

**North Carolina Department of Health and Human Services
Division of Medical Assistance**

CONTROLLED SUBSTANCES TASK FORCE

Approved Minutes

August 10, 2009

The North Carolina Medicaid Narcotic Task Force met on Monday, August 10, 2009, at 3:00 p.m. in room 297 of the Kirby Building.

Participants present: Craigan Gray, M.D., Tara Larson, Patti Forest, M.D., Howard Peckman, Pharm.D., Glenda Adams, Pharm.D., Leah Terrell, Pharm.D., Kay Sanford, M.S.P.H., Fred Wells Brason II, Scott Proescholdbell, M.P.H.; Fred Eckel, M.S., Angie Yow, R.N., Brad Griffith, M.B.A., Bill Bronson

Participants via telephone: Hans Hansen, M.D., Bert Bennett, Ph.D., Karen Matthew

The meeting was called to order by Glenda Adams. Participants introduced themselves.

The minutes from the May 11, 2009 meeting were reviewed. The acronym for the Government Accountability Office will be corrected to GAO. A motion was made and seconded to approve the minutes with the correction noted. Participants unanimously approved the minutes.

A thank you was extended to Bill Bronson and Kay Sanford for writing articles about the Controlled Substance Reporting System that were published in the July 2009 Medicaid General Bulletin and June 2009 Medicaid Pharmacy Newsletter. A copy of the article that was published in the Medicaid Pharmacy Newsletter is included as Attachment 1.

Fred Brason had the opportunity to attend the FDA Risk Evaluation and Mitigation Strategies (REMS) for Certain Opioids meeting on May 27 and 28, 2009. Mr. Brason shared that the meeting was focused on ways to limit the risk involved with high risk opioids. The FDA has authority to require REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) when necessary to ensure that the benefits of a drug outweigh the risks. REMS implementation is targeted for 2011. Mr. Brason shared information at the FDA meeting about Project Lazarus and the Chronic Pain Initiative in Wilkes County, which was the only initiative presented looking at educating those involved. He stated that the unintentional poisoning deaths so far in 2009 in Wilkes County are 37, which is tied with the total number of deaths in 2008. Handouts were provided (see Attachment 2) that summarized the FDA meeting as well as a website for additional information. The website is:

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>.

Bill Bronson provided an update about the recent legislation regarding the Controlled Substance Reporting System (CSRS). The medical examiners' bill (Senate Bill 628) was passed by the legislature and was signed by the Governor on August 7, 2009. This bill will allow medical examiners to have access to the CSRS for the purpose of investigating deaths. Additional areas covered in SB628 include allowing prescribers to communicate with others who have access to the CSRS as well as increasing the frequency of dispenser reporting to the CSRS from bi-weekly to weekly starting January 2010. Mr. Bronson stated that the bill allowing sheriff's access to the CSRS was not passed. It was sent for further study, and this time, members of the CSRS staff will be allowed to contribute to the discussions.

Mr. Bronson stated that there are inaccuracies in the CSRS database, one of which is a result of pharmacists using the incorrect prescribers' DEA numbers. This could result in a false impression that a patient is seeing multiple prescribers. He said it is important to remind providers that the database is not 100% accurate and to give the patient the benefit of doubt initially.

Karen Matthew asked if there has been any change to the bill to add pharmacies not originally included to report to the CSRS such as dispensing from the physician's office. Mr. Bronson responded that at this time, dispensing from physician's office is not reported. Out of state mail order pharmacies are required to report to the CSRS. Ms. Matthew also asked if there was any advancement about the CSRS advisory committee running reports looking at unusual prescribing practices. Mr. Bronson responded that the CSRS is not looking at prescribers. He added that the CSRS was awarded a two year enhancement grant.

Kay Sanford requested that a "wish list" of considerations she provided prior to the Task Force's first meeting be distributed to the task force. See Attachment 3. One of the items for consideration is to have Medicaid mandate that providers who prescribe a controlled substance be required to check the CSRS to see if the patient has prescriptions for other controlled substances.

Tara Larson asked about a link on point of sale to the CSRS database.

Mr. Bronson mentioned that the 2007ASAP format for the CSRS includes a method of payment, which would capture cash payments. Currently the CSRS uses an earlier version of ASAP that does not capture the method of payment. He indicated that it would be costly to update the program.

Action item: Bill Bronson to provide an article for the Medicaid Bulletin about the changes passed by legislation regarding the CSRS.

Angie Yow, Quality, Evaluation, and Health Outcomes (QEHO), reported on a study that looked at recipients who went to the Emergency Department (ED) with a complaint of dental pain and had five or more prescriptions for narcotics, based on paid claims. Recipients were not included if they had a diagnosis of cancer or a chronic condition that would justify the need for ongoing pain control. 197 recipients were identified in the calendar year 2006 and the first quarter of 2007. Medical records were reviewed looking for predetermined criteria that defined narcotic seeking behavior. Below are the findings from the initial review.

