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HEALTH CARE ALERT | NIXON PEABODY LLP

March 9, 2020

COVID-19 health care update: CMS guidance — payment, surveys, lab testing and more

By Sarah Swank and Joanna Cohen

Government agencies are working to update guidance as they race to keep up with the developments related to novel coronavirus 2019 (COVID-19). On March 4, 2020, the Centers for Medicare & Medicaid Services (CMS) attempted to reassure the public and health care providers by issuing a press release regarding its commitment to ensuring that health care facilities are prepared to respond to the threat of COVID-19 and limit the spread of the disease. CMS issued three sets of guidance on March 4 and FAQs on March 5, 2020, detailing infection control, payment, and specific information for nursing homes and hospitals on addressing cases of COVID-19.

A call to action — infection control

CMS issued a call to action for health care providers to ensure that they have implemented infection control procedures, which are required as a condition of participation in the Medicare and Medicaid programs. Specifically, CMS is requiring all health care providers to immediately review their procedures to ensure compliance with CMS infection control requirements and the guidelines from the Centers for Disease Control and Prevention (CDC). CMS announced that it has deployed an infection prevention specialist to CDC's Atlanta headquarters to assist with real-time guidance development.

State surveys and inspections — *not* business as usual

CMS announced that effective immediately, all non-emergency inspections are suspended. State Survey Agencies and Accrediting Organizations will focus their facility inspections exclusively on issues related to infection control and other serious health and safety threats, such as allegations of abuse, beginning with nursing homes and hospitals. On March 4, CMS also issued three memoranda to State Survey Agencies, State Survey Agency directors, and Accrediting Organizations to inspect thousands of Medicare-participating health care providers across the country, including nursing homes and hospitals. The first memorandum lists the categories of surveys that will continue as part of CMS's focus on infection control and emergent issues. Notably, statutorily required inspections will continue in the 15,000 nursing homes across the country. Effective immediately, surveys will be limited to the following (in priority order):

- All immediate-jeopardy complaints (a situation in which an entity's noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm,

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serious impairment, or death or harm) and allegations of abuse and neglect;

- Complaints alleging infection control concerns, including facilities with potential COVID-19 or other respiratory illnesses;
- Statutorily required recertification surveys (Nursing Home, Home Health, and Hospice facilities, and immediate care facilities for Individuals with Intellectual Disabilities (ICF/IID));
- Any re-visits necessary to resolve current enforcement actions;
- Initial certifications;
- Surveys of facilities/hospitals that have a history of infection control deficiencies at the immediate-jeopardy level in the last three years; and
- Surveys of facilities/hospitals/dialysis centers that have a history of infection control deficiencies at lower levels than immediate jeopardy.

The memorandum also includes protocols for surveyors' investigations of facilities in which COVID-19 is identified or suspected. Specifically, surveyors must notify CMS of any COVID-19 confirmed case or presumptive positive case identified and, before initiating any federal compliant or recertification survey of the affected facility, CMS will coordinate with the CDC and other governmental agencies to approve the facility for survey. CMS will then approve an on-site survey of the affected facility if either (i) the reported conditions at the facility are triaged at immediate jeopardy or (ii) the complaint or reported incident involves infection control concerns in the facility. Other surveys will be conducted offsite. CMS provided key guidance on inspectors' use of adequate personal protective measures during an inspection in affected facilities.

COVID-19 in nursing homes and hospitals

In the other two memoranda, CMS provided critical answers to common questions that nursing homes and hospitals may have with respect to addressing COVID-19 cases.

- **Nursing Home Visitors.** CMS addressed restrictions on visitation, stating that nursing homes should screen visitors for the following:
  - International travel to restricted countries within the last 14 days;
  - Signs or symptoms of a respiratory infection, such as a fever, cough, and sore throat; and
  - Contact with someone with or under investigation for COVID-19.

  CMS further provides that nursing homes may restrict visitors meeting such criteria from entry to the facility and provides protocols for employees meeting such criteria. A facility may restrict or limit visitation rights for reasonable clinical and safety reasons, including "to prevent community-associated infection or communicable disease transmission to the resident. A resident's risk factors for infection (e.g., immunocompromised condition) or current health state (e.g., end-of-life care) should be considered when restricting visitors."
- **Hospital Visitors.** CMS states that hospitals should screen visitors, patients, and staff for the same criteria as nursing homes. Medicare regulations require hospitals to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights, and the reason(s) therefore such restrictions or limitations. CMS sub-regulatory guidance identifies infection control as an example of when clinical

restriction may be warranted. Patients must be informed of their visitation rights and any restrictions or limitations.

