CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN AND DUR ACTIONS: BACKGOUND FOR INITIAL DISCUSSION

BACKGROUND

As described in the background section of the previous report on the High Morphine Equivalent Dosing (Med) and Doctor Shopping Educational Initiatives, the Office of Inspector General of the Department of Health and Human Services (OIG) has strongly recommended that steps must be taken to address opioid misuse and diversion. The OIG 2016 Work Plan will focus on state actions taken through drug utilization review (DUR) programs to address opioid misuse and abuse in state Medicaid.[1] Efforts are directed to protect "an expanding Medicaid program from fraud, waste, and abuse."

> ➢ **REVISED** States' actions based on Medicaid drug utilization reviews
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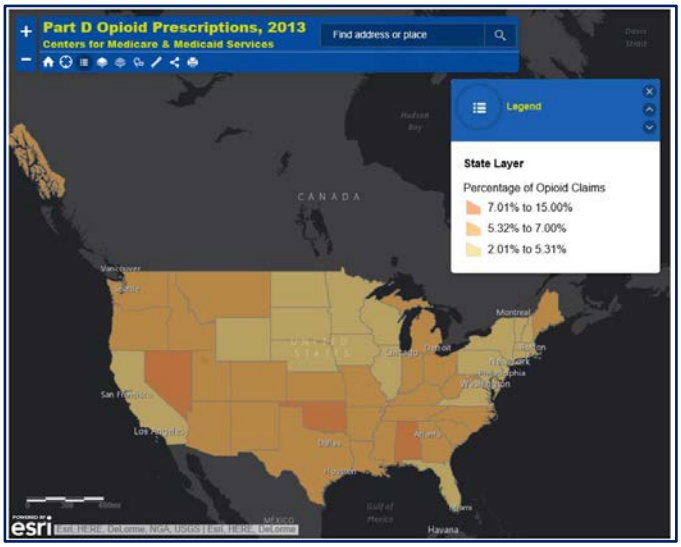
> We will review the education and enforcement actions that States have taken on the basis of information generated by their drug utilization review (DUR) programs related to inappropriate dispensing and potential abuse of prescription drugs, including opiates. We also will review State oversight of and coordination with MCOs' DUR programs and any resulting actions related to inappropriate dispensing of opiates.

