COVID-19: AN ADVOCATES GUIDE TO BENEFICIARY-RELATED MEDICARE CHANGES

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1. INTRODUCTION TO COVID-19 BILLS

The global COVID-19 crisis has led to many changes in health care rules, including in the Medicare program. Most of the changes are slated to be temporary, but advocates will need to watch which provisions do and do not remain after the crisis. While a number of the changes affect health care providers, including payment and waivers of certain requirements, this chapter focuses on many of the COVID crisis changes that relate to beneficiaries and their access to covered care. This chapter describes but does not analyze or critique these changes.

As of November 9, 2021, Congress had passed six bills relating to the COVID-19 crisis:

- 1. On March 6, 2020, President Trump signed into law the Coronavirus Preparedness and Response Supplemental Appropriations Act, H.R. 6074¹ (sometimes referred to as COVID Bill #1);
- 2. On March 18, 2020, President Trump signed into law the Families First Coronavirus Response Act, H.R. 6201² (COVID Bill #2);
- 3. On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act, H.R. 748³ (COVID Bill #3);
- 4. On April 24, 2020, President Trump signed into law the Paycheck Protection Program and Health Care Enhancement Act, H.R. 266⁴ (referred to as an interim emergency funding package);
- 5. On December 27, 2020, President Trump signed into law the Consolidated Appropriations Act, 2021, H.R. 133⁵; and
- 6. On March 11, 2021, President Biden signed into law the American Rescue Plan Act of 2021 (ARP), H.R. 1319.⁶

While there are some Medicare coverage provision changes in these six bills, most of the Medicare-related changes have been issued by the Centers for Medicare & Medicaid Services (CMS) through regulation and sub-regulatory guidance pursuant to waiver authority under section 1135 of the Social Security Act. CMS has published a number of rules related to the pandemic, including the following: on April 6, 2020, CMS published an Interim Final Rule (hereinafter referred to as the IFR). On May 8, 2020, CMS published a second Interim Final Rule (hereinafter referred to IFR 2). On September 2, 2020, CMS published a third Interim Final Rule. On November 6, 2020, CMS published a fourth Interim Final Rule.

For the most up-to-date information, consult the CMS resources cited in Table A.

Table A. Regularly Updated CMS Resources.

In order to get the most up-to-date information about Medicare and COVID-19, see CMS's website which includes various resources that are regularly updated, including the following:

- "Current Emergencies" webpage: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page
- "Coronavirus Waivers and Flexibilities" webpage: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers
- List of blanket waivers document: "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers": https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf (updated Oct. 7, 2021)
- Medicare Learning Network (MLN) article "Medicare Fee-For-Service (FFS) Response to the Public Health Emergency on the Coronavirus (COVID-19)": https://www.cms.gov/files/document/se20011.pdf (revised Sept. 8, 2021)

Most of the Medicare-related changes have been made retroactive to March 1, 2020, and will last until the public health emergency (PHE) related to the COVID-19 crisis is lifted. Most recently, the PHE was extended on October 15, 2021 for an additional 90 days, into January 2022.

2. OVERVIEW OF MEDICARE-RELATED COVID CHANGES

Recognizing the urgency of the COVID crisis, CMS has stated that pre-crisis Medicare policy could inhibit maximum use of provider capacity and access to care that could be effective in efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public. Accordingly, CMS has looked for practical ways to remove barriers to urgent and necessary health care.

There are new rules regarding Medicare telehealth and telecommunications to replace in-person visits, expanded policies for inpatient stays to protect beneficiaries and providers, and revised definitions of many outpatient services to make the health care delivery system as flexible and productive as possible. The overarching goal is to navigate the health care crisis by temporarily re-prioritizing health care delivery and Medicare coverage. One of the biggest policy changes relating to Medicare is the broad expansion of what are considered coverable telehealth services. As noted in the Interim Final Rule (IFR), "[s]tarting on March 6, 2020, Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence."

Since many of the temporary Medicare-related rules involve the use of telehealth services, advocates should be aware that Medicare beneficiaries can be charged cost-sharing for such services. As noted in the IFR, however, "the Office of Inspector General (OIG) issued a Policy Statement to notify physicians and other practitioners that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations" under federal programs, including Medicare. 12

3. SPECIFIC MEDICARE COVERAGE CHANGES

A. MEDICARE PART A

Acute Care Hospitals

Extra days in a hospital can be covered for inpatients who would have been discharged but were diagnosed with COVID-19 and had to stay longer under quarantine. 13

Differential charges for a private room are lifted if the room is medically necessary. 14

Hospitals and other entities will temporarily be able to perform tests for COVID-19 for people at home and in other community-based settings, under certain circumstances. 15

Hospitals will not be required to have written policies about processes and visitation of patients who are in COVID-19 isolation.¹⁶

Hospitals will also have more time to provide patients with a copy of their medical record. 17

Hospital discharge planning will focus on ensuring that patients are discharged to an appropriate setting with the necessary medical information and goals of care. CMS is waiving detailed regulatory requirements to provide information regarding discharge planning, as outlined in 42 C.F.R. §§482.43(a)(8), 482.61(e), and 485.642(a)(8). 18

Hospitals are allowed greater flexibility to furnish inpatient services, including routine services, outside the hospital. Although hospitals need to continue to exercise sufficient control and responsibility over the use of hospital resources in treating patients regardless of whether that treatment occurs in the hospital or outside the hospital under arrangements with other providers. On the providers of the hospital under arrangements with other providers.

Hospitals are allowed to house acute care inpatients in (typically) excluded distinct part units of the hospital, such as inpatient rehabilitation or inpatient psychiatric units, where the distinct part unit beds are appropriate for acute care inpatients.²¹

Hospitals are allowed to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit because of capacity or other exigent circumstances related to the COVID-19. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others

are safely cared for.22

Hospitals are allowed to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit, as long as appropriate for providing care and intensive rehabilitation services. The hospital should continue to bill for inpatient rehabilitation services.²³

Critical Access Hospitals (CAH)

Critical access hospitals (CAHs) do not have to limit the number of beds to 25 and length of stay to 96 hours or less.

A doctor of medicine or osteopathy does not need to be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH.

The minimal federal personnel qualifications for clinical nurse specialists, nurse practitioners, and physician assistants is removed, allowing CAHs to employ individuals in these roles who meet state licensure requirements.

Staff licensure, certification, or registration is deferred to state law.

Restrictions are suspended regarding rural location and location relative to other hospitals and CAHs, allowing the CAH flexibility in the establishment of surge site locations.²⁴

Long-Term Care Hospitals (LTCHs)

Long-term care hospitals (LTCHs) can maintain its designation even if more than 50 percent of its cases are less intensive. The current LTCH site-neutral payment methodology can be temporarily paused.²⁵

The 25-day average length of stay requirement for LTCHs, allowing LTCHs to be paid as LTCHs, will not include patient stays where a LTCH admits or discharges patients in order to meet the demands of the emergency. This also applies to facilities not yet classified as LTCHs but seeking classification as a LTCH.²⁶

Extended Neoplastic Disease Care Hospitals (ENDCH)

The 20-day average length of stay requirement that allows extended neoplastic disease care hospitals (ENDCHs) to be excluded from hospital inpatient payment system will not include patient stays where an ENDCH admits or discharges patients in order to meet the demands of the emergency.²⁷

Skilled Nursing Facilities (SNFs)

As of August 25, 2020, CMS, in chart form, summarizes and provides links to its guidance and updates for nursing homes during the pandemic.²⁸

Revisions to/expansions of eligibility and coverage criteria: The three-day inpatient hospital stay requirement for Part A skilled nursing facilities (SNFs) coverage has been waived, regardless of whether the care the beneficiary requires has a direct relationship to COVID-19.²⁹ UPDATE: CMS is waiving the requirement for a three-day prior hospitalization for coverage of an SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay for those people who experience dislocations, or are otherwise affected by COVID-19.³⁰

SNF benefits for residents who have exhausted Part A benefits are extended for another 100 days if there is any arguable nexus to the PHE. (The 100-day coverage limit is waived.) CMS rules conflict, however, regarding whether the waiver must be related to COVID-19.³¹ See §A.03[A][5](m) for further discussion of the conflict. UPDATE: CMS has clarified qualifications for coverage since March, but many concerns continue to be raised about waiver application. For certain beneficiaries who have recently exhausted their SNF benefits, a one-time renewal of 100 days of SNF coverage is authorized without first having to start a new benefit period, if the beneficiary had been delayed, or prevented by the emergency itself, from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances.³²

The Center for Medicare Advocacy has compiled resources for the 100-day coverage limit waiver into an advocate toolkit, located at the following link: https://medicareadvocacy.org/center-for-medicare-advocacy-toolkit-

how-to-obtain-an-additional-100-days-of-medicare-coverage-in-a-skilled-nursing-facility-during-the-covid-public-health-emergency/

Nurse practitioners, in addition to physicians, may now perform some medical exams on Medicare patients at skilled nursing facilities so that patient needs, whether COVID-19 related or not, continue to be met in the face of increased care demands.³³

Physician and non-physician practitioners are not required to perform in-person visits for nursing home residents, such visits are allowed to be conducted, as appropriate, via telehealth options.³⁴

Physicians are permitted to delegate any required physician tasks or visits to a nurse practitioner, physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with the physician, and who is licensed by a state and performing within the state's scope of practice. Any task delegated must remain under the supervision of the physician. A physician may not delegate any task prohibited under state law or by the facility's own policy. Requirements for the frequency of physician visits and supervision by physicians remain unchanged. The facility must continue to provide or arrange for the provision of physician services 24 hours a day in case of an emergency. 86

Infection Control and Residents

Communal dining and all group activities are cancelled. UPDATE: Residents are not forced to eat in their rooms, but may eat in dining rooms if they practice social distancing. Residents should practice social distancing at all times.³⁷

CMS confirms (June 23, 2020) that residents may participate in communal activities, such as dining and group activities, while maintaining social distancing, hand hygiene, and using face coverings or masks (Question 4 in Frequently Asked Questions). ³⁸ Guidance (September 17, 2020) confirms communal dining and activities may occur "so long as residents adhere to the core principles of COVID-19 infection prevention." ³⁹

Facilities should actively screen residents and staff "for fever and respiratory symptoms."

