



Falling Through the Regulatory and Pricing Gaps: What to do about Compounded Drugs, Medical Foods, and Convenience Packaged Products

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Background

Problem: Categories of pharmaceutical products, such as compounded drugs (CDs), medical foods (MFs), and convenience packages (co-packs) are increasingly prescribed at high prices because they are not covered by current fee schedules or regulated by the FDA. The use of these products within California Workers' Compensation System (CA WCS) increased from 6.3% to 12% over 3 years after a 2007 regulation closed this same loop-hole for repackaged drugs. This increased use resulted in \$58 million in new billings in 16 months.

The rapid growth in use and high prices for these products is a growing problem for other US State Workers' Compensation Systems and also for healthcare systems in Europe and developing countries.

Solution: California Assembly Bill #378 Effective Jan, 2012

In 2011, California lawmakers enacted Assembly Bill 378 (AB #378), which came into effect January 1, 2012. The legislative intent of this statute was to control the increase in physician-dispensed prescriptions for compounded drugs, medical foods, and convenience packages in CAWCS.

- CD must be billed at the ingredient level
- Prohibited separate reimbursement for ingredients with no NDC.
- Reimbursement for CD ingredients are capped at a maximum of 100% Medi-Cal rates
- CDs, MFs, and co-packs are now also prohibited from self-referral
- The maximum reimbursement for a CD dispensed by a physician = 300% of the physician office's Documented Paid Cost (DPC), but <\$20 above DPC

Workers' Compensation System (WCS)
Health insurance scheme which provides wage replacement and medical benefits to employees injured in the course of employment

Objective

To evaluate if state-level pricing schemes/ regulations reduce utilization, billed, and paid amounts of pharmaceutical products that fall through regulatory and pricing gaps, using CA WCS as an example.

Methodology

Data: All drug prescription claims from the CA WCS from 2011 to 2013

Independent Variable: California Assembly Bill #378 effective Jan 1, 2012

Dependent Variables: Prescription frequency, billed, and paid amounts for MF, CD and Co-packs

Study design: Pre-post comparison evaluated by two-tailed T-test

Medical Foods

Foods that are specially formulated and intended for the dietary management of a disease that has distinctive nutritional needs that cannot be met by normal diet. MFs are not approved by FDA, do not require a prescription, and are not on most Fee Schedules.

Convenience Packs

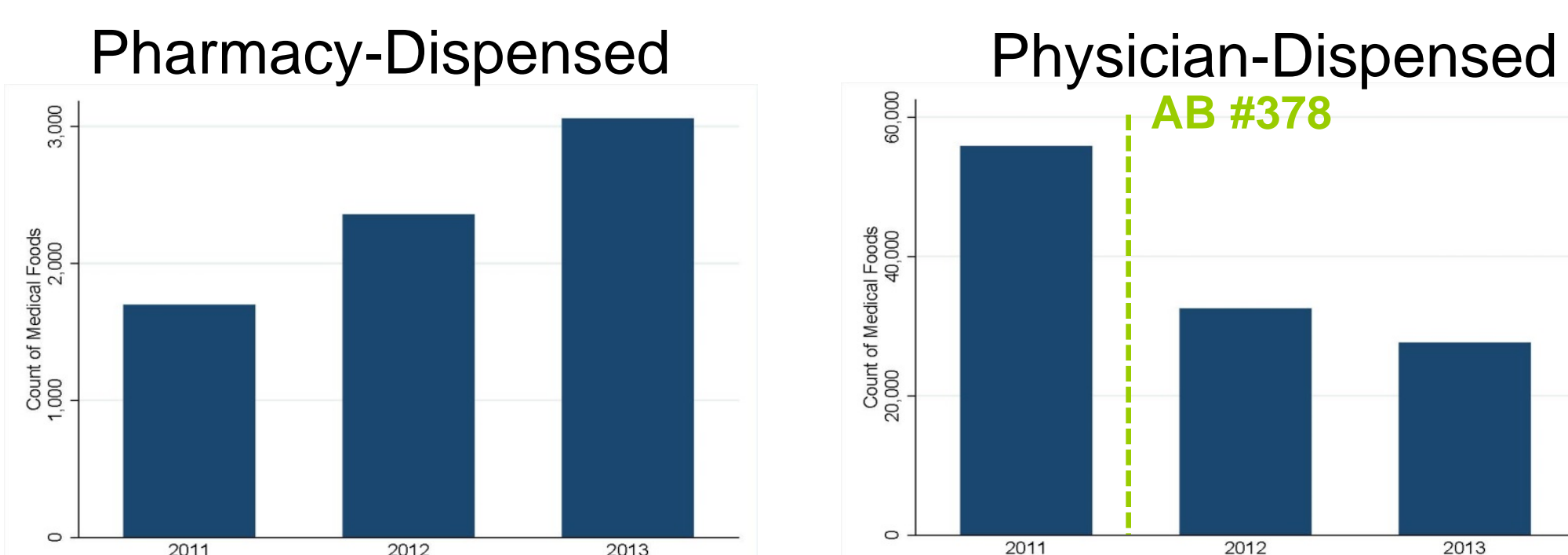
A combination of a generic drug and a medical food, which are manufactured separately, then packaged together and dispensed as a single unit for convenience.

