Nevada Department of Health and Human Services

Division of Health Care Financing and Policy

Pharmacy/DME Program MONTHLY News

PHARMACY AND DME IN THE NEWS

Pharmacy/DME in the News

TRUMP BUDGET SEEKS 12% HHS CUT, MEDICAID WORK RULES, FDA BOOST – The Trump administration released an overview of its proposed 2020 budget, including a bid to cut funding for federal health programs, and pressed for Medicaid block grants and expansion of its work rules. In a presentation to congress, the White House highlighted funding proposals for popular public health issues, including ongoing efforts to combat the misuse of opioids. In total, the White House is seeking $871 billion for the Department of Health and Human Services (HHS), which is a cut of 12% from the 2019 estimated level.

This reduction in funding would cut the National Institutes of Health (NIH) budget by $4.5 billion. The White House is also seeking $4.8 billion to HHS to 'sustain critical investments in opioid surveillance, prevention, treatment, recovery support services, and research.' Included is $8.6 billion in funding for a border wall as a response to the opioid crisis.

The White House is seeking to provide the US Food and Drug Administration (FDA) with $6.1 billion, which is $643 billion more than the 2019 estimated level. This proposal includes $55 million for opioid related efforts. There is a proposed $291 million that will fund a multiyear initiative focused on ending the HIV epidemic in America by 2030.

For Medicaid, the White House is proposing to require 'able-bodied, working-age individuals to find employment, train for work, or volunteer (community service) to receive' services from Medicaid. This would make federal-state health programs operate more like Temporary Assistance for Needy Families program. The budget outline proposes 'comprehensive Medicaid financing reform' by switching to per-capita cap or block grants. The White House stated that 'a new Federal-State partnership is necessary to eliminate inefficient Medicaid spending, including repeal of the Medicaid expansion' created by the Affordable Care Act of 2010.

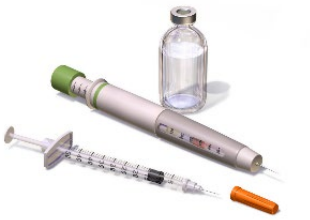
FDA APPROVES BREXANOLONE *(ZULRESSO)*, FIRST DRUG FOR POSTPARTUM DEPRESSION – The FDA announced the approval of the first-ever drug indicated for the treatment of postpartum depression. Zulresso is administered under medical supervision as a continuous infusion over a total of 60 hours (2.5 hours).

The mechanism of action is different from the currently available antidepressants. It is chemically identical to endogenous allopregnanolone, which is a hormone that decreases after childbirth. Zulresso acts as a positive allosteric modulator of gamma-aminobutyric acid-A (GABAA) receptors, which can become dysregulated after birth.

Infusions must be only made available to patients at certified health care facilities due to concerns about serious risks, including excessive sedation or sudden loss of consciousness. Patients must have continuous pulse oximetry monitoring during the entire infusion and must be accompanied during interactions with their child(ren) while receiving the infusion.

ELI LILLY OFFERS LOWER-PRICED VERSION OF ITS LISPRO INSULIN – Eli Lilly and Company announced the launch of an "authorized generic" called *Insulin Lispro*. The lower-priced version of Humalog will be manufactured through a subsidiary, ImClone

Systems. This will be an alternative for patient's paying out-of-pocket, including those who are uninsured, who have high deductibles, or who are in the Medicare Part D coverage gap ("donut hole"). The list price will be $137.35 per vial and $265.20 per five-pack of KwikPens. This is roughly half the price of the branded versions. Insured patients will not pay the price listed and can access Humalog as they have been.



NEW COMPOUND GETS ORPHAN DRUG STATUS FOR HUNTINGTON'S DISEASE – MP-101 has received an orphan drug designation from the FDA for the treatment of Huntington's disease. This drug is a mitochondrial targeted compound that has shown to protect both spiny neurons and general neurons and minimize brain-volume loss. These effects combined could significantly alter disease progression. Mitochon Pharmaceuticals will be initiating phase 1 studies in normal, healthy volunteers this year and phase 2 studies are expected to take place in 2020.

