

## REVIEW OF LIBERMAN ET AL. ARTICLE

**Article Title:** Adherence to Medication under Mandatory and Voluntary Mail Benefit Designs. American Journal Managed Care. 2011; 17(7):e260-e269.

**Author:** Liberman JN, Hutchins DS, Shrank WH, Slezak J, Brennan TA.

**Funded By:** CVS Caremark

**Population Examined:** Population based employer sponsored pharmacy insurance patients that offer mandatory mail or voluntary mail benefit through CVS Caremark

**Study Objective:** Compare adherence rates under voluntary and mandatory mail benefit designs.

**Methods:** Matched retrospective observation of patients.

**Study sample:** Any patient who met all of the following criteria:

- Valid demographics (age, sex, zip code)
- Valid Pharmacy Risk Score – proprietary algorithm using pharmacy claims to provide an estimate on healthcare costs.
- A paid retail 30-day pharmacy claim between January 1 and March 31, 2009.
- No previous paid pharmacy claim for a drug in the same class in the previous 6 months
- Continuously eligible for pharmacy benefits.

**Study period:** July 1, 2008 – March 31, 2010.

- January 1, 2009 – March, 31, 2009 was index period.
- Twelve month follow-up period following index claim

**Variables:**

- Dependent
  - MPR – “persistency days” total number of days supply / 365 (follow-up period)
  - Optimum MPR – MPR of  $\geq 80\%$
- Confounding Variables
  - Age, Sex, Pharmacy Risk Score, Geographic Region, Index therapeutic class, out-of-pocket cost for index claim, previous mail user
- Independent
  - Mail group – mandatory or voluntary

**Statistics:** Logistic regression – to analyze the optimum MPR and mandatory mail benefit

**Key Author Conclusions:**

- “By restricting pharmacy choice and access, mandatory mail appears to cause some members to discontinue therapy prematurely”
- “When members choose to discontinue rather than switch pharmacy channels, the unintended consequence is a reduction in medication adherence and the potential for increased medical expenses.”
- “Individuals without previous use of mail-service pharmacy are particularly sensitive to this plan design and are an important population to target for interventions to support adherence”

### Key Takeaways:

1. Study is not representative and uses opaque methods that may bias the results.
2. There is simply no way to draw any practical conclusions about the effect of mandatory mail on adherence from this study.

### ESI Critique:

Although informative, this study has several limitations in both the methodology and conclusions drawn from the analysis.

- **The analysis pits retail against an unrealistic implementation of mandatory mail.** The authors included only patients who had a single 30-day retail pharmacy in one of the drug classes under study during the index period. Express Scripts patients enrolled in Exclusive Home Delivery (i.e., mandatory mail) typically receive two courtesy fills in retail before being required to switch to home delivery.
- **The analysis cherry picks a small subgroup most likely to face challenges with mandatory mail.** The CVS study limited their analysis to patients who are new to therapy. In reality, the vast majority of patients enrolled in Exclusive Home Delivery are not new to therapy but instead are current users. The authors themselves note that they excluded 77% of study-eligible patients from mandatory mail-order program since they only selected patients with a 30-day retail prescription claim in the index period.
- **The analysis fails to guarantee true apples to apples comparison.** Understandably, the study did not randomize patient assignment to delivery channel; this is a very difficult study design to pull off. The solution is to use statistical techniques to adjust for any likely differences in the patients between the two channels, such as the presence of other comorbid conditions or underlying disease severity, which may affect adherence independently of home delivery program membership. Unfortunately, the authors included a “proprietary” pharmacy risk score to perform these adjustments. Because this score is hidden, it is impossible to tell what factors were controlled for and whether the observed differences represent a true effect or an artifact of the risk score.
- **The analysis incorrectly equates lack of a claim with non-adherence.** Although it seems clear that a patient who fails to fill a prescription must be nonadherent, the evidence suggests otherwise. Express Scripts has conducted research surveying mandatory and voluntary mail-order patients who had appeared to have discontinued therapy. We found that 68% of these patients reported getting their medication by paying out-of-pocket, choosing a lower-cost alternative, switching to over-the-counter products or by obtaining samples from their physician’s office.
- **The bottom line.** The CVS study compares an unrealistic implementation of mandatory mail to retail in a non-representative sample of patients using a statistical method that is not open to review for potential bias. **There is simply no way to draw any practical conclusions about the effect of mandatory mail on adherence from this study.**

### Key Implications for Plan Sponsors

- It is important to note that Express Scripts recognizes that Mandatory Mail may present challenges for a small subset of the client population. With this in mind, ESI has a dedicated Member Call Center to assist patients with conversion to Home Delivery.



- The observational, non-representative, cross-sectional study design does not allow one to draw a conclusion of causality between adherence and medical costs what are applicable to all mail-order users, either in voluntary or mandatory mail-order programs. It cannot be surmised from this study that decreased adherence was associated with any negative clinical outcome or an increase in downstream healthcare costs.