Over the past few months federal health agencies have been at work on a number of proposals, final rules and guidance to the states. Among the top issues were: proposals for reforming prescription drug costs, the future of hospital payments, 1332 waivers, changes to health insurance plans and the future of how medical providers are paid. See below for activity over the past few months and always feel free to follow up with us at haley.nicholson@ncsl.org or margaret.wile@ncsl.org.

April 2019

- The Centers for Medicare and Medicaid Innovation (CMMI) and Health and Human Services (HHS) released new Centers for Medicare and Medicaid (CMS) Primary Care Initiatives. They include five new, voluntary payment models looking at value-based care and are designed to update current Comprehensive Primary and Next Generation Accountable Care Organization (ACO) programs. The aim of the models is to incentivize providers to give higher quality health services, greater care coordination and require that they take on more financial risk for patients outcomes. Four of the models will start on Jan. 1, 2020 with the other to start the following year.

May 2019

Prescription Drugs:

- CMS finalized a rule regarding prescription drug pricing for Medicare Part D programs. After the proposed rule was released in November 2018, CMS took out previous provisions that would have let Medicare Part D plans exclude prescription drugs in protected classes when drug makers raise the prices faster than inflation or when companies create new formulations of drugs that are already on the market. The proposed rule also looked at allowing Part D plans to expand their work on step therapy and prior authorization for protected class drugs.

The Part D policy included in the final rule will require formularies for drugs in six categories including: antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals and antineoplastic, and codifies the existing policy on these classes since 2006.

- Issued guidance for Medicaid and Children’s Health Insurance Plan (CHIP) managed care plans in regard to the calculation of a plan’s Medical Loss Ratio (MLR). The MLR is the percent of health insurance premium revenue that goes toward actual medical claims and activities. CMS regulations require these types of plans to report an MLR and use a target of 85% for MLR when developing plan rates, with the remaining 15% only to be used for administrative costs and profits. There is concern that some managed care plans are not accurately reporting pharmacy benefit spread pricing when calculating and reporting MLRs.

  - Under current MLR regulations for Medicaid and CHIP, managed care plans require them to exclude prescription drug rebates from the amount of claims costs that are used to calculate an MLR. Under this guidance, prescription drug rebates will mean any price concession or discount received by the managed care plan or PBM, regardless of
who pays the rebate or the discount. This is ultimately working to ensure that spread pricing is not used to artificially inflate a Medicare or CHIP managed care plan’s MLR.

-Spread pricing is when health plans contract with Pharmacy Benefit Managers (PBMs) to manage their prescription drug benefits. As part of this contract PBMs keep a portion of the amount paid to them by the health plans for prescription drugs. This creates a spread between the amount the health plans pay the PBM and the amount the PBM will reimburse the pharmacy for a patient’s prescription.

**Providers and Payments:**

- CMS finalized a rule to remove a 2014 regulation that allowed states to divert part of their Medicaid provider payments to third parties that could be used to fund other costs on behalf of the provider. After reviewing the provision, the agency said it could have resulted in provider payments being diverted in ways that did not align with the law or, in some instances, may have happened without a provider knowing. The agency received over 7,000 comments during the proposed rule phase.

**Waivers:**

- Following up on the release of updates to the Section 1332 Waiver program now known as the State Relief and Empowerment Waiver/State Innovation Waiver program, CMS, HHS and the Department of Treasury made a request for information (RFI) for additional ideas and suggestions on these waiver concepts that states could use when developing one. CMS also released four waiver concepts to provide states with examples of they can use as well.

**Substance Use Disorder and Behavioral Health:**

- Released guidance to states about two additional quarters of enhanced Federal Medical Assistance Percentage for certain Substance Use Disorder (SUD)-focused health homes. This guidance comes after the passage for the SUPPORT for Patients and Communities Act that extended the enhanced match period for SUD-focused homes. This will only apply to SUD-focused health home state plan amendments that were approved on or after Oct. 1, 2018. If a state is interested in submitting a proposal to receive additional quarters of funding for SUD-focused health homes they will need to submit a state plan amendment and a letter of request for this extension.

**June 2019**

**Social Determinants of Health and Coordinated Services:**

- CMS postponed its plan to undo a regulation that required state Medicaid programs to provide transportation for enrollees to travel to and from non-emergency medical appointments. The proposed rule is now expected to come out in 2021.