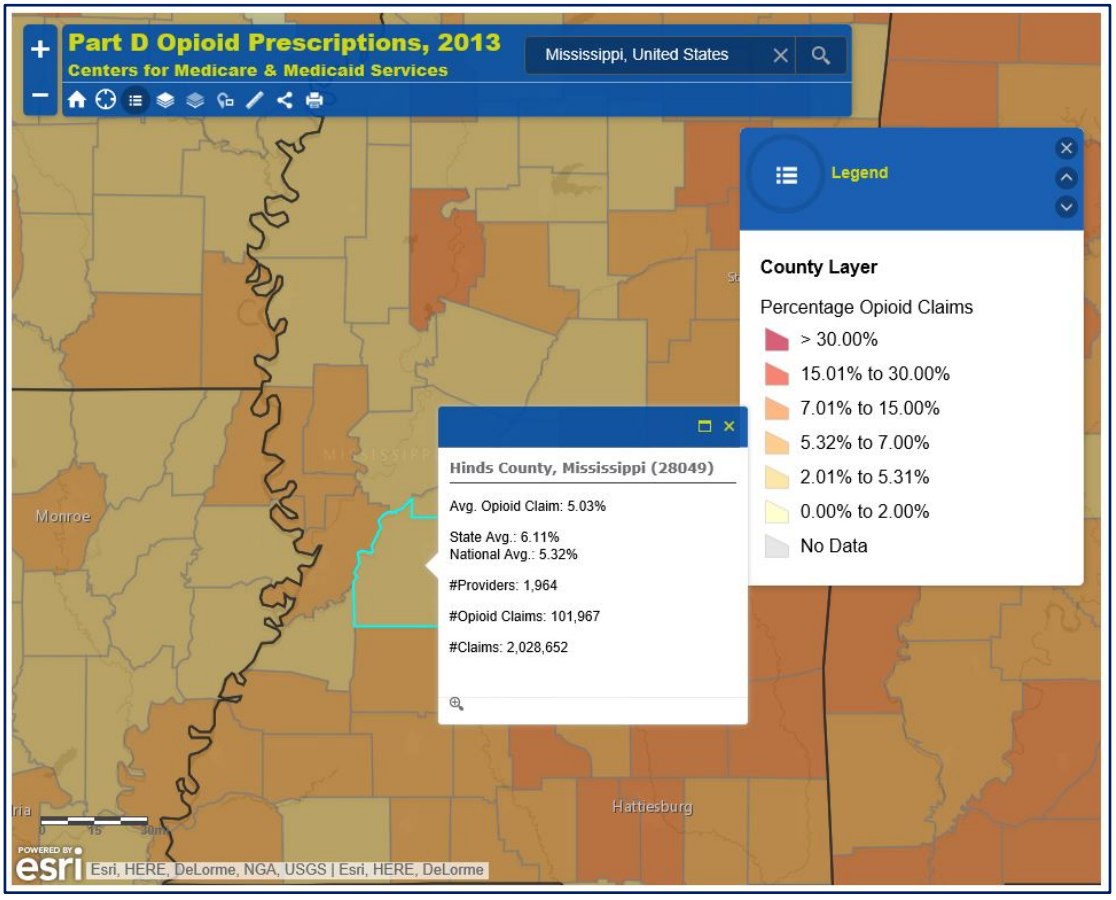
Various efforts have been underway in Mississippi to address the opioid abuse problem. The Mississippi Prescription Drug Monitoring Program (MPMP) was established to help providers, professional boards and drug enforcement agencies track prescriptions for opioids and other controlled substances. The Board of Medical Licensure required all physicians to be enrolled in the MPMP by December 2013. The Board of Pharmacy required all pharmacists to be enrolled by December 2015. Providers can use the MPMP to identify potentially inappropriate use by patients when they are considering writing a prescription or when they are requested to fill a prescription for an opiate. Mississippi Medicaid uses the MPMP to evaluate potential drug abuse cases, to make decisions about prior authorization (PA) approvals and to make decisions about assigning beneficiaries to the lock-in program. The lock-in program limits which and how many providers and pharmacies a beneficiary can use.

Recently, the Centers for Medicare and Medicaid Services (CMS) announced a new tool that allows providers and others to track the number of opioid prescription claims in their communities, counties and states. The tool – The Opioid Heat Map – shows local level data of de-identified Medicare Part D opioid prescription claims, comparing the local area to data across the country

[1] OIG Work Plan 2016, p 31. http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf

(https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html). The data currently used in this mapping tool is from 2013 Medicare Part D prescription drug claims. The tool was developed in response to the increasing amount of deaths each year related to drug overdose for both opioid-based pain relievers and from illicit drugs like heroin. CMS noted that in 2013, overdose from prescription opioid pain relievers claimed more than 16,000 lives, with more than 145,000 people dying from these overdoses in the last decade. Two images from the mapping tool show the ratings by state and the statistics for Hinds County with the state and national averages.





The Centers for Disease Control and Prevention (CDC) released draft Guidelines for Prescribing Opioids for Chronic Pain for public comment, which is due by January 13. The draft guideline summarizes scientific knowledge about the effectiveness and risks of long-term opioid therapy and provides recommendations for when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. The draft Guideline identifies important gaps in the literature where further research is needed.

It is intended to be used by primary care providers who are treating patients with chronic pain (i.e., pain lasting longer than 3 months or past the time of normal tissue healing) in outpatient settings. The draft Guideline is intended to apply to patients aged 18 years of age or older with chronic pain outside of palliative and end-of-life care. The Guideline is not intended to apply to patients in treatment for active cancer. The Guideline is not a federal regulation; adherence to the Guideline will be voluntary. The complete guideline and background materials are available and comments can be provided at:

http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-0001

The following is an excerpt from the CDC document.

