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Governor

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

DRUG USE REVIEW (DUR) BOARD

Location of Meeting:
Washoe County Administration Complex
Commission Chambers (Building A)
1001 E. 9th Street
Reno, Nevada 89512

Meeting Minutes
December 15, 2005

Committee Members Present:

David England, Pharm.D., Chairman
Keith Maddonald, R.Ph.
Steven Parker, M.D.
Steven Rubin, M.D.
Amy Schwartz, Pharm.D., (called in)

Absent:

Marjorie Uhalde, M.D.

Others Present:

Coleen Lawrence DHCFP, Vickie Langdon DHCFP, Darrell Faircloth AGO, Jeff Monaghan FHSC, Dawn Daly FHSC, Shirley Hunting FHSC, Katie Roberts Glaxo Smith Kline, Doug Powell Forest Labs, Marty Roddy Forest Labs, Tom Holt Schering Plough, Joe Sirna Alpha, Kirk Huffaker Schering Plough, Edward Lewis Pfizer, Sandy Sierawski Pfizer, Alan Sloan Purdue, Susan Fisher Astra Zeneca, Eric Rouse Eli Lilly, Nancy Fairchild Sepracor.

I. Call to Order and Roll

David England, Chairman, called the meeting to order at 1:05 p.m.

II. *Discussion and Approval of September 22, 2005 Minutes

MOTION: Keith Macdonald motioned to accept the minutes as written.

SECOND: Amy Schwartz

VOTES: Unanimous

MOTION CARRIED

III. Review by First Health Services of Actions Taken by Board During the Past Year

Jeff Monaghan presented a summary of DUR Board actions taken from December 2004 to September 2005:

- Discussion of educational program regarding Atypical Anti-psychotic Agents. Concept tabled due to lack of funding source.
- Quantity billing limits established on several drugs in order to safeguard against over-billing errors. Review of claims subsequent to this initiative has shown a reduction in billing errors.
- Pro DUR reports presented at each meeting detailing the types of Pro DUR messaging that occurred during the previous quarter. Denials implemented for Pro DUR severity level one conflicts.
- Clinical PA edits instituted or revised for the following drugs: Cox II inhibitors, Fentanyl Transdermal Patches, Anti-fungal Onychomycosis Agents, Ramipril (Altace®), Ketoralac (Toradol®), Fentanyl Citrate (Actiq®), Crestor®, Inhaled Anti-Cholinergics
- Top 10 Therapeutic Drug Classes reviewed at each meeting. Trends and changes discussed. The top three drug classes based on payment amount continue to be anti-psychotics, analgesic narcotics, and anti-hemophilic blood factors.
- The Committee expressed the desire to focus on the analgesic narcotics in terms of retrospective utilization review (Retro DUR) and clinical edits.
- Educational program held in Las Vegas and Reno regarding Opioid Therapy. Focus was on appropriate therapy as well as transitioning patients between different long-acting opioids.

He presented narcotic utilization graphs (attached) noting that the total amount paid per month remains level with only a slight upward trend. There has been a slow but consistent increase in the average claims per utilizer per month; both the number of utilizers and the average amount paid per eligible recipient per month remain relatively flat. Actiq® activity has decreased due to the implementation of quantity limits and clinical PA edits.

Dave England asked if any letters or documentation have been received from practitioners stating that there have been issues or complications with patients not being able to get analgesics due to restrictions. Mr. Monaghan replied no.

Mr. England asked if there is data correlating diagnosis associated with utilization. Ms. Daly stated that for this category, only the diagnosis of cancer is required and Mr. Monaghan added that because an ICD-9 code is not required on all prescriptions, that type of data would not be available. Dr. Rubin suggested looking at what provider types are prescribing the meds and Mr. Monaghan stated that use of the dummy prescriber number would skew that data.

IV. Overview by First Health Services of Medicare Part D Implementation and Discussion of Medicaid Impact

Coleen Lawrence stated legislation was passed whereby Medicare-Medicaid eligible (dual-eligible) recipients will receive prescription drug coverage through a Medicare Part D Prescription Drug Plan (PDP). Prescription co-pays (\$1 for generics, \$3 for brands) will now be required for dual-eligible recipients effective January 1, 2006. Nevada's State Pharmacy Assistance Program, Senior Rx, will be covering the co-pay for these recipients. Dual-eligibles will be subject to their PDP coverage, however, Nevada Medicaid will continue to pay for OTC drugs,

vitamins, barbiturates, benzodiazepines and cough and cold medications which are currently covered by Medicaid but in most cases, will not be covered by their Medicare drug plan.