-Medicaid covers non-emergency medical transportation (NEMT) services since the program began. It is not a mandatory benefit under Medicaid but states were required
to cover it. NEMT benefits have been utilized with ride-sharing companies like Uber and Lyft. It is estimated around 10% of Medicaid beneficiaries use NEMT for rides to a variety of appointments and is reserved for those who have no other access to reliable transportation.

**Providers and Payments:**

- Delayed for a year finalizing updates from a 2016 proposed rule on hospital conditions for participation. CMS received feedback from stakeholders that they would not be able to meet the three-year timeline when CMS was due to publish the final rule. Some of the policies that were supported:
  - Moving from the term “licensed independent practitioner” to “licensed practitioner,” allowing hospitals to use physician assistants to the full extent of their scope of practices per state law.
  - Reducing burdens around critical access hospital dietary and nutritional services.
  - Infection control and antibiotic stewardship policies were supported, but some stakeholders were concerned that the agency was underestimating the time and effort required to implement these policies, as well as the time needed for proposed Quality Assessment and Performance Improvement requirements. Both proposals received requests for delayed implementation.

- Sought additional feedback on its Patients Over Paperwork campaign. Asked for comments on: ways to cut down on any unnecessary requirements for prior authorization procedures, beneficiary eligibility determinations and any burdens on rural providers and dual Medicare and Medicaid enrollees. This request is focused also on ideas for regulatory, sub regulatory, policy, practice and procedural changes, with an emphasis on new ideas not received from the first-round RFI on this initiative.

**Prescription Drugs:**

- Continued conversation on 340B reimbursement cuts, hospital price transparency requirements and site-neutral pay cuts. Previous proposals that looked at reducing reimbursements for Part B drugs purchased through 340B were halted after a district court ruling that CMS did not have the authority to do so. Proposals from CMS on 340B practices were also stopped following concerns that certain payment systems are pushing too quickly for the consolidation of provider practices and hospitals.
  - Previous rule released would have phased in pay reductions over a two-year period that could be a $380 million cut in 2019 and $760 million cut in 2020. As a result, AHA and AAMC sued CMS over the cuts and the lawsuit is ongoing.
July 2019

Data and Enrollment

- Released April 2019 Medicaid and CHIP enrollment numbers across the U.S. Each month all states and the District of Columbia provide data about their Medicaid and CHIP eligibility and enrollment data. Enrollment can also be broken down by specific state.

As of April 2019:

- **72,380,727 individuals** were enrolled in Medicaid and CHIP in the **51 states** that reported enrollment data for April 2019.

- **65,743,387 individuals** were enrolled in Medicaid.

- **6,637,340 individuals** were enrolled in CHIP.

Providers and Payments:

- Followed up on an informational bulletin to state Medicaid agencies that assisted states in helping make accurate eligibility determinations and ensure appropriate financing for claims with a proposed rule.

  - The proposed rule would remove regulatory language requiring states to document whether Medicaid payments in fee-for-service systems are working to enroll enough medical providers to assure patients have enough access to covered care and services. This is in response to states’ concerns with administrative burden associated with current requirements after Medicaid regulations were adopted in 2015 that required them to establish and periodically update on access monitoring review plans (AMRPs). The regulations applied to a few medical services including primary care, behavioral health and pre- and post-natal obstetric services among others.

  - The proposal would also leave in requirements that states maintain documentation of payment rates. It would remove the requirements for states when developing and updating an AMRP and to submit certain analysis when proposing to reduce or change provider payment rates. States would also still be required to submit information and analysis that shows compliance when submitting State Plan Amendments (SPAs). It proposes to remove the regulatory requirements for the process states must follow before submitting a SPA that would reduce or restructure Medicaid service payment rates. Comments are due on Sept. 13, 2019.

- Announced one proposed and one final rule on the safety and quality of nursing homes. The rules were part of the agency’s five-part approach that is working to ensure high-quality long term care facility system also known as LTC facilities or nursing homes. The proposed rule would allow nursing homes to focus resources on their residents by saving $616 million in
administrative costs and allow these facilities to eliminate prescriptive requirements including unnecessary details of the Quality Assurance Improvement Program.

- The final rule updated requirements nursing homes must meet to use binding arbitration agreements. The rule will start in September 2020 and allows nursing homes under Medicare and Medicaid to offer patients contracts to resolve future disputes through arbitration rather than courts. Arbitration agreements will also be prohibited from blocking or discouraging patients from contacting local or federal authorities and allows binding arbitration agreements, but will prohibit nursing homes from requiring incoming residents to sign binding arbitration agreements to receive care.

