

Health Policy Update – March 24, 2020

President Declares National Emergency for COVID-19

On March 13, President Trump issued a Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. The declaration empowers the Secretary of Health and Human Services (HHS) to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance programs and of the Health Insurance Portability and Accountability Act throughout the duration of the public health emergency.

Notably, this action, in combination with the first COVID-19 response bill passed by Congress, led to an expansion of allowable telehealth services under Medicare. Under the new waiver authorities, Medicare patients will be eligible for telehealth services regardless of location (including patient homes), effective for services provided on or after March 6, 2020.

To read the national emergency declaration, [CLICK HERE](#).

To read the press release from CMS on the new regulatory flexibilities under the national emergency declaration, [CLICK HERE](#).

To read FAQs on the new Medicare telehealth authorities, [CLICK HERE](#).

Congress Passes Second COVID-19 Response Package, Prepares Phase Three

Last week, President Trump signed the Families First Coronavirus Response Act (H.R. 6201) into law, the second COVID-19 response bill largely aimed at supporting critical safety net programs and expanding access to coronavirus testing and treatment. A third legislative package, which is meant to provide relief for businesses and individuals impacted by recent efforts to curtail the spread of the virus is currently being negotiated by lawmakers and the White House.

The Families First Act would require many small businesses to provide paid sick and medical leave, increase funding for nutrition assistance and unemployment benefits, and expand coronavirus testing and treatment without cost-sharing. Specifically, the bill includes provisions that

- establish a new federal paid sick leave program requiring employers to provide two weeks of paid leave to employees directly affected by the coronavirus outbreak;
- expand the Family and Medical Leave Act (FMLA) requiring employers to provide up to ten weeks of paid FMLA to employees caring for their own child during the outbreak;
- clarify that new Medicare beneficiaries qualify for expanded telehealth services;
- increase funding for unemployment benefits and related grants to states;
- expand access to coronavirus testing and treatment without cost-sharing;
- temporarily increase the Medicaid federal medical assistance percentage (FMAP) for eligible states and territories; and
- provide supplemental appropriations for nutrition and food assistance programs

The Families First Act builds on an earlier supplementary funding bill signed into law on March 6 that appropriates \$8.3 billion to support federal efforts to prevent, prepare for and respond to the pandemic. That package included billions in

additional funding for procure medical supplies and supplement the Strategic National Stockpile and support the Centers for Disease Control and Prevention, the National Institutes of Health, the FDA, the State Department and other federal agencies in their response to the ongoing public health crisis.

To view the text of the bill, [CLICK HERE](#).

To read a summary of the bill, [CLICK HERE](#).

CMS Releases Recommendations on Elective Surgeries During COVID-19 Response

On March 18, the Centers for Medicare & Medicaid Services (CMS) announced recommendations to delay all elective surgeries, and non-essential medical, surgical, and dental procedures during the COVID-19 pandemic. According to CMS, this will not only preserve equipment but also free up the health care workforce to care for the patients who are most in need and allow patients to remain at home to limit the spread of the virus.

The recommendations provide a framework for facilities and clinicians to implement immediately. According to CMS, decisions about proceeding with non-essential surgeries and procedures should be made at the local level by the clinician, patient, hospital, and state and local health departments and based on patient risk, availability of beds, staff and personal protective equipment, and the urgency of the procedure.

The new recommendations come after United States Surgeon General Jerome Adams, MD urged hospitals across the country to suspend elective procedures amidst the coronavirus emergency as well as recommendations from the American College of Surgeons (ACS), which called on health systems to "thoughtfully review" all scheduled operations and consider canceling or postponing them "until we have passed the predicted inflection point" in the disease spread and "can be confident that our health care infrastructure can support a potentially rapid and overwhelming uptick in critical patient care needs."

The American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, and the Children's Hospital Association also sent a letter to the Surgeon General recommending that providers be allowed to make determinations for canceling elective and nonurgent procedures based on a case-by-case evaluation of factors, rather than a blanket directive.

To read CMS' recommendations, [CLICK HERE](#).

To read the ACS recommendations, [CLICK HERE](#).

To read the joint letter sent to the Surgeon General, [CLICK HERE](#).

White House Releases Drug Pricing Principles, CBO Releases Score for Senate Finance Committee Bill

In an op-ed published in the *Wall Street Journal* March 10, White House Domestic Policy Council Director Joe Grogan outlined a list of five principles the Administration is urging Congress to adhere to when crafting legislation to address drug prices. The principles, which strongly echo the content of a bipartisan Senate bill that passed the Finance Committee last year are:

- Cap annual out-of-pocket expenses in Medicare Part D.
- Provide an option to cap monthly expenses, allowing beneficiaries to spread costs throughout the year.

