

January 9, 2020



D.C. Update: FDA releases final guidance on flavored e-cigarettes, CMS provides several updates for OTPs, and more



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Meet the Member

Sheri Dawson, Regional Director for Region VII

Sheri Dawson, representing Region VII on the NASADAD Board of Directors, has served as Director of the Division of Behavioral Health in the Nebraska Department of Health and Human Services (DHHS) since being appointed by Governor Pete Ricketts in 2015. She also serves as Vice President on the National Association of State Mental Health Program Directors (NASMHPD) Board of Directors and is a State Commissioner Representative on the NASMHPD Research Institute (NRI) Board of Directors.



She has committed over 32 years to the prevention, treatment and recovery of individuals with mental illness and/or substance use disorders. She has served in a variety of roles in public health at Nebraska DHHS over the last 18 years and previously served in nursing administration roles in mental health and substance use treatment. As a nurse she is passionate about ensuring that mental health and substance use is a normalized and integrated part of the healthcare conversation. She believes system change is a journey, not a destination and there is power in partnerships.

Around the Agencies

MACPAC releases report on oversight of IMDs

The Medicaid and CHIP Payment and Access Commission (MACPAC) recently released a [report](#)

Report to Congress on Oversight of Institutions for Mental Diseases

DECEMBER 2019

MACPAC | Medicaid and CHIP Payment and Access Commission

regarding oversight of institutions for mental diseases (IMDs) as required by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The commission found that despite the IMD exclusion, a provision that prohibits federal Medicaid payments for IMDs, States have found various avenues to pay for mental health and substance use disorder (SUD) services in these facilities. As described in the announcement, States have utilized Section 1115 demonstration waivers and statutory exceptions to provide care to adults age 65 and older and youth under the age of 21. States are also making use of a recent provision in the SUPPORT Act that allows States to make

payments under State plans for individuals with an SUD. MACPAC also found that State licensure agencies, accrediting bodies, and other payers do not have standards specific to IMDs and there is no federal certification process for these providers.

CMS provides several updates for OTPs

The Centers for Medicare and Medicaid Services (CMS) announced several updates regarding Medicare coverage for Opioid Treatment Programs (OTPs). As of January 1, 2020, Medicare-enrolled OTPs can begin billing Medicare for services. CMS recently released a [memo](#) to all Medicare Advantage organizations addressing continuity of care for dually eligible beneficiaries. CMS also released a [list](#) of Medicare-enrolled OTPs including the OTP number assigned by the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Provider Identifier (NPI), address, and the date they enrolled. There is also a [FAQ page](#) and [Messages to OTPs](#) page which includes all messages that have been sent to OTPs since the release of the final rule on November 1, 2019. Finally, Medicare Administrative Contractor (MAC) calls were held in December regarding billing, claims processing, and payment and the [materials](#) are now available online.

Millennium Health donates drug testing data to HHS

The Department of Health and Human Services (HHS) recently [announced](#) a partnership with Millennium Health to provide near real-time drug testing data to enhance efforts related to curbing the overdose crisis. The donation by Millennium Health will assist HHS in their work with State and local officials to determine geographical drug trends and to target coordination of healthcare resources to prevent overdoses. As described in the announcement, data from the Emerging Threat Intelligence Program will provide drug use trends from urine drug-test results obtained from all 50 States, the District of Columbia, and medical practices to identify community level indicators of illicit drug use.

CCBHC demonstration program extended through May 2020

The Certified Community Behavioral Health Clinic (CCBHC) demonstration program has been extended through May 22, 2020 as part of the FY 2020 package passed in December. The program is currently operating in eight States including Minnesota, Missouri, Nevada, New Jersey, New York, Oklahoma, Oregon, and Pennsylvania, and the funding package provides a \$50 million increase to the CCBHC expansion grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA).

SAMHSA accepting applications for National Peer-Run Training and TA Center for Addiction Recovery Peer Support grant

The Substance Abuse and Mental



Health Services Administration (SAMHSA) is currently accepting [applications](#) for the National Peer-Run Training and TA Center for Addiction Recovery Peer Support (APR-CoE) grant. The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires that TA and

training must be provided by recovery community organizations (RCOs) and peer support networks and the APR-CoE grant will assist in the promotion of peer recovery support services. SAMHSA intends to issue 1 grant of up to \$949,784 per year for four years to a public or private non-profit entity.