ERs OFTEN MISS CHANCE TO SET OVERDOSE SURVIVORS ON 'BETTER PATH' –A recent study of West Virginia Medicaid claims analyzed 301 nonfatal overdose claims in 2014 and 2015. Researchers looked at hospital codes for opioid poisoning and followed the patients' treatment. Follow-up treatment included mental health visits, opioid counseling visits, or prescriptions for psychiatric and substance abuse medications.

The study found that per month fewer than 10% of people received medications like naltrexone or buprenorphine to treat a substance use disorder. It was noted that during the month of the overdose, about 15% received mental health counseling. Following a period of 12 months, this average fell to fewer than 10% per month.

Andrew Kolodny, co-directors of Opioid Policy Research at the Heller School for Social Policy and Management at Brandeis University, stated that it's an opportunity being missed in emergency rooms. Kolodny compared this missed intervention as someone who came into the emergency room with a heart attack. It's often taken for granted as a given that the patient will leave with heart medication and a referral to a cardiac specialist. It should also be considered for patients who come in with an overdose to start buprenorphine in the hospital and leave with a referral to other forms of treatment. Increasing training for health professionals remains integral to undermine what happens once an overdose patient leaves the hospital.

FDA COMMISSIONER SCOTT GOTTLIEB RESIGNING- Scott Gottlieb, MD, is resigning from his position as the commissioner of the US FDA, effective April 5, 2019.

Dr. Gottlieb focused his tenure at the FDA regulating e-cigarettes, calling vaping a scourge among American teenagers and had just announced that the agency would be going after retailers that repeatedly illegally sold e-cigarettes to minors. Gottlieb had also been advocating agency policies to bring down the high cost of pharmaceuticals, and have overseen the issuance of long-awaited regulations and policies including addressing the safety of sunscreens.

HHS Secretary Alex Azar said that Gottlieb "has been an exemplary public health leader, aggressive advocate for American patients, and passionate promotor of innovation…"

The National Cancer Institute (NCI) Director Norman "Ned" Sharpless, MD, is slated to step in as interim chief of the FDA in early April. Azar said he expects Sharpless to continue with efforts for which Gottlieb has been praised.

CMS SEEKS RECOMMENDATIONS THAT ALLOW AMERICANS TO PURCHASE HEALTH INSURANCE ACROSS STATE LINES–The Centers for Medicare and Medicaid (CMS) issued a request for information (RFI) that solicits recommendations on eliminating barriers to enhance the ability to sell health insurance across state lines. This is adding to President Trump's Executive Order, "Promoting Healthcare Choice and Competition Across the United States."

CMS is interested in feedback on how states are taking advantage of Section 1333 of the Patient Protection and Affordable Care Act, providing for the establishment of a regulatory framework that allows two or more states to enter a Health Care Choice Compact. By expanding the sale of health insurance coverage across state lines could provide more options to people with access to one issuer and give them an opportunity to pick a plan meets their needs at a lower cost. This RFI will be open for public comment for 60 days.

OWNER OF WASHINGTON, D.C. BASED DURABLE MEDICAL EQUIPMENT COMPANY SENTENCED TO PRISON FOR ROLE IN $9.8 MILLION MEDICAID FRAUD SCHEME- Waveney Blackman, owner of a Washington D.C.-based durable medical equipment company, was sentenced to 42 months in prison for her role in a scheme to submit $9.8 million in fraudulent claims to Medicaid. Blackman pled guilty in October 2018 to one count of health care fraud. She was sentenced to serve three years of supervised release and to pay $9,412,394 is restitution. Blackman will also be required to forfeit $9,431,979.

Ms. Blackman admitted to billing Medicaid for expensive wound care products that were not purchased and not provided during the timeframe of January 2010 through June 2016. The $9.8 million was traced to two bank accounts, a Mercedes, and seven real estate properties.

