CMS and IRS Release New Information on COVID-19

March 12, 2020

Guidance on EMTALA, Medicare Advantage/Part D, high-deductible health plans, facemasks, and home health agencies and dialysis centers

The Centers for Medicare & Medicaid Services (CMS) and the Internal Revenue Service (IRS) released a number of new documents related to COVID-19, including:

- Emergency Medical Treatment and Labor Act (EMTALA) requirements;
- Medicare Advantage (MA) and Part D requirements and flexibilities;
- Cost-sharing for high-deductible health plans;
- Respirator and facemask use for health care workers; and
- Health and safety for home health agency (HHA) and dialysis providers.

Please share this advisory with the appropriate individuals in your organization (e.g., executive team, epidemiologist and infection control, emergency department (ED) staff, emergency preparedness staff, employee health and heads of services (e.g., environmental services, resources and materials managers, hospital engineers), billing department, clinical leadership team).

Select highlights from the newly released guidance that are important for hospitals and health systems are listed below.

**Highlights**

CMS and IRS have released a number of new documents related to COVID-19, including:

- Hospitals and health systems’ requirement to adhere to existing obligations for screening, stabilization and transfers under EMTALA, with latitude to establish screening sites away from the ED, but on the hospital campus.
- MA plans’ and Part D sponsors’ requirements and flexibilities to remove potential barriers to care, such as cost-sharing, prior authorization and limits on drug refills.
- IRS guidance to employers permitting the waiving of cost-sharing for employees in high deductible health plans.
- Clarifications around the acceptable uses of different types of respirators and facemasks for health care workers.
- Recommendations for screening and treatment of patients and staff at HHAs and dialysis centers.

**SUMMARY OF THE CMS AND IRS GUIDANCE**

**EMTALA:** CMS issued a memo to State Survey Agency (SSA) directors with information concerning implications of COVID-19 for their compliance with EMTALA. It includes a question and answer document specific to EMTALA obligations and COVID-19, which emphasizes the importance of reliance on Centers for Disease Control and Prevention (CDC) guidance regarding isolation and infection control measures. The document also includes a fact sheet for addressing increased surges in the numbers of patients presenting to the ED.

The guidance reinforces hospitals existing obligation for screening, stabilization and transfer, stating that hospitals and critical access hospitals are expected to consider current CDC guidance and public health officials in determining whether they have the capability to provide appropriate isolation required for stabilizing treatment and/or to accept appropriate transfers.

It does establish some latitude for hospital and health system for setting up screening sites away from the ED. Specifically, CMS states that alternative screening sites may be located in other buildings on a hospital’s campus or in tents in the parking lot, as long as they are determined to be an appropriate setting for medical screening activities and meet the clinical requirements of the individuals referred to these settings. Hospitals may also set up screening sites at off-campus, hospital controlled sites, and encourage the public to go to those sites instead of the hospital for screening. **However, an individual who presents to the ED or hospital campus may not be directed to go to one of these sites.**

**MA, Part D Requirements and Flexibilities:** On March 10th CMS issued guidance to MA plans and Part D sponsors that details the requirements on and flexibilities available to plans to help patients access care during a disaster or emergency. As part of the guidance, CMS reminded plans and sponsors that they are required to have, and should review, business continuity plans to address any potential operational disruptions during such a disaster or emergency.

**MA Plans:** MA plans in states where the governor has declared an emergency **MUST** take certain steps to reduce barriers to care. These include covering services at out-of-network providers at in-network cost-sharing and waiving gatekeeper referral requirements. Such MA plan benefit changes are not subject to the standard 30-day notice requirements. All changes must be uniformly provided to similarly situated plan enrollees who are affected by the disaster or emergency. **MA plans MAY** take other actions to assist beneficiaries, including:
• Waiving or reducing cost-sharing for COVID-19 laboratory tests, telehealth benefits or other services to address the outbreak.
• Expanding access to telehealth services beyond those approved by CMS in the plan’s benefit package.
• Waiving prior authorization requirements that would apply to tests for or treatments of COVID-19.

Plans that implement any of the above flexibilities must do so uniformly to similarly situated plan enrollees who are affected by the disaster or emergency. The Department of Health & Human Services (HHS) Office of Inspector General (OIG) has advised that plan actions consistent with this guidance would satisfy the safe harbor to the federal anti-kickback statute set forth at 42 CFR 1001.952(1).

Finally, CMS advised MA plans that the HHS Secretary could direct the Medicare Administrative Contractors (MACs) to pay providers directly for services provided to MA enrollees. If that occurs, the MACs would seek reimbursement from MA plans for the covered services.