> Opioids are commonly prescribed for pain. An estimated 20% of patients presenting to physician offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription.[2] In 2012, health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills.[3] Opioid prescriptions per capita increased 7.3% from 2007 to 2012, with opioid prescribing rates increasing more for family practice, general practice, and internal medicine compared with other specialties.[4] Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among providers on how to use opioid pain medication.[3]
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> Prevention, assessment, and treatment of chronic pain are challenges for health providers and systems. Pain might go unrecognized, and patients can be at risk for inadequate pain treatment, particularly racial and ethnic minorities, women, the elderly, persons with cognitive impairment, and those with cancer and at the end of life.[5] Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause[5]. Estimates of the prevalence of chronic pain vary, but it is clear that the number of persons experiencing chronic pain in the United States is

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[2] Daubresse M, Chang HY, Yu Y, et al. Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000–2010. Med Care 2013;51:870–8.

[3] Paulozzi LJ, Mack KA, Hockenberry JM. Vital signs: variation among states in prescribing of opioid pain relievers and benzodiazepines—United States, 2012. MMWR Morb Mortal Wkly Rep 2014;63:563–8.

[4] Levy B, Paulozzi L, Mack KA, Jones CM. Trends in opioid analgesic-prescribing rates by specialty, U.S., 2007–2012. Am J Prev Med 2015;49:409–13.

[5] Institute of Medicine. Relieving pain in America: a blueprint for transforming prevention, care, education, and research. Washington, DC: The National Academies Press; 2011.

substantial. The 1999–2002 National Health and Nutrition Examination Survey estimated a prevalence of current widespread or localized pain lasting at least 3 months of 14.6%. [6] The overall prevalence of common, predominantly musculoskeletal pain conditions that can be chronic (e.g., arthritis, rheumatism, chronic back or neck problems, and frequent severe headaches) was estimated at 43% among adults in the United States [7] based on a survey conducted during 2001–2003. Most recently, analysis of data from the 2012 National Health Interview Study revealed an estimated prevalence of daily pain of 11.2%.[8] It is hard to estimate the number of persons who could potentially benefit from opioid pain medication long term. Although evidence supports short-term efficacy of opioids for reducing pain and improving function in non-cancer nociceptive and neuropathic pain in trials lasting <16 weeks,[9] few studies to assess the long-term benefits of opioids for chronic pain (pain lasting >3 months) with outcomes examined at least 1 year later have been conducted.[10] On the basis of data available from health systems, researchers estimate that 9.6 to 11.5 million adults, or approximately 3%–4% of the adult U.S. population, were prescribed long-term opioid therapy in 2005.[11]

In the past decade, while the death rate for the top leading causes of death such as heart disease and cancer has decreased substantially, the death rate associated with opioid pain medication has increased substantially.[12] Since 1999, more than 140,000 persons have died from overdose related to opioid pain medication in the United States.[13]

More than 16,000 deaths occurred in 2013, four times the number of overdose deaths related to these drugs in 1999. [14] Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths.[15] The Drug Abuse Warning Network estimated that >420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available.[16]

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[6] Hardt J, Jacobsen C, Goldberg J, et al. Prevalence of chronic pain in a representative sample in the United States. Pain Med 2008;9:803–12.

[7] Tsang A, Von Korff M, Lee S, et al. Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders. J Pain 2008;9:883–91.

[8] Nahin RL. Estimates of pain prevalence and severity in adults, United States, 2012. J Pain 2015;16:769–80.

[9] Furlan A, Chaparro LE, Irvin E, Mailis-Gagnon A. A comparison between enriched and nonenriched enrollment randomized withdrawal trials of opioids for chronic noncancer pain. Pain Res Manag 2011;16:337–51.

