

# Academic Articles & Reports Roundup: October 2017

Happy November! In this Roundup, we cover five articles from October. The topics this month include: (1) pharma-tribal cooperation and the patent system, (2) Medicare subpopulations with the highest preventable spending, (3) privacy protections in All-Payer Claims Database legislation, (4) medical spending on autism spectrum disorder, and (5) a game theory model to understand hospital competition.

## Pharma-Tribal Cooperation Undermines the Patent System

The Association for Accessible Medicine paper [\*Patent-Assignment Transactions Between Brand-Name Drug Companies and Native American Tribes Will Undermine A Healthy Patent System and Harm Patients\*](#) arises from Allergen's attempt to avoid the USPTO's review of its patents by renting sovereign immunity from St. Regis Mohawk Tribe and assigning them all of Allergen's patents. The authors, William Jay and Jaime Santos, argue that such practice by the drug company is harmful to competition between brand name and generic drugs.

The tribe, on behalf of Allergen, could seek to dismiss all proceedings determining the invalidity of Allergen's patents (i.e. *inter partes* review [IPR] by USPTO) by invoking the tribe's sovereign immunity. The authors argue that if this pharma-tribal cooperation were accepted, flawed patents would become harder to eliminate. Consequently, generic drugs would be delayed from entering the market, as generic drug makers cannot easily challenge brand name drug patents or may shy away due to heightened risk. In doing so, consumers would have to continue to rely on brand name drugs, which can cost upward of five times the price of a generic drug.

To discourage Allergen's strategy, the authors suggest that

the USPTO could conclude that (1) tribal sovereign immunity may not apply to administrative reviews that do not resemble civil litigation, such as an *inter partes* review, or (2) the USPTO is not precluded from conducting a “second look” review of granted patents that were expressly transferred to avoid an adverse *inter partes* review decision.

## **Determining Medicare Subpopulations with the Highest Preventable Spending**

In [Concentration of Potentially Preventable Spending Among High-Cost Medicare Subpopulations](#) (*Annals of Internal Medicine*), Jose Figueroa et. al. conducted a two-prong approach study to provide physicians and accountable care organizations with cost-saving measures. First, the study differentiates Medicare’s “high-need, high-cost” beneficiaries into subpopulations. Second, the study determines how much of the Medicare spending is preventable under each subpopulation.

First, over six million Medicare beneficiaries were divided into six subpopulations: (1) nonelderly disabled, (2) frail elderly, (3) major complex chronic illness, (4) minor complex chronic illness, (5) simple chronic illness, and (6) relatively healthy (those with no chronic conditions). The top ten percent spenders of all the beneficiaries are considered “high-cost.” Within the subpopulations, frail elderly had the highest proportion of high-cost beneficiaries (46.2%), while nonelderly disabled (14.3%) and major complex chronic illness (11.1%) rounded up the second and third place. While 5% of the total health care spending was considered preventable, the researchers found that as much as 43.9% of high-cost spending for the frail elderly subpopulation was preventable. In total, the frail elderly subpopulation had 51.2% of all total potentially preventable spending despite being only 8.6% of the Medicare beneficiary population.

Second, the researchers looked into (a) preventable hospitalizations and (b) preventable ER visits (ER visits that

did not lead to admission). To further differentiate spending, the researchers subcategorized the spending 30 days after an admission or ER visit. High-cost beneficiaries in all subpopulations had the most potentially preventable spending in inpatient settings within acute hospitals. With the exception of the frail elderly, the most potentially preventable spending in an outpatient spending was related to physician services and tests.

## **All-Payer Claims Database Legislation Should Include Strong Privacy Provisions**

In the Source on Healthcare Price & Competition white paper, [All-Payer Claims Databases: The Balance Between Big Healthcare Data Utility and Individual Health Privacy](#), Andrew Kelly and the Source's Executive Editor, Jaime King, urge California to establish an All Payer Claims Database ("APCD") that is subject to HIPAA laws and the California Medical Information Act ("CMIA") along with an independent oversight body that will, among other duties, protect personal health information in the APCD.

