Below is an update on activity in federal health agencies over the past few months. This includes draft, final rules and guidance to the states. Among the top issues were: implementation and proposals for new medical payment systems and transparency, updates on implementing health-related legislation from Congress, and keeping states updated on public health emergencies. Always feel free to follow up with us at haley.nicholson@ncsl.org or margaret.wile@ncsl.org.

**Centers for Medicare and Medicaid Services**

**August 2019**

- Released an informational bulletin regarding heightened scrutiny as it applies to construction of settings that could be institutional per home and community-based services (HCBS) requirements. This updates 2016 guidance and allows states to submit a setting for heightened scrutiny/review prior to Medicaid beneficiaries receiving services in these new settings. States, providers, builders and other stakeholders are encouraged to review alternatives to the development of new institutional settings and said requirements can be done at the state and federal levels based on the experiences of non-Medicaid beneficiaries.

- Asked for public comments on the 2020 Core Set Annual Review Draft Report. The report is compiled by a multi-stakeholder group that reviews and makes recommendations on child and adult health care quality measures in Medicaid and the Children’s Health Insurance Program (CHIP).

- Provided guidance to states on the implementation of the new Medicaid Drug Utilization Review (DUR) provisions. This was required under the SUPPORT for Patients and Communities Act of 2019. The DUR provisions were designed to reduce opioid related fraud, misuse and abuse. The provisions included:
  - Requirements regarding opioid prescription claim reviews at the point of sale,
  - Monitoring and management of antipsychotic medication in children,
  - Identification of processes to detect fraud and abuse,
  - Mandatory DUR report updates, and
  - Requirements for Medicaid Managed Care Organizations.

- Final rule released approving a 3 percent all-in pay increase for Medicare’s inpatient prospective payment services in 2020. This will provide up to $3.8 billion in additional funding to hospitals and is a decrease in price from the originally proposed regulation. The impacts on hospitals and amounts received will vary, and the rule is working to address current payment practices where hospitals in higher-wage cities get paid more than those in rural areas. The rule also made changes related to Medicare graduate medical education (GME) for teaching hospitals, payments to critical access hospitals, and revises existing requirements for quality reporting by specific Medicare providers. The final rule was implemented on Oct. 1, 2019.
• Provided technical assistance and guidance to states and other stakeholders to ensure compliance with the 21st Century Cures Act. This came at the request of many states and stakeholders to clarify certain electronic visit verification (EVV) requirements. Resources included: frequently asked questions of EVV requirements for beneficiaries with live-in caregivers and the provision of durable medical equipment and services used partially in the home and partially in the community.

• Released information to states about new flexibilities in defining essential health benefits (EHB) in Medicaid Alternative Benefit Plans (ABP). The information provided over three new options states can use when choosing benchmark plans to define EHB and what states with existing ABPs can continue to use under their current benchmark plans. Those states selecting new benchmark plans must use one of the new options starting on or after Jan. 1, 2020.

• Issued information on how state Medicaid agencies can support the implementation of the Emergency Triage, Treat and Transport (ET3) Model. This is a voluntary, five-year Capability Maturity Model Integration payment model looking to reduce unnecessary transport to the Emergency Department. Information included a framework for states to use to assess their own regulatory landscape and Medicaid payment structure to determine the state’s ability to implement the ET3 interventions.

• Released a fact sheet to help medical providers correctly bill for nursing home services while abiding by the “three-day stay” requirement. This came as a response to an Office of Inspector General report that found CMS had improperly paid most claims when many providers were not complying with the three-day rule between 2013 and 2015. CMS and related health care stakeholders have also agreed to revisit this requirement.

• Published a report on Medicaid Long-Term Services and Support Systems, highlighting states that have seen the greatest progress in rebalancing these systems from institutional care to HCBS.

**September 2019**

• Released information reminding states of their obligations and responsibilities for state Medicaid provider payments made to third parties, also known as the Medicaid Provider Reassignment Final Rule. CMS wants a process for states to assure payments are made in accordance with statute and will be monitoring for state’s compliance with the final rule.

• Issued a final rule to help stop fraud and abuse in Medicare, Medicaid and CHIP programs including the creation of new enforcement authorities to oversee fraud and abuse of these programs. The final rule creates several new authorities as well as a new “affiliations” authority that will allow CMS to identify individuals and organizations posing an undue risk of fraud or waste. These determinations can be based on previous relationships where organizations were connected to abuse cases.
• Released, The Omnibus Burden Reduction final rule. This is responding to the executive order on improving kidney health in America by strengthening the organ donation process, and changes transplant center requirements by giving providers more flexibility to support patients needing transplants. This will be done by eliminating data submission requirements for re-approval in the organ transplant process. Additionally, Medicare-certified hospitals are required to develop and maintain ongoing Quality Assessment and Performance Improvement (QAPI) programs that will be streamlined and allow multiple hospitals to use a unified QAPI program. This will also reduce reviews and program evaluations that rural health clinics and federally qualified health centers are required to conduct from annually to once every two years.

