on these findings, a framework consisting of key characteristics of an AED scheme was developed and, subsequently, applied to an inventory of existing AED schemes, compiled through a comprehensive review of relevant peer-reviewed and ‘grey’ literature available as of August 2009. RESULTS: The framework contained 11 characteristics of AEDs that grouped into 3 sequential dimensions: (1) System level (Decision problem; Objective; Engagement; Evaluation); (2) Organisational (Governance; Financing); and (3) Research design (Scope; Level of Operations; Test Criterion; Test Implementation; Response to Test Result). It was applied to the inventory in the form of a ‘checklist’ followed by critical appraisal tools. In general, information found for each of the schemes was limited and did not address questions comprising the checklist. CONCLUSIONS: Information upon which to evaluate AED schemes is sparse, yet necessary for moving forward with efforts to ensure their use represents value for money.

**PHP15**
**EVALUATION OF PATIENT ASSISTANCE PROGRAM AVAILABILITY AND ELIGIBILITY FOR TOP 200 BRAND AND GENERIC DRUGS IN THE UNITED STATES**

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OBJECTIVES: This study examined the availability of and eligibility requirements for pharmaceutical patient assistance programs (PAPs) for the most commonly prescribed medications in the United States. METHODS: RxAssist.org, an electronic database of PAPs, was utilized to collect information on the availability (brand and/or generic) and eligibility (citizenship, permanent residency, insurance, and income limits) for each of the “Top 200 drugs by dispensed prescriptions” for 2008. Pharmaceutical companies were contacted directly or their websites were searched when additional clarifications were needed. Chi-square analyses were used to assess for differences in eligibility requirements by drug availability (brand vs generic).

RESULTS: Of 136 unique chemical entities, 111 (81.6%) of these drugs were available in RxAssist.org. 69 (62.2%) of the available drugs were brand only, 20 (26.1%) generic only and 13 (11.7%) had both brand/generic forms. There were differences found in PAP eligibility requirements for citizenship (p < 0.001), permanent residency (p < 0.001), and private insurance status (p < 0.001) by drug availability (brand versus generic), but not for income limits (p = 0.051). Some programs allow Medicare Part D patients to apply for PAP; however, each claim is evaluated on a case-to-case basis. CONCLUSIONS: Both brand and generic drugs are widely available to low-income applications through PAPs, but results suggest that U.S. citizenship and permanent residency are more likely to be required by PAPs for brand versus generic drugs. PAPs also provide some options for the uninsured—which those with either private insurance or Medicare Part D coverage.

**PHP16**
**LOW SOCIOECONOMIC STATUS IS A RISK FACTOR FOR CPAP ACCEPTANCE AMONG ADULT OSAS PATIENTS REQUIRING TREATMENT**

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OBJECTIVES: To evaluate whether socioeconomic status (SES) plays a role in the patient’s decision to accept (purchase) continuous positive airway pressure (CPAP) treatment for obstructive sleep apnea syndrome (OSAS) (according to the Israeli National Health Insurance Law) among patients purchasing CPAP treatment and/or paying for it (co-payments). METHODS: Cross-sectional prospective study in the University-affiliated Sleep Disorder Center in Beer-Sheva, Israel. Adult patients (age ≥ 18 years), suspected of having OSAS, were consecutively recruited between March 2007 and December 2007. Questionnaires were completed prior to diagnosis to elicit socioeconomic status, sleeping habits, and access to sources of information on OSAS and its treatments. At the conclusion of the adaptation period, a second questionnaire was completed to explore the reasons for commencing or declining treatment. RESULTS: Among the newly diagnosed (polysonographically) adult OSAS patients, 162 required CPAP and underwent attendant titration and a 2-week adaptation period. Only 40% of these patients (n = 65) decided to purchase CPAP therapy. They were older, and typically had higher apneahypopnea indexes (AHIs) and higher income levels than the patients who declined CPAP treatment. Multivariate logistic regression (adjusting for body mass index and Epworth Sleepiness Scale) revealed that whether a patient purchased CPAP was determined by (OR, 95% CI): income level (2.4; 1.2–4.6), age (+1 year) (1.07, 1.01–1.1), AHI (≥ 35 vs <5 events/hr) (4.2, 1.4–12.0), receiving positive feedback about the experiences of family or friends with CPAP (2.9, 1.3–5.7), and sleeping separate from spouse (4.3, 1.4–13.3). CONCLUSIONS: In addition to the already known determinants of CPAP acceptance, patients with low SES were less receptive to CPAP treatment than those with higher SES. CPAP support and patient education programs should be tailored for low SES people in order to increase rates of treatment initiation and adherence.