APCDs collect and aggregate third party payer data derived from medical, dental, and pharmacy claims. Because such data includes personal health information and state agencies are not covered entities subject to HIPAA and CMIA, the authors point out that the implementation of an APCD must include a mechanism to protect patient privacy and data security. Using California's SB 1159 as an example, the authors argue that legislation establishing the APCD should state that an APCD is *subject to* HIPAA and relevant state statutes on medical information privacy. The use of *subject to* rather than *comply with* ensure that the HIPAA and state laws could be enforced.

Furthermore, the authors argue that an independent oversight body, comprised of broad representation ranging from patient advocates to privacy advocates, should be established along with the creation of an APCD. Noting that HIPAA and state laws

are just a baseline, the authors argue that the oversight body can ensure that there is significant data privacy and security protection for the APCD data and subsequent disclosure.

Finally, the authors recommend that APCD legislation include explicit language identifying under what circumstances and to whom identifiable and deidentified data can be released, as well as provide explicit language that identifiable data disclosures will only be done after rigorous review.

## **State Mandates Increase Medical Spending on Autism Spectrum Disorder**

In [\*Effects of State Insurance Mandates on Health Care Use and Spending for Autism Spectrum Disorder\*](#) (Health Affairs), Colleen L. Barry, Andrew J. Epstein, Steven C. Marcus, et. al. found state insurance mandates to be effective in increasing use and spending on autism spectrum disorder (“ASD”) treatments.<sup>[1]</sup> Prior to state insurance mandates, commercial insurers either did not provide or provided minimal coverage for ASD treatments.

The state mandates requiring commercial insurers to cover ASD-specific behavioral therapies led to a 3.4 percentage overall increase in the probability of using ASD services and a \$77 increase in monthly spending for ASD services. This increase was more profound for younger children. Even after spending was broken down by specific categories (ASD-specific outpatient|behavioral and functional therapy), younger children had a greater increase in monthly spending than older children.

Furthermore, each additional year the state insurance mandate was in effect increased the monthly spending of ASD services. Thus, while the monthly spending of ineligible children remained relatively stable, the monthly spending of eligible children increased, causing a greater gap between the two groups with each passing year. This upward trend in spending

of the latter group is theorized to be the result of the lag in full implementation due to establishing regulations and providing additional training.

### **Game Theory Model to Understand Hospital Competition**

In [\*Hospital Competition in Prices and Quality: A Variational Inequality Framework\*](#) (*Operations Research for Healthcare*), Anna Nagurney and Karen Li propose a game theory model to better understand competition between hospitals and help improve operational efficiencies in terms of pricing and quality for a hospital's medical procedures. The model captures hospitals competing in pricing and quality, with upper and lower bounds imposed to accommodate hospital limitations and various regulations such as minimum quality standards or fixed pricing. Rather than looking at the hospital overall, the model breaks down by examining medical procedures for each hospital.

This model consists of a demand function, a cost function, and a utility function, which combine to determine the equilibrium pricing and quality of each procedure at each individual hospital. Through this model, each hospital can standardize the demand for each procedure by accounting for pricing and quality of the same procedure at competing hospitals. Hospitals could use this to determine whether pricing of a procedure is too high or too low compared to other hospitals, as well as compare the quality level and incurred demand of a procedure with other hospitals. Finally, hospitals could use this model to calculate net revenue and utility.

This model, in its application, reveals that the quality of smaller hospitals may fall without the altruism benefit. Thus, smaller hospitals may seek to emphasize the degree of altruism to maintain a higher quality of care and remain competitive. Further applications in which costs associated with quality were reduced due to innovations or better education led to a higher net revenue, higher overall utility, and higher

quality. As such, hospitals may be able to use this proposed model to determine strategies for operational efficiencies.

That's all for this month. As always, if you find articles or reports that you think should be included in the monthly Roundup, please [send](#) them our way. Enjoy your reading!

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[\[1\]](#) However, state mandates were limited by ERISA, which prevents state mandates from extending to self-insured plans. Since half of Americans are on self-insured plans, state mandates do not encompass all people who need coverage for ASD treatments.