Recommendations for social distancing are provided. 40

Updated guidance issued April 27, 2021 cites CDC guidance on activities and dining based on resident vaccination status. Fully vaccinated residents may participate in activities and dining without face coverings or social distancing; the presence of unvaccinated residents means all residents should use face coverings when not eating; unvaccinated residents should physically distance themselves from others.⁴¹

Screening and Testing of Residents and Staff

Facilities should actively screen residents and staff "for fever and respiratory symptoms." 42

Guidance issued on July 22, 2020:

- Implement symptom screening of everyone, including residents, staff, visitors, outside health care workers, and vendors.
- Ensure all staff are using appropriate PPE, to the extent that PPE is available, and consistent with CDC guidance.
- Ensure that staff wear facemasks "and full PPE when providing care to a resident with known or suspected COVID-19."
- Use separate staff for COVID-19-positive residents and, with State and local leaders, "designate separate facilities or units within a facility" to cohort COVID-19-positive residents and residents whose COVID-19 status is unknown. Ensure that COVID-19-positive units and facilities "have the capacity, staffing, and infrastructure to manage higher intensity patients, including ventilator management" and maintain "strict infection control practices and testing protocols."
- Use consistent assignment of staff to residents.

• Inform residents and families of restrictions on visits and "procedures for placement in alternative facilities for COVID-19-positive or unknown status." ⁴³

Interim final rule with comment published September 2, 2020, and effective that day, requires testing of residents and staff. Detailed rule also addresses documentation of testing, requirement to take action to prevent transmission when a resident or staff member tests positive, and procedures when residents or staff refuse testing.⁴⁴

CMS's prescriptive guidance for the interim final testing rule identifies "triggers" (symptomatic individual identified, outbreak, routine testing) that determine when residents and staff must be tested. It also defines routine testing intervals for staff; these intervals depend on the community's COVID-19 positivity rate. 45

CMS provides information about payer hierarchy for COVID-19 testing in Medicare, Medicaid and uninsured, and private insurance.⁴⁶

On September 29, 2020, CMS revised its COVID-19 testing methodology to determine the rate of coronavirus in counties. The county positivity rate determines how frequently facilities must test staff.⁴⁷

In April 2021, CMS updated its guidance on COVID-19 testing for staff and residents, based on vaccination status.⁴⁸

In September 2021, CMS revised guidance, issued in August 2020, on COVID-19 testing requirements for nursing facilities, now requiring "staff testing based on the facility's county level of community transmission instead of county test positivity rate." CMS also revises guidance for testing residents.⁴⁹

Vaccinations

Interim final rule with comment published May 13, 2021 requires facilities to develop policies and procedures about vaccinations.⁵⁰ CMS describes requirements of the interim final rule to state survey agencies.⁵¹

CMS reports resident and staff COVID-19 vaccination rates on Care Compare. 52

An interim final rule with comment published November 5, 2021 requires all staff except full time telework staff to be fully vaccinated for COVID-19 by January 4, 2022.⁵³

• Facility Training

CMS Issues toolkit for telehealth and telemedicine.⁵⁴

Beginning May 28, CMS (QIO) is conducting an eight-week national nursing home training series on infection prevention programs for nursing facilities.⁵⁵

QIOs provide technical assistance to nursing facilities, focusing on approximately 3,000 facilities with a history of infection control deficiencies. ⁵⁶

CMS and CDC developed an on-demand Nursing Home COVID-19 Training program to supplement existing training. Educational modules include materials on cohorting strategies and using telehealth.⁵⁷

CMS announced training in infection control, five modules for frontline caregivers and ten modules for management.⁵⁸

Agency for Healthcare Research and Quality announces AHRQ ECHO National Nursing Home COVID-19 Action Network to provide free training and mentorship to nursing facilities "to increase the implementation of evidence-based infection prevention and safety practices to protect residents and staff."⁵⁹

As of November 17, 2020, CMS publicly recognized the 1,092 nursing facilities where 50 percent or more of their staff have completed free CMS training in infection control (125,506 individuals in 7,313 facilities, approximately 12.5 percent of the staff have received training). CMS calls on nursing homes to urge their staff to take the training.⁶⁰

CMS also issued a toolkit of state actions to mitigate COVID-19 in nursing facilities.⁶¹

On November 17, 2020, CMS reported 12.5 percent of approximately one million nursing home staff members have taken free CMS training on COVID-19 and urges facilities to require their staff to take the training. ⁶²

• Strike Teams

Between July 18 and 20, 2020, CMS sent federal Task Force Strike Teams to 18 nursing facilities in Illinois, Florida, Louisiana, Ohio, Pennsylvania, and Texas "to provide onsite technical assistance and education to nursing homes experiencing outbreaks."⁶³

In September 2021, CDC announced \$500 million for state-based strike teams to help nursing homes with staffing, training, and assistance.⁶⁴

Admission Practices

Facilities can admit patients diagnosed with COVID-19 from a hospital, as long as they follow CDC guidance for transmission-based precautions. Facilities that cannot follow these precautions should not admit patients with COVID-19.

If possible, facilities should dedicate a wing/unit for residents coming from or returning from hospital stays; such residents should remain in those units for 14 days.⁶⁵

CMS describes ways of cohorting (grouping) residents by COVID status (positive, negative, suspected) following admission:

- in-facility cohorting (cohorting residents on dedicated floors, units, wings, or a group of room at the end of a unit); and
- inter-facility cohorting (certified facilities transferring or discharging residents to cohort residents with the same COVID status; certified facilities transferring residents to non-certified locations and providing care with their own staff, possibly with other facilities' residents; and certified facilities transferring residents to Federal or State run facilities by Order of Governmental Authority (e.g., FEMA)).⁶⁶

SNFs may admit new residents who have not received Level 1 or Level 2 Preadmission Screening. Level 1 assessments may be performed post-admission.

On or before the 30th day of admission, new patients admitted to SNFs with mental illness or intellectual disability should be referred promptly by the SNF to State program for level 2 Resident Review.⁶⁷

CMS describes "effective cohorting" as a core principle of COVID-19 infection prevention.⁶⁸

CDC provides new guidance on new admissions, readmissions, and residents who leave their nursing facility for more than 24 hours.⁶⁹

• Leaving the facility

Although CMS recognizes that residents have the right to leave their nursing facility and may want to spend holidays with family, it recommends that residents not leave the facility during the public health emergency. If residents do leave, however, CMS urges that residents follow precautions during their absence. It recommends that facilities screen and test residents and place residents on transmission-based precautions when they return.⁷⁰

CDC provides new guidance on new admissions, readmissions, and residents who leave their nursing facility for more than 24 hours. 71

CMS's revised policy allows residents to "leave the facility as they choose." When they return, they should be screened for signs or symptoms of COVID-19; tested, if they have been in close contact with someone who has Covid-19; and, if not fully vaccinated, placed on quarantine. Residents developing signs of symptoms should be placed on Transmission-Based Precautions, regardless of vaccination status. Residents absent for 24 hours or more "should generally be managed as a new admission or readmission."

• Discharge Practices

If residents are suspected of having COVID-19, facilities should contact local health department for guidance.

Transfer to hospital is not required, even if the facility does not have an airborne infection isolation room (AIIR), if the facility can follow CDC infection prevention and control practices.

Residents may need hospital for higher level of care.

If residents do not require hospitalization, they can be discharged home, in consultation with state or local public authorities, "if deemed medically and socially appropriate." Residents should wear facemasks and isolate in their rooms with the door closed until discharged home.⁷⁴

In general, if two or more certified long-term care (LTC) facilities want to transfer or discharge residents between themselves for the purposes of cohorting, they do not need any additional approval to do so. However, if a certified LTC facility would like to transfer or discharge residents to a non-certified location for the purposes of cohorting, it needs approval from the State Survey Agency.⁷⁵

Visitors

All visitors are banned, except for certain compassionate care situations, such as end-of-life situations. Visitors should perform hand hygiene and use personal protective equipment, such as facemasks, and restrict visit to resident's room "or other location designated by the facility."