- **Transfers between Nursing Homes and Hospitals.** CMS detailed the process for transferring patients between nursing homes and hospitals in cases where COVID-19 is suspected or diagnosed; the circumstances under which providers should take precautionary measures (isolation and mask wearing) for patients and residents diagnosed with COVID-19 or showing signs and symptoms of COVID-19; and the considerations for discharge of patients with COVID-19.
- **Healthcare Professional Monitoring and Restrictions.** CMS advises that nursing homes should screen and monitor staff for the following:
  - International travel to restricted countries within the last 14 days;
  - Signs or symptoms of a respiratory infection, such as a fever, cough, and sore throat; and
  - Contact with someone with or under investigation for COVID-19.

  Health care providers with signs and symptoms of a respiratory infection should not report to work. Any staff who develop signs and symptoms of a respiratory infection while working should (i) immediately stop work, put on a facemask, and self-isolate at home; (ii) inform the facility's infection preventionist and include information about individuals, equipment, and locations the person had contact with; and (iii) contact and follow the local health department recommendations for next steps. Nursing homes should refer to the CDC guidance for exposures that might warrant restricting asymptomatic health care providers from reporting to work.

For more information, register for our webinar *COVID-19 Update — Health Care: Essential steps for hospitals and health care entities to prepare and respond now*, live on Tuesday, March 10, 2020, at 1:30 p.m. Eastern.

Medicare payment[1]

CMS previously provided guidance and code related to laboratory testing for COVID-19. Recent guidance and FAQs shed light on payment under original Medicare (i.e., Medicare fee-for-services) ("Original Medicare") and Medicare Advantage, as follows:

Medicare Fee-for-Service

- **Diagnostic Tests.** Medicare Part B typically covers medically necessary clinical diagnostic laboratory tests ordered by a health care provider, which are not generally subject to coinsurance or deductible, and medical necessary imaging tests, such as CT scans, as needed for treatment purposes for lung infections, which are subject to coinsurance and deductible. A new Healthcare Common Procedure Coding System (HCPCS) code (U0001) has been developed for health care providers and laboratories to bill for laboratory testing of patients for COVID-19 using the CDC's diagnostic testing panel. A second HCPCS code (U0002) has been developed to bill for COVID-19 testing using other techniques. The Medicare claims processing system will be able to accept these codes on April 1, 2020, for dates of service on

[1] See our prior alert, "Preparing for COVID-19: Eight essential steps for hospitals to protect patients, employees, and their communities."

or after February 4, 2020.

- **Inpatient Hospital Stays.** Medicare Part A covers medically necessary inpatient hospital care, which may be subject to coinsurance and deductible.
- **Inpatient Quarantines.** There may be Medicare beneficiaries with COVID-19 who do not need acute patient care but need to be quarantined in a private hospital room. Hospitals with both private and semiprivate rooms may not charge patients a differential for a private room if the private room is medically necessary. Patients who are otherwise ready for discharge and remain in the hospital under quarantine do not have to pay an additional deductible. If a beneficiary is a hospital inpatient for medically necessary care, Medicare will pay hospitals the diagnosis-related group (DRG) rate and any cost outliers for the entire stay, including quarantine. The DRG rate and any cost outliers include the payment for when a patient has to be isolated or quarantined in a private room.
- **Ambulatory Settings.** Medicare Part B covers medically necessary ambulatory services, including doctors' services, hospital outpatient department services, home health services, durable medical equipment, mental health services, and other medical services, which are generally subject to coinsurance and deductible.
- **Prescriptions.** When considering whether to pay for more than a 30-day supply of Part B drugs, Medicare and its contractors will consider each request on a case-by-case basis and make decisions locally. In general, local Medicare contractors will take into account the nature of the drug, patient's diagnosis, extent and likely duration of disruptions to the drug supply chain during an emergency, and other relevant factors to determine whether an extended supply of the drug was reasonable and necessary.
- **Vaccinations.** Medicare Part B pays for certain preventive vaccines (coinsurance and deductible do not apply). Medicare Part B pays for other vaccines directly related to medically necessary treatment of an injury or direct exposure to a disease or condition (subject to coinsurance and deductible).
- **Ambulance Services.** Medicare covers ground ambulance transportation when beneficiaries have to be transported to a hospital, critical access hospital, or skilled nursing facility for medically necessary services when transportation in any other vehicle could endanger the beneficiary's health. A ground ambulance may temporarily stop at a doctor's office without affecting the coverage status of the transport. Medicare may pay for an airplane or helicopter ambulance to a hospital if the beneficiary needs immediate and rapid ambulance transportation that a ground ambulance cannot provide. Should the nearest appropriate facility be unavailable during an emergency, Medicare may pay for transportation to another facility as long as it is the nearest facility available and equipped to provide the care. In some cases, Medicare may pay for limited, medically necessary, nonemergency ambulance transportation upon a doctor's order stating that it is medically necessary. Medicare pays for ambulance transports under its Ambulance Fee Schedule and coinsurance and deductible would apply.
- **Telehealth.** Medicare pays for "virtual check-ins" for patients to connect with their doctors and certain other practitioners with whom the patient has an established relationship if the communication is not related to a medical visit within the prior seven days and does not lead to a medical visit within the next 24 hours (or soonest appointment available). Medicare also pays for patients to communicate with their doctors through online patient

