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March 2020

The Coronavirus Crisis—The Impact of Federal Liability Immunity, Waivers, and Guidance on Health Care Providers

As novel coronavirus (COVID-19) cases are identified daily, the federal government, through the Department of Health and Human Services and the Centers for Medicare & Medicaid Services, continues to address the pandemic through various measures that affect health care providers.

Recent federal government agency actions in response to COVID-19 include providing liability immunity for activities related to medical countermeasures against COVID-19, issuing specific 1135 waivers of certain federal regulations to provide additional flexibility to health care providers, providing guidance to health care providers on COVID-19 response efforts through state survey agency memoranda, updating available frequently asked questions related to COVID-19, developing new reimbursement codes for COVID-19 laboratory testing, and suspending many non-emergency CMS surveys to focus facility inspection resources on immediate jeopardy and complaints related to infection control and other serious health and safety threats.

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As suspected and new COVID-19 diagnoses increase in frequency, the U.S. Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS") are taking action to update or revise some federal health care regulatory policies with significant impact on health care providers. HHS and CMS are expected to continue issuing additional policies and guidance to support health care industry stakeholders that are at the front lines of containing and mitigating the pandemic. As the federal government and health care industry stakeholders learn more about this coronavirus from experts on the front line, CMS and other HHS agencies are releasing updated guidance and resource materials quickly with additional guidance expected to be released soon. The following summary highlights some of the recent actions HHS and CMS have taken since March 4, 2020, that impact health care providers.

PROVIDER LIABILITY IMMUNITY (EXCEPT FOR WILLFUL MISCONDUCT)

On March 10, 2020, HHS Secretary Azar issued a declaration pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act") to provide liability immunity for certain activities related to medical countermeasures against COVID-19. Immunity extends to individuals and entities that manufacture, distribute, administer, prescribe, or use "Covered Countermeasures" against claims of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration of use of Covered Countermeasures, except for claims involving "willful misconduct." Covered Countermeasures include "qualified pandemic or epidemic products" and drugs, biological products, or devices authorized for emergency use in connection with COVID-19. The declaration is retroactively effective as of February 4, 2020, and was published on March 17, 2020 in the Federal Register.

CMS WAIVERS UNDER SECTION 1135 OF THE SOCIAL SECURITY ACT (1135 WAIVERS)

On March 13, 2020, following federal declaration of a national emergency, CMS activated a limited number of "blanket" (all provider) 1135 Waivers that are retroactively effective as of March 1, 2020, including the following:

- Waiving the three-day inpatient stay requirement for coverage of skilled nursing facility services;
- Waiving the 25-bed limit for critical care hospitals;
- Allowing hospitals to bill for services provided to acute care inpatients housed in excluded distinct part units (e.g., inpatient rehabilitation facilities ("IRFs"), long-term care hospitals ("LTCHs"), skilled nursing facilities, cancer hospitals, psychiatric units, and children's hospitals) if the beds are appropriate for the acute care patients and patients' medical records note that such housing is caused by capacity issues related to the disaster or emergency;
- Waiving a new physician order, new medical necessity documentation, and the face-to-face examination currently required, to replace durable medical equipment that was lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the COVID-19 emergency;
- Allowing reimbursement for care provided to patients relocated to acute care hospitals from excluded inpatient psychiatric units and excluded inpatient rehabilitation units, and, in the case of IRFs, waiving the "60 percent" rule for existing IRFs;
- Allowing LTCHs to exclude patients stays where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement (which allows these facilities to be paid as LTCHs);
- Providing flexibilities for Medicare Administrative Contractors ("MACs") to extend timing requirements to home health agencies in emergencies for Outcome and Assessment Information Set data and to avoid auto cancellation of Requests for Anticipated Payments;
- Temporarily waiving out-of-state providers' state license requirements;
- Temporarily suspending certain Medicare enrollment provider screening requirements (such as application fee, criminal background check, and site visit) and establishing a hotline for providers to enroll and receive temporary Medicare billing privileges; and
- Extending timeline to file an appeal and waiving certain timelines and other requirements for processing appeals for claim denials under Medicare Fee for Service, Medicare Advantage, and Part D programs.

While many of these waivers will help improve access and care during the anticipated health care surge, CMS did not provide

blanket waivers for many other federal regulations that may require flexibility to comply with recent state and federal guidance related to patient triage, hospital discharge, and visitor restrictions at facilities.

Notably, CMS confirmed that providers may seek specific waivers from CMS Regional Offices. States may also submit requests for waivers to CMS regarding certain Medicaid and CHIP program requirements. On March 17, 2020, the first state waiver was granted for Florida facilitating flexibility for the state to waive prior authorization requirements, expedite provider enrollment, suspending skilled nursing home screening requirements, and allowing for alternative care settings in unlicensed facilities if a facility is evacuated. For more information about state and provider waivers, please see the CMS-issued fact sheet.