Ombuds visits are restricted except in compassionate care situations (and case-by-case review by facility). In (Question 7 of seven Frequently Asked Questions, June 23, 2020), CMS confirms the authority of ombudsman to have immediate access to residents, even if in-person visitation is not possible. CMS revises earlier guidance to confirm the ombudsman program's immediate access to residents.

Visitors are advised to monitor themselves for 14 days after leaving facility. 78

Guidance for nursing homes on alternatives to in-person visits:

- Provide alternative means of communication for residents—phone, videoconference.
- Create a listserve to update families.
- Assign a staff member as the primary contact to communicate with families.
- Offer a phone line with voice recording, updated at set times daily.⁷⁹

Civil money penalty funds, up to one device for 7–10 residents and a maximum of \$3000 per facility, may be used to purchase communicative devices, such as tablets or web-cams, to enable residents to communicate with family members.⁸⁰

On May 18, 2020, CMS released recommendations for state and local officials to help them determine whether to reopen nursing facilities to visits by families and others: 81 CMS suggests that states consider case status in the community, case status in the nursing home, adequate staffing, access to adequate testing, universal source control, access to adequate personal protective equipment, and local hospital capacity as they move through three phases of reopening. Visitors should not be allowed until, under Phase 3, there have been no new nursing home onset COVID-19 cases for 28 days.

In Frequently Asked Questions No. 7 (June 23, 2020), CMS revises its guidance on visitation, recognizing "the toll of separation from family and other loved ones." More flexible guidance on visitation broadens the opportunity for "compassionate care" and identifies creative visitation, such as outdoor visitation sessions.

Superseding and replacing all prior guidance on visitation, CMS released new guidance on September 17, 2020 that discusses outdoor and indoor visitation and visitor testing, provides additional examples of compassionate care visits, and prohibits a facility from restricting visits "without a reasonable clinical or safety cause" if it has had no COVID-19 cases in 14 days and the county's positivity rate is low or medium.⁸³ CMS issues Frequently-Asked Ouestions about the September visitation policy.⁸⁴

Facilities may each use of up \$3000 of CMP funds to purchase tents or clear dividers for outside visits.85

CMS issues revised guidance on March 10, 2021 that allows all residents to have in-person visits with their families. 86

Updated guidance issued April 27, 2021 adds explicit references to guidance from CDC on indoor visitation and notes that a resident's quarantine status may hinder outdoor visitation.⁸⁷

In a dramatic reversal on November 12, 2021, CMS says "Visitation is now allowed for all residents at all times." In addition, "facilities can no longer limit the frequency and length of visits for residents, the number of visitors, or require advance scheduling of visits." 89

• Physical Environment

With state approval, allow a non-SNF building to be temporarily certified and available for use by an SNF in the event there are isolation processes for COVID-19-positive residents.

If there is a state need to quickly set up a temporary COVID-19 isolation and treatment location, CMS will waive certain conditions of participation and certification requirements for opening an SNF.

SNFs may temporarily allow rooms not normally used as a resident's room to be used to accommodate beds. Rooms that may be used for this purpose include activity rooms, meeting/conference rooms, dining rooms, or other rooms, as long as residents can be kept safe, comfortable, and other applicable requirements for participation are met consistent with a state's emergency preparedness or pandemic plan.⁹⁰

• Additional "flexibilities" (waivers) for facilities (not discussed above)

Including resident assessment data, staffing data, requirement that nurse aides not work for more than four months unless they have taken 75-hour training program.⁹¹

CMS reinstates requirement that nursing facilities submit payroll-based staffing data, beginning with the second quarter of 2020 (April–June). 92

Effective May 10, 2021, CMS ends four emergency blanket waivers: (1) notifying residents before transfer or discharge; (2) notifying residents before room or roommate change; (3) care planning requirements; and (4) minimum data set timeframe requirements.⁹³

CMS does not end waiver of nurse aide training requirements, but writes (1) the four-month regulatory framework will be reinstated when the blanket waiver ends, and (2) states should "evaluate" their aide training and competency evaluation programs and "consider allowing some of the time worked by the nurse aides during the PHE to count toward the 75-hour training requirement."⁹⁴

• Facility Reporting Requirements

CMS reinforces "an existing requirement that nursing homes must report communicable diseases, healthcare-associated infections, and potential outbreaks to State and Local health departments." In rulemaking that will follow (see below), CMS requires facilities to report these data to the Centers for Disease Control and Prevention (CDC) in a standardized format and frequency defined by CMS and CDC. After a two-week grace period, failure to report cases of residents or staff who have confirmed COVID-19 and Persons under Investigation (PUI) will result in an enforcement action. CMS also announces that it will issue a "new requirement for facilities to notify residents" and their representatives to keep them up to date on the conditions inside the facility, such as when new cases of COVID-19 occur. 95

• Interim Final Rule (IRF2), with comment

Facilities must inform resident, their representatives, and families, by 5 p.m. the next calendar day, when the facility has a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms within 72 hours of each other. Notification may be by "email listserves, website postings,

paper notification, and/or recorded telephone messages." Individual notification is not required. Here is no penalty for failing to inform residents, representatives, and families, as there is for failing to file information about COVID-19 at least weekly with the CDC.

CMS releases data June 4 on deaths and cases reported to CDC^{97} and updates the information on the last Wednesday of each month (through a link on *Nursing Home Compare*).

Surveys

Suspension of standard (annual) surveys; surveys limited to (1) complaint or facility-reported incidents triaged as immediate jeopardy and (2) targeted infection control surveys, 98 if surveyors have sufficient personal protective equipment. 99

On June 1, 2020, CMS revised its guidance to transition states to more routine survey and oversight activities, once a state enters Phase 3 of the Nursing Home Reopening guidance, "or earlier, at the state's discretion." ¹⁰⁰

On June 4, 2020, CMS released data on targeted infection control surveys. ¹⁰¹ The Center for Medicare Advocacy's analysis of the data documented that less than 3 percent of surveys were cited with an infection control deficiency. ¹⁰² CMS updates the data the last Wednesday of each month through a link on *Nursing Home Compare*.

On August 17, 2020, CMS revised the guidance to authorize additional onsite surveys at nursing facilities for states in Phase 3 or earlier, at their discretion. 103

CMS revised the focused infection control survey protocol to require surveyors to include samples of residents and of staff and to determine compliance with the requirements for an infection preventionist and for testing. 104

The requirement for focused infection control surveys is rescinded and CMS expects states "to resume conducting recertification surveys on a regular basis," prioritizing surveys according to potential risk to residents (e.g., a history of noncompliance) or allegations of noncompliance in abuse or neglect; infection control; violations of transfer or discharge requirements; insufficient staffing or competency; Special Focus Facilities or candidates; or other quality of care issues (e.g., falls, pressure ulcers). CMS provides instructions to state agencies for investigating complaints or facility-reported incidents that were backlogged as a result of the pandemic. 106

• Enforcement

Suspension of enforcement (denial of payment for new admissions; per day civil money penalties) for all deficiencies other than immediate jeopardy deficiencies. 107

CMS announced "enhanced enforcement" for infection control deficiencies. 108

On August 17, 2020, CMS addressed enforcement; it expanded the desk review policy for plans of correction, described processing enforcement cases according to three dates (cases started before March 23, cases started March 23–May 31, and cases started on or after June 1), and described when and how civil money penalties would be collected. 109

An interim final rule with comment published September 2, 2020, codifies civil money penalties for failure to report to the CDC, as required. 110

National Studies

The National Nursing Home Commission announced April 30, 2020 that it will conduct a comprehensive assessment of the nursing home response to the pandemic. The Commission will be run by the Mitre Corporation, with a report expected by September 1, 2020. CMS announced the 25 Commission members on June 19, 2020. CMS released the Commission Final Report in September 2020 and simultaneously issued a press release stating that the Report validates the federal response to the coronavirus pandemic and a point-by-point comparison of the Commission's recommendations and the agency's actions. Commission member Eric Carlson (Justice in Aging) dissented from the report in full.

National Academy of Sciences announces new ad hoc committee to examine how the United States delivers,

finances, regulates, and measures quality of nursing home care, focusing on challenges arising from COVID-19.117

Frequently Asked Question: Does CMS intend extension of covered SNF days to apply only to COVID-19 impacted beneficiaries or to all beneficiaries?

Question: Can a Medicare Part A beneficiary who has exhausted his or her SNF benefits, but continues to need and receive skilled care in the SNF (e.g., for a qualifying feeding tube), renew SNF benefits under the section 1812(f) waiver regardless of whether or not the SNF or hospital was affected by the COVID-19 emergency?