Compounded Drugs

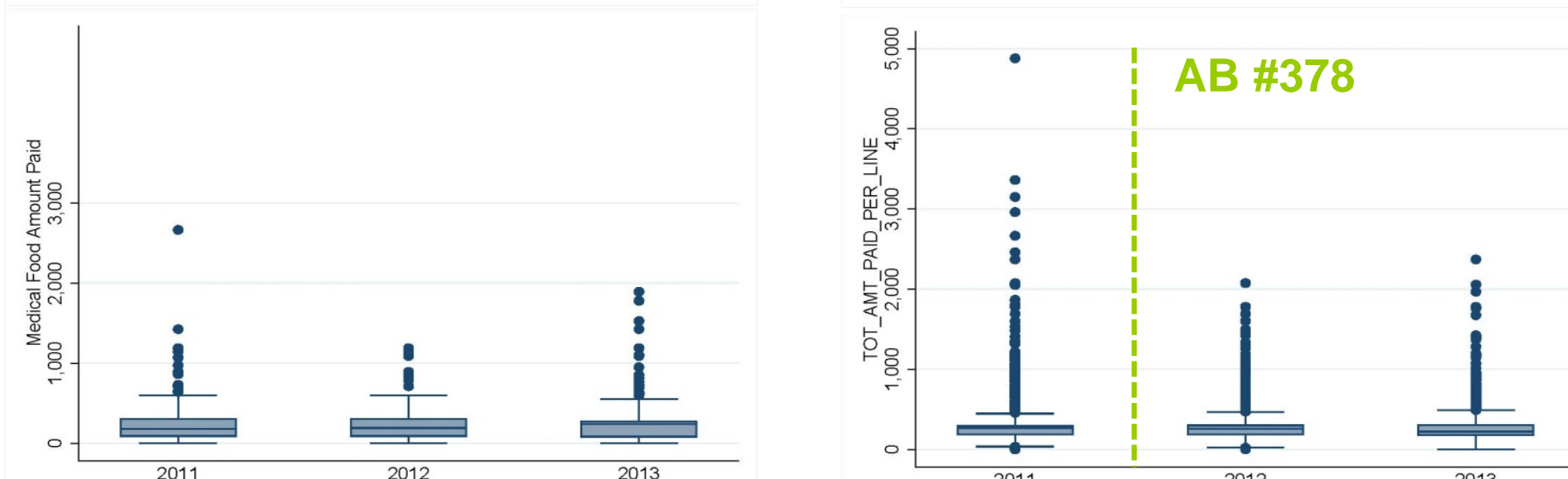
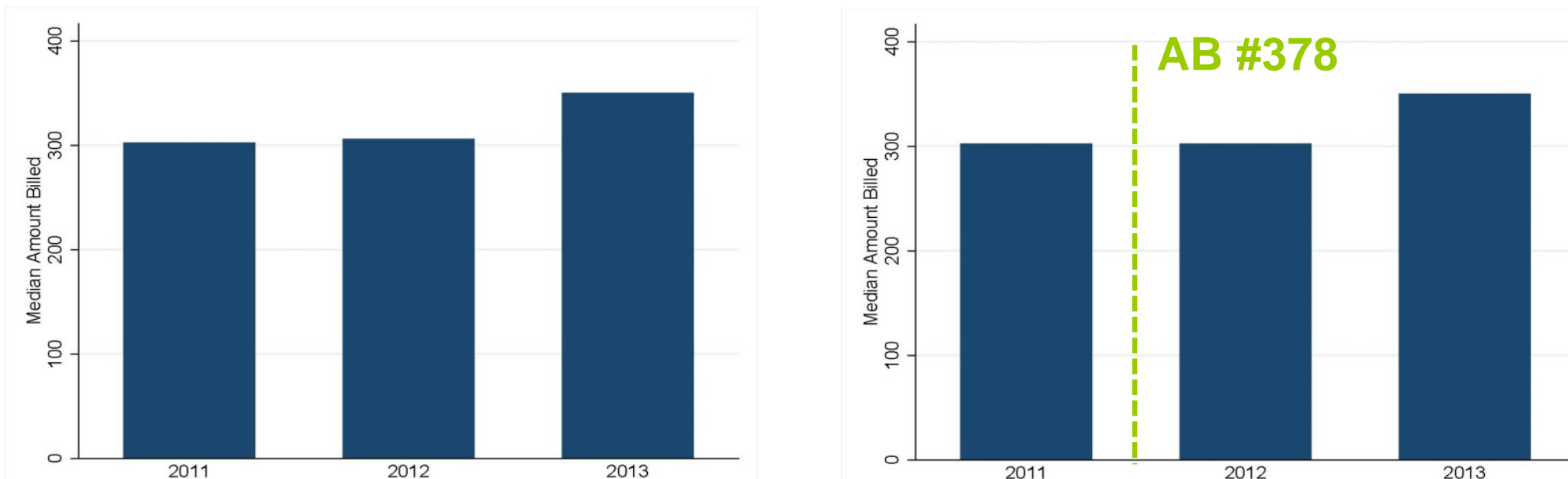
Medications that are produced by combining and tailoring of ingredients to meet individual patient's special medical needs. CDs are regulated by state pharmacy boards if in small quantities.