**Part D Sponsors:** Part D of the Social Security Act requires that the rules on pharmacy network access “include adequate emergency access for enrollees.” As with previous presidential declarations of emergency or disaster, this authority gives Part D sponsors the ability to take certain actions to respond to expected disruptions in access to covered Part D drugs. Additionally, such steps also may be taken in states where the governor has declared an emergency or state of emergency resulting from COVID-19. The following actions provide mandatory and permissive options for Part D sponsors:

- **MUST** ensure enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when obtaining covered drugs from an in-network pharmacy cannot reasonably be expected.
- **MAY** relax “refill-too-soon” edits and allow for an enrollee to obtain the maximum extended day supply (if available and requested) if circumstances reasonably are expected to result in a disruption in access to drugs.
- **MAY** relax any plan-imposed policies that may discourage certain methods of delivery, such as mail or home delivery.
- **MAY** choose to waive prior authorization requirements that would otherwise be applied to Part D drugs used to treat or prevent COVID-19. NOTE: This option exists for Part D sponsors absent a disaster or emergency, as well.

CMS previously issued guidance on coverage and payment of COVID-19 under Medicare, Medicaid and the Children’s Health Insurance Program and the Individual and Small Group Markets.
**IRS Guidance to Employers:** The IRS issued guidance to employers that allows plans that are structured as high deductible health plans (HDHPs) to waive the deductible for testing and treatment of COVID-19 without putting the plans’ HDHP qualification at risk. Such qualification is necessary to protect the preferential tax treatment of employee contributions to health savings accounts. Such action is permitted until the IRS issues further guidance.

**Use of Respirators and Facemasks:** On March 10th CMS sent a memo to SSAs to clarify its policies on the use of respirators and facemasks by healthcare personnel. Specifically, the memo implements CDC guidance by stating that facemasks, which protect the wearer from splashes and sprays, are an acceptable temporary alternative to respirators, which filter inhaled air, for most medical services when the supply chain of respirators cannot meet demand. Until the supply chain is restored, available respirators should be prioritized for procedures that are likely to generate respiratory aerosols, which would pose the highest exposure risk to health care workers. Once the supply chain for respirators is restored, facilities with a respiratory protection program should return to use of respirators for patients with known or suspected COVID-19. Facilities that don’t currently have such a program, but care for patients infected with pathogens such as COVID-19 for which a respirator is recommended, should implement a respiratory protection program.

The memo also implemented the Food and Drug Administration’s (FDA) approval of a CDC request for an emergency use authorization (EUA) to allow health care workers to use certain industrial respirators during the COVID-19 outbreak in health care settings. The FDA concluded that respirators approved by the National Institute for Occupational Safety and Health (NIOSH), but not currently meeting the agency’s requirements, may be effective in preventing health care personnel from airborne exposure that can cause serious or life-threatening illness. This allows health care workers to use the NIOSH-approved respirators in a health care setting during the COVID-19 outbreak, even though they are not currently regulated by the FDA. The appendices to the EUA letter list approved Filtering Facepiece Respirators (FFRs) and can be found on FDA’s website (Appendix A and Appendix B).

The memo also alerts state surveyors that they are not required – on a temporary basis – to validate the date of a facility’s last annual test of the fit of N95 masks worn by workers in Medicare- and Medicaid-certified facilities, so as to minimize the number of discarded masks associated with such testing.

**HHAs and Dialysis Centers:** CMS’s guidance to HHAs echoes recommendations set forth by CDC, with specific information on:

- When it is safe to treat patients at home;
- When patients should be considered for hospitalization; and
- Recommendations for family member exposure when evaluating and caring for patients with known or suspected COVID-19.

CMS recommends HHAs remain vigilant, regularly monitor patients for symptoms, and communicate effectively with patients, family members and other caregivers. The guidance includes a frequently asked questions section.

For dialysis centers, CMS advises the identification of high-risk individuals prior to appointments or upon arrival. Patients with fever or symptoms of a respiratory infection, international travel within the last 14 days to restricted countries, and contact with someone with known or suspected COVID-19 should be screened immediately. CMS also recommends screening visitors, gives detailed instructions for staff who have either been exposed or are showing signs of illness, and provides an FAQ section.

Additional Resources
More information regarding COVID-19 can be found on the [IDPH website](https://www.idph.gov), [Chicago Department of Public Health website](https://www.chicago.gov/city/en/depts/health/servs/dph.html), [CDC website](https://www.cdc.gov), and [IHA website](https://www.ihaweb.org).