Mr. Monaghan stated also of pertinence is the impact on the overall dollars and claims volume from a Medicaid standpoint. By moving the dual-eligibles from Medicaid drug coverage to Medicare drug coverage, Medicaid expenditures for drugs, effective January 1, 2006, will decrease by an estimated 40%. Though the dual-eligibles are less than 20% of the total Medicaid recipients, they are high utilizers. Ms. Lawrence added that pharmacy expenditures will drop over the next year, however, the overall impact in Medicaid medical costs is not known. Over the next year, medical services will be trended to determine the impact.

Keith Macdonald asked how many dual-eligible recipients are in Nevada and Mr. Monaghan stated currently, there are approximately 16,000. Mr. Monaghan said due to public awareness of the new Medicare drug coverage program, there may be people who apply for Medicaid now that did not in the past possibly increasing future Medicaid rolls.

Mr. Monaghan stated that CMS has on-line resources available to access enrollment information should a dual-eligible recipient not be aware of which plan they are assigned to or in situations where auto enrollment has not occurred. He added that the best resource for providers and patients to access information is www.medicare.gov.

- V. Discussion and Action by Board on the Following Drugs and/or Drug Classes:
 - A. Update by DHCFP on Status of Medicaid Payment for Erectile Dysfunction Drugs

Mr. Monaghan stated that DHCFP has issued a procedure memo directing First Health to deny claims for the class of medications used for erectile dysfunction, effective January 1, 2006. The Federal Government has passed legislation which will no longer provide Federal Financial Participation to Medicaid programs for drugs used to treat erectile function. Nevada Medicaid will continue coverage of these medications when used for the diagnoses of primary pulmonary hypertension (PPH) [ICD-9 code 416.0] or pulmonary arterial hypertension (PAH) [ICD-9 code 416.8].

Keith Macdonald asked if there will be a stop on the claim for these products by NDC. Ms. Lawrence replied that the ICD-9 code for pulmonary hypertension will be required on the prescription for the claim to process. Mr. Monaghan stated that prescribers are being notified of the ICD-9 requirement.

- *B. Sildenafil (Revatio® and Viagra®)-Action by Board to require Inclusion of Diagnosis Code for Pulmonary Arterial Hypertension on Drug Claims

Mr. Monaghan stated that DHCFP and First Health are recommending payment for sildenafil if there is a diagnosis of pulmonary arterial

hypertension or primary pulmonary hypertension. Sildenafil is the only drug approved for these medical diagnoses.

Dr. Parker felt patients who currently take sildenafil for PAH should be notified now to ensure continuity of care. Ms. Lawrence said a report can be run listing those recipients and Ms. Daly added that there are approximately five recipients currently taking this medication for PAH. A report will be generated and the prescribers and/or pharmacies for these recipients will be notified regarding the ICD-9 requirement for PAH.

MOTION: Keith Macdonald motioned to require the inclusion of the diagnosis code for primary pulmonary hypertension (ICD-9 416.0 or pulmonary arterial hypertension ICD-9 416.8) for sildenafil claims.

SECOND: Steven Parker

VOTES: Unanimous

MOTION CARRIED

Public Comment

Sandy Sierawski, Pfizer, stated that her company would like to see their products used appropriately. Her research of a similar product indicated that approximately 27 prescriptions were filled for pulmonary hypertension for that product. She recommended that for patients with this disease state, consideration be given to notifying physicians of the approved agents and diagnosis requirement.

VI. Presentation by First Health Services and Discussion by Board of Prospective Drug Utilization Review (Pro DUR) Reports

Jeff Monaghan presented the ProDUR reports (attached). He stated that the anti-hemophyllic factors continue to increase. In reviewing the top fifty drugs ranked by payment amount, he noted that four out of the top six are anti-psychotic tranquilizer agents. Comparing the top ten therapeutic classes ranked by payment amount, the percentage change in payment amount compared to a year ago in the analgesic narcotic class has decreased significantly (3.51%). The increase of 36.37% in the antipsychotic category (H7X) is largely due to one drug, Abilify®.

