MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE FEBRUARY 16, 2012 MEETING

DUR Board Members:	Present	Absent
Gera Bynum, R.Ph.		✓
Edgar Donahoe, M.D. **(Co-Chair)**	✓	
Laura Gray, M.D.		✓
Antoinette M. Hubble, M.D.	✓	
Cherise McIntosh, Pharm.D.	✓*	
Lee Merritt, R.Ph.	✓	
Paul Read, Pharm.D.		✓
Mark Reed, M.D. **(Chair)**	✓	
Dennis Smith, R.Ph.	✓	
Cynthia Undesser, M.D.	✓†	
Vicky Veazey, R.Ph.	✓	
Total	**8**	**3**

* Dr. McIntosh joined the meeting at 2:10p.m.
† Dr. Undesser joined the meeting at 2:20p.m.

Also Present:

Division of Medicaid (DOM) Staff:
Judith Clark, R.Ph., DOM Pharmacy Bureau Director; Shannon Hardwick, R.Ph., DOM Clinical Pharmacist, DUR Coordinator, Sheila Meadows, DOM Bureau Director for Care Coordination

MS-DUR Staff:
Kyle Null, Pharm.D., Clinical Director; Ben Banahan, Ph.D., Project Director

ACS Staff:
Leslie Leon, Pharm.D.

Visitors:
Joey Giamfortone, Reckitt Benckiser; Danny Duke, Merck; Callista Goheen, Medimmune; Bonnie Blankenship, UM pharmacy student; Joseph W. Blackston, UnitedHealthcare (MS-CAN), Jason Dees, Magnolia Health Plan (MS-CAN), Kim Elston, Novo Nordisk; Jeff Stockard, Walgreens, Darlene Bitel, Shire US, Inc.; Scott LaSorsa, Genentech

Ms. Clark provided opening comments to the DUR Board and to the visitors present. She noted that Dr. Dees has resigned from the DUR Board and is now employed at Magnolia Healthcare. Ms. Clark recognized that representatives from Magnolia Healthcare and United Healthcare were present as visitors to the meeting. She reminded those attending that visitors were not allowed to speak at DUR Board Meetings and she requested that all comments or questions be held until the end of the meeting, including questions to MS-CAN representatives, DOM staff, and to Sheila Meadows, the DOM Bureau Director for Care Coordination. Ms. Clark closed by mentioning that Dr. David Dzielak was recently named as new DOM Executive Director.

Call to Order: Dr. Mark Reed, Chairman of the DUR Board, called the meeting to order at 2:05p.m. Dr. Reed asked to table minutes and to move forward with the resource utilization report until a quorum was present.

Resource Utilization Review:
Dr. Null reviewed the resource utilization report. No unexpected trends were noted. Dr. Null commented on the expected increase in antibiotic and related seasonal cough and cold product use, as well as the increase in palivizumab (Synagis) use, which is also a seasonal norm. Ms. Clark reminded the Board that all the data presented are from Medicaid fee-for-service claims.

Pharmacy Program Update:
Ms. Hardwick reminded the Board that Goold Health Systems (GHS) is the new vendor for the preferred drug list (PDL) as of January 2012. Ms. Hardwick noted that new PDL information is available on the DOM website, with an updated format. Ms. Hardwick directed the Board to the Winter Edition of the Mississippi Medicaid Pharmacy Program Update Newsletter; page 4 of newsletter contains detailed information on the new criteria for use of non-statin lipotropic agents. Ms. Hardwick pointed out that an updated 90-day list, including some prenatal vitamins and oral contraceptives, will go into effect April 1, 2012. Ms. Hardwick reviewed some coverage changes in prenatal vitamins due to some manufacturers pulling out of the drug rebate program, including the manufacturers of Neevo and Neevo DHA, and the fact that drugs from manufacturers not participating in the drug rebate program could not be covered by DOM. Dr. Null noted that Neevo and Neevo DHA represent a significant proportion of utilization in the prenatal category.

Dr. McIntosh joined the meeting at 2:10p.m. Upon her arrival, Dr. Reed asked for a motion to accept the minutes from the meeting of November 17, 2011. Dr. Reed made a motion to accept the minutes with a second motion from Dr. Hubble. All voted in favor of the motion.

New Business:
High Doses of Citalopram Associated with Abnormal Heart Rhythms
Dr. Null reviewed an FDA safety issue of dose-dependent QT-interval prolongation with the use of citalopram. The FDA safety alert resulted in a labeling change removing the use of citalopram 60mg for the treatment of depression due to the increased risk of QT-interval prolongation without substantial evidence to support increased effectiveness at that dose. A review by MS-DUR of DOM data did not indicate any problem not being adequately addressed by the hard edit in the POS system today. No recommendation was requested from the DUR Board.