Answer: If the patient has a continued skilled care need (such as a feeding tube) that is unrelated to the COVID-19 emergency, then the beneficiary cannot renew his or her SNF benefits under the section 1812(f) waiver as it is this continued skilled care in the SNF rather than the emergency that is preventing the beneficiary from beginning the 60 day "wellness period." 118

But See...CMS states elsewhere: "for certain beneficiaries who recently exhausted their SNF benefits, [the waiver] authorizes renewed SNF coverage without first having to start a new benefit period (this waiver will apply only for those beneficiaries who have been delayed or prevented by the emergency itself from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances)." 119

Inpatient Rehabilitation Facilities (IRFs, also known as Inpatient Rehab. Hospitals/IRHs)

The intensive rehabilitation therapy requirement for inpatient rehabilitation facilities (IRFs) coverage, commonly defined as the "3-hour" rule (15 hours of therapy a week), is relaxed, but IRFs should instead make a note in the medical record to explain why this requirement is not able to be met due to specified issues arising from the COVID-19 crisis. ¹²⁰ The waiver is not limited to particular IRFs or patients, regardless of whether a patient was admitted for standard IRF care or to relieve acute care hospital capacity. ¹²¹

Telehealth services can be used for the required three physician supervision visits per week. 122

The post-admission physician evaluation can count as one of the "face-to-face" visits, if it is performed. 123

The post-admission physician evaluation requirement, at §412.622(a)(4)(ii), is removed for all IRFs. 124

IRF coverage criteria continue to be required, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE. IRF documentation requirements must be present in the IRF medical record, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE. An interdisciplinary team approach to care is required, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE. 125

Psychiatric Hospitals

Licensed practitioners, rather than licensed independent practitioners, will be allowed to practice in psychiatric hospitals, pursuant to state laws. 126

All Hospitals

Hospitals are allowed to screen patients at a location offsite from the hospital's campus, so long as not inconsistent with a state's emergency preparedness or pandemic plans. 127

Patient Rights

For hospitals impacted by a "widespread outbreak of COVID-19," as updated on the CDC website, hospitals would not be required to meet the following:

• Time frames to provide a copy of a medical record

- Written policies and procedures related to patient visitation of patients who are in COVID-19 isolation and quarantine processes
- Requirements about seclusion. 128

• Discharge Planning

Requirements are waived to provide detailed discharge planning.

Hospitals must assist patients, families, or patient's representative in selecting post-acute care provider by using and sharing data that includes quality measures and resource use measures that are relevant and applicable to the patient's goals of care and treatment preferences.

However, more detailed requirements are waived, including the following:

- A list of Home Health Agencies (HHAs), Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), or Long-Term Care Hospitals (LTCHs) that are available to the patient.
- Information to the patient explaining their freedom to choose among participating Medicare providers and suppliers of post-discharge services.
- Disclosure by the hospital of any financial interest the hospital has in any HHA or SNF to which a patient is referred. 129

Medical Records

Requirements for the form, content and retention of medical records are waived so long as not inconsistent with a state's emergency preparedness or pandemic plan.

Hospitals are allowed "flexibility" in completion of medical records that are usually required within 30 days following discharge. 130

• Advance Directives

Hospitals and CAHs are not required to provide information to patients about their advance directive policies. 131

• Use of Non-Hospital Buildings/Space

Non-hospital buildings/space may be used for patient care and quarantine sites, provide the location is approved by the state and as long as not inconsistent with a state's emergency preparedness or pandemic plan.¹³²

• Telemedicine for Patients in the Hospital

Telemedicine may be furnished to the hospital's patients through an agreement with an off-site hospital. 133

Physician Services in the Hospital

Medicare patients are not required to be under the care of a physician, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.¹³⁴

• Anesthesia Services

A certified registered nurse anesthetist (CRNA) does not have to be supervised by a physician. CRNA supervision will be at the discretion of the hospital and state law. (Waiver applies to hospitals, CAHs, and Ambulatory Surgical Centers (ASCs), so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.)¹³⁵

• Utilization Review (UR)

Hospitals are not required to have a utilization review (UR) plan that meets specified requirements. The medical necessity of the admission, duration of stay, and services provided do not have to be evaluated by a UR committee or through a UR plan, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. ¹³⁶

Nursing Services

Nursing staff are not required to keep a current nursing care plan for each patient. Hospitals are not required to have policies and procedures in place to establish which outpatient departments are not required to have a registered nurse present.¹³⁷

Food and Dietetic Services

A current therapeutic diet manual approved by the dietician and medical staff does not need to be readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge sites. 138

• Respiratory Care Services

Hospitals are not required to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures.¹³⁹

Home Health

Physician assistants, nurse practitioners, and clinical nurse specialists can: (1) order home health services; (2) establish and periodically review a plan of care for home health services (e.g., sign the plan of care), (3) certify and re-certify that the patient is eligible for Medicare home health services. However, IFR 2 clarifies that those non-physician practitioners would only be able to practice to the top of their state licensure as they are allowed to practice in accordance with state law. CMS review of state prescriptive authority websites reveals that a majority of states require physician collaboration for non-physician practitioners. However, IFR 2 clarifies that those non-physician collaboration for non-physician practitioners.

Initial assessments and determination of a patient's homebound status may be performed by a home health agency remotely or by record review. 142

Occupational therapists (OTs) from home health agencies can now perform initial and comprehensive assessments on all homebound patients who are receiving therapy services as part of the plan of care, regardless of whether occupational therapy is the service that establishes eligibility, allowing home health services to start sooner and freeing home-health nurses to do more direct patient care. It is unchanged that OTs and other therapists are not permitted to perform assessments in nursing only cases. ¹⁴³

The requirement for a nurse to conduct an onsite visit every two weeks for home health aide supervision is waived. This includes waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the patient's Plan of Care, as this may not be physically possible during the COVID crisis. 144

• Home Health and Telecommunication

For home health coverage, Medicare continues to require in-person visits (defined as when a home health agency employee enters the beneficiary's home and provides a covered service) and only in-person visits can be reported on the home health claim. 145

Once a home health agency achieves the number of in-person visits to exceed a low-utilization payment amount (LUPA), all additional visits (in-person or telecommunication) will count toward the full bundled payment.

Telecommunication technology, tele-visits, and remote-monitoring can be substituted for in-person visits only

when the physician:

- Notes the technology in the Plan of Care (this can be retro-changed prior to final billing),
- States how the use of technology is ties to patient-specific needs, and
- States how the use of such technology will help to achieve the goals outlined in the Plan of Care. 146

The required face-to-face encounter for home health can be conducted via telehealth (i.e., two-way audio-video telecommunications technology that allows for real-time interaction between the physician/allowable practitioner and the patient). Telecommunications technology can include, for example, remote patient monitoring; telephone calls (audio only and TTY); and two-way audio-video technology that allows for real-time interaction between the clinician and patient. Again, however, only in-person visits can be reported on the home health claim. 148

• Homebound definition

Homebound definition expanded to include that it is medically contraindicated for individual to leave home:

- Due to a confirmed or suspected diagnosis of COVID-19, or
- The patient has a condition that may make the patient more susceptible to contracting COVID-19
- The record must indicate:
 - A physician certification that it is medically contraindicated for a person to leave home.
 - Documentation as to why the individual condition of the patient is such that leaving home is medically contraindicated.
 - Documentation that the medical contraindication makes it such that there exists a normal inability for an individual to leave home and leaving home safely would require a considerable and taxing effort.
- Example of a covered home health service from the Interim Final Rule "Even if the patient is confined to the home because of a suspected diagnosis, a home health visit solely to obtain a nasal or throat culture would not be considered a skilled service because it would not require the skills of a nurse to obtain the culture as the specimen could be obtained by an appropriately trained medical assistant or laboratory technician. However, a home health nurse, during an otherwise covered skilled visit, could obtain the nasal or throat culture to send to the laboratory for testing." ¹⁴⁹

• Clinical Records

Home health agencies have ten business days to provide a patient's clinical medical record to the patient at no cost, when requested by the patient, instead of four days. ¹⁵⁰

• Patient Assessment Reporting

The home health comprehensive assessment must be completed within 30 days, extending the 5-day completion requirement. The 30-day submission requirement is waived, but home health agencies must submit the assessment data prior to submitting their final claim. ¹⁵¹

Hospice

The requirements for a nurse to conduct an onsite visit every two weeks for hospice aide supervision is temporarily waived. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan. ¹⁵²

Competency testing of hospice aides for those tasks that must be observed being performed on a patient can be done utilizing pseudo patients, such as a person trained to participate in a role-play situation or a computer-based mannequin device, instead of actual patients. Hospices also do not have to assure that each hospice aide receives 12 hours of in-service training in a 12-month period. 154

Routine home care can be provided through telecommunications, if it is feasible and appropriate to do so to ensure that patients can continue receiving services that are reasonable and necessary for the palliation and management of their terminal illness and related conditions without jeopardizing the patients' health or the health of those who are providing such services.