DMA Defined Definition of Narcotic Seeking Behavior	Recipient Count
Vague presenting symptoms	151
Vague discharge diagnoses (mouth/gum pain)	123
Specific request for narcotics	34
Previous episodes of drug seeking behavior	36
Refusal of non-narcotic medications	19
Demanding/aggressive behavior	22
Positive toxicology screen (illegal subst., alcohol, narcotic)	46
History of alcohol/substance abuse	84
>3 ER visits	145
Received prescription for narcotics	170

Ten recipients met a second set of criteria that included all of the following:

1. refusal of non-narcotic medications
2. more than three ED visits
3. one of the following criteria:
 - a. specific request for a narcotic
 - b. previous episode of drug seeking behavior
 - c. refusal of non-narcotic medications, high dose of narcotic required.

For nine of the recipients, numbers were provided for the total prescriptions paid by Medicaid (including the number of narcotics and antianxiety prescriptions), those who went to multiple pharmacies, the number of ED visits and those patients who visited multiple Emergency Departments.

Brad Griffith, QEHO, reported on a study looking at imaging procedures and paid claims for narcotics (includes tramadol). The primary focus was on one recipient who had 135 episodes of imaging procedures within a two-year period and prescriptions totaling 1,814 days supply of narcotics—or about 2.5 days supply for each day of the two-year period. Imaging costs alone incurred for this one recipient were over \$102,000.

Glenda Adams looked at prescribers who wrote prescriptions for narcotics from the GC3 class of H3A in June 2009. There were 9869 prescribers who wrote prescriptions for narcotics that were paid by Medicaid. This group was narrowed down to those who wrote more than 100 prescriptions and the prescribers were matched with the list of providers registered with the CSRS. There were 151 prescribers who wrote over 100 prescriptions in June 2009. Of these, 16 were registered with the CSRS; 24 of the 151 were using institutional DEAs. There are many prescribers who are not using the CSRS as a tool.

Dr. Adams also presented a report looking at Medicaid recipients who had more than 12 Emergency Department (ED) visits in one year (June 1, 2008 through May 31, 2009). Narcotic claims were then pulled for the selected group with the intent to see if there was a correlation between the number of ED visits and the number of paid claims for narcotics.

Dr. Adams provided a brief overview of a paper she is working on with Tim Whitmire from the State Center for Health Statistics looking at unintentional poisoning deaths in Medicaid recipients during the 2007 calendar year.

Dr. Forest suggested looking further into muscle relaxant use. She also suggested that the Task Force define issues to look at with substance abuse and treatment options for substance abusers. Is there a way to have Medicaid's computer system linked to other computer systems, such as the CSRS?

It was suggested to develop guidelines on what types of behavior we want to report on and then devise a treatment protocol.

Ms. Sanford stated that in North Carolina, 80-90% of drugs that result in fatalities are from controlled substances. One-third of the deaths are from heroin and cocaine (5% of these are heroin), one-third are from methadone and one-third from other opioids, controlled substances and other substances grouped together. This pattern has been consistent since 2003. Ms. Sanford also reported that the average age of death for all three drug categories is 39 years, but the age of death varies by drug category (methadone average death age is 29; cocaine average death age is 39 and other opioids average death age is 49).

Teenage deaths have also increased, but reflect a small proportion of those who unintentionally die from drug overdoses.

Tara Larson suggested establishing treatment protocols. Bert Bennett suggested thinking in terms of getting people into treatment. He emphasized that not all treatments are equal.

Dr. Forest suggested the following action items:

1. Have an alert or override at point of sale when an excessive number of narcotic prescriptions are filled?
2. Can DMA's database interact with the CSRS database?
3. Identify recipients who are abusing opioids and refer them to a substance abuse treatment program as well as provide a medical home and a pharmacy home.
4. Establish treatment protocols for providers about when and how to refer recipients to substance abuse treatment programs.
5. Look at utilization of muscle relaxants.

Colocation and reverse colocation models were discussed. This is where the primary care provider also has a mental health provider on staff and a visa versa.

The next meeting is scheduled for Monday, October 5, 2009, 3:00 p.m. – 5:00 p.m. in room 297 of the Kirby Building. The next step is to identify subgroups to look at specific issues and have deliverables.

The meeting was adjourned at 5:00 p.m.

Prepared by Glenda Adams, Pharm D.

