# Abstracts

notes, and discussions with on-site health care professionals. **RESULTS:** The final sample included 100 clinics, with an average of 73.4 patients per unit. CMS provided estimated CMAs for 89 of these units. In 75 of 89 clinics, the case mix adjuster detected in the study was lower than that ascertained by CMS (mean difference = 0.09). In 14 units, the CMA was higher than reported by CMS (mean difference = 0.04). The average CMA for the 89 units was 1.21 versus 1.28 reported by CMS for these same units, with uneven geographic distribution on the difference. The inability to replicate CMS CMAs would result in a 7% decrease in payment, with a differential from CMS projected payments of > \$350 million over a 4 year period. CONCLU-SIONS: Without access to Medicare claims data, we were unable to replicate CMS CMAs, representing the potential for significant underpayment for dialysis units under the proposed prospective payment system.

#### THE NON-LINEAR RELATIONSHIP BETWEEN DOSING FREQUENCY AND BREAK-EVEN COSTS IN CAPITATED ESRD REIMBURSEMENT Mayne T, Krishnan M, Mutell R

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BACKGROUND In 2011, a new prospective payment system will be instituted for Medicare payments for dialysis. Payments will be calculated per session. It is unclear how long-acting medications will fare under this new system, i.e., if patients are administered a monthly medication and then miss subsequent sessions, how will this impact revenue? OBJECTIVES: Model reimbursement for one long-acting drug under the proposed bundled payment system from the provider perspective. METHODS: We assumed that there would be one set of case mix adjusters (CMAs) and outlier payment for all currently separately billables; that monthly drugs are truly administered only once per month; and that all payments are made in full, i.e., all 20% co-pays are made in full. We included 3 levels of drug utilization (for one drug) and 3 levels of other resource utilization, each ranging from 33% below to 33% above the current mean reported by CMS. We included 4 levels of rebates ranging from 0% to 50%. We examined 16 different CMAs, ranging from 0.6 to 3.6 in increments of 0.2. We varied the number of dialysis sessions in a month from 1 to 13. This  $3\times3\times4\times16$ × 13 matrix produced 7488 solutions. RESULTS: The model showed providers will incur losses when a patient receives a full drug dose in 1 session and misses all subsequent sessions, unless manufacturers provide significant rebates/price reductions. Losses occur even at 50% discounts when CMAs fall below 0.80. Greatest losses do not always occur when there is only 1 session in a month, but can occur at 2 to 7 sessions (J-shaped curve). CONCLUSIONS: Losses on long-acting medications will occur, but can be mitigated and in some cases eliminated through manufacturer pricing discounts. However, the relationship between component costs, CMA and session number are non-linear.

## ERYTHROPOIESIS-STIMULATING AGENT DOSING AND HEMOGLOBIN TRENDS OVER TIME IN CHRONIC KIDNEY DISEASE PATIENTS NOT ON DIALYSIS

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OBJECTIVES: This study evaluated dosing trends and hemoglobin levels over time in patients with chronic kidney disease (CKD) not on dialysis receiving epoetin alfa (EPO) or darbepoetin alfa (DARB), 2 erythropoiesis-stimulating agents (ESAs). METHODS: An analysis of medical claims between July 2000 and March 2009 from the Ingenix IMPACT database was conducted. Patients <sup>3</sup>18 years, newly initiated on ESAs, with <sup>3</sup>1 claim for CKD were included. Patients diagnosed with cancer, receiving chemotherapy or dialysis, or receiving both agents were excluded. Average weekly ESA dose, weighted by the treatment duration, was calculated and reported by semester to evaluate trends over time. For the subset of patients with laboratory data, semi-annual mean of baseline and achieved hemoglobin levels were assessed over time. RESULTS: A total of 4,182 ESA-treated patients were identified (EPO 2684; DARB 1,498). Mean age was 64.2 and 63.2 in EPO and DARB groups, respectively, whereas proportion of women was 51% and 55%. The mean weekly dose was relatively stable for both ESAs over time (EPO: mean: 10,652 units; median: 10,623 units; 25th-75th percentiles: 9,872- 11,609 units; DARB: mean: 41 mcg; median: 42 mcg; 25th-75th percentiles: 38-43 mcg); however, a slight decreasing trend was observed in more recent years (2006-2008). Analysis of laboratory results revealed a declining trend in mean baseline hemoglobin over time (10.5 g/dL in 2003S1 vs. 10.1 g/dL in 2008S2) consistent with recent treatment guidelines. A decreasing trend was also observed in mean achieved hemoglobin during the treatment episode (11.9 g/dL in 2003S1 vs. 10.9 g/dL in 2008S2). Furthermore, the proportion of patients with achieved hemoglobin >12 g/dL decreased from 41% before April 2006 to 23% in April 2007, after the KDOQI guidelines changed. CONCLUSIONS: This analysis of data from CKD patients not on dialysis reported relatively stable ESA dosing trends and decreasing trend in hemoglobin levels during the study period.