- The use of such technology must be included in the Plan of Care and must be tied to patient-specific needs as
 identified in the comprehensive assessment and the measurable outcomes that the hospice anticipates will occur
 as a result of implementing the plan of care.
- For the purposes of claim submission, only in-person visits (with the exception of social work telephone calls) should be reported on the claim. However, hospices can report the costs of telecommunications technology used to furnish services under the routine home care level of care as "other patient care services." ¹⁵⁵

Hospice providers can provide services to a Medicare patient receiving routine home care through Telecommunications technology can include, for example, remote patient monitoring; telephone calls (audio only and TTY); and two-way audio-video technology that allows for real-time interaction between the clinician and patient, if it is feasible and appropriate to do so. Only in-person visits can be reported on the hospice claim. 156

Face-to-face encounters for purposes of recertification of hospice can be conducted via telehealth (i.e., two-way audio-video telecommunications technology that allows for real-time interaction between the hospice physician/hospice nurse practitioner and the patient). 157

Hospice nurses are relieved of hospice aide in-service training tasks so they can spend more time with patients. 158

Hospices are not required to use volunteers. 159

The time frames for updating the comprehensive assessments may be extended from 15 to 21 days, but the assessments and updates must be completed. 160

Hospices are not required to provide non-core hospice services, including physical therapy, occupational therapy, and speech-language pathology. ¹⁶¹

B. MEDICARE PART B

COVID-19 Testing

COVID-19 test is covered with no cost-sharing in either traditional Medicare or an MA plan. Updated rules from CMS waive requirement that there be a doctor's or other provider's written order; during the PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law. 162

Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, CMS is also removing the same ordering requirements for a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus. The ordering requirements are waived for these additional diagnostic laboratory tests only when they are furnished in conjunction with a COVID-19 diagnostic laboratory test as medically necessary in the course of establishing or ruling out a COVID-19 diagnosis or of identifying patients with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection. 163

Medicare will pay laboratory technicians to travel to a beneficiary's home to collect a specimen for COVID-19 testing, eliminating the need for the beneficiary to travel to a healthcare facility for a test and risk exposure to themselves or others. There will be additional payment during the PHE in the form of a specimen collection fee of \$23.46 generally, and \$25.46 for an individual in an SNF or by a laboratory on behalf of a HHA, for COVID-19 testing and to provide a travel allowance for a laboratory technician to collect a specimen for COVID-19 testing from a non-hospital inpatients or homebound patients. 164

Medicare Part B will cover beneficiary cost-sharing for provider visits during which a COVID-19 diagnostic test is administered or ordered. 165

Note: this does not mean that all COVID-related treatment is covered without cost-sharing. According to CMS, "cost-sharing does not apply for COVID-19 testing-related services, which are medical visits that:

are furnished between March 18, 2020 and the end of the Public Health Emergency (PHE); that result in an order for or administration of a COVID-19 test; are related to furnishing or administering such a test or to the evaluation of an individual for purposes of determining the need for such a test; and are in any of [certain] categories of HCPCS evaluation and management codes"¹⁶⁶

• COVID-19 Serology ("Antibody") Test

Medicare covers this test without cost-sharing for the beneficiary. ¹⁶⁷ According to CMS, a "blood-based serology test can be used to detect whether a patient may have previously been infected with the virus that causes COVID-19 by identifying whether the patient has antibodies specific to the SARS-CoV–2 virus." In IFR 2, CMS states that "during the PHE for the COVID-19 pandemic, Medicare will cover FDA authorized COVID-19 serology tests as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection." ¹⁶⁸

COVID-19 Vaccine

- The COVID-19 vaccine is covered under Part B with no cost-sharing. 169
- Medicare may be able to cover a vaccine given in a beneficiary's home, ¹⁷⁰ including group living situations. ¹⁷¹
- Note that Medicare Advantage (MA) enrollees have their vaccines covered outside of their plan in 2020 and 2021 (Medicare pays providers directly for the vaccine, and MA plans are not responsible for such costs). MA plans are responsible for paying for vaccines in 2022.¹⁷²

Booster Shots

- Authorized booster shots are covered by Medicare with no cost-sharing.¹⁷³
- CDC Guidelines¹⁷⁴ state: If you're 65 or older and you're fully vaccinated for COVID-19, you can get a COVID-19 vaccine booster shot. You can also get a booster shot if you're over 18 and have underlying medical conditions, live in a long-term care facility, or work or live in a high-risk setting.
- Booster shots are now available for the Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines.

You can get a booster shot at least six months after you complete your second dose of the Pfizer or Moderna vaccine. Or, you can get a booster shot of the Johnson & Johnson vaccine at least two months after your first dose.

COVID-19 Treatments

• Monoclonal Antibody Treatments

Medicare can cover such treatment at a physician's office, healthcare facility or at a beneficiary's home. ¹⁷⁶ Medicare will cover with no cost-sharing to a beneficiary ¹⁷⁷ if the individual:

- Has tested positive for COVID-19.
- Has a mild to moderate case of COVID-19.
- Is at high risk of progressing to a severe case of COVID-19 and/or at high risk of requiring hospitalization.

• Enhanced Medicare Payments for New COVID-19 Treatments

Hospital Inpatient Stays

In order to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments hospital during the COVID-19 PHE, the Medicare program will provide an enhanced payment for eligible inpatient cases that involve use of certain new products authorized or approved to treat COVID-19. The enhanced payment will be equal to the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the cost of

a COVID-19 stay beyond the operating Medicare payment (including the 20 percent add-on payment under section 3710 of the CARES Act) for eligible cases.

Outpatient Hospital Department

CMS wants to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments provided in a hospital outpatient setting during the COVID-19 PHE. Therefore, in this IFC, CMS has excluded FDA-authorized or approved drugs and biologicals (including blood products) authorized or approved to treat or prevent COVID-19 from being packaged into Comprehensive Ambulatory Payment Classification (C-APC) payment when these treatments are billed on the same claim as a primary C-APC service. Instead, Medicare will pay for these drugs and biologicals separately throughout the course of the PHE. 178

Telehealth (General)

Medicare beneficiaries are allowed to receive a wider range of healthcare services without having to travel to a facility. Previously, covered telehealth only included services provided by doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers. CMS has waived a number of requirements in order to expand the list of providers that can provide telehealth services during the PHE to include "all those that are eligible to bill Medicare for their professional services. As a result, a broader range of practitioners, such as physical therapists, occupational therapists, and speech language pathologists can use telehealth to provide many Medicare services." ¹⁸⁰

Telehealth services are distinguished from brief communications or Virtual Check-Ins, which are short patient-initiated communications with a healthcare practitioner, and E-visits, which are non-face-to-face patient-initiated communications through an online patient portal.¹⁸¹

As noted above, Medicare beneficiaries can be charged for cost-sharing for telehealth services, but providers have the option waive or reduce cost-sharing during the current COVID crisis. ¹⁸² In IFR 2, CMS states "Practitioners should educate beneficiaries on any applicable costsharing."

Providers can deliver telehealth via phone and video chat at home or any health care facility (office, hospital, nursing home, clinic) (but see below re: audio-only). In general, telehealth must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site. ¹⁸⁴ Telehealth includes routine visits, mental health counseling, preventive health screenings for cancer and other illnesses.

During the COVID crisis, telehealth is paid at same rate as in-person services. The requirement that patients must have seen the doctor within past three years is waived. More than 80 additional services are covered by Medicare when furnished via telehealth. These include emergency department visits, initial nursing facility and discharge visits, and home visits, which must be provided by a clinician that is allowed to provide telehealth. ¹⁸⁵ CMS has posted a list of covered telehealth services here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

Virtual Check-In services, or brief check-ins between a patient and their doctor by audio or video device, through audio or video phone, email, secure text or patient portal could previously only be offered to patients that had an established relationship with their doctor. Now, doctors can provide these services to both new and established patients. ¹⁸⁶

In general, audio-only telehealth¹⁸⁷ is limited to the following:

- To evaluate beneficiaries by audio phones
- For virtual check-in services, or brief check-ins between (1) a patient and (2) a physician or non-physician practitioner eligible to use evaluation/management codes, regardless of whether the patient is new or established (see below).

For example, opioid treatment programs can allow the therapy and counseling portions of the weekly bundles of services, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls (see discussion below). 188

• Behavioral health counseling and education services 189

Note that the Consolidated Appropriations Act (Dec. 2020) permanently expands access to telehealth services in Medicare to allow beneficiaries to receive mental health services via telehealth, including from the beneficiary's home, as long as s/he has been seen in person at least once by the physician or non-physician practitioner during the six months prior to the first telehealth service.

