



Information Alert

State-Federal Relations Division

Over the past few months President Donald Trump's administration has made several announcements regarding health policies. Below is an overview of those relevant to health programming and policies in the states. If you have additional questions, please email haley.nicholson@ncsl.org.

Announcements from the Food and Drug Administration

- Earlier this year former Federal Drug Administration Commissioner Scott Gottlieb made an announcement regarding [new programs](#) to: work with all stakeholders to streamline the prescription drug approval process, provide flexibility in prescription drug manufacturing and lower manufacturing and prescription drug costs. These new programs will not change the current federal requirements or provisions on drug manufacturing and will not deter the Federal Drug Administration (FDA) from upholding high standards for prescription drug quality.
- The FDA released guidance encouraging drug companies to enter the over-the-counter market to [increase access to naloxone](#). The FDA worked to develop a model with easy to use instructions. This was crafted to increase access for communities to naloxone, which can reverse the effects of an opioid overdose.
- As Gottlieb is nearing the end of his tenure he has laid out several initiatives including a roadmap for drug compounding. The FDA will be issuing guidance, proposing rules and hosting a public meeting and listening sessions focusing on: maintaining quality drug manufacturing and compliance, creating lists of bulk drug substances, finalizing FDA's partnership with states and clarifying compounding requirements for hospitals and health systems.
- A full list of FDA press releases and news can be found [here](#).

Announcements from the Centers for Medicare and Medicaid Services

- Building on previous guidance and in compliance with the SUPPORT for Patients and Communities Act, Centers for Medicare and Medicaid Services (CMS) released a bulletin, [Medicaid Strategies for Non-Opioid Pharmacologic and Nonpharmacologic Chronic Pain management](#). The document provides states with information on mandatory and optional items and services for non-opioid treatment and pain management that is given under the state

Medicaid program, and outlines what Medicaid authorities' states can use for these types of pain management therapies.

- Earlier this year, CMS closed a comment period on a [proposed rule](#) that would change Medicare Advantage regulations and the Prescription Drug Benefit program (Part D) to support health and drug plans negotiations by providing more flexibility that could lower prices and reduce out-of-pocket drug costs for Part C and D enrollees. The rule looked at making changes for Part D plan sponsors to address the areas of: prior authorization and step therapy, current practices around protected class drugs and pricing practices for existing and current drugs under the program. CMS recently issued the final rule. Insurers' average payments will increase from those in the proposed rule but with a lower average payment rate in 2018. Implementation of these policies will begin in 2020.
- A new service delivery model between ambulance suppliers and providers with qualified health care practitioners was announced by CMS. The [Emergency Triage, Treat and Transport \(ET3\)](#) model will allow medical providers to work together to provide treatment on the scene, via telehealth, and with alternative destinations to provide services to Medicare beneficiaries who are accessing care through 911 services. This model is encouraging providers in primary care and urgent care settings to develop access to services for low-acuity 911 calls. Implementation will start in early 2020 and will continue over a five-year period.
- CMS released updated guidelines for state monitoring and evaluation efforts for [1115 waivers](#). Guidelines include templates states can use for 1115 waiver implementation and required quarterly and annual monitoring data to CMS. They also released further guidance to states interested in applying for [work and community engagement requirements](#) within an 1115 waiver application, including how to test if these kinds of programs can assist with increasing or sustaining employment.
- Updated guidance was [released to State Medicaid Directors](#) regarding activities for home and community based services (HCBS). This guidance allows states to clarify the processes by which states can demonstrate to CMS that a setting does not have the qualities of a HCBS institution but does have similar qualities of a home and community-based setting. This was released to provide further guidance on a 2014 CMS rule on HCBS standards of [heightened scrutiny](#).
- An overview of these topics and other CMS news can be read [here](#).

Announcements from the Department of Health and Human Services

- Health and Human Services (HHS) released their 2019 Annual Performance Plan and Report. Read the entire report [here](#).
- HHS released a proposed rule on a number of [health insurance parameters and payments](#). The actions within this rule builds upon steps taken by CMS under the 2017 Market Stabilization Rule and the 2019 Payment notice. The provisions covered under this rule include:

- **Exchange and Qualified Health Provisions and Direct Enrollment:** For insurance plan years in 2019 on non-exchange websites.
 - **Navigator Programs under Federally-facilitated Exchanges:** Increases flexibility around requirements and training for navigators.
 - **Prescription Drug Benefit:** HHS will work to align with the White House’s Patients First Blueprint proposed policies on prescription drug pricing as permitted by applicable state law.
 - **Segregation of Funds for Abortion Services:** Offers health insurance plan options that encourage qualified health plans that provide coverage of non-Hyde Amendment abortion services starting in 2020, and to the extent allowed under state law.
 - **Silver Loading:** Proposed support of Cost Sharing Reduction payments, and asked for input on what stakeholders thought of [silver loading](#) state-based exchange plans.
 - **Payment Parameter Provisions:** Starting with 2020 insurance plan years proposes using payment parameters to use data from the three previous years to determine future risk adjustment practices and encouraged moving away from previous databases that were used for individual and small group market populations.
 - These are several of the proposed changes that were included in the rule; for additional resources [read here](#). Key dates on the implementation of these different proposals can be found [here](#). This 2020 Notice of Benefit and Payment Parameters has been under review by the White House Office of Management and Budget.
- HHS released two proposed rules addressing the [interoperability and required sharing of patient data](#) between hospitals, doctors and electronic health record developers on providing health information on patients, insurers and digital health innovators. These proposed rules consider using existing CMS authority to require health care providers to use standardized methods of sharing data including standards that use web-based technologies in other sectors like banking, and encourage an increase in consumer-facing apps. These rules were developed partly because of the 21st Century Cures Act around the law’s different requirements for acceptable exemptions and information-blocking rules.
 - For more HHS announcements, [read here](#).