**Waivers:**

- Provided new resources on State Relief and Empowerment Waivers also known as section 1332 waivers. Resources include: checklist of required waiver elements and model templates to help states understand and navigate the 1332 waiver application process.
- Released refreshed data on the Medicaid and Children’s Health Insurance Program Scorecard. The first scorecard was released in 2018 and provided measures that were voluntarily reported by states. The three areas of the scorecard focuses on: State Health System Performance, State Administrative Accountability and Federal Administrative Accountability. In this latest round, updated data was provided on the State Health System Performance pillar pages.
- Announced support for pregnant women, mothers and babies impacted by SUD. Resources for all groups can be found under the, Caring Recovery for Infants and Babies bulletin here, and the Help for Moms and Babies bulletin here. They contain information on how provisions under the SUPPORT Act of 2019 provide new coverage options for state Medicaid programs to help mothers, babies and pregnant women who are dealing with SUD. This includes services and options for children neonatal abstinence syndrome and women in need of SUD treatment and recovery services in pre- and post-natal conditions.
Providers and Payments:

- HHS and CMS announced the CMS Primary Cares Initiative. This will be a new set of payment models used to deliver care for patients while looking at ways to reduce administrative burdens and encourage primary care providers to spend more time with patients. The models will be developed by the Innovation Center.

- The five payment model options are:
  - **Primary Care First (PCF) and Primary Care First-High Need Populations**: These two will test whether financial risk and performance-based payments that reward primary care practitioners and other clinicians are easy to understand and have actionable outcomes that will reduce Medicare expenditures. They will provide payment to practices through simplified total monthly payment as well as an option with higher payments to practices that specialize in care for high-need patients including those with chronic conditions.

  - Both models incentivize providers to reduce hospital utilization and total care by rewarding them through performance-based payment adjustments. The PCF model will be tested for five years and will start in January 2020.

  - **Direct Contracting- Global, Professional and Geographic**: These three options are focused on primary care allowing providers managing care for Medicare fee-for-service (FFS) beneficiaries. This model looks to engage primary care practice sites and a wider variety of organizations that have worked with financial risk and serving larger patient populations like: Accountable Care Organizations (ACOs), Medicare Advantage plans and Medicaid managed care organizations. When these organizations deliver greater system efficiencies and better quality of care, they will be financially rewarded. Options for this model will focus on patients with complex, chronic needs.

    - The type of payment models an organization participates in will receive a fixed monthly payment ranging from a portion of expected primary care costs up to the total cost of care. Those in the global payment option of this model will take on full financial risk while those in the professional model will share financial risk with CMS.

    - CMS and HHS are aiming to better align care for Medicare and Medicaid dual eligible patients in an FFS, offer new participation and payment options to primary care and other related providers, and provide a new way of coordinated care for dually eligible Medicare and Medicaid beneficiaries enrolled specifically in Medicaid managed care and FFS.
May 2019

Providers:
- HHS released a rule that would expand faith-based protections for healthcare personnel. Under the rule, health care providers, insurers and employers can refuse to provide or pay for certain medical services such as abortion, sterilization or assisted suicide, if they violate providers’ moral or religious beliefs. The rule also includes language around parents’ rights to refuse several specific types of care for their children. Under the rule the HHS Office for Civil Rights will require health-care providers to maintain records and report with any of the office’s requests.

Prescription Drugs:
- CMS announced a final rule that would have required pharmaceutical companies to disclose list prices for prescription drugs over $35 that were covered by Medicare or Medicaid in television ads. This was a follow up action item from the administration’s American Patients First blueprint. Right before the rule was to take effect this July, a federal judge overruled it.

June 2019

Health Insurance:
- HHS along with the Departments of Labor and Treasury released a final regulation to expand the use of health reimbursement arrangements (HRAs). The rule will permit employers offering traditional group health plans an excepted HRA benefit of up to $1,800 per year, even if the employee doesn’t enroll in the traditional group help plan. They can reimburse an employee for certain qualified medical expenses including premiums for vision, dental and short-term, limited duration insurance. The regulation will start in January 2020 and will also allow employers to use individual coverage HRAs to their employees with tax-preferred funds to cover the costs of health insurance coverage they purchase in the individual market, subject to certain conditions. Conditions would include a notice requirement to ensure employees are aware of the benefit. The General Accounting Office also did an assessment of the rule.

Public Health:
- Released $1 million in Ryan White HIV/AIDS Program grants to 10 metropolitan areas through the Health Resources and Services Administration (HRSA). These grants will go to what are known as Part A jurisdictions under the Ryan White HIV/AIDS Program, and will provide technical assistance as part of larger efforts announced by the administration to end the HIV epidemic. Activities funded under the grants will include: community engagement, enhancing core medical and support services, infrastructure support and information dissemination efforts.