STATE SURVEY AGENCY GUIDANCE FOR HEALTH CARE PROVIDERS

On February 21, 2020, CMS updated its State Operations Manual to provide new guidance to surveyors for applicable Medicare Conditions of Participation and interpretative guidance, including new regulatory requirements related to Infectious Disease and Antibiotic Stewardship Programs for acute care hospitals and critical access hospitals. Also, since March 4, 2020, CMS has issued additional survey memoranda to provide information and guidance with respect to COVID-19. These memoranda provide specifically targeted advice to hospitals, hospital emergency departments, nursing homes (initial and most recent guidance issued March 13, 2020), hospice, home health agencies, and dialysis facilities. CMS addresses a variety of issues related to identification and treatment of patients with COVID-19, including the following:

- Screening staff and patients with questions about recent travel and severity of infection to determine hospitalization or self-isolation;
- Transferring patients between nursing homes and hospitals that have suspected or diagnosed COVID-19 cases;
- Precautionary measures for patients and residents who have been diagnosed or show symptoms of COVID-19;
- Emergency Medical Treatment and Labor Act requirements;
- Regular monitoring and effective communications with patients, family members, and other caregivers;
- Restricting all nursing home visitors and non-essential health care personnel, except for certain compassionate care situations, such as end-of-life;
- Advising all permitted nursing home visitors and any individuals who enter the facility to monitor for signs and symptoms of respiratory infection for 14 days and notify the facility immediately if symptoms occur; and
- Cancelling all communal dining and group activities at nursing homes and encouraging residents to practice social distancing.

Providers are also encouraged to consider the actions states and local governments may have taken, such as issuing emergency declarations or orders that may impact operational responses to CMS guidance. Please refer to the Jones Day *Commentary* entitled "The Impact of State Emergency Declarations and Actions to Combat Coronavirus on Health Care Providers" for additional information about how state emergency declarations may affect providers.

Therefore, providers may wish to reconcile the CMS guidance with non-waived federal regulations, as well as any state or local emergency declaration or order requirements. Ultimately, providers may need to seek provider-specific CMS Regional Office waivers to promote compliance with federal, state, and local guidance.

GUIDANCE TO LIMIT NON-ESSENTIAL MEDICAL AND SURGICAL PROCEDURES (INCLUDING DENTAL)

To assist in the management of vital resources during the COVID-19 outbreak, on March 18, 2020, CMS issued guidance recommending that providers postpone non-essential medical and surgical procedures, including dental exams and procedures, until further notice. CMS identified the following factors be considered on a case-by-case basis:

- Current and projected cases in the facility and region;
- Provider's supply of personal protective equipment;
- Staffing availability;
- Bed availability, especially intensive care unit beds;

• Ventilator availability;
• Health and age of the patient; and
• Urgency of the procedure.

The decision to limit non-essential medical and surgical procedures ultimately remains with local healthcare delivery systems, including state and local health officials and providers with direct responsibility to their patients. A tiered matrix of more detailed recommendations is included in the CMS guidance to assist providers in decision-making to limit procedures. CMS also noted that this guidance is meant to be refined during the public health emergency based on feedback from subject matter experts.

MEDICARE ADVANTAGE ("MA") AND PRESCRIPTION DRUG PLANS ("PDP")

CMS issued guidance to MA Plans and PDPs requiring that MA plans offering Medicare Parts A, B, and C benefits cover COVID-19 testing and treatment at non-contracted facilities at the same cost-sharing levels as at contracted facilities. Similarly, CMS indicated that PDPs must cover Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. Additionally, in order to encourage patients to seek care, MA plans are allowed (but not required) to, for example, waive cost-sharing for clinically indicated COVID-19 tests and treatments and expand access to certain telehealth services. PDPs may waive prescription refill limits to avoid a disruption in access to drugs, relax restrictions on home or mail delivery of prescription drugs, and waive prior authorization requirements for Part D drugs used to treat or prevent COVID-19.

FREQUENTLY ASKED QUESTIONS ("FAQS") FOR STATE MEDICAID AND CHIP AGENCIES

On March 12, 2020, CMS posted FAQs for state Medicaid and CHIP agencies to provide guidance in responding to COVID-19. The FAQs address topics including resources available to states, eligibility and enrollment flexibility questions, and questions about benefit, cost-sharing, telehealth, financing, and workforce flexibilities. Periodic FAQ updates are expected as CMS receives and answers additional questions from states.

FAQS ON ESSENTIAL HEALTH BENEFITS ("EHB") COVERAGE FOR INDIVIDUAL AND SMALL GROUP INSURANCE

On March 13, 2020, CMS issued FAQs explaining that for individual and small health insurance markets, COVID-related services, such as testing, isolation/quarantine, and vaccination, will be covered EHB for which CMS advised coverage must be provided under the current federal rules.

