amount ESI pays to participating pharmacies, it is not possible to calculate the cost of the transparent model.

Based on discussions with Pat Gagne at CTI and review of an additional report produced by CGI related to detail proceeds performed to verify rebates received from three pharmaceutical manufacturers, there were no limitations on access to the data needed to perform the scope of work CGI was hired to conduct. CGI was limited to on-site review of contracts at the pharmaceutical manufacturers, but access was provided. None of CGI's work related to ESI's contractual arrangements with participating pharmacies.

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[8] MRA is the term used to indicate the price the state will be charged for MAC items in pricing structures with guaranteed rates. MAC is maximum allowable cost is the maximum price contracted to be paid to participating pharmacies for particular generic drugs, as specified on ESI's MAC list.