Clinicians can provide remote patient monitoring services for patients, no matter if it is for the COVID-19 disease or a chronic condition. For example, remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry. 190

Telehealth for Home Dialysis Patients

The requirement that a nephrologist conduct some of the required periodic evaluations of a patient on home dialysis face-to-face is eliminated during the COVID crisis, allowing these vulnerable beneficiaries to get more care in the safety of their home.¹⁹¹

Telephone Evaluation and Management (E/M) Services (including Routine Office Visits)

There are many circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate. In IFR 2, CMS states that since "audio-only services are being furnished as substitutes for office/outpatient E/M services, we recognize that they should be considered as telehealth services, and are adding them to the list of Medicare telehealth services for the duration of the PHE." CMS states it will be separately issuing a waiver of the requirements that Medicare telehealth services must be furnished using video technology for such services. ¹⁹²

Services are available for both new and established patients. Services may be furnished by, among others, LCSWs, clinical psychologists, and physical therapists, occupational therapists, and speech-language pathologists when the visit pertains to a service that falls within the benefit category of those practitioners.¹⁹³

Hospital Outpatient Services Furnished at Home

In the new Interim Final Rule (IFR 2),¹⁹⁴ CMS outlines flexibilities that are available to hospitals to enable them to furnish outpatient services to beneficiaries in their homes (or other temporary expansion locations), when such a location is considered to be a "Provider-Based Department" (PBD) of the hospital, as permitted under the waivers in effect during the COVID-19 PHE. Some of these flexibilities also apply to services provided by Community Mental Health Centers (CMHC)¹⁹⁵ as well as the Partial Hospitalization Program (PHP),¹⁹⁶ an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression and schizophrenia.

IFR 2 clarifies regulatory flexibilities for hospital outpatient therapeutic services furnished to beneficiaries in their homes or other temporary expansion locations for the duration of the COVID-19 PHE, and considered hospital outpatient therapeutic services in three categories:

- 1. Hospital outpatient therapy, education, and training services, including partial hospitalization program services, that can be furnished other than in-person, and are furnished in a temporary expansion location (which may be the patient's home) that is a PBD of the hospital or an expanded CMHC;
- 2. Hospital outpatient clinical staff services furnished in-person to the beneficiary in a temporary expansion location; and
- 3. Hospital services associated with a professional service delivered by telehealth.

Note that CMS states that there are a range of services that "can be furnished by the hospital to a patient in the hospital (including the patient's home [...]) using telecommunications technology [including] outpatient therapy, counseling, and educational services that hospital clinical staff can furnish incident to a physician's or qualified [nurse practitioner's] service during the COVID-19 PHE" as long as the individual is registered as an outpatient of the hospital.¹⁹⁷

Note concerning outpatient hospital services and home health services: CMS states that "during the time period that the patient is receiving services from the hospital clinical staff as a registered outpatient, the patient's place of residence cannot be considered a home for purposes of [home health] services. [...] When the patient is not receiving outpatient services by the hospital, the patient's home can be considered a home for purposes of the home health benefit and the [home health agency] can furnish and bill for home health services. The hospital should be aware if the patient is under a home health plan of care, and it must not furnish services to the patient that could be furnished by the [home health agency] while the plan of care is active. That is, to the extent that there is some overlap between the types of services a [home health agency] and a [hospital outpatient department] can provide, and the patient has a current home health plan of care, the hospital should only furnish services that cannot be furnished by the [home health agency]." 198

Therapy Services (Physical Therapy/PT, Occupational Therapy/OT, Speech Language Pathology/SLP)

Physical therapists (PT), occupational therapists (OT), and speech-language pathologists (SLP) are now authorized to provide full Medicare-covered telehealth services. ¹⁹⁹ Such providers can also provide evaluation and management services. ²⁰⁰

A PT or OT who established a maintenance program can delegate the performance of maintenance therapy services to therapy assistants—appropriately supervised occupational therapy assistant (OTA) or physical therapy assistant (PTA), when clinically appropriate.²⁰¹

Ambulance Transport²⁰²

Treat in place, pursuant to the American Rescue Plan Act of 2021, CMS is waiving requirements that an ambulance service include transportation of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under Medicare regulations but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the public health emergency.²⁰³

The list of destinations for ambulance transportation is expanded to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with emergency medical services (EMS) protocols established by state and/or local laws where the services will be furnished.

Based on EMS protocols, a patient suspected of having COVID-19 that requires a medically necessary transport may be transported to a testing facility to get tested for COVID-19 instead of a hospital in an effort to prevent possible exposure to other patients and medical staff.

Ambulance destinations may include, but are not limited to any location that is an alternative site determined to be part of any of the following:

- Hospital
- Critical Access Hospital
- Skilled Nursing Facility
- Community Mental Health Center
- Federally Qualified Health Center
- Regional Health Center
- Physician's Office
- Urgent Care Facility
- Ambulatory Surgery Center

- Dialysis Service Center (when an End Stage Renal Disease Facility Not Available)
- Patient's Home

The expanded list of destinations will apply to medically necessary emergency and non-emergency ground ambulance transports of beneficiaries.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

If durable medical equipment, prosthetics, orthotics or supplies (DMEPOS) are lost, destroyed, irreparably damaged or otherwise unusable or unavailable, contractors can waive the following requirements:

- Face-to-face encounter
- New physician's order
- New medical necessity documentation²⁰⁴

Suppliers must still include a narrative description on the claim explaining the reason the equipment must be replaced.

Suppliers must maintain documentation indicating DMEPOS was lost, destroyed, irreparably damaged or otherwise unusable or unavailable as a result of the COVID crisis.

Medicare will cover a broader array of respiratory devices and equipment such as non-invasive ventilators, multifunction ventilators, respiratory assist devices, and continuous positive airway pressure devices. Medicare will also cover respiratory-related devices and equipment for any medical reason determined by clinicians so that patients can get the care they need; previously, Medicare covered them under certain circumstances.

Prior authorization requirements are suspended for power mobility devices (PMDs) and pressure reducing support surfaces (PRSS). Also, the implementation of Prior Authorization (PA) of Lower Limb Prostheses scheduled to begin on May 4, 2020 is delayed. Durable medical equipment Medicare Administrative Contractors will continue to accept and review voluntary prior authorization requests for the affected HCPCS codes on the Required Prior Authorization List; however, claims associated with a non-affirmation decision or claims submitted without requesting prior authorization that would normally cause a payment denial will be processed for payment for the duration of the COVID-19 PHE. Claims bypassing prior authorization may be selected for post-payment review after the PHE has ended.²⁰⁵

• DMEPOS Signature Requirements

CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.²⁰⁶

DMEPOS Signature on Orders

DMEPOS items, except for Power Mobility Devices (PMDs), can be provided via verbal order. A signature is required prior to submitting claims for payment but the order can be signed electronically. PMDs require a signed, written order prior to delivery.²⁰⁷

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

• Staffing Requirements

A nurse practitioner, physician assistant, or certified nurse-midwife does not need to be available to furnish patient care services at least 50 percent of the time the rural health clinics (RHCs) and federally qualified health centers (FQHCs) operate.

CMS continues to require a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist be available to furnish patient care services at all times the clinic or center operates.

• Physician Supervision of Nurse Practitioners

The physician does not need to provide medical direction for activities, consultations, and supervision of nurse practitioners, only to the extent permitted by state law.

The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for activities, consultations and supervision of the remaining health care staff.

Temporary Expansion Locations

If services are furnished in more than one permanent location, RHCs and FQHCs are not required to be independently considered for Medicare approval.²⁰⁸

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)

To the extent National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs) (including Medicare Learning Network (MLN) Articles) requires a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements do not apply during the COVID crisis.

Some face-to-face encounter requirements for DMEPOS Power Mobility Devices (PMDs) are mandated by statute for program integrity purposes. While statutory requirements are not waived the use of telehealth in accordance with Medicare guidelines was previously permitted for power mobility devices.²⁰⁹

CMS will not enforce the required clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including Articles). These policies include, but are not limited to:

- NCD 240.2 Home Oxygen
- NCD 240.4 Continuous Positive Airway Pressure for Obstructive Sleep Apnea
- LCD L33800 Respiratory Assist Devices (ventilators for home use)
- NCD 240.5 Intrapulmonary Percussive Ventilator
- LCD L33797 Oxygen and Oxygen Equipment (for home use)
- NCD 190.11 Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management
- NCD 280.14 Infusion Pumps
- LCD L33794 External Infusion Pumps.²¹⁰

To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service, procedure or any portion thereof, the chief medical officer or equivalent of the facility can authorize another physician specialty or other practitioner type to meet those requirements.