Results

Medical Foods

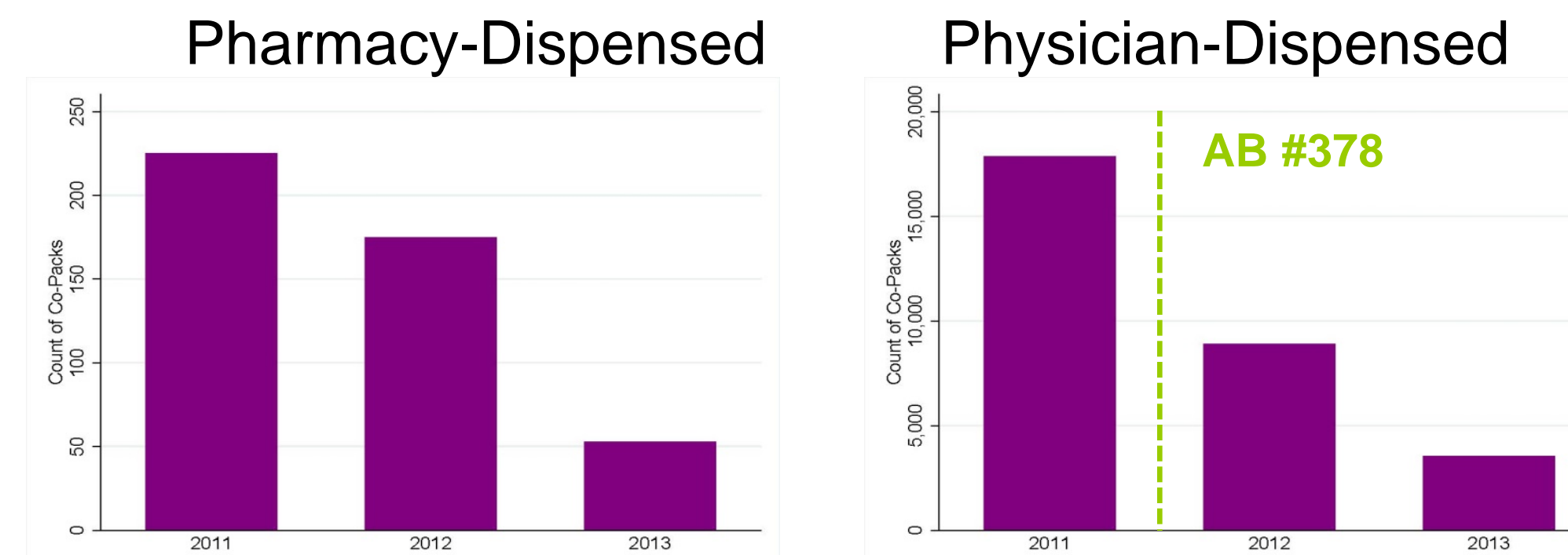


T-Test	Mean Difference	95% Confidence Interval	t	P-value	df
Pharmacy-Dispensed	-.0011	-.0012, -.0010	-15.7675	.0000	2800000