Mr. Macdonald asked if the CPI is factored in the percent change in total payment amount and Mr. Monaghan said there is no adjustment for inflation. He stated that one of the moderating effects is the Preferred Drug List (PDL). In looking at the categories that were impacted by the PDL, the percent change in payment amount reflects what occurred; e.g., SSRI's -14.14% (H2S class) and the gastric acid secretion reducers -14.07% (D4K).

Dr. Rubin felt the Board should monitor the utilization of new drugs and the potential unnecessary shift in costs.

VII. * Presentation by First Health Services and Action by Board

A. Implementation of Prospective Drug Utilization Review Denial on claims indicating "Acetaminophen Greater Than 4 Grams per Day". This action

would ensure that the pharmacist had reviewed and acted on this message prior to filling the prescription.

Jeff Monaghan stated that currently, conflict messages related to severity level one denials require the pharmacist to enter the appropriate intervention and outcome code to override the denial. In general, if there is a dose that exceeds the parameters that have been established by First Data Bank (non-severity level one), the pharmacist will be prompted with a message but will not be required to enter an intervention and outcome code. He referred to the study he sent to the members regarding the incidence of liver failure due to acetaminophen toxicity and recommended that when the system prompts the pharmacist that the acetaminophen dose has exceeded 4gms per day, the pharmacist will be required to enter a response code. Hopefully, this will ensure that the pharmacist is aware of the high dose and interacts by consulting with the patient.

Mr. England asked what severity level code is prompted now for that and Mr. Monaghan replied that there is none, as dose level is not rated by the system. This would be activated as a denial and require a response.

Dr. Parker asked if there are multiple prescriptions filled for pain meds and another prescription is filled which exceeds the limit; i.e., more pills than there are days in the month, would the system pick that up. Mr. Monaghan replied yes adding that if the recipient is getting Vicodin® and Percocet®, the system will add the acetaminophen dose in both. A warning message will be prompted that acetaminophen 4gms/day has been exceeded and the pharmacist will need to look at the patient profile to see what is triggering the warning. The system will look at all medications that have been entered into the system.

Keith Macdonald asked if 4gms is conservative and Mr. Monaghan replied that is the label threshold; the accepted threshold. In looking at the Medicaid population and the study, a patient prone to being on narcotic analgesics, antidepressants and possibly uses alcohol, raising the threshold could be of concern.

Dr. Parker stated that it's not an absolute but at that point, the risk becomes greater and the patient and physician need to be aware and possibly consider other alternatives.

Mr. England said that this is defensible particularly with regard to the black box warning discussions from previous meetings. This is not a black box warning but should be taken into account. If the dosage is exceeded, there may be issues. He felt this is a reasonable request, which can make an impact on the patient and prescriber and should be promoted.

MOTION: Dr. Parker motioned to accept the ProDUR denial on claims indicating acetaminophen greater than 4 grams per day as presented.

SECOND: Steven Rubin

VOTES: Unanimous
MOTION CARRIED

Mr. England asked when this would take effect and Mr. Monaghan stated within 30-60 days.

VIII. Presentation by First Health Services of Retrospective Drug Utilization Review Results

Jeff Monaghan presented a summary of all RetroDUR results for the period 5/03 through 8/05. One main area the Board was interested in focusing on was narcotic analgesics. The report highlights RetroDUR done relative to that class of drugs. Mr. Monaghan pointed out that there has been a moderating effect in the overall utilization and expense of long-acting narcotic analgesics.

Mr. Monaghan gave a brief overview of RetroDUR. He stated that each month criteria are chosen and run against claims' history for a month. Exceptions fall out and those profiles are reviewed. Three hundred profiles are reviewed monthly and letters are generated to the physician for those profiles that have fallen into those exception criteria. Physicians are asked to fax back a preprinted response form (did you interact with the patient; was therapy changed, etc.). Mr. Monaghan proposed involving pharmacies in this review process by generating letters directly to the pharmacies. The first criteria chosen for pharmacy letters is acetaminophen dose >4gms per day. Approximately 250 Medicaid patients are receiving acetaminophen in doses exceeding 4gms per day. He presented an example of a letter which could be used to alert the pharmacy that the criteria threshold is being exceeded. He added that many states are lettering pharmacies.

Keith Macdonald stated that at the time of dispensing, the patient may not be in the pharmacy and the prescription is placed in "will call". The pharmacist has no interaction with the patient. The pharmacist receives the letter, has to go back to the patient records and call that patient. Is there a bullet point card or note that can be included to advise the patient to talk to the pharmacist?