• Opportunity announced for 10 states to apply for a wellness program demonstration project. This gives states and issuers new flexibilities when designing and offering wellness programs for individual market health plans. States will be allowed a broader range of wellness programs than are currently available under law. They can develop innovative ideas to improve individual’s health by allowing issuers to offer premium cost savings or other incentives for people choosing to engage in healthy activities. States will have to submit required data on: the number of participants, rewards provided, overall issuer cost savings and changes in participant behavior among other areas.

**October 2019**

• Released the first annual Substance Use Disorder (SUD) Data Book. The report has data on SUD diagnosis, enrollment type, and uses of treatment services at the national and state level among Medicaid beneficiary populations. Data from the report is from 2017, an online tool will also be available on Medicaid.gov.

• Released proposals to change the physician-self referral and anti-kickback statute regulations to help providers’ participation in value-based pay models. Changes to the existing statue include: new and permanent exceptions to the Stark Law for value-based payments in and outside of Medicare, and the inclusion of a new safe harbor allowing for certain incentives beneficiaries can only get through CMS demonstrations.

• Published the Basic Health Program final federal funding methodology for 2019 and 2020. This data will help determine federal payment amounts for program years 2019 and 2020 to states electing to establish a Basic Health Program under the Affordable Care Act (ACA) offering health coverage to low-income individuals eligible to purchase coverage through ACA exchanges.

**November 2019**

• Finalized changes to the Physician Fee Schedule that will include: changes to simplify documentation and coding requirements for doctor’s office visits, adding a new Part B benefit for opioid treatment programs (OTP) and increasing payment for care services provided to patients after they leave the hospital. Beginning in 2021, CMS will align certain evaluation and management codes adopted by the American Medical Association. The changes also included a
reduction in requirements for physician’s supervision of physician’s assistants, and they can now practice more broadly in accordance with state law and state scope of practice.

• Released 2019 Medicaid and CHIP Scorecard, with more recent data in this year’s scorecard. CMS has also expanded information on the National Context pages and added measures to the State Health System Performance and State and Federal Administrative Accountability Scorecard pillars.

• Proposed a rule promoting transparency in the Medicaid program by establishing new reporting requirements for states asking them to provide CMS with information on supplemental payments to Medicaid providers. The proposed rule looks at the financing of supplemental and base Medicaid payments through non-federal share payments including states’ uses of health care-related taxes. Comments are due by Jan. 17, 2020.
**August 2019**

- Awarded **$400 million to combat the opioid crisis**. Funding includes:
  - $200 million to 1,208 health centers to increase access to high quality, integrated behavioral health services;
  - $111 million to 96 rural organizations across 37 states as part of the Rural Communities Opioid Response Program initiative;
  - $70 million to Opioid Workforce Expand Programs, and
  - $17 million to the Graduate Psychology Education Program to 49 APA accredited schools, universities and other nonprofit organizations.

- Announced **two pathways for drug importation**, that would allow patients to import certain drugs from Canada. There were some exceptions for biologics (including insulin), controlled substances and intravenously injected drugs. One of the pathways would allow drug manufacturers to import versions of Food and Drug Administration (FDA)-approved drugs they are selling in other countries, or to use the same drug at a different price in the U.S.

- Proposed 42 CFR Part 2 Reforms that would change **federal regulations governing the confidentiality of patient records** created by federally-assisted substance use disorder (SUD) programs. The proposed rule would modify several sections of 42 CFR Part 2 to encourage care coordination among providers and update reporting requirements to more accurately reflect the SUD and treatment landscape. Proposals included:
  - Updating the definition of what constitutes a Part 2 record and its applicability;
  - Clarification for messages on personal devices not used by a Part 2 program during the regular course of business and not having to record messages deleted due to a SUD patients message activity, and
  - Would give providers under the rule access to central registries to see if a patient is enrolled in an opioid treatment program and receiving medications as a part of SUD treatment.

**September 2019**

- Awarded $9 million through the Health Resources and Services Administration (HRSA) to launch the **Rural Maternity and Obstetrics Management Strategies** program. Three states: Missouri, New Mexico and Texas will receive up to $600,000 in a planning year and up to $800,000 in three implementations years to pilot, test and develop models improving access to and providing continual maternal obstetrics care in rural communities.

- Awarded more than **$50 million to fund 77 health centers across 23 states**, Puerto Rico and the Commonwealth of the Northern Mariana Islands to provide operational support for new organizations to become **HRSA Health Center Program** grantees and for existing health centers to establish new service delivery sites.
• Awarded $352 million in funding to 56 states, territories and nonprofit organizations through its Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV Program).