To the extent NCDs and LCDs require a physician or physician specialty to supervise other practitioners, professionals or qualified personnel, the chief medical officer of the facility can authorize that such supervision requirements do not apply.²¹¹

Covered items and services must still be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be paid under Medicare Parts A or B. Physicians, practitioners and suppliers must continue to document the medical necessity for all services. The medical record must be sufficient to support payment for the services billed.²¹²

Clinical indications for therapeutic continuous glucose monitors in LCDs will not be enforced. For example, CMS will not enforce the current clinical indications restricting the type of diabetes that a beneficiary must have or relating to the demonstrated need for frequent blood glucose testing in order to permit COVID-19 infected patients with diabetes to receive a Medicare-covered therapeutic continuous glucose monitor. This discretion is intended to permit COVID-19 patients to more closely monitor their glucose levels given that they are at risk for unpredictable impacts of the infection on their glucose levels and health. The use of therapeutic continuous glucose monitors may allow patients to proactively treat their diabetes and prevent the need for hospital-based diabetic care. Practitioners will also have greater flexibility to allow more of their diabetic patients to better monitor their glucose and adjust insulin doses from home by using a therapeutic continuous glucose monitor.²¹³

Opioid Treatment Programs

Allows the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met.²¹⁴

In updated guidance, CMS notes that periodic assessments can be furnished during the PHE via two-way interactive audio-video communication technology; in addition, in cases where beneficiaries do not have access to two-way audio-video communications technology, the periodic assessments may be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met.²¹⁵

Note that the new Interim Final Rule provides the following is a list of resources posted on the Substance Abuse and Mental Health Services Administration (SAMHSA) website:

- Opioid Treatment Program (OTP) Guidance (Mar. 16, 2020), available at: https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.
- OTP Guidance for Patients Quarantined at Home with the Coronavirus available at: https://www.samhsa.gov/sites/default/files/otp-covid-implementation-guidance.pdf.
- FAQs: Provision of Methadone and Buprenorphine for the Treatment of Opioid Use Disorder in the COVID-19
 Emergency available at: https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.
- COVID-19 Public Health Emergency Response and 42 C.F.R. Part 2 Guidance available at: https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf.
- Considerations for the Care and Treatment of Mental and Substance Use Disorders in the COVID-19 Epidemic: March 20, 2020, available at: https://www.samhsa.gov/sites/default/files/considerations-care-treatment-mental-substance-use-disorders-covid19.pdf.

Remote Physiologic Monitoring (RPM)

Remote physiologic monitoring (RPM) services can be furnished to new patients, as well as to established patients.

Consent to receive RPM services can be obtained once annually, including at the time services are furnished.

The physician or other health care practitioner should (but is not required to) review consent information with a beneficiary, obtain the beneficiary's verbal consent, and document in the medical record that consent was obtained.

Home Infusion Services 216

Physicians that furnish physicians' services, including medically necessary injected or infused drugs, in the patient's home can also do so incident to their professional services, under contract with auxiliary personnel, to leverage additional staff and technology necessary to provide care outside their office setting under direct supervision

using interactive audio-video technology.

For example, physicians may enter into contractual arrangements with a home health agency, a qualified infusion therapy supplier, or entities that furnish ambulance services in order to utilize their nurses or other clinical staff as auxiliary personnel under leased employment. In such instances, Medicare payment for the physicians' direct and "incident-to" services would be made to the billing practitioner who would then make the appropriate payment to the contracted entity (for example, the HHA).

Payments would be made in accordance with the physician fee and would not be considered a home health service under the Medicare home health benefit or a service under the home infusion therapy services benefit. Rather, the entity with which the physician contracts would seek payment for any services they provided from the billing practitioner and would not submit claims to Medicare for such services.²¹⁷

C. MEDICARE PARTS C and D

COVID-19 Related Updates to Medicare Parts C and D Enrollment

A special enrollment period (SEP) was available nationwide to residents of all states, tribes, territories, and the District of Columbia from March 1, 2020 through June 30, 2020.²¹⁸ This SEP allowed eligible beneficiaries one opportunity to make a missed election regarding Medicare Advantage or Part D coverage if he or she had another valid election period at the time and did not make an election during that election period. This SEP has now expired and has not been renewed.

Medicare Advantage (MA)

Medicare Advantage (MA) plans must provide coverage for COVID-19 diagnostic testing, including the associated cost of the visit in order to receive testing. ²¹⁹ Coverage must be provided at no cost to the beneficiary. ²²⁰

42 C.F.R. §422.100(m) authorizes special requirements during a disaster or emergency related to Medicare.

MA plans must:

- Cover benefits at non-contracted facilities as long as those facilities have participation agreements with Medicare.
- Waive, in full, gate-keeper referral requirements.
- Provide same cost-sharing for in and out-of-network.
- Make changes immediately without 30-day notification, e.g., reductions in cost-sharing, waiver of priorauthorization.

CMS is temporarily relaxing enforcement of rules that prevent MA plans from changing benefits mid-year in connection with the COVID outbreak, and encourages MA plans to, among other things, expand benefits, add additional benefits, and institute "more generous cost-sharing" as long as such measures are "provided uniformly to all similarly situated enrollees." Among the things that MA plans may do are the following (they generally must do so on a uniform basis for all enrollees):²²¹

- Implement additional or expanded benefits that address issues or medical needs raised by the COVID-19 outbreak, such as covering meal delivery or medical transportation services.
- Waive or reduce enrollee cost-sharing for beneficiaries impacted by the outbreak, for example, waive or reduce enrollee cost-sharing for COVID-19 treatment, telehealth benefits or other services to address the outbreak.
- This flexibility is limited to when a waiver or reduction in cost-sharing can be tied to the COVID-19 outbreak.
- Waive or relax plan prior authorization requirements at any time in order to facilitate access to services.
 - Note that in August 2021 CMS issued a memo to MA plans "strongly encourage[ing]" them "to waive or relax plan prior authorization requirements and utilization management processes to facilitate the movement

of patients from general acute-care hospitals to post-acute care and other clinically-appropriate settings, including skilled nursing facilities, long-term care hospitals, inpatient rehabilitation facilities, and home health agencies."²²²

- Employ flexibility concerning involuntary disenrollment for non-payment of premiums.
 - This is applicable to Part D plans, too
 - If a plan does not choose to eliminate its disenrollment policy, CMS encourages plans to increase the mandatory grace period (at least two months) to a longer period of time
- Employ flexibility concerning disensollment of members temporarily absent from the plan's service area.
 - Plans can extend the period of time members may remain enrolled while temporarily absent from the plan service area through the end of the year, or the end of the public health emergency, whichever is earlier.
 - CMS notes: Individuals who remain absent from the service area will be disenrolled January 1, 2021, if the public health emergency is still in effect at that time, or six months after the individual left the service area, whichever is later.
- CMS is temporarily relaxing enforcement of rules requiring Special Needs Plans (SNPs) to disenroll individuals who lose special needs status.
- Expand access to telehealth.

Telephone Confirmation: Beneficiaries should contact their MA plan to confirm specific waivers—recommend getting full name of customer service individual and note date/time of the call.

On-line Confirmation: Beneficiaries should copy or electronically save waiver information on-line that they rely on, in case it should change.

Part D Plans (Including MA-PDs)/Prescription Refills

Medicare Part D plans and Medicare Advantage-Prescription Drug plans are required to provide up to a 90-day supply of a prescription medication if requested by a beneficiary. ²²³ CMS has further clarified: ²²⁴

- Plans "must suspend all quantity and days' supply limits under 90 days for all covered Part D drugs (as defined in 42 C.F.R. §423.100) other than such limits resulting from safety edits"
- With respect to a 90-day supply of drugs, plans "must permit enrollees to obtain the total days supply prescribed for a covered Part D drug (as defined in 42 C.F.R. §423.100) up to a 90-day supply" in one fill (or one refill) if:
 - Requested by the enrollee;
 - Prior Authorization or Step Therapy requirements have been satisfied; and
 - No safety edits otherwise limit the quantity or days supply."
- Plans may otherwise continue to utilize their formularies, tiered cost-sharing benefit structures, and approved prior authorization (PA) and step therapy (ST) requirements.

Plans can waive or relax prior authorization requirements "at any time that they otherwise would apply to Part D drugs used to treat or prevent COVID-19, if or when such drugs are identified."²²⁵ Plans can also choose to waive or relax PA requirements at any time for other formulary drugs in order to facilitate access with less burden on beneficiaries, plans, and providers.

Pharmacists can authorize emergency refills when prescribers are not available to provide refill renewal prescriptions, when consistent with State emergency declarations. ²²⁶

Plans must ensure enrollees have access to covered drugs at out-of-network pharmacies when enrollees cannot reasonably be expected to use in-network pharmacies.²²⁷ Enrollees remain responsible for any cost-sharing under their plan and additional charges (i.e., the out-of-network pharmacy's usual and customary charge), if any, that exceed the plan allowance.

Plans may relax restrictions on mail and home delivery.²²⁸

Plans must relax "refill-too-soon" edits.²²⁹ Plans continue to have operational discretion as to how these edits are relaxed as long as access to Part D drugs is provided at the point-of-sale.

CMS permits plans to relax restrictions on use of preferred retail or mail-order pharmacy, but does not require.

D. MISCELLANEOUS

COVID-19-Related Updates to Medicare Parts A and B Enrollment

Between March 17, 2020 and June 17, 2020, CMS granted equitable relief in the form of additional time to use an Initial Enrollment Period (IEP), General Enrollment Period (GEP), or a Special Enrollment Period (SEP) (such as the SEP for when a beneficiary's enrollment in employer coverage based on current employment ends) in order to file an application for Part B, premium-Part A, or to refuse automatic Part B. This period has expired and has not been renewed.²³⁰

Effective Tuesday, May 26, 2020, a new online process for handling Medicare Part B SEP enrollment is available online. The online process provides beneficiaries the option to complete the Medicare enrollment forms under an SEP for SSA to process. The online Medicare Part B SEP enrollment link www.ssa.gov/Medicare-PartB-SEP is available on both SSA and CMS websites effective Tuesday, May 26, 2020. Once the beneficiary completes the online enrollment forms, the forms will automatically transmitted to the SSA Field Office of jurisdiction.