## PUK28

#### ASSESSMENT OF RECENT ERYTHROPOIESIS-STIMULATING AGENT GUIDELINES CHANGES ON DOSING PATTERNS IN CHRONIC KIDNEY DISEASE PATIENTS NOT ON DIALYSIS

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OBJECTIVES: To compare the utilization of epoetin alfa (EPO) and darbepoetin alfa (DARB), 2 erythropoiesis-stimulating agents (ESAs), in chronic kidney disease (CKD) patients not receiving dialysis before and after the National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (KDOQI) Anemia Treatment Guideline changes in March 2007. METHODS: An analysis of medical claims from Ingenix IMPACT (2006–2008) and Medicare 5% (2006–2007) databases was conducted. Patients ≥18 years, newly initiated on ESAs, with ≥1 claim for CKD were included. Patients diagnosed with cancer, receiving chemotherapy or dialysis, or receiving both agents were excluded. Patients initiating ESA prior to March 31, 2007 were classified into the pre-guideline changes group and compared with patients initiating ESA after March 31, 2007 using the same time window prior and after KDOQI guideline changes. Dose per injection and cumulative dose evaluated up to 16 weeks after treatment initiation were compared. RESULTS: A total 3427 patients were identified from both data sources. Following guideline changes, a lower number of patients initiated ESAs changes in the IMPACT database (1,059 pre- vs. 518 post-guideline changes) while the number of ESA-treated patient was more stable in the Medicare database (875 pre- vs. 975 post-guideline change). Among ESA-treated patients, the mean number of injections per patient decreased after the KDOQI guideline changes (pre- versus post-guideline changes: IMPACT-EPO: 4.0 vs. 3.8; DARB: 2.9 vs. 3.1; Medicare-EPO: 5.4 vs. 5.1; DARB: 4.9 vs. 4.6). Mean cumulative dose administered per patient also decreased post-KDOQI guideline changes [IMPACT-EPO Units: 95,147 vs. 86,898 (9% decrease) for pre- versus post-guideline changes, DARB mcg: 374 vs. 340 (9% decrease); Medicare-EPO Units: 104,739 vs. 103,265 (15% decrease), DARB mcg: 557 vs. 520 (4% decrease)]. CONCLUSIONS: This observational study suggests that the recent KDOQI guideline changes impacted the ESA utilization patterns in CKD patients not receiving dialysis. A trend toward decreased ESA utilization was observed.

### POSTER SESSION II

PUK26

PUK27

#### HEALTH CARE USE & POLICY STUDIES - Consumer Role in Health Care

PHPI

#### MORE EFFECTIVELY ENGAGING CONSUMERS IN COMPARATIVE EFFECTIVENESS RESEARCH Seidenfield JD<sup>I</sup>, Sonnad S<sup>I</sup>, Gruman J<sup>2</sup>

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**OBJECTIVES:** Current efforts to influence health care using comparative effectiveness research (CER) often miss the opportunity to incorporate patient and consumer perspectives. The Center for Medical Technology Policy (CMTP) seeks to generate evidence for decision-makers and recognizes the importance of including patients and consumers as fellow decision-makers. This paper reports on the formation of and recommendations from a Patient and Consumer Advisory Committee (PCAC) for CMTP. METHODS: Following a literature review on consumer advocacy in health and interviews with experts regarding appropriate structure and training for effective patient and consumer engagement in CER, CMTP convened a workgroup of consumer and patient advocates to review practices and create a set of recommendations for strengthening the patient and consumer voice in CMTP's prioritization of technologies and development of guidelines for CER study designs. RESULTS: The workgroup's key recommendations for technology prioritization include 1) how and when to solicit input on technology topics from patient/consumer groups; 2) the role of patients/ consumers in setting priorities that reflect public values; 3) the information requirements of patients / consumers to serve as effective public representatives; and 4) the characteristics of patients/consumers that would contribute a broad perspective. For the development of study design guidelines, 1) gather patient/consumer information preferences via semi-structured interviews; 2) address patient/consumer identified outcomes; 3) consider having advocates who are also subject-matter experts review and comment on summaries from stakeholder meetings in addition to the public representatives who directly participate; and 4) consult with patient/consumer advocates about the suitability of disseminating project findings. CONCLUSIONS: As CER has expanded, a clear need has emerged for guidance on engaging public representatives in this area. There is a risk that the public's voice will be lost in the CER enterprise unless action is taken to champion and bring it to the forefront of the discussion.