Mr. Monaghan asked, as in Mr. Macdonald's pharmacy, if there is a comments section in the pharmacy system and if so, could a comment be included in the patient profile when the letter is received to alert the pharmacist to consult with the patient and Mr. Macdonald replied yes. Mr. Monaghan asked if a bullet point or educational sheet was included with the letter, how would that guarantee the patient would receive it the next time he went to the pharmacy.

Dave England suggested including web addresses for informational Internet sites in the letter and the recipient could access more information. If the recipient has no Internet access, the pharmacist could access the information via the Internet and print it out for the recipient at the time of dispensing.

Amy Schwartz reminded the committee that not all community pharmacies have access to the Internet.

Dr. Parker suggested attaching a note to the prescription which states that the pharmacist needs to talk to the patient before they get the drug.

Coleen Lawrence recommended working with the Retail Association of Nevada and pharmacists on how this process can be operationalized.

Mr. England accepted the recommendation.

Ms. Swartz asked if data is being collected on the dollars saved by implementing the prior authorization process, edits, etc.

Mr. Monaghan stated that an annual drug utilization review report is compiled for CMS and the State and can be provided to the Board upon request. RetroDUR reports are also generated that quantifies the savings that RetroDUR impacts.

IX. Old Business

A. Update from First Health Services Regarding Implementation of Denials for Pro DUR Severity Level One Messages

Jeff Monaghan informed the Board that denials for ProDUR severity level one messages has been fully implemented.

X. Discussion by Board Regarding Areas of Focus for Upcoming Year

Coleen Lawrence stated that per section 1927 of the Social Security Act, the DUR Board is charged with education of prescribers/providers and over/under-utilization of drugs. The focus this past year has been on drug edits. She stated that she would like the focus this year to be on education and asked the Board to submit recommendations prior to the next meeting.

Mr. England reminded Ms. Lawrence that the issue last year when trying to put together the program for antipsychotics was not the education or providers, but the funding requirements. Ms. Lawrence stated at that time, no one came forward to fund that initiative, but felt there could be other ways to provide education; e.g., profiling and working with recipients, use of the web page at the pharmacy level, targeting certain provider types, taking reports and focusing on certain classes and see the outcome for the next year. She stated that next year there will be more focus on the lock-in program and working with recipients on their use of drugs.

Mr. England stated that he would like to see some focus on pharmacoeconomics as well as food and drug interactions.

Mr. Macdonald offered two suggestions: 1) drug utilization review in consideration of age, and 2) some individuals will obtain the maximum amount of opioids through Medicaid and continue to get products with cash from another source as well. He recommended working with the Controlled Substance Abuse Prevention Task Force in identifying these individuals who may be far exceeding the acetaminophen daily dose as well as other opioids.

Mr. England stated that hospitals are more regulated than community practice particularly when it comes to JACHO and national patient safety goals. He felt patient health care should be looked at as a continuum and that some of the patient safety goals should be applied in all settings not just hospitals. He said the source of information for this can be found at the Institute of Safe Medical Practice website.

Ms. Schwartz asked if education development would be a joint effort between DUR and the P&T Committee. Mr. Monaghan replied that it certainly could be and that there is room for discussion about partnerships with other entities such as the school of pharmacy and the regulatory boards. Ms. Schwartz stated that she is responsible for the post-graduate education efforts at the college of pharmacy and offered to facilitate for the college.

Public Comment

Kirk Huffaker, Schering Plough, stated that since the last DUR meeting, the FDA has released some onerous information regarding long-acting beta-agonists. This may be an opportunity to look at that class for the provider network and going along with the national heart, lung and blood institute guidelines as far as the appropriate treatment protocols for mild, moderate and severe asthma.

XI. Review of meeting schedule for CY 2006

A tentative meeting schedule for 2006 was presented to the Board. The next meeting is scheduled for March 23, 2006, in Las Vegas.

XII. Public Comment

Ms. Lawrence, on behalf of DHCFP, thanked and welcomed a new DUR Board member, Dr. Steve Rubin. Dr. Rubin was uniquely chosen because of his specialty in psychiatry and also gerontology.

Dr. Rubin expressed his appreciation for his appointment to the Board. He stated that his goals will include both public and practitioner education.

XIII. *Adjournment

MOTION: Keith Macdonald motioned for adjournment.

SECOND: Steven Rubin

Meeting adjourned at 2:29 p.m.