Physician-Dispensed	.0049	.0048, .0050	122.3127	.0000	19000000

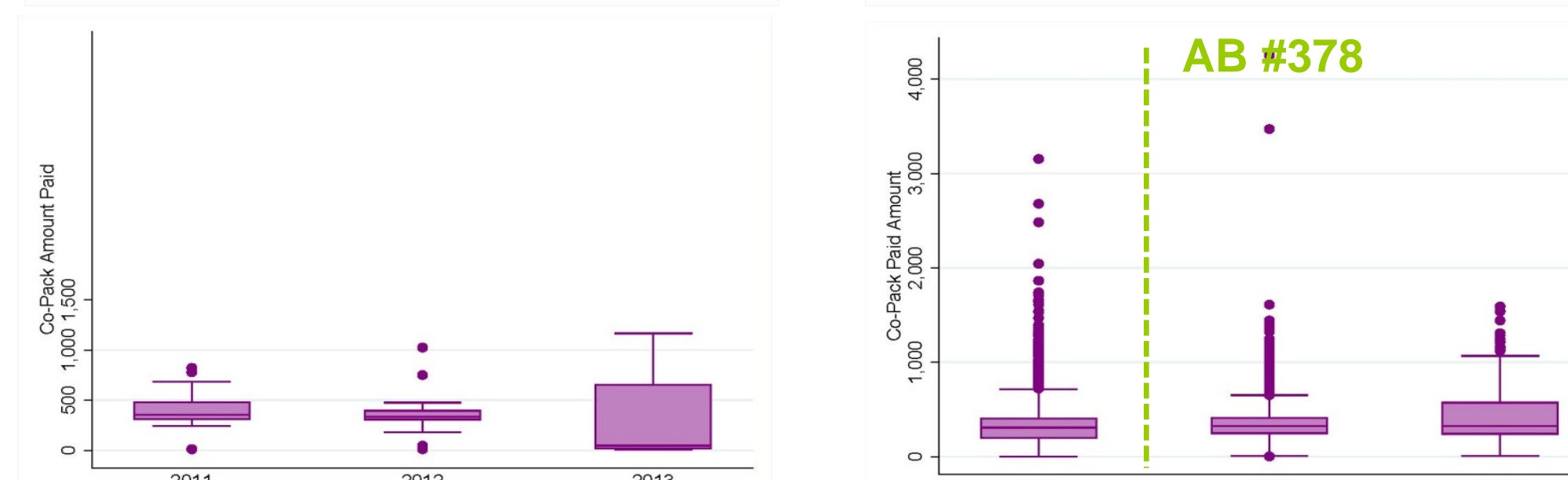
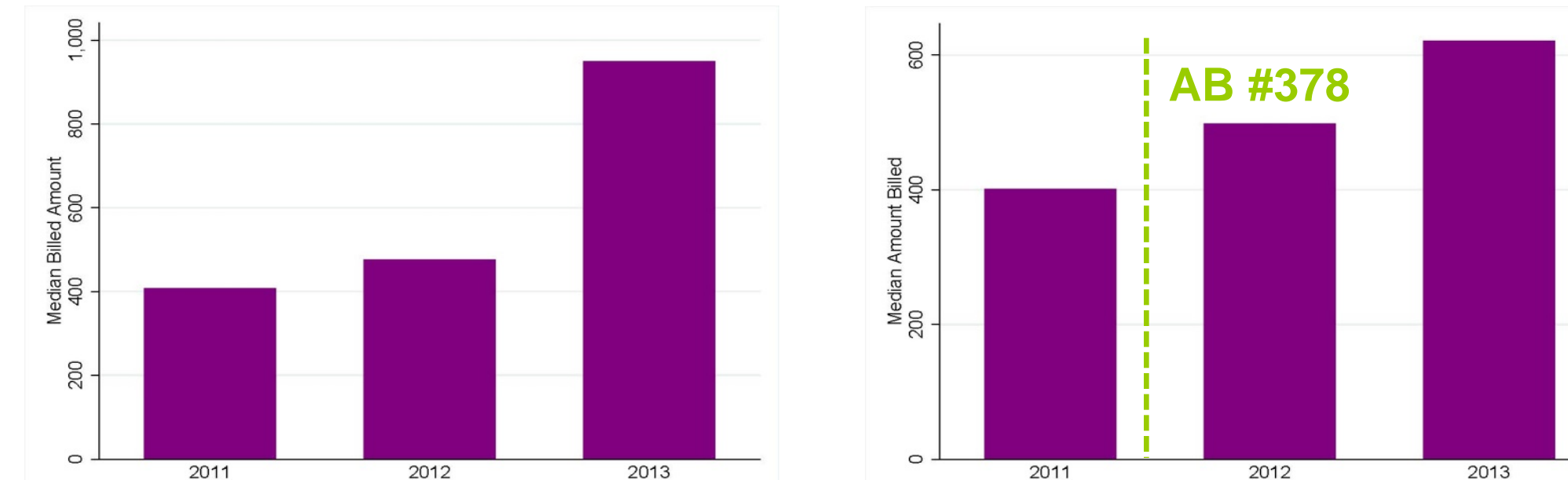