- Protect beneficiaries from a new coverage gap that could increase some seniors' out-of-pocket costs by as much as \$1,250 annually.
- Increase the share of drug costs insurers have to pay once seniors have hit the annual out-of-pocket maximum, encouraging them to negotiate better prices.
- Limit drug manufacturers' annual price increases without jeopardizing future innovation.

Separately, the Congressional Budget Office (CBO) released an updated cost estimate for the Finance Committee bill, which is co-sponsored by Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR). The CBO found the bill would save the government \$94 billion over 10 years, reduce seniors' out-of-pocket spending by \$72 billion and reduce premiums by \$1 billion. The cost estimate includes the addition of a new measure that would reduce Part D beneficiaries' co-insurance from 25 percent to 20 percent.

To read Joe Grogan's op-ed on the White House's drug pricing principles, [CLICK HERE](#).

To read the updated CBO cost estimate of the Senate Finance Committee bill, [CLICK HERE](#).

New Medicare Part D Model for Insulin Released

On March 11, the Centers for Medicare & Medicaid Services (CMS) announced a new model that would lower out-of-pocket insulin costs for seniors with Medicare Part D.

This voluntary model would allow Part D sponsors to cap seniors' copays for insulin at \$35 per month, saving them as much as \$446 annually. Coinciding with the model's announcement, CMS released two Request for Applications (RFAs), one for Part D sponsors and one for pharmaceutical manufacturers, and both are invited to apply to participate beginning January 1, 2021.

To encourage sponsor participation, CMS would provide additional risk corridor protection for calendar years 2021 and 2022 for plan benefit package (PBP) that have higher enrollment from insulin-dependent diabetic patients. Eligible pharmaceutical manufacturers would also volunteer to participate in the model by responding to the RFA and executing a model-specific contract addendum to the Manufacturer Coverage Gap Discount Program.

To view a fact sheet on the Part D Senior Savings Model, [CLICK HERE](#).

HRSA to No Longer Issue 340B Guidance, Citing Limited Authority

The Health Resources and Services Administration (HRSA) is no longer planning to issue new guidance on the 340B program according to reporting by *Inside Health Policy*.

HRSA had previously told the Government Accountability Office (GAO) that it does not have appropriate statutory authority to implement the GAO's recommendations or otherwise enforce or clarify the definition of eligible patients and hospitals under the program. This sentiment was echoed in HRSA's FY2021 budget justification released alongside the Administration's budget proposal.

A senior HRSA official reportedly told *Inside Health Policy*, "Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures program requirements across all the interdependent aspects of the Program are met."

The Administration's FY 2021 budget includes such a request for additional authority that would enable it to better regulate the program, including which patients and hospitals are eligible to receive 340B drug discounts.

To read HRSA's FY2021 budget justification, [CLICK HERE](#).

NCCN Releases Recommendations for Standardizing Quality Measurements in Oncology

On March 10, the National Comprehensive Cancer Network (NCCN) published a curated list of high-impact measures for assessing quality improvements in cancer care. The article, "Quality Measurement in Cancer Care: A Review and Endorsement of High-Impact Measures and Concepts," was published in the March 2020 issue of *Journal of the National Comprehensive Cancer Network*.

After reviewing 528 existing oncology quality measures and new measure concepts that could be appropriate for development, the committee created 22 recommendations based on importance, supporting evidence, opportunity for improvement, and ease of measurement.

Robert W. Carlson, MD, CEO of NCCN said, "These recommendations from NCCN differ from certification programs—we are sharing them free-of-charge to allow cancer programs everywhere to be more efficient and focused with their resources while tracking quality improvements."

To read the full list of measures, [CLICK HERE](#).

Report Shows Decline in Cancer Death Rates

On March 12, the National Cancer Institute published a new report finding that cancer death rates decreased by an average of 1.5 percent per year from 2001 to 2017. The report, titled "Annual Report to the Nation on the Status of Cancer," was published in the journal *Cancer*.

These decreases were seen in all major racial and ethnic groups and among men, women, adolescents, young adults, and children. In addition to the report, researchers released a companion paper assessing the progress toward the federal government's 10-year national objectives known as "Healthy People 2020." Researchers identified progress in four common cancers: lung, prostate, female breast and colorectal.

The paper found that Healthy People 2020 targets for reducing death rates were met for all cancers combined as well as for lung, prostate, female breast, and colorectal cancers overall.

To read the full report, [CLICK HERE](#).

To see the "Healthy People 2020" indicators, [CLICK HERE](#).