[APIS releases update to State-by-State alcohol and recreational cannabis policies](#)

The Alcohol Policy Information System (APIS), a project within the National Institute on Alcohol Abuse and Alcoholism (NIAAA), recently released their annual [update](#) of State-by-State alcohol and recreational cannabis policies. The update addresses changes in State alcohol and recreational policy statues and regulations occurring through January 1, 2019. Highlights from the update include changes to underage drinking laws, retail sales, pricing and taxation, pregnancy and alcohol, and blood alcohol concentration laws. Highlights pertaining to recreational cannabis policy include the legalization of recreational use in several States and provisions to recreational cannabis use laws already in effect in other States.

[FDA releases final guidance on flavored e-cigarettes](#)

The Food and Drug Administration (FDA) [announced](#) the release of final [guidance](#) regarding enforcement of unauthorized flavored cartridge-based e-cigarettes, to include fruit and mint flavors that appeal to children. As described in the announcement, companies that do not cease manufacture, distribution, and sale of these products within 30 days risk FDA enforcement actions. The FDA will focus on the following products that do not have premarket authorization: any flavored, cartridge-based electronic nicotine delivery system (ENDS) other than tobacco or menthol flavors; all other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and any ENDS product that is targeted to minors or likely to promote use of ENDS by minors.

Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <https://www.regulations.gov>. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2019-D-0661.

For questions regarding this guidance, contact the Center for Tobacco Products at (Te) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. - 4 p.m. ET.

Additional copies are available online at <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

January 2020

Centers for Disease Control and Prevention
MMWR
Weekly / Vol. 68 / No. 50

Morbidity and Mortality Weekly Report
December 20, 2019

[Research Roundup CDC releases study on driving under the influence of marijuana and illicit drugs](#)

A new [study](#) conducted by the Centers for Disease Control and Prevention (CDC) examined the prevalence of individuals driving under the influence of marijuana and illicit drugs. The study, published in the Morbidity and Mortality Weekly Report (MMWR), found that in 2018 approximately 12 million (4.7%) U.S. residents aged 16 and older reported driving under the influence of marijuana and 2.3 million (0.9%)

reported driving under the influence of illicit drugs other than marijuana during the past 12 months. The study also found that reports of driving under the influence of marijuana and other illicit drugs were most common among people aged 21-25 years and were higher among males than females. The study concluded that additional data is needed to clarify the contribution of drug and polysubstance use to impaired driving prevalence rates. Researchers suggest implementing strategies to prevent alcohol, drug, and polysubstance-impaired driving in tandem with standardized testing of impaired drivers to further advance understanding and prevention efforts.

Study finds 90% of opioid overdose deaths are accidental

A [research letter](#) published in the *Journal of the American Medical Association* indicated that most opioid overdose deaths are accidental. Researchers from the National Institute on Drug Abuse (NIDA), Centers for Disease Control and Prevention (CDC), and Columbia University, conducted a review of data from the National Vital Statistics System and analyzed death certificates for individuals aged 15 and older. Results of the study indicated that more than 90% of opioid overdose deaths were unintentional compared to 4% of deaths classified as suicide. Researchers noted that the rise in unintentional deaths could be a result of the increase in synthetic opioids such as fentanyl.

Upcoming Events

SAMHSA webinar on creating a recovery-oriented workplace culture

The Substance Abuse and Mental Health Services Administration (SAMHSA) announced a Recovery LIVE! webinar that will focus on how employers can support employees living with mental illness or substance use disorders (SUD). Hosted by SAMHSA's Bringing Recovery Supports to Scale Technical Assistance Center Strategy (BRSS TACS), the webinar will present strategies for the recruitment, hiring, and retention of employees in recovery. Presenters will discuss relevant human resource policies and practices and information on how to create a recovery-oriented workplace culture. The webinar will be held on January 23, 2020 from 2:00-3:00 p.m. EST and registration can be found [here](#).
