

March 19, 2020

New Information on Elective Surgery, PPE Conservation and Additional COVID-19 Issues

Also flexibility on COVID-19 testing, production of medical supplies and COVID-19 diagnosis coding

The Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), as well as other organizations, have released a number of new documents and other information related to COVID-19. This includes:

- Recommendations for handling elective surgeries in response to COVID-19;
- Updated strategies for providers to optimize the use of personal protective equipment (PPE), including eye protection, isolation gowns, facemasks and N-95 respirators;
- Updated Food and Drug Administration (FDA) guidance on COVID-19 testing;
- The granting of authority to the Secretary of Health and Human Services (HHS) to prioritize the production and distribution of certain medical supplies and equipment; and
- A new effective date for the ICD-10-CM diagnosis code for COVID-19.

Key Takeaways

New information related to COVID-19 includes:

- Recommendations and considerations for postponing elective surgeries.
- A series of updated strategies for optimizing PPE supplies when operating at conventional, contingency and crisis supply levels.
- Guidance allowing states to take responsibility for tests developed and used by laboratories in their states.
- The granting of authority to HHS to require companies to accept and prioritize contracts from the government and to prioritize the production and distribution of certain medical supplies and equipment to the nation's health care system and others most in need at this time.
- A new effective date of April 1 for the ICD-10-CM diagnosis code for COVID-19.

What You Can Do: Please share this advisory with your executive management team, hospital epidemiologist, infection control leadership, emergency department (ED) director, emergency preparedness staff, employee health staff and heads of services (e.g., environmental services, resources and materials managers, hospital engineers pediatrics and critical care), billing department, as well as your clinical leadership team.

The following are select highlights from the documents that are important to hospitals and health systems.

HIGHLIGHTS OF THE RESOURCES

Guidance on Elective Surgeries. CMS last night set forth a [tiered framework](#) that hospitals and health systems could use to evaluate whether to provide elective surgeries during community spread of COVID-19. CMS provides recommendations on whether to perform or postpone the surgery based on the urgency of the procedure, health of the patient and surgical setting. Among other factors, CMS said providers should consider the supply of PPE equipment in the region, ventilator availability and staffing availability.

CMS emphasizes that decisions are left up to the local delivery systems, including state and local health officials and surgeons who have direct responsibility to their patients. The agency intends to refine the guidance over the duration of the COVID-19 outbreak based on feedback from subject matter experts.

In a statement AHA said, “America’s hospitals and health systems are intensely focused on the challenge of dealing with COVID-19 as they continue to provide medical care for patients and work to protect their communities. We simply could not manage this crisis without the hard-working and dedicated physicians, nurses and other front line staff who care for patients and maintain our facilities and equipment.

“As we make additional preparations, it’s important to recognize that the cancellation of elective procedures – which the medical community needs to be prepared to implement – should be determined at the local, community level in consultation with hospitals and the clinical recommendations of physicians and nurses. It is important to recognize the definition of ‘elective’ procedures includes important life saving measures that will continue to be necessary. In issuing this framework, CMS took an appropriate step that provides a balanced approach to address this matter.”

Strategies for Optimizing PPE. The CDC [issued](#) an updated series of strategies for optimizing PPE supplies. This includes distinct guidance for conventional, contingency and crisis supply levels with regard to eye protection, isolation gowns, facemasks and N-95 respirators. For example, CDC states that when no facemasks are available, possibilities include reusing or producing homemade versions of masks (for example, bandanas or scarfs), which would ideally be used in combination with a face shield that covers the entire front and side of the face. CDC states that in the absence of gowns, the following are preferable: disposable laboratory coats, reusable (washable) patient gowns, reusable (washable) laboratory coats, disposable aprons or a combination of clothing to protect from exposure to body fluids.

Updated FDA Guidance on COVID-19 Testing. The FDA March 17 [issued](#) several updated policies on testing for COVID-19. First, FDA is putting in place a policy that will allow states to take responsibility for tests developed and used by laboratories in their states, similar to the action the FDA granted to the New York State Department of Health last week. Laboratories developing tests in these states can engage directly with the appropriate state authorities, instead of with the FDA. These laboratories will not have to pursue an Emergency Use Authorization (EUA) with the FDA.

In addition, FDA expands application of a policy originally outlined in Feb. 29 guidance. Specifically, FDA will allow commercial test manufacturers to distribute, and labs to use, new commercially developed tests prior to the FDA granting an EUA. The policy was originally applicable only to laboratories certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments.

Allocation of Resources. The President March 18 issued an [Executive Order](#) that invokes the [Defense Production Act](#) to expand production of PPE and ventilators and other emergency medical supplies to ensure that the healthcare system is able to surge capacity and capability to respond to the spread of COVID-19. Under the EO, the Secretary of HHS is granted the authority to require companies to accept and prioritize contracts from the government in order to “promote the national defense” for health and medical resources, or in this case to produce PPE, ventilators, and any additional other specific health and medical resources he deems to be scarce and critical. The Secretary also has the authority to “allocate materials, services, and facilities as deemed necessary or appropriate to promote the national defense.” In doing so, HHS, in consultation with the Secretary of Commerce and other heads of federal agencies, may determine “nationwide priorities and allocations of all health and medical resources, including controlling the distribution of such materials (including applicable services) in the civilian market, for responding to the spread of COVID-19 in the United States.”

New Diagnosis Code for Coronavirus. The CDC [announced](#) that its new ICD-10-CM diagnosis code U07.1, COVID-19, will be effective on April 1, 2020, instead of Oct. 1, 2020. This off-cycle update is an exception to the code updating process established under HIPAA.