[10] Chou R, Deyo R, Devine B, et al. The effectiveness and risks of long-term opioid treatment of chronic pain. Evidence Report/Technology Assessment No. 218. AHRQ Publication No. 14-E005- EF. Rockville, MD: Agency for Healthcare Research and Quality; 2014. Available at http://www.effectivehealthcare.ahrq.gov/ehc/products/557/1971/chronic-pain-opioid-treatment- report-141007.pdf2014.

[11] Boudreau D, Von Korff M, Rutter CM, et al. Trends in long-term opioid therapy for chronic non- cancer pain. Pharmacoepidemiol Drug Saf 2009;18:1166–75.

[12] National Center for Health Statistics. Health, United States, 2014: with special feature on adults aged 55–64. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2015.

[13] CDC. QuickStats: rates of deaths from drug poisoning involving opioid analgesics—United States, 1999–2013. MMWR Morb Mortal Wkly Rep 2015;64:32.

[14] CDC. QuickStats: rates of deaths from drug poisoning involving opioid analgesics—United States, 1999–2013. MMWR Morb Mortal Wkly Rep 2015;64:32.

[15] CDC. Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. MMWR Morb Mortal Wkly Rep 2011;60:1487–92.

[16] Substance Abuse and Mental Health Services Administration. The DAWN report: highlights of the 2011 Drug Abuse Warning Network (DAWN) findings on drug-related emergency department visits. Rockville, MD: US Department of

> Opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. In 2013, an estimated 1.9 million persons abused or were dependent on prescription opioid pain medication (based on DSM-IV criteria).[17] Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder,[18, 19, 20] highlighting the value of guidance on safer prescribing practices for providers.

The CDC guidelines have sparked considerable controversy[21] with regard to the secrecy surrounding the development process and concerns about overly restricting patients' access to needed medications. Major recommendations included in the proposed guidelines is provided in Appendix B.

Regardless of changes that might result from comments received, the final guidelines will probably be very similar to the proposed guidelines and should have significant impact on criteria that will be used by drug utilization review (DUR) programs. A 2015 article reviewing actions taken by Oklahoma Medicaid's DUR during the last few years to control opiate use is included in Appendix C.[22] Actions taken by Oklahoma Medicaid include:

- quantity limits,
- pharmacy lock-in program,
- prior authorization program,
- step-therapy programs,
- prospective drug utilization review,
- limit on number of prescriptions,
- preferred brand authorization,
- age restrictions, and
- prescriber contract requirement.

Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality; 2013.

[17] Substance Abuse and Mental Health Services Administration. Results from the 2013 National Survey on Drug Use and Health: summary of national findings. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration; 2014.

[18] Edlund MJ, Martin BC, Russo JE, et al. The role of opioid prescription in incident opioid abuse and dependence among individuals with chronic noncancer pain. Clin J Pain 2014;30:557–64.

[19] Zedler B, Xie L, Wang L, et al. Risk factors for serious prescription opioid-related toxicity or overdose among Veterans Health Administration patients. Pain Med 2014;15:1911–29.

[20] Bohnert AS, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. JAMA 2011;305:1315–21.

[21] Medscape Medical News, December 18, 2015. CDC Opioid Guideline Lands, Controversy Continues, (accessed 12/20/15) http://www.medscape.com/viewarticle/856203.

[22] Keast SL, Nesser N, Farmer K (2015) Strategies aimed at controlling misuse and abuse of opioid prescription medications in a state Medicaid program: a policymaker's perspective, The American Journal of Drug and Alcohol Abuse, 41:1, 1-6, DOI: 10.3109/00952990.2014.988339. Available at: http://dx.doi.org/10.3109/00952990.2014.988339

ACTION REQUESTED:

MS-DUR is providing you this information in preparation of a full review of all Division of Medicaid DUR activities and efforts related to prescribing of opioids, which will take place at the April 2016 meeting. We ask that you review the information included and at the link provided and be prepared to provide feedback and comments as input to guide us in preparing for the April meeting.