AB #378 is associated with decreased utilization of physician-dispensed MFs as compared with pharmacy-dispensed MF's, where utilization rose significantly. While the median billed amount increased in both datasets, the median paid amount decreased in the physician-dispensed dataset after AB #378.

Convenience Packages

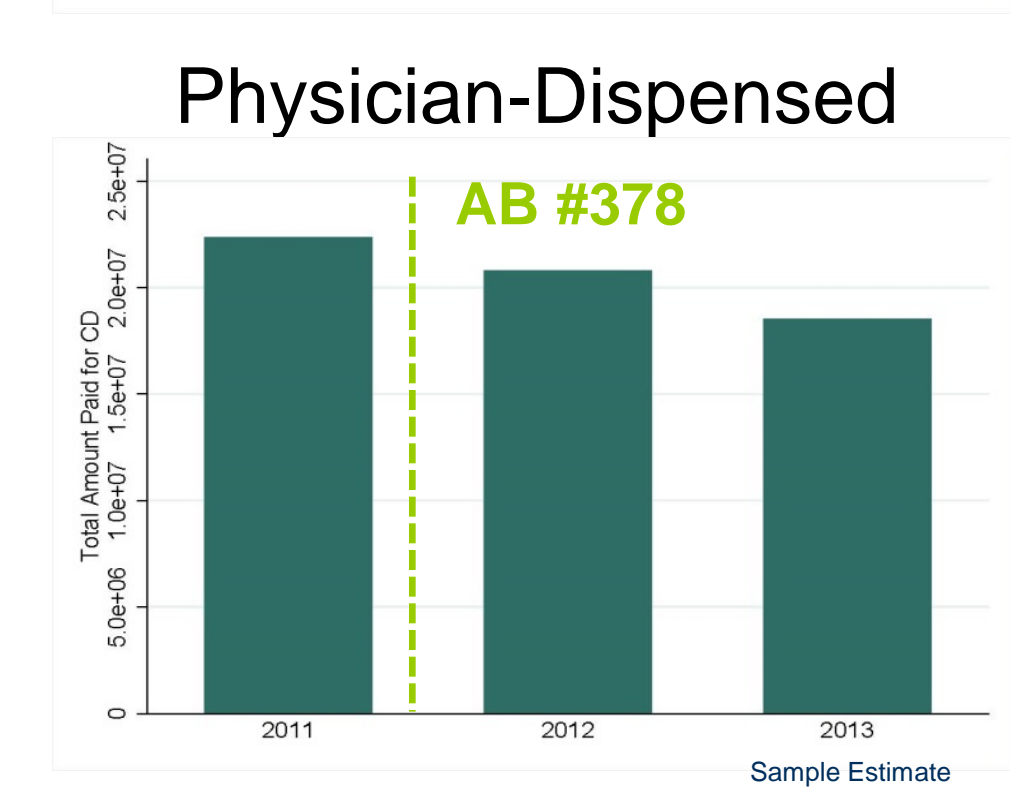
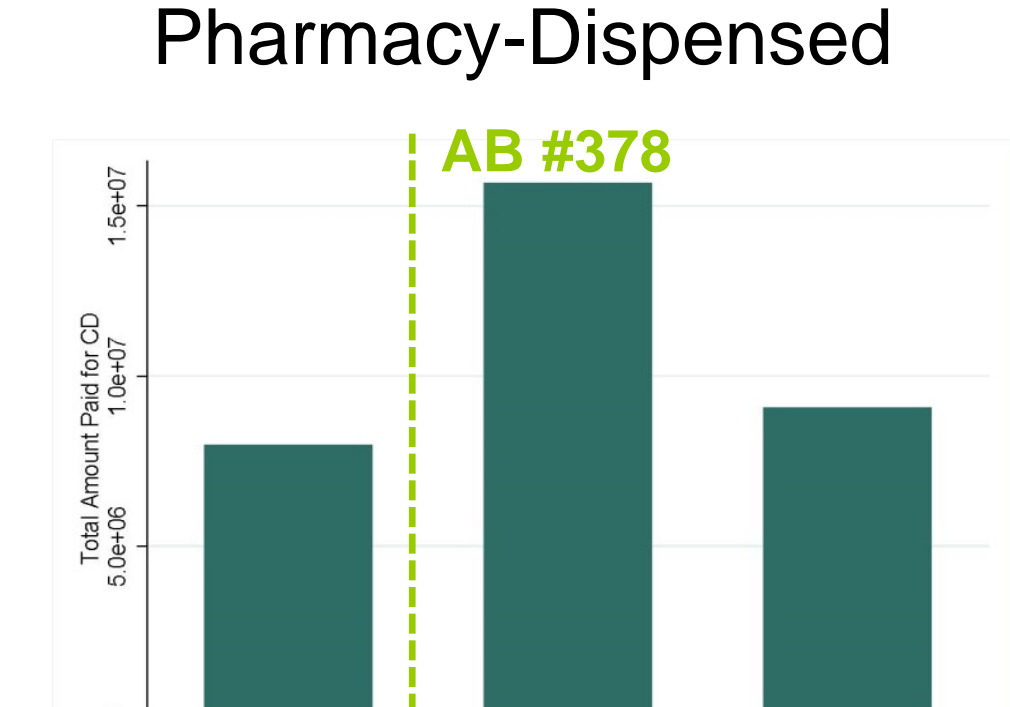