Providers and Payments:
- President Donald Trump signed an executive order (EO) regarding medical billing practices. The EO addressed different measures on healthcare transparency and pricing. After the release of
the EO there will be 60 days where HHS will propose a regulation requiring hospitals to publicly post billing information based on negotiated rates for common health items and services.

-HHS, the Department of Treasury and the Department of Labor will issue a proposed rule asking for comments on other billing aspects. HHS will also work with the U.S. attorney general and the Federal Trade Commission to issue a report on current private sector practices on health care pricing and transparency.

-Another report will also be developed by HHS, the Departments of Defense and Veterans Affairs called the Health Quality Roadmap, which will evaluate data and quality measures across Medicare, Medicaid, CHIP, the Health Insurance Marketplace, the Military Health System and the Veterans Affairs Health System.

**July 2019**

**HHS Priorities:**

- In a speech before the organization, Better Medicare Alliance, HHS Secretary Alex Azar outlined several administrative health priorities. The priorities were under the following areas: reform financing, delivering value, and improving health.

  - **Reforming Financing:** emphasis on protecting Medicare and private insurance, protections for those with preexisting conditions, the ability of the Medicare Advantage program to be a more flexible choice for seniors, opposition to proposals on creating a Medicare for All program and emphasis on providing different insurance options including short-term insurance association health plans and health reimbursement arrangements.

  - **Delivering Value:** part of the HHS Secretary's initial priorities in this area on transparency around price and quality for medical services, advancing patient-centered health IT, reforming regulations, moving from paying from medical procedures to paying for outcomes and lowering prescription drug costs.

  - **Improving Health:** discussed the administration’s announcement from this year’s State of the Union on tackling the HIV epidemic that focused on where half of all new HIV infections are occurring and the plan to end the epidemic in the U.S. within 10 years, addressed maternal mortality and morbidity as the U.S. continues to have one of the highest maternal mortality rates in the developed world. Also discussed looking at ways to develop a comprehensive strategy that will improve payment incentives, boost adoption of best health care practices and addressing preventable risks as well as strategies to work on these issues in rural communities, among several other initiatives being worked on.
**Health Insurance:**
- A federal judge upheld the administration’s expansion of short-term plans. A U.S. district judge in Washington ruled against health insurance companies that sued the administration after they finalized a rule to expand different parameters of these types of plans. Short-term plans will last up to 12 months instead of three. The plans originally were created as a short-term gap option for consumers as they often don’t cover benefits to the extent most exchange and employer plans do.

**Substance Abuse Disorder and Behavioral Health:**
- Published a report to Congress on the agency’s Action Plan to carry out certain requirements under the SUPPORT for Patients and Communities Act. The Action Plan provides technical assistance and support to states in developing and expanding innovative state strategies and providing housing-related supports and services related to care coordination for patients with substance use disorders.

**Funding Announcements:**
- Announced $20 million through HRSA to 27 organizations in Rural Residency Planning and Development Program (RRPD) grants. The organizations chosen represent recipients across 21 states to receive $750,000 over a three-year period to develop new rural residency programs and getting accreditation for the programs. The RRPD program is run by HRSA’s Federal Office of Rural Health Policy and Bureau of Health Workforce. Both are working on a multi-year initiative by HRSA to expand the physician workforce in rural areas. Recipients of the awards include rural hospitals, community health centers, health centers operated by the Indian Health Service, Indian tribes or tribal organizations and schools of medicine.

- Awarded $42 million to fund 49 Health Center Controlled Networks (HCCNs) through HRSA. Funding will help over 1,183 federally funded health centers across all 50 states, the District of Columbia and Puerto Rico to expand the use of health information technology. HCCNs are groups of health centers that work together to improve operation and clinical practices by making technology easier for providers and patients to use while increasing patient information and security.

---

**NIH May 2019:**
- The National Institute of Health (NIH) released updates and materials for its program “All of Us,” a program that was launched in 2018 to enroll 1 million Americans from diverse communities. Since the program has started, more than 230,000 people have joined, and almost 80% of participants come from communities that have been historically underrepresented in biomedical research. For a list of upcoming events including state listening sessions click here.
June 2019:

- The administration announced it will no longer fund medical research using fetal tissue. NIH funds around 200 external research projects that use fetal tissue but there are only three NIH-run projects that will be affected.