OBJECTIVES: To conduct a study to assess value perceptions and the evidence needs for key stakeholders of medical product manufacturers, including payers and employers. This study was a structured, qualitative assessment of influential U.S. health plans and companies. METHODS: Telephone survey interviews were used to collect data from fifteen private U.S. payer representatives and payer-related experts. Phone and in-person interviews were conducted with twenty-six U.S. employer representatives. Working behavioral assumptions were constructed for the payer and employer groups, and stakeholder-specific discussion guides were used to facilitate the survey interviews. RESULTS: The top payer findings suggest that health plans are most interested in clinical safety, efficacy, and effectiveness evidence. Payers' demands are increasing for more clinical utility and clinical performance studies providing comparative information for medical products. Cost and cost-effectiveness were identified as important but secondary considerations for coverage and reimbursement decisions. The employers surveyed exhibited substantial diversity in their approach to providing health care benefits for employees. The majority of employers and payers reported that consumer-directed health care (CDHC) plans are increasing in scope and will play a larger role moving forward. Most reported that the effects of CDHC on costs and long-term health outcomes are unclear. Recent trends associated with health care costs increasing faster than inflation contribute to employers' difficulty with defining “value in health care” and to their challenges associated with evaluating return on investment for health care expenditures. CONCLUSION: U.S. employers and payers are struggling with clearly defining the concept of medical product value. Payers rely on phase III randomized controlled trials as their primary evidence source for covering medical products, yet request additional post-marketing comparative studies. Employers are largely engaged in cost-shifting to employees and are trying to select younger and healthier workforces to reduce their health care expenditures.

THE VOLUNTARY INCENTIVE STRUCTURE OF PEDIATRIC EXCLUSIVITY AND ITS IMPACTS ON PHARMACEUTICAL INDUSTRY BEHAVIOR AND GENERIC DRUG ENTRIES

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OBJECTIVES: The FDA Modernization Act of 1997 created a six-month of market exclusivity extension in exchange for pharmaceutical companies’ pediatric studies for the drugs of potential benefits to the pediatric population. This study examines how the voluntary incentive structure of the exclusivity has impacted on the pharmaceutical industry's efforts to obtain the exclusivity and how the rule has been used to delay generic entries for the exclusivity period. METHODS: By using 63 drugs whose patent expired between 1999 and 2003, obtained from the FDA, several descriptive analyses were performed. The percentage of drugs with pediatric exclusivity was described by several important factors, especially focusing on main use of the drugs. Next, all the drugs were divided into two groups—drugs with exclusivity vs. no exclusivity—and then generic competition degree was presented by each group for two years following the initial patent expiration of each drug. RESULTS: A bigger firm was good at filing the exclusivity that needs additional clinical study (p < 0.05). The competition level in each drug’s therapeutic class was positively associated with having the exclusivity. The drugs with exclusivities were more likely to treat chronic conditions that include many blockbuster drugs. The firms have applied for pediatric extension over the drugs with larger market size (p < 0.01). For pediatric exclusivity group, there were no generic competitors until six months and then there was a dramatic increase of generic entries after the exclusivity expired whereas no-pediatric group didn’t show notable increasing trend during the observation period. CONCLUSION: The market size of a drug was the most important factor to acquire the pediatric exclusivity that has been a tool for an originator firm to delay generic competition. It implies the incentive structure based on willingness of industry has not always achieved the primary goal of “safety of children”.