**PHP17**
**WHAT FACTORS PREDICT FAVORABLE MEDICARE COVERAGE?**

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OBJECTIVES: There is a lack of understanding and empirical basis regarding what factors are important in the Medicare National Coverage Determination (NCD) decision-making process. The objective of this study was to determine what factors predict favorable NCD decisions. METHODS: NCDs from 1999 through 2007 were reviewed using publicly available decision memoraanda posted on the CMS website (n = 140). Data abstracted from decision memoranda were supplemented with cost-effectiveness information identified from an independent literature review. When a decision memo included coverage decisions for multiple devices and/or conditions, an entry was made for each coverage decision in the memorandum. The United States Preventive Services Task Force (USPSTF) guidelines were used to grade the supporting clinical evidence. We created a dataset with the following variables: quality of supporting clinical evidence, availability of alternative interventions, cost-effectiveness of intervention, type of intervention, and coverage requester. Logistic regression was used to determine what variables predicted favorable coverage. RESULTS: Good quality supporting clinical evidence was associated with an odds ratio (OR) of favorable coverage (91% CI) of 12.74 (3.02–53.74). Interventions estimated to be dominant, i.e. less costly and more effective, or have an estimate of cost-effectiveness of <$50k per QALY were associated with an OR of 18.86 (4.62–77.00) and 3.91 (1.00–13.40) respectively. Availability of alternative interventions for the same indication was associated with a decreased likelihood of coverage with an OR of 0.01 (0.03–0.33). Type of intervention, and coverage requester were not significant predictors. CONCLUSIONS: The findings suggest that good quality supporting clinical evidence and favorable estimates of cost-effectiveness predict favorable CMS coverage decisions. The availability of alternative interventions for the same indication reduced the likelihood of a favorable coverage decision. The findings indicate that Medicare’s coverage process is evidence and value-based, though more research is needed on the impact of decisions.

**PHP18**
**EVALUATION OF MEDICARE PART D PHARMACY AND MEDICAL UTILIZATION PATTERNS BY COVERAGE PHASE FOR COMMON CHRONIC DISEASES**

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OBJECTIVES: To evaluate the percent of patients reaching the coverage gap and catastrophic phase and their pharmacy and medical utilization for the treatment of common chronic conditions (asthma, COPD, cardiovascular disease, diabetes, hyperlipidemia, hypertension (HTN), heart failure (HF)) among patients enrolled in Medicare Advantage with Part D coverage (MAPD). METHODS: Retrospective claims analysis using medical/pharmacy claims and enrollment data from a large National Us Plan offering MAPD benefits. Patients with full-year enrollment in 2007 and ≥1 select condition based on claims in 2006 were identified. Phase transitions were based on pharmacy expenditures and in the coverage gap. Eligible patients were excluded. Outcomes included the proportion of patients filing any medication per national guidelines, proportion of days covered (PDC) for patients filing ≥1 compliance (MPR) for patients filing ≥2 and medical utilization of costs overall and by phase. RESULTS: The percentage of patients reaching the coverage gap ranged by condition from 18%–36% with 2%–6% reaching catastrophic. For all conditions, non-catastrophic coverage gap however, patients filling medications in the gap spent on average ≥5% (HTN) to 160% (depression) more out-of-pocket compared to their non-catastrophic phase. As with pharmacy utilization, medical also decreased during the coverage gap. Overall, the proportion of patients filling any acceptable medication for their condition ranged from 40% (COPD) to 95% (HF). The proportion of those with ≥80% PDC range from asthma (19%) to HF (76%) while compliance rates for patients filing MPR (≥ 80%) ranged from Asthma (37%) to HF (87%). CONCLUSIONS: A fairly high percent of patients reached the coverage gap in 2007 and incurred substantially larger out-of-pocket expenses. Once in the gap, both medical and pharmacy utilization on average decreased. Medication compliance persistence was less than optimal overall and with up to one-third of patients reaching the gap there is further potential for reduced quality care that could negatively impact the health of an aging population.