TELEHEALTH

On March 5, 2020, CMS issued a fact sheet that discusses use and benefits of telehealth to diagnose and treat COVID-19 and related reimbursement issues. Please refer to the Jones Day *Commentary* entitled "Telemedicine and COVID-19: CMS Touts Virtual Check-Ins, Has Authority to Implement Telehealth Waivers" for a more detailed analysis of the recent CMS telehealth guidance. On March 17, 2020, CMS released the much anticipated waivers that will expand Medicare coverage and payment for virtual services that will expand telehealth benefits on a temporary and emergency basis under the current 1135 Waiver and Coronavirus Preparedness Supplemental Appropriations Act.

NEW HCPCS CODES FOR COVID-19 LABORATORY TESTING REIMBURSEMENT

CMS announced in a March 5, 2020, press release that it developed two new Healthcare Common Procedure Coding System ("HCPCS") codes for providers and laboratories to bill for COVID-19 tests and track new cases of the virus. Providers using the CDC test for COVID-19 may bill for that test using the newly created HCPCS code (U0001). Laboratories and health care facilities may use a second new HCPCS code (U0002) to bill Medicare as well as other health insurers that choose to adopt this new code for non-CDC laboratory tests for COVID-19.

Although reimbursement is available for dates of service on or after February 4, 2020, the Medicare claims processing system is not required to accept and process such claims until April 1, 2020. It is unclear what reimbursement amount will be available for these tests. Until Medicare implements national payment rates, local MACs are charged with establishing the payment amount for these new HCPCS codes. Reimbursement is only available for medically necessary tests, and documentation supporting the clinical indications will be required for both symptomatic and asymptomatic individuals. CMS suggested that health care providers consult their MACs with any laboratory testing reimbursement questions, and noted that as with other laboratory tests, there is no beneficiary cost sharing under fee-for-service Medicare.

FAQS ON REIMBURSEMENT FOR COVID-19 SERVICES

On March 6, 2020, CMS issued FAQs for health care providers regarding Medicare payment for services related to COVID-19. In addition to addressing reimbursement for diagnostic laboratory services and the new HCPCS codes discussed above, the FAQs contain information on reimbursement for physician services (including telehealth), hospital services, drugs, and vaccines under Part B, ambulance services, and Medicare payment to facilities accepting government resources.

SUSPENSION OF MANY NON-EMERGENT SURVEYS AND PRIORITIZING OF SURVEYS

In order to focus limited survey and licensing resources during this public health emergency, effective as of March 4, 2020, and until further notice, CMS directed state survey agencies and accrediting organizations to reprioritize surveys by concentrating facility inspections on immediate jeopardy and issues related to infection control and other serious health and safety threats, such as allegations of abuse—beginning with hospitals and nursing homes. The March 4, 2020, memorandum stated that surveys will be limited to the following (in priority order):

- All immediate jeopardy complaints (a situation in which entity non-compliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death) 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 (skilled nursing facilities, home health, hospice, and ICF/IID facilities);
- Any revisits 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.

On March 13, 2020, CMS also issued FAQs regarding the guidance to State Survey Agencies suspending non-emergency survey inspections. These FAQs include a series of questions and answers directed to state agency surveyors, health care facilities, patients and caregivers, and accrediting organizations. The FAQs include useful information regarding: 1) the types of surveys that are to continue; 2) what health care facilities can expect during the suspension period; 3) what the suspension means to patients and caregivers and how to report quality of care concerns; and 4) and how accrediting organizations are to operate during the suspension.

As health care providers prioritize internal resources and attention to focus on COVID-19 concerns and pending health care surge needs, providers may want to designate an internal stakeholder to implement active record collection of all COVID-19 related protocols, education, training, and reminders provided to staff, medical staff, contractors, and vendors. If surveyed, a health care provider would then have a complete record of its ongoing operational measures to promote compliance with emergency preparedness, CMS guidance, and Medicare Conditions of Participation, as well as any applicable local or state orders, directives or guidance.

KEY TAKEAWAYS

1. Frequent HHS and CMS updates, guidance, and actions related to COVID-19 are expected.

2. Due to the rapidly evolving situation and response by the federal government, monitoring updates to HHS and CMS guidance, including participating in stakeholder webinars and calls, is a valuable tool for health care providers to promote compliance and maintain CMS survey readiness.

3. The currently released 1135 Waivers are designed to vary application of some Medicare requirements to improve COVID-19 related care coordination and access for patients. In addition, CMS has developed new HCPCS for CDC and non-CDC laboratory tests for COVID-19 performed by health care providers and laboratories.

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