Attachment 1

The Controlled Substances Reporting System -- The State's Newest Tool to Make Prescribing Opioids and Other Controlled Substances Safer and Easier

In July 2007, the N.C. Department of Health and Human Services began operating the State's first prescription monitoring program, called the Controlled Substances Reporting System (CSRS). The CSRS is a centralized outpatient database to "improve the State's ability to identify controlled substance abusers or misusers and refer them for treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of controlled substances." By N.C. law (Article 5E. North Carolina Controlled Substances Reporting System Act § 90-113.70-76), all outpatient dispensers of controlled substances in North Carolina are *required* to report data to the CSRS. These data are a subset of the standard data routinely collected by most third-party vendors who provide payment reimbursement services to pharmacies and the specific information that must be reported on each prescription is established by law.

Medicaid and other medical providers who are practitioners with a current DEA registration and licensed pharmacists may easily apply for access to the CSRS by completing a short enrollment application available on the CSRS website: <http://www.dhhs.state.nc.us/MHDDSAS/controlledsubstance/index.htm>. The CSRS link is also available on the DMA Outpatient Pharmacy website under "Related Sites" (<http://www.ncdhhs.gov/dma/pharmacy/index.htm>). Because the CSRS prescription profile documents what and how many prescriptions for controlled substances have been dispensed to a patient, providers and pharmacists now have an additional tool by which to decide whether or not to write or refill a prescription. Running a CSRS profile should be seen as a universal precaution when prescribing any controlled substance. Because of the strict confidentiality provisions in the CSRS Act, it is important to note that only the registered practitioner may access the system. Unless the current Act is changed (revised legislation is pending in the 2009 legislature), it will continue to be unlawful to discuss CSRS findings with anyone (including other practitioners), except the patient.

Additional information on the CSRS is available by calling John Womble or William Bronson at the Division of Mental Health, Developmental Disabilities and Substance Abuse Services (MHDDSAS), Drug Control Unit, (telephone 919-733-1765, Monday through Friday between 9 a.m. and 5 p.m.).

Attachment 2

**Division of Medical Assistance
Task Force, Opioid Misuse, Abuse and Diversion
August, 10, 2009**

**CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Meeting – May 27, and May 28, 2009
Risk Evaluation and Mitigation Strategies for Certain Opioids
Hilton Washington D.C./Gaithersburg Hotel, 920 Perry Parkway, Gaithersburg, MD 20877**

May 2009 Public Hearings and Status Report: Fred Wells Brason II

FDA REMS and Opioid Analgesics

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>

- I. Eighty (80) participants; patient advocates, pain patient advocates, bereaved families, industry wide stake holders, Pharmacy's, Physicians, Pain Foundations, Research analysts, reform advocates, community intervention and prevention, etc.
- II. 4000 docket submissions currently under FDA review
 - a. Central questions are:
 - i. Since the program is required to test and evaluate each component before it is finalized, the question of how to do a pilot is huge. The methadone makers have suggested that methadone for pain be the first drug in the REMS and that it be evaluated as such. It is interesting to note that the methadone makers are all generic, so there is no promotion of the drug to doctors or consumers. However, the FDA has been close-lipped on this proposal.
 - ii. Which components to emphasize?
 1. The most likely components in the REMS will be patient education, prescriber education and pharmacist education. There is discussion of a physician certification process like there is for buprenorphine, but would also include pharmacies (and maybe pharmacists?). There is talk of an expanded patient information guide on extended-release/long-acting opioids in general, supplemented by a drug-specific information packet.
 - a. Opinion: problematic; most patients do not read information provided currently, when read, behaviors rarely change, storage in pharmacy for such packets.
 2. There has also been some talk of a public hearing for restricting extended-release/long-acting opioids to ONLY cancer patients, with a "compassionate use" policy that would require physicians to obtain prior approval to use these drugs in non-malignant pain. However, this is likely to be beyond the legal powers of FDA and this plan is not likely to happen.
 3. REMS require IMPROVEMENTS in patient care. However, all proposals have attempted to adjust the "risk-benefit" balance by reducing the "risk" side. Most of the "risk" that FDA cites is in non-patients. Yet, there is nothing being done to improve the "benefit" side of the equation, specifically for those in pain. This is a fundamental flaw of the proposed REMS in its current form and may likely not be rectified.
 4. Opioid patient "registry": not likely at this point.

Attachment 3

TO: Glenda Adams
FROM: Kay Sanford
DATE: May 8, 2009
RE: Areas for discussion by the Task Force to Prevent Drug Abuse, Misuse and Diversion

I believe there are some areas that your Task Force might like to consider discussing as strategies to reducing the misuse, abuse and diversion of controlled substances, especially opioids, in the Medicaid population.

First, train physicians how to more safely prescribe controlled substances. I believe that this can be done best by having the DUR recommend/require that all physicians who seek Medicaid reimbursement for pain management be registered with the NC Controlled Substances Reporting System (CSRS) and be required to run a CSRS patient prescription profile prior to writing a prescription for a controlled substance and at least every six months thereafter if the prescription(s) is renewed or a prescription for a new/different controlled substance is being considered.