• HRSA published a Guide for Rural Health Collaboration, focusing on how rural providers can coordinate to identify health needs and create partnerships to address them.

**October 2019**

• Awarded $13.5 million through the Centers for Disease Control and Prevention (CDC) to conduct state and local planning and to kick off community involvement for the administration’s proposed initiative to end new HIV infections in America also known as the, “What is ‘Ending the HIV Epidemic: A Plan for America.’” Funding includes $12 million for accelerating state and local HIV planning with the HHS Minority HIV/AIDS fund and giving awards to 32 CDC-funded state and local health departments. The remaining funding has been awarded to the National Alliance of State and Territorial AIDS Directors with $1.5 million per year from 2019 to 2023 based on current resources, and to enhance local health departments capacity to end the epidemic in prioritized 57 geographic areas experiencing the highest HIV infection rates in the U.S.

• Provided $16 million through the Agency for Healthcare Research and Quality to help primary care practices increase their efforts in addressing unhealthy alcohol use. Funding was awarded to six grantees working with more than 700 primary care practices over three years to implement and evaluate strategies that will increase the use of evidence-based interventions including: screening for unhealthy alcohol use; brief interventions for adult patients who drink too much and medication-assisted treatment for patients with alcohol use disorder.

**November 2019**

• Issued a Notice of Nonenforcement to inform the public of certain regulatory provisions in The Uniform Administrative Requirements, Cost Principles and Audit Requirements for HHS Awards. The notice outlined that requirements will not be enforced because of concerns from the prior administration’s implementation of the Regulatory Flexibility Act. This included a proposed rulemaking to revise and reissue HHS grant regulation. The revisions will address a 2016 rulemaking that required grantees to comply with applicable nondiscrimination provisions. This will apply to all previously enacted legislation to ensure the protection of religious liberty if HHS complies with all applicable Supreme Court decisions in administering its grant programs.

• Announced a final hospital price transparency rule that was part of a 2020 outpatient hospital rule effective January 2021. Under the final rule, hospitals are required to make public their standard charges for all items and services. The charges must be machine-readable, on display, include common medical billing or account codes, include descriptions of the item or service and updated annually. Hospitals will also be responsible for publicly posting charges for “shoppable services” by listing the costs of 300 services they negotiated with specific payers. Of the 300 services that will list costs, CMS will choose 70, and hospitals can choose the remaining 230. It will also require monitoring, auditing and corrective action plans ensuring compliance with the transparency rules with a penalty of $300 per day for hospitals that do not comply.
August 2019:

- CDC Director, Robert R. Redfield, M.D., released a statement regarding the first death related to the outbreak of severe lung disease in those using e-cigarette or “Vaping” devices.

September 2019

- Awarded $301 million in new funding to stop drug overdoses and deaths in the new Overdose Data to Action funds to states and jurisdictions. These programs will help CDC and HHS gain a better understanding of why and among whom, overdoses and deaths are taking place, and use this information across the country to increase prevention and response efforts. Funds will support work in 47 states, Washington D.C., two territories and 16 counties and cities.

October 2019

- Announced 1,888 confirmed and probable lung injury cases and deaths associated with the use of e-cigarette, or vaping products. The cases were reported by 49 states (except Alaska), the District of Columbia and the U.S. Virgin Islands. There were 37 deaths confirmed in 24 states as well. Ongoing information on the investigation into the lung injury cases, can be found here.

Federal Drug Administration

October 2019

- Provided update on a variety of work being done to implement the SUPPORT Act. The legislation provided the Federal Drug Administration (FDA) and other agencies with new authorities to help in their efforts to confront the opioid crisis. Along with law enforcement and customs related work they also:
  - Clarified FDA regulation of non-addictive pain products;
  - Submitted ways the agency has used evidence-based prescribing guidelines;
  - Outlined efforts to enhance the safety aspects of packaging and disposal of certain opioids, and
  - Conducted a study with CMS on the adequacy of access to opioids under Medicare and guidelines for reducing their abuse and misuse.
- Awarded 12 new clinical trial research grants worth more than $15 million over the next four years. The grants will go to the development of medical products for patients with rare diseases and awarded to principal investigators from academia and industry across the country.
- Provided an update on the ongoing outbreak of severe lung injuries and deaths to say that consumers should stop the use of vaping products containing tetrahydrocannabinol (THC) and should not modify or add any substances like THC or other oils to vaping products purchases in stores.
• Approved **Descovy a type of pre-exposure prophylaxis (PrEP)**, a type of drug used to reduce the risk of HIV-1 infection. PrEP drugs are used as an HIV prevention method for people who do not have HIV but take medicine daily to reduce their risk of getting HIV.