



## COVID-19: Key Federal Regulatory Documents

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Updated: March 26, 2019

This memo updates our key documents from CMS, FDA and other agencies initially reported on March 19. For the complete list of CMS documents related to COVID-19, click [here](#).

### HHS:

Resources for Hospitals and Healthcare Professionals Preparing for Patients with Suspected or Confirmed COVID-19 – click [here](#) (3/25/20)

Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19, Hoarding Prevention Measures Under Executive Order – click [here](#) (3/25/20)

### CMS:

New Guidance Regarding Enhanced Medicaid Funding for States – Federal Medical Assistance Percentage (FMAP) Frequently Asked Questions (FAQs) – click [here](#) (3/26/20)

Guidance on Payment and Grace Period Flexibilities for Issuers Offering Coverage on the Federally-facilitated Exchanges and State-based Exchanges on the Federal Platform – click [here](#) (3/24/20)

### FDA:

Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry - click [here](#) (3/25/20)

FDA added hydroxychloroquine sulfate to category 1 under the Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act – click [here](#) (3/25/20)

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### CMS:

CMS Approves 11 Additional Medicaid Section 1135 Waivers – click [here](#) (3/23/20)

CMS Reporting Requirement Exceptions and Extensions - click [here](#) for details (3/22/20)

Click [here](#) for CMS checklists and tools (3/22/20) to permit states to

- access emergency administrative relief,
- make temporary modifications to Medicaid eligibility and benefit requirements,
- serve individuals with disabilities and the elderly in their homes, and
- modify payment rules

### HRSA:

HHS Awards \$100M to Health Centers for COVID-19 - Click [here](#).

#### FEMA:

FEMA Funds Available for Not-For-Profit Providers - click [here](#) for details.

#### FDA:

FDA's Updated Guidance on Ventilators - click [here](#) for the letter and [here](#) for the detailed guidance document (3/22/20)

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National emergency designation -click [here](#). (3/13/20)

#### Elective Surgeries:

Click [here](#) for the one-page overview and [here](#) for the two-page recommendation to limit non-essential planned surgeries and procedures. (3/18/20)

#### Waivers:

- Blanket waivers for COVID 19: Click [here](#) for the CMS Fact Sheet and [here](#) for the CMS press release. (3/13/20)
- For additional waivers, click [here](#) for the 1/31/20 Public Health Emergency declaration.

#### Coverage Guidance:

- [Frequently Asked Questions to Assist Medicare Providers \(PDF\)](#) (3/6/20)
- Fact sheet: [Medicare Coverage and Payment Related to COVID-19 \(PDF\)](#) (3/5/20)
- Fact sheet: [Medicaid and CHIP Coverage and Payment Related to COVID-19 \(PDF\)](#) (3/5/20)
- FAQs for Medicaid and CHIP, click [here](#). (3/12/20)
- CMS Guidance re Medicare Advantage and Part D Plans. Click [here](#) for the Press release and [here](#) for the Memorandum. (3/10/20)

#### Clinical and Technical Guidance:

- EMTALA requirements related to COVID-19 click [here](#). (3/9/20)

#### Billing & coding guidance:

- [Frequently asked questions about Medicare fee-for-service emergency-related policies and procedures \*\*without\*\* an 1135 waiver \(PDF\)](#) (3/16/20)
- [Frequently asked questions about Medicare fee-for-service emergency-related policies and procedures \*\*with\*\* an 1135 waiver \(PDF\)](#) (3/16/20)
- Fact sheet: [Medicare Administrative Contractor \(MAC\) COVID-19 Test Pricing \(PDF\)](#) (3/13/20)

- [COVID-19: New ICD-10-CM Code and Interim Coding Guidance](#) (2/20/20)

Telehealth:

- Click [here](#) for the CMS Fact Sheet, including billing information; click [here](#) for the FAQs. (3/17/20)
- For the OIG Policy Statement, click [here](#) and [here](#) for the OIG Fact Sheet. (3/17/20)

Facemasks/respirators:

- Click [here](#) for the CMS press release and [here](#) for CMS Memo; Click [here](#) for FDA Press Release (3/10/20)

Laboratories:

- FDA Regulatory Relief for Diagnostic Testing, click [here](#) (3/16/20)

If you have questions, please feel free to contact any member of the Strategic Health Care team at 202-266-2600.