To further physician education on the use of opioids and other controlled substances, I'd also suggest that this task force and/or the DUR recommend to the Division of Medical Assistance that all physicians under the aegis of the DMA be mailed a copy of the universal precautions for pain medicine (see below), a ten step approach to the assessment and management of all chronic pain patients (Gourlay DL and Heit HA. Universal Precautions in Pain Medicine: the Treatment of Chronic Pain With or Without the Disease of Addiction. Medscape Neurology & Neurosurgery. 2005: 7(1).)

I'd further recommend that all Medicaid medical care providers strongly consider the co-prescribing of naloxone to patients being prescribed an opioid who are thought to be at increased risk of opioid-induced respiratory depression. The American Journal of Public Health has just published an article promoting the co-prescribing of Naloxone to patients who receive prescriptions for high dose opioids as an antidote to opioid-induced respiratory depression. (Kim D, Irwin KS and Khoshnood K. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. Am J Public Health. 2009;99:402-407.) This article concludes that "data from recent pilot programs demonstrate that lay persons are consistently successful in safely administering naloxone and reversing opioid overdose." (op cit, p. 402.) Naloxone is an antidote for opioid-induced respiratory depression and its prescribing to the lay population is similar in concept to the prescribing of Epi-Pens to patients with severe allergies. Wilkes County, in conjunction with the Chronic Pain Initiative run by the Northwest Community Care Network, is pilot testing the prescribing of naloxone to high risk Wilkes county residents who are treated in the Wilkes Regional Hospital emergency department for accidental drug overdoses and/or substance abuse of opioids or Wilkes County residents who are treated for severe chronic pain by Wilkes County physicians in their out-patient clinics (Project Lazarus). The program also includes an educational component that teaches patients how to be responsible users of their prescribed opioids and teaches their family and peers how to recognize the signs and symptoms of an opioid overdose, and how to call 911, perform rescue breathing and how to administer naloxone through a syringe with a nasal adaptor.

The following 10 steps are an adaptation of the universal precautions approach to the management of all chronic pain patients¹. By using these 10 steps, stigma is reduced; patient care is improved; and overall risk is contained.

1. **Make a diagnosis with appropriate differential.** Identify treatable causes for pain, when they exist, and any associated co-morbid conditions, such as substance use disorders and psychiatric illnesses. Direct therapy to the cause of the pain; address co-morbid conditions.
2. **Psychological assessment, including risk of addictive disorders.** Complete a sensitive and respectful assessment of personal and family history of substance misuse. Include urine drug testing and profiles from the NC Controlled Substances Reporting System². Offer patients with suspicious results further assessment for possible substance use disorders. Consider patients who refuse such assessment unsuitable for pain management with a controlled substance.
3. **Informed consent.** Discuss the proposed treatment plan with the patient, including anticipated benefits and foreseeable risks, before obtaining written informed consent from each patient.
4. **Treatment agreement.** Clearly set forth (preferably in writing) expectations and obligations of the medical care provider and the patient that set boundaries for possible early identification and intervention around aberrant behaviors. Combine treatment agreement with informed consent and have medical care provider and patient sign and date the document.
5. **Pre- and post-intervention assessment of pain level and function.** Obtain and maintain an objective written assessment of the patient's pain level with pain scores and level of function prior to and during treatment. Base treatment goals on agreed upon improvements.
6. **Appropriate trial of opioid therapy with or without adjunctive medication.** Individualize treatment regimens, including opioids and adjunctive medications, on the basis of subjective and objective clinical findings.
7. **Reassessment of pain score and level of function.** Continue or modify therapeutic trial based on regular patient assessment, including corroborative support from family or other knowledgeable third parties.
8. **Assess the "4 A's" of pain.** Direct therapy and support your pharmacologic options based on assessment of the patient's analgesia, activity, adverse effects and aberrant behavior.
9. **Periodically review pain diagnosis and comorbid conditions, including addictive disorders.** Treatment focus may need to change over time reflecting the evolution of each patient's underlying illnesses and diagnostic tests. If an addictive disorder predominates, aggressive treatment of an underlying pain problem will likely fail if not coordinated with treatment for the concurrent addictive disorder.
10. **Documentation.** Careful and complete recording of the initial evaluation and each follow-up is both medicolegally indicated and in the best interest of all parties. Thorough documentation combined with an appropriate doctor-patient relationship will reduce medicolegal exposure and risk of regulatory sanction.

¹ Gourlay Douglas L; Heit Howard A. Universal precautions in pain medicine: the treatment of chronic pain with or without the disease of addiction. Medscape Neurology & Neurosurgery. 2005

² Use the prescription monitoring program in the medical care provider's state, when available.