**PHP19**
**PREVALENCE AND PREDICTORS OF ANTIDEPRESSANT PRESCRIBING IN ELDERLY NURSING HOME RESIDENTS IN THE UNITED STATES**

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OBJECTIVES: This study examined the prevalence of antidepressant drug use and factors associated with their use among elderly nursing home residents in the United States using the 2004 National Nursing Home Survey (NNHS). The study involved analysis of prescription and resident files of a nationally representative sample of residents aged 65 years from the 2004 NNHS data. The analysis focused on the prescribing of any antidepressant, including selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), serotonin modulators, and other antidepressants such as mirtazapine and bupropion. A descriptive weighted analysis was performed to examine the prevalence patterns. Multiple logistic regres-
sion within conceptual framework of Andersen’s Behavioral Model was used to examine the predisposing, enabling and need characteristics associated with antidepressant use. RESULTS: The overall prevalence of antidepressant use was found to be 46.22% (95% CI, 45.16–47.27). The most prescribed class of antidepressants was SSRI (35.3%), followed by serotonin modulators (10.05%), SNRIs (6.02%), MAO inhibitors (5.06%) and MAO inhibitors (0.02%). Citalopram (28%) was the highest prescribed individual antidepressant followed by atomoxetine (22.05%). Among the predisposing characteristics, age, race, and marital status were significantly associated with antidepressant use. Enabling factors like Medicare or Medicaid payment source and facility bed capacity predicted antidepressant use. Among need characteristics, likelihood of receiving antidepressant prescription decreased with increased dependence in decision making ability and out of bed mobility. Also presence of depressed mood indicators, history of falls and fractures, and an increase in number of medications prescribed had positive association with antidepressant prescription. CONCLUSIONS: Nearly half of elderly nursing home residents received antidepressants. Pre-disposing, need, and enabling factors played important roles in use of antidepressives. Overall, the study findings suggest that antidepressant treatment is highly prevalent in nursing homes possibly due to increased recognition of symptoms in the elderly population.

**PHP22**

**UTILIZATION OF PRESCRIBED PAIN MEDICATIONS PRIOR TO THE INITIATION OF DULOXETINE THERAPY**

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OBJECTIVES: Duloxetine is approved for the treatment of major depressive disorder (MDD) and general anxiety disorder (GAD), and for the management of diabetic peripheral neuropathic pain (DPNP) and fibromyalgia. It has also demonstrated significant pain relief among patients with chronic lower back pain (CLBP) and osteoarthritis. For patients with each of these conditions, this study assessed pain medication use prior to duloxetine initiation. METHODS: A large, US administrative claims database was used to identify discontinued duloxetine initiators during 2007 and 2008 who had any of the 6 medical conditions mentioned above during the 12 months prior to duloxetine initiation. Initiation was defined as no duloxetine pill coverage in the previous 90 days. Utilization of pain-related medications including anticonvulsants, NSAIDs, and muscle relaxants, was assessed over the 6 or 12 months prior to duloxetine initiation, respectively. RESULTS: The study identified 44,838 duloxetine initiators in 2008, with 13,809, 3,289, 1,501, 8,731, 7,871, and 18,987 in the MDD, GAD, DPNP, fibromyalgia, osteoarthritis, and CLBP groups, respectively. Antidepressant use was high across all conditions over the 12 months prior to duloxetine initiation, especially among patients with MDD (83.5%) or GAD (78.8%). Anticonvulsant utilization was highest in DPNP (63.4%) and fibromyalgia (55.0%), lowest in GAD (39.9%), but similar between other groups (ranged 42.3–48.9%). Opioids were used more frequently across groups (51.8–82.8%), with the highest (lowest) use among CLBP (GAD) patients. GAD patients had the lowest NSAID use (32.1%), while osteoarthritis patients had the highest utilization (59.4%). The use of muscle relaxants ranged between 28.2% (GAD and DPNP) and 54.3% (CLBP). Pain medication use in the 90 days prior to study initiation was consistently lower. Results for 2007 initiators were similar. CONCLUSIONS: Patients used several types of pain medications prior to initiating duloxetine across disease states.