portals, which occur over a seven-day period. These communications must be initiated by the patient, although practitioners may educate beneficiaries about the availability of the service. In addition, beneficiaries in rural areas may use communication technology to have full visits with their physicians, provided that they occur at telehealth originating sites and meet other requirements. Medicare can also pay doctors for certain non–face-to-face care management services and remote patient monitoring services. All such telehealth services are subject to coinsurance and deductible.

Medicare Advantage

Medicare Advantage ("MA") is an alternative to Original Medicare. MA plans cover Medicare Part A and Part B services and usually prescription drugs covered under Part D. MA plans must cover all medically necessary Part A and Part B services covered under Original Medicare. MA plans can also cover items and services beyond those covered by Original Medicare.

MA plan enrollees are protected from "surprise billing," which is when an enrollee receives unexpected bills from out-of-network providers. When MA enrollees obtain plan-covered services in an HMO, PPO, or Regional PPO, they may not be charged or held liable for more than plan-allowed cost sharing. CMS has advised MA organizations that they may waive or reduce enrollee cost-sharing for COVID-19 laboratory tests effective immediately, provided they do so on a uniform basis. CMS consulted with the Office of Inspector General (OIG) and OIG advised that should an MA organization choose to voluntarily waive or reduce enrollee cost-sharing for COVID-19 laboratory tests, such waivers or reductions would satisfy the safe harbor to the federal anti-kickback statute set forth at 42 CFR 1001.952(l).

- **Telehealth.** MA plans may provide enrollees with access to Part B services via telehealth in any geographic area and from a variety of places, including a beneficiary's home. Therefore, it is possible that MA enrollees can receive clinically appropriate services for COVID-19 treatment via telehealth.
- **Prescriptions.** Part D Sponsors that offer prescription drug coverage must provide a standard level of coverage to ensure beneficiaries have adequate access to Part D drugs. Many sponsors offer plans with different levels of coverage that may exceed the minimum CMS requirements.
- **Vaccines.** Under current law, once a vaccine becomes available for COVID-19, Medicare will cover the vaccine under Part D. All Part D plans will be required to cover the vaccine.
- **Prior Authorizations.** MA organizations and Part D Sponsors may choose to waive plan prior authorization requirements that otherwise would apply to tests or services related to COVID-19.

Conclusion

CMS appears to be taking steps to ensure that health care facilities in the United States are prepared to respond to the threat of the COVID-19 and has provided guidance to support actions by hospitals and nursing homes to address potential and confirmed COVID-19 cases. CMS guidance mitigates the transmission of the disease, including with respect to screening, discharges, transfers, and visitation.

For additional information, please see the following materials published by CDC, CMS, and AHLA:

- Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease (COVID-19), Centers for Disease Control and Prevention, March 7, 2020.
- Coverage and Payment Related to COVID-19 Medicare, Centers for Medicare & Medicaid Services, March 5, 2020.
- CMS Announces Actions to Address Spread of Coronavirus, Centers for Medicare & Medicaid Services, March 4, 2020.
- Suspension of Survey Activities, Centers for Medicare & Medicaid Services, Ref: QSO-20-12-All, March 4, 2020.
- Guidance for Infection Control and Prevention Concerning Coronavirus Disease (COVID-19): FAQs and Considerations for Patient Triage, Placement and Hospital Discharge, Centers for Medicare & Medicaid Services, Ref: QSO-20-13-Hospitals, March 4, 2020.
- Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes, Centers for Medicare & Medicaid Services, Ref: QSO-20-14-NH, March 4, 2020.
- Responding to COVID-19—7 Steps for Hospitals to Protect Patients, Employees, and Communities, American Health Lawyers Association, March 4, 2020.

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