DIFFERENCES IN CHRONIC DISEASE CARE OF PRE_MEDICARE INDIVIDUALS BETWEEN METROPOLITAN AND NON-METROPOLITAN SETTINGS

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OBJECTIVES: Differences between metropolitan and non-metropolitan setting in the management of chronic conditions in patients 55 to 64 years of age can result in higher morbidity rates in non-metropolitan areas. We will look at the association between the geographic setting and indicators of care management for visits in this population. METHODS: Data from the National Ambulatory Medical Care and National Hospital Ambulatory Medical Care surveys were combined for years 2001 to 2004. NAMCS and NHAMCS collect visit data from medical records of randomly selected physician offices, hospital outpatient departments, and hospital emergency departments during randomly selected time periods through the year. A metropolitan area is an urban area with a core population of at least 50,000. Visit data were weighted by the inverse of selection probability and used to provide average average estimates. Visits having diagnoses codes for hypertension, diabetes, COPD, heart disease, stroke, and cancer were selected based on the ICD-9-CM codes. Number of chronic diseases, medications mentioned, therapeutic and preventive services performed, and diagnostic procedures ordered per visit were compared between metropolitan and non-metropolitan settings. SUDAAN software was used to develop a Poison regression model to perform the comparisons. Source of payment, gender, and race for patients were included in the model as covariates. The effect of the number of previous visits on the outcomes will be examined in future. RESULTS: Although rural visits had a higher number of chronic conditions (1.14 vs. 1.11, p < 0.05), they had a smaller number of therapeutic and preventive services performed per visit (1.22 vs. 2.73, p < 0.01) and had a lower number of diagnostic and screening procedures ordered per visit (2.61 vs. 3.04, p < 0.05). CONCLUSION: The differences in care management in the years preceding Medicare eligibility could have implications for utilization of services once this population enrolls in Medicare.

THE TRENDS IN PRESCRIBING OF HERBAL MEDICINES IN AMBULATORY SETTINGS IN THE UNITED STATES 1993–2004

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OBJECTIVES: The use and awareness of herbal medicines has been on the rise. Although most of these products are over the counter (OTC), it is less known how often they are recommended during office-based physician visits. Purpose: The objective of this study was to investigate the trends in prescribing of herbal medicines in the ambulatory medical setting in the U.S. METHODS: This study was a retrospective analysis of the National Ambulatory Medical Care Survey (NAMCS) and
the National Hospital Ambulatory Medical Care Survey (NHAMCS) data from 1993 through 2004. Both are national probability surveys of visits to office-based physicians and ambulatory services in hospital emergency and outpatient departments and provide weights to obtain nationally representative estimates. Seventy-six different medicines of herbal origin were identified based on their generic codes and the visits in which they were prescribed were calculated for each year. RESULTS: In 1993, of the total 1.6 billion NAMCS & NHAMCS visits, herbal medication was prescribed in 0.14% ambulatory visits [2,328,901 (95% C.I.: 2,298,097–2,359,705)]. This proportion increased to 0.26% in 2004 or 2,883,006 visits (95% C.I.: 2,821,529–2,944,483) of the total 1.1 billion visits. The five most commonly prescribed medications were Psyllium, Senna, Garlic, Ginkgo and Ipecac. Forty-nine of the total seventy-six study drugs were never prescribed during a physician visit throughout the study period. CONCLUSION: The trend of prescribing of herbal medications during office-based physician visits has risen over the past decade but is limited to selected herbal products and is not widespread.

**PHP14**

**POLYPHARMACY IN ELDERLY PATIENTS AT THE MEXICAN INSTITUTE OF SOCIAL SECURITY: SATISFACTION AND COSTS**


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OBJECTIVES: To identify cases of polypharmacy (PF) and to describe their social and clinical characteristics, satisfaction and costs in elderly patients who attended Family Medicine health care services at the Mexican Institute of Social Security (IMSS).