Utilization of Simvastatin 80mg Following an FDA Safety Announcement
Dr. Null reviewed the MS-DUR analysis of simvastatin 80mg utilization. The data indicate that most prescribers were adhering to the FDA recommendations of lowering the simvastatin dose to 40mg or less or changing therapy to an alternative statin. The FDA recommendations further state that individuals on stable therapy of simvastatin 80mg for 12 months or greater with no evidence of myopathy could remain on therapy. Dr. Null pointed out that some “new start” cases have occurred since the FDA safety announcement in June 2011 without any prior claims for statin use, which is in conflict with the FDA recommendations. MS-DUR proposed that the Board recommend a hard clinical edit be implemented, such that a new start claim for 80mg simvastatin be rejected at the point of sale. Approval of an 80mg claim would require 12 months of stable prior use with no evidence of myopathies during that period. Dr. Null noted that he did not find evidence of myopathies in the claims data as a part of the analysis. Ms. Clark confirmed that implementation of this clinical edit would result in a prior

authorization at the point of sale (i.e., a "hard edit), which would require further clinical justification from the prescriber. Mr. Smith asked for clarification on the 12 months of stable therapy, questioning whether the rule should be written as 12 consecutive months or if stable therapy would be defined as a certain number of fills (e.g., 9 fills) out of the prior 12 months. Ms. Clark mentioned that the details would be worked out in collaboration with the prospective DUR vendor, ACS. Dr. Hubble made motion to approve the recommendation for a new edit, which was seconded by Mr. Merritt. The motion was approved unanimously.

Desmopressin Nasal Spray Use in Nocturnal Enuresis
Dr. Null reviewed the analysis for the use of desmopressin nasal spray to treat nocturnal enuresis and noted that use appears to be appropriate based on MS-DUR analysis and does not make any recommendation for change at this time. Dr. Undesser joined the meeting at the conclusion of this review (2:20p.m.).

Suboxone/Subutex Utilization and PA Process
Dr. Banahan reviewed the background of Suboxone/Subutex and the new protocol developed by DOM. Dr. Banahan briefly noted that the new protocol was developed based on analysis conducted by MS-DUR, clinical consultations by DOM and MS-DUR, and a review of the literature and what other state Medicaid programs were doing. Dr. Banahan reviewed the specific points in the new protocol noting that Suboxone is covered for opioid-addiction treatment and not for pain; beneficiaries will be covered for a cumulative maximum of 24 months (720 days) of therapy after implementation of the new coverage guidelines and maximum dosing limits will be implemented. Dr. Banahan emphasized that the coverage would be calculated as a cumulative – not consecutive – 24 months. Cumulative days are counted as the total days supply for all prescriptions regardless of daily dose. This would mean that beneficiaries would receive a total of 24 months of therapy, not necessarily in one 24 month period. Dr. Banahan reviewed the new dosing guidelines, in which Suboxone and Subutex prescriptions will be reviewed at initial fill and at each refill and a SmartPA approval will be issued when appropriate based on the following criteria:

- Treatment must be for diagnosis of addiction not pain.
- Initial treatment start:
    - A maximum daily dose of 24 mg/day for the first month of therapy
    - A maximum of 16 mg/day for the next 4 months of therapy
    - A maximum of 8 mg/day maintenance dose for the remainder of time on therapy up to a cumulative 24 months of coverage.

Dr. Banahan noted that the MS-DUR analysis indicated that many prescribers have begun therapy at 16mg and made no attempt to taper the dose. Further, a refill gap of 60 days (90 calendar days from last fill of 30 day supply to current attempt to refill) will be considered to be a discontinuation of therapy that requires a restart in treatment. Dr. Banahan noted that the beneficiary can only have 1 restart of therapy, regardless of cumulative days covered, and reviewed the dosing for restart of treatment to be limited to:

- A maximum of 16 mg/day for 2 months of therapy
- A maximum of 8 mg/day maintenance dose for the remainder of time on therapy up to a cumulative 24 months of coverage.

Dr. Banahan noted that Subutex can only be given during pregnancy and that prescriptions for 2mg strength tablets have a quantity limit of 60, which limits use to the titration phase when tapering

patients off of therapy or for maintenance at very low doses. He also mentioned that beneficiaries cannot have prescription for more than 5 day supply of opiate while on Suboxone therapy. Opiate prescription presented for more than 5 day supply will be rejected with message to pharmacy that patient is on Suboxone therapy and cannot have opiate prescription for more than 5 day supply and remain on Suboxone/Subutex therapy. Suboxone/Subutex refills will be rejected if an opiate prescription for more than 5 day supply has been filled within last 30 days. A maximum of two 5-day opiate prescription fills can be covered while on Suboxone therapy.