**PHP23**

**A TREND ANALYSIS OF DISCONTINUED NEW MOLECULAR ENTITIES IN THE US**

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OBJECTIVES: To examine the influence of inexpensive generic programs on prescription medication acquisition behavior of patients. METHODS: Cross-sectional survey of 200 consecutive patients during regularly scheduled appointments to an adult general medicine clinic. Questions were asked to determine the type of pharmacy patients obtained their current prescription medication from; whether they were aware of focused programs selling generic medication for a reduced cost; whether they had filled a prescription recently using a reduced cost generic program, and if they did, whether they had other medications filled at the same pharmacy. Demographic data was also obtained. Data were analyzed using descriptive statistics. Respondents were categorized as having filled a prescription using an inexpensive generic program or not. Differences in demographics and medication-related variables between the two groups were analyzed using Student’s t-test for continuous variables or Chi-squared analysis. Equivalence Evaluations. Descriptive statistics, chi-square tests, logistic regression, and survival analysis were performed. For the Kaplan-Meier survival curves, drug discontinuation was defined as being discontinued from the market. In this study, a trend analysis was performed to examine the pattern of discontinued NMEs approved by the FDA from 1980 to 2008. METHODS: Data were derived from the FDA, Federal Register, Micromedex, Medline, Lexis-Nexis, journal articles, governmental web pages and other publicly available documents. A drug was considered discontinued if it was deleted from the 2009 version of the FDA’s Orange book: Approved Drug Products with Therapeutic Equivalence Evaluations. Descriptive statistics, chi-square tests, logistic regression, and survival analysis were performed. For the Kaplan-Meier survival curves, drug discontinuation was defined as discontinuing a drug from the market. In this study, a trend analysis was performed to examine the pattern of discontinued NMEs approved by the FDA from 1980 to 2008. RESULTS: A total of 703 NMEs were approved during the study period. Of the 101 NMEs that were discontinued, 29 were due to safety concerns. Controlling for other factors, the odds (OR) of a drug being discontinued for reasons other than safety and efficacy were significantly higher than the odds of being discontinued for safety reasons (p < 0.05). Compared to other therapeutic classes, anti-infective drugs were more likely to be discontinued (p < 0.05). Results from the Kaplan-Meier survival analysis revealed the estimated probability of discontinuing a NME from the market over a 20 year time period was 15.0%. CONCLUSIONS: Survival analysis provided useful estimates for the probability of discontinuation. Safety concerns for NMEs were not the foremost reasons for drug discontinuation; rather financial reasons may contribute to a larger portion of discontinuations. However, additional studies are needed to assess how probabilities for drug discontinuation are influenced by decision-making entities regarding drug approval, drug development and innovation, and drug policy.

**PHP24**

**THE PRESCRIPTION DRUG BURDEN FOR US ADULTS BETWEEN THE AGES OF 55 TO 64**

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OBJECTIVES: With US health care reform proposing to extend Medicare coverage to individuals between the ages of 55–64, the pressure for coverage will dramatically increase. We examined demand for five drug markets—cholesterol, diabetes, depression, hypertension and pain—for this age group compared to others. We also compared the cost burden under Medicare Part D compared payers to highlight the demand for more affordable drugs from individuals that are not yet eligible for Medicare coverage. METHODS: For each drug market, total prescriptions (TRx), new patient prescriptions (NPRx), and average prescription size were obtained for each of the age groups analyzed (518, 19–35, 36–44, 54–64, 65+). For each drug market, average out of pocket cost (OPC) was also compared between Medicare beneficiaries and other patients. Data were collected for eight quarters, spanning November 2007 to November 2007.