METHODS: Cross sectional study in 260 elders (> 65 years old) who attended a Family Medicine facility at the IMSS in Mexico City. A survey and a concurrent review of medical records were performed to identify characteristics of drug prescription and patients' satisfaction in the previous 3 months. The WHO definition of polypharmacy was used to classify this prescribing pattern: simultaneously consumption of more than 3 drugs. Costs were estimated from an institutional perspective and are expressed in US dollars (USD). RESULTS: Mean age was 71 years (6.9 SD), 60.8% were female, 15.8% illiterate, 35.3% married, 10.4% single and 35.4% widow/widower. A high percentage (86.2%) reported having a chronic disease; the main problems were hypertension (57.7%), diabetes (35.4%), and sleep problems (35.4%). Satisfaction with medication was: very high 56.9%, high 28.5%, mild 8.1%, low 1.2%, and very low 0.8%. Drug mean cost per patient was 6.6 USD (per month) with a standard deviation of 21.9 USD. Prescription of 3 drugs at the same time was reported in 64.2% and polypharmacy in 49.2%. CONCLUSION: Our study found that polypharmacy was a common prescribing pattern in Family Medicine services. Prescription of 3 drugs at the same time and polypharmacy might lead to an important proportion of health care costs. Among the elderly population the proportion of chronic conditions was high, as was satisfaction with drug treatment. It is possible that there is a trade-off between improvement of symptoms and adverse side effects of drugs; therefore it would be necessary to research the quality of life, drug prescription and its justification in these patients.

**PHP15**

**STUDYING THE IMPACT OF CO-PAYMENT DIFFERENTIAL ON GENERIC DISPENSING RATE IN A MANAGED CARE POPULATION**

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OBJECTIVES: The purpose of this study was to determine the impact of copayment differential between tier-one and tier-two medications on the generic dispensing rates. METHODS: A pre-post study design with control group analysis was conducted to investigate the effect of a changing copayment structure on the Generic Dispensing Rate (GDR). Clients that changed their copayment structure during the 2006 fiscal year were identified. Data from five clients from pharmacy claims database maintained by a large pharmacy benefit manager (PBM) were collected. Study clients had one of the three effective dates during which they changed their copayment structures: January 1, 2006; July 1, 2006; or October 1, 2006. Two clients that did not change their copayment in 2006 were included as control groups. Differences in the copayment amount and percentage change in GDR for pre and post periods were computed and compared using independent t-tests. In addition, an adjusted GDR was calculated by subtracting a nominal increase in the control groups from each of the study groups. RESULTS: Clients that changed their copayment structure in January 1, 2006 reported a mean GDR increase of 2.36% with a mean $8.32 increase in their copayment amount (p-value < 0.05). Similarly, clients who changed their copayment structure in July 1, 2006 demonstrated a mean GDR increase of 4.06% with a mean $9.13 increase in their copayment amount (p-value < 0.05). While clients that changed their copayment structure during October 1, 2006 period showed a net increase in GDR of 2.7% with a $3.36 increase in copayment amount. Such changes were also found to be statistically significant when compared to the changes reported by the control clients. CONCLUSION: Increasing the copayment amount between tier-one and tier-two demonstrated a positive impact on GDR thereby translating into potential savings for the clients.

**PHP16**

**COMPARING GENERIC DISPENSING RATES AMONG THREE DIFFERENT RETAIL CHANNELS**

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OBJECTIVES: To compare generic dispensing rate (GDR) among 30-day retail program, mandatory 90-day retail program and voluntary 90-day retail program. METHODS: This analysis was conducted using pharmacy claims data from a pharmacy benefit manager (PBM). Patients who were new to either Ace-Inhibitor, statins or SSRIs in March-May 2005 were identified and followed-up for a period of 12-month to measure their GDR. Patients had retail 30-day supply only during the study period were included in 30-day retail program, patients had mandatory 90-day supply during the study period were in mandatory 90-day retail program, and similarly, patients had voluntary 90-day supply were in voluntary 90-day retail program. GDR was measured by claim level as well as patient level, which was the number of generic claims and/or patients using generic medications divided by total number of claims and/or total patients. All claims were normalized to a 30-day supply. RESULTS: About 4678 claims and 907 patients in 30-day retail program, 1438 claims and 138 patients in mandatory 90-day retail program, 5136 claims and 538 patients in voluntary 90-day retail program. GDR was found to be relatively higher in voluntary 90-day retail program (47.65%, 47.77%).