Dr. Banahan then reviewed the MS-DUR recommendations for provider and patient education and MS-DUR monitoring. Dr. Banahan noted that because there are relatively few "active" Suboxone prescribers serving Mississippi Medicaid beneficiaries, a targeted educational program would be an effective means of alerting providers to the updated protocol. He also discussed educational outreach targeted towards patients receiving Suboxone to let them know about coverage issues, the titration schedule and potential issues with taking opioids during Suboxone therapy.

Dr. Donahoe asked for confirmation on number of prescribers currently writing Suboxone. Dr. Banahan responded that any given year will have 60 to 100 Suboxone prescribers for Medicaid beneficiaries. Ms. Clark noted that many beneficiaries taking Suboxone do not consistently stay on therapy. Dr. Reed commented that the protocol seemed very well thought out, but questioned whether 5 day limit on opioid is sufficient to deal with major surgery, etc. and whether a longer period (such as 10 days) might be more appropriate. Ms. Clark replied that each outlier case would be reviewed individually so that no one is overlooked. Mr. Smith noted that a 5 day supply would translate to 10 tablets (based on a quantity limit of 62 tablets in 31 days), which is not a realistic 5 day supply, given every 4 to 6 hour dosing on many pain medicines. Ms. Clark reminded that a maximum quantity override could be submitted to help providers manage this quantity limitation.

Dr. McIntosh commented that in the internal medicine clinic where she works would one of the physicians would have prescribed a narcotic to a Suboxone patient if she had not been present to catch it. As a result, she recommended that prescriber education be expanded to include a separate general education piece for all prescribers to understand that narcotics cannot be prescribed for patients on Suboxone. Ms. Clark noted that a good addition to the education piece would be to encourage prescribers to register to gain access to the Prescription Drug Monitoring Program (PDMP).

Dr. Donahoe expressed that he felt that the 24 months of cumulative therapy was overly generous, noting that he thought it should be limited to 12 months or even less. Dr. Reed concurred and noted that the data provided by MS-DUR would support a limit of 12 months of therapy. Ms. Clark noted that it might be preferable to be conservative at first and then progressively lower the therapy length, if supported by the data and emerging knowledge about Suboxone treatment.

Mr. Smith asked about past Suboxone recommendations that were not implemented by DOM. Ms. Clark responded that many factors were involved, but managing a drug like Suboxone is difficult because of all of the components involved that affect other bureaus within Medicaid (e.g., medical services, billing for labs, etc.).

Dr. Donahoe made a motion to accept the recommendations. The motion was seconded by Dr. McIntosh. The motion passed unanimously. Dr. Donahoe asked that utilization data be reviewed with Board at the August and November DUR Board meetings. Ms. Clark mentioned that this is extremely complicated and involved electronic prior authorization and that Medicaid has been working on this for

several months. Ms. Clark said that the goal implementation date for this effort is May 1, 2012, but it may need to be pushed back to June 1, 2012 in order to get everything in place, including provider education. Ms. Clark noted that Medicaid gives providers at least a 30 day notice prior to changes and that she would like to give them more notice if possible.

Exceptions Monitoring Criteria Recommendations
Dr. Null reviewed the exceptions criteria recommendations and noted several typos that needed to be corrected, including adding "drug-disease contraindication" to the exception type on exception items 3 and 4. Additionally, the field type 1 for item 4 should read "azilsartan" rather than "captopril." Finally, the exception type on item 6 should be "drug-drug interaction." Dr. Null pointed out that criteria 1-12 are new criteria for exception monitoring and the last criterion (on page 78) is a revision to a previous criteria based on labeling changes made by the FDA. Dr. Reed moved that all criteria be accepted as a block vote. The motion was seconded by Mr. Merritt and passed unanimously.

Other Business
Ms. Clark asked for feedback on the new PDL format. Dr. McIntosh indicated the new format was very helpful because it showed the criteria required for prior authorization, which she mentioned was helpful in considering whether to submit a prior authorization.

Next Meeting Information:
Dr. Reed announced next meeting date is May 17, 2012 at 2:00p.m. and thanked everyone for making the effort to attend the DUR Board meeting in order to have a quorum. The meeting adjourned at 2:58p.m.

Submitted,
Evidence-Based DUR Initiative, MS-DUR