T-Test	Mean Difference	95% Confidence Interval	t	P-value	df
Pharmacy-Dispensed	.0003	.0002, .0003	12.1223	.0000	2800000
Physician-Dispensed	.0018	.0017, .0018	83.7868	.0000	19000000



AB #378 is associated with reduced utilization of both pharmacy-dispensed and physician-dispensed co-packs. The median billed amount increased in both dataset. While the median amount paid for physician-dispensed co-packs is greater, the distribution of the amount paid is greater for pharmacy-dispensed than pharmacy-dispensed co-packs.

Compounded Drugs



T-Test	Mean Difference	95% Confidence Interval
Pharmacy-Dispensed	-39.93	-43.08, -36.78
Physician-Dispensed	2.55	1.60, 3.40

T-Test	t	P-value	df
Pharmacy-Dispensed	-24.83	.0000	118544
Physician-Dispensed	5.29	.0000	739453

AB #378 is associated with a reduction in total cost of physician-dispensed CDs in the CA WCS. In contrast, AB #378 is associated with increased total cost of pharmacy-dispensed CDs.

Conclusions

- Regulations (e.g. AB #378) can reduce utilization of pharmaceutical products that fall outside the normal FDA regulated drug categories. In CA WCS, AB #378 implementation is associated with: 43% reduction of MF utilization the first year and 18% reduction the second year, 53% reduction of co-pack utilization the first year and 63% reduction the second year, and \$2.55 reduction per CD ingredient.
- Pricing regulations can reduce pricing differentials and allow health systems to effectively allocate their resources.
- It is crucial to implement comprehensive regulations to control both physician-dispensed and pharmacy-dispensed prescriptions. Patterns indicate that dispensing pharmacies, not regulated by AB #378, experienced a flux of prescriptions that are regulated in dispensing physician practices.