The FBI, HHS-OIG, and the District of Columbia's Office of the Inspector General's Medicaid Fraud Control Unit investigated this case, which was brought as part of the Medicare Fraud Strike Force, under the supervision of the Criminal Division's Fraud Section and the U.S. Attorney's Office for the District of Columbia. The Fraud Section leads the Medicare Fraud Strike Force. Since it's inception in March 2007, 4,000 defendants have been charged for billing the Medicare program for more than $14 billion.

DME FRAUD IS COMMITTED WHEN A PROVIDER:

- Submits bills for services not rendered (i.g., "gang visits" is when a provider visits a nursing home and bills for services for all, or nearly all residents. The physician may not have provided services to

all residents but bills as if they did, or, the physician may provide services whether every resident needs it or not.
- Upcodes a service- for example: submitting a bill for surgery when only a bandage was placed over a cut.
- Unbundles services- submits separate billing for lab services that include three or four tests combined as one and which are supposed to be billed as one.
- Solicits, offers, or receives a bribe or a kickback- often recruiters or "cappers" may stop beneficiaries on the street, or knock on their door and offer money or promotional gifts as incentives to entices them to a take a "free" medical exam. Then the patient is presented with a list for durable medical equipment that they do not need.
- Bills "non-covered" services as covered- for example, billing routine toenail clipping as foot surgery.

CMS LAUNCHES 'WHAT'S COVERED' APP- The 'What's Covered' app allows beneficiaries to easily access accurate, consistent information on specific medical items or services that are covered by Medicare. CMS administrator Seema Verma stated, 'The new app is the next in a suite of products designed to give consumers more access and control over their Medicare information.' The 'What's Covered' app is available for free in both Google Play and the Apple App Store.

CMS's eMedicare initiative also includes online decision support to help beneficiaries understand and evaluate coverage options and costs between Medicare and Medicare Advantage. This initiative shows how their choices will impact their estimated out-of-pocket costs; price transparency tools allows for the comparison of national average costs of certain procedures; a webchat option in the Medicare Plan Finder; and surveys across Medicare.gov so beneficiaries can provide feedback and input.

FDA APPROVED DRUG PRODUCTS – March 2019

APPROVAL DATE	DRUG NAME	ACTIVE INGREDIENTS	SUBMISSION CLASSIFICATION	INDICATION
03/11/2019	Trazimera	Trastuzumab-qyyp		A biosimilar indicated for the treatment of human epidermal growth factor receptor-2 (HER2) overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
03/12/2019	Rocklatan	Netarsudil; Latanoprost		Indicated to reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
03/18/2019	Zykadia	Ceritinib		A kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.
03/19/2019	Zulresso	Brexanolone	Type 1- New Molecular Entity	A positive allosteric modulator of gamma-aminobutyric acid-A (GABAA) receptor indicated for

				the treatment of postpartum depression.
03/20/2019	Sunosi	Solriamfetol	Type 1- New Molecular Entity	A selective dopamine and norepinephrine reuptake inhibitor (DNRI) indicated for the use of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA).

UPCOMING PROGRAM EVENTS

PHARMACY

Pharmacy and Therapeutics Meeting (P&T) – Next quarterly meeting Thursday June 27, 2019

Recent- March 28, 2019

Annual Review- September 26, 2019

Drug Utilization Review Board (DUR) – Next quarterly meeting, Thursday April 25, 2019

Public Hearing- April 30, 2019

- HPV Vaccine age expansion
- Clarification of definition for severe eosinophilic phenotype asthma within Monoclonal Antibody Agents
- Update age in criteria for Kalydeco

DME

All State DME Workgroup Meeting - April 15, 2019

Spring Medtrade Conference, Las Vegas, NV - April 16-18, 2019

OTHER MEETINGS

Medical Care Advisory Committee (MCAC)- April 9, 2019

Tribal Consultation Meeting- April 10, 2019

FQHC Quarterly Meeting- April 25, 2019