Individuals who are receiving Social Security benefits before their 65th birthday are considered to be in their IEP and are automatically enrolled in Part A and Part B. Those who do not want to be automatically enrolled in Part B must refuse the coverage within 60 days of receiving their IEP package. Instructions on how to refuse the coverage are included in the IEP package. Individuals may also contact the Social Security Administration at 1-800-772-1213 (TTY users should call 1-800-325-0778) for more information on how to refuse the coverage.

Individuals interested in enrolling in Medicare Part B coverage who are eligible to apply under an SEP, should complete forms CMS-40B and CMS-L564 (PDF); both forms are available in English and Spanish versions. The CMS-40B application is completed entirely by the individual enrolling in Part B.

For the CMS-L564 enrollment form:

- Section A:
 - Must be completed by individuals enrolling in Part B
- Section B:
 - Can be completed by the employer; OR
 - If it isn't feasible for your employer to complete the form, leave Section B (the rest of the form) blank and provide at least one of the items listed below. Acceptable proof of employment, Group Health Coverage Plan (GHP), or Large Group Health Plan (LGHP) include but are not limited to:
 - income tax returns that show health insurance premiums paid;
 - W-2s reflecting pre-tax medical contributions;
 - pay stubs that reflect health insurance premium deductions;
 - health insurance cards with a policy effective date;
 - explanations of benefits paid by the GHP or LGHP; and
 - statements or receipt that reflect payment of health insurance premiums.

In addition to using the online process mentioned above, individuals can fax their completed enrollment forms to SSA toll-free at 1-833-914-2016, or mail the request to their local SSA field office. Although SSA offices are closed for walk-in service, requests received by mail are still being processed and SSA offices may be able to

schedule an in-person appointment in certain situations. Appointments may not be immediately available, depending on local health and safety conditions and staffing.

Generally, SSA will schedule an in-person appointment in dire need situations. Dire need exists, for health and Medicare purposes, when someone:

- Is without food or shelter, including utilities or is without medical care or coverage and needs to apply for or reinstate benefits.
- Currently receives benefits and has an urgent need for payment to meet expenses for food, shelter, or medical treatment, and you cannot receive the payment electronically.²³¹

Individuals can find the address and phone number for their local field office using the Social Security Office Locator, https://secure.ssa.gov/ICON/main.jsp.

CMS has created a page for additional questions and answers.²³²

Notice Delivery in Institutions

CMS has relaxed certain requirements surrounding delivery of notices to individuals receiving institutional care who are in isolation, including:²³³

- Hard copies of notices may be dropped off with a beneficiary by any hospital worker able to enter a room safely.
- If the hospital worker is unable to enter a room safely, a contact phone number should be provided for a beneficiary to ask questions about the notice.
- If a hard copy of the notice cannot be delivered, notices to beneficiaries may also delivered via email, if a beneficiary has access to email in the isolation room.

Notices should be annotated with the circumstances of the delivery, including the person delivering the notice, and/or when and to where the email was sent.

Beneficiary representative notice delivery may be made via telephone or secure email to beneficiary representatives who are offsite. The notices should be annotated with the circumstances of the delivery, including the person delivering the notice:

- Via telephone, and the time of the call, or
- When and to where the email was sent.

Medicare Appeals

CMS has issued guidance applicable to appeals in traditional Medicare, Medicare Advantage and Part D.²³⁴ Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the traditional Medicare program, MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), can do the following:

- Allow extensions to file an appeal
- Waive timeliness requirements for requests for additional information to adjudicate the appeal. MA plans may extend the time frame to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.
- Process an appeal even with incomplete Appointment of Representation forms but "communicating" to the other party (beneficiary to provider or provider to beneficiary).
- Process requests for appeal that do not meet the required elements using information that is available.

Use all flexibilities available in the appeals process as if good cause requirements are satisfied.

In general, if Medicare appeal deadlines have expired, but a party shows a good cause reason for missing the deadline, the decision-maker (Medicare contractor, MA plan, etc.) has discretion to extend the time frame for filing an appeal; the COVID-19 crisis by itself can now be used to satisfy good cause requirements.

Although the CMS guidance does not address appeals filed by beneficiaries and those assisting them (other than providers), the Center for Medicare Advocacy urges such individuals who are filing appeals in good faith to explicitly note on their appeal documentation that they are requesting good cause allowances for any late filings due to the national COVID-19 emergency.

Information Regarding Providers

Licensure Jurisdiction: Requirements that out-of-state providers be licensed in the state where they are providing services is waive if they are licensed in another state. This applies to Medicare and Medicaid.²³⁵

Enrollment:

- A toll-free hot-line is established for non-certified Part B suppliers, physicians and non-physician practitioners to enroll and receive temporary Medicare billing privileges.
- The following screening requirements are waived:
 - Application fee (42 C.F.R. §424.514)
 - Criminal background checks associated with FCBC (42 C.F.R. §424.518)
 - Site visits (42 C.F.R. §424.517)
- All revalidation actions are postponed.
- Licensed providers are allowed to practice outside their state of enrollment.
- Pending or new applications from providers are expedited.

Non-Discrimination re: Provision of Health Services

The Department of Health and Human Services (HHS) Office of Civil Rights (OCR) issued a bulletin aimed at ensuring that covered entities do not unlawfully discriminate against people with disabilities when making decisions about their treatment during the COVID-19 health care emergency.²³⁶

The bulletin notes, in part: "persons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative 'worth' based on the presence or absence of disabilities or age." Decisions by covered entities concerning whether an individual is a candidate for treatment should be based on an individualized assessment of the patient based on the best available objective medical evidence.

Non-Essential Care

On March 18, 2020, CMS issued a press release²³⁷ and guidance (subsequently updated)²³⁸ that presented recommendations to providers that all elective surgeries, non-essential medical, surgical, and dental procedures be delayed during the COVID-19 outbreak. The guidance suggested that a "tiered framework is recommended to prioritize services and care to those who require emergent or urgent attention to save a life, manage severe disease, or avoid further harms from an underlying condition."

On April 19, 2020, CMS released an electronic notice titled "Recommendations to Re-Open Health Care Systems in Areas with Low Incidence of COVID-19" and released recommended guidelines. ²³⁹ The announcement stated: "As states and localities begin to stabilize, the Centers for Medicare & Medicaid Services (CMS) is issuing guidance on providing essential non-COVID-19 care to patients without symptoms of COVID-19 in regions with low and stable incidence of COVID-19. This is part of Phase 1 in the Trump Administration's Guidelines for Opening Up

America Again." CMS notes that "[t]he recommendations update earlier guidance provided by CMS on limiting non-essential surgeries and medical procedures. The new CMS guidelines recommend a gradual transition and encourage health care providers to coordinate with local and state public health officials, and to review the availability of personal protective equipment (PPE) and other supplies, workforce availability, facility readiness, and testing capacity when making the decision to re-start or increase in-person care."

State Medicaid Issues for Dual Eligibles

In order to respond to the COVID-19 national emergency, CMS has approved Medicaid Disaster Relief State Plan Amendments (SPAs), Section 1115 Waivers; Section 1135 Waivers; and 1915 (c) Waiver Appendix K strategies in order to allow states the ability to expand access to care.

The Secretary of Health and Human Services (HHS) can use Section 1135 of the Social Security Act (SSA) to temporarily modify or waive certain Medicaid requirements in order to ensure access to health care during this national health crisis. Section 1135 of the Social Security Act can be triggered once the president declares a disaster or emergency under the Stafford or National Emergencies Act and the HHS Secretary declares a public health emergency. Section 1135 can also be used in combination with Section 1115, which allows the Secretary to approve state demonstrations. CMS has also approved 1915 (c) Waiver Appendix K strategies that states can take under the existing Section 1915(c) home and community-based services (HCBS) waiver authority in order to respond to the emergency.²⁴⁰

According to CMS, to date, CMS has approved more than 115 requests submitted by states in response to the COVID-19 pandemic.²⁴¹ CMS also recently released additional guidance to states on the COVID-19 relief bill, Families First Coronavirus Response Act.²⁴² The guidance is in the form of a set of Frequently Asked Questions (FAQs) that addresses enhanced federal Medicaid funding and other topics related to the national health emergency. The guidance includes information relevant for those dually eligible for Medicare and Medicaid.

The CMS guidance explains that during the emergency, someone who is in an adult eligibility Medicaid group and ages into Medicare must maintain the same amount, duration and scope of medical assistance. This means that if a beneficiary only qualifies for Qualified Medicare Beneficiary (QMB) or another Medicare Savings Program (MSP), then the state must enroll the person into the MSP, continue the prior Medicaid benefits, and also add the MSP benefits and protections (for a QMB, that would mean Medicare premium payments, cost-sharing, and billing protections). Medicare would pay primary with Medicaid paying secondary.²⁴³

The guidance also includes information that outlines requirements that states maintain an individual in the Medicare Savings Program (MSP) that provides coverage equivalent to the coverage they had prior to the emergency. This means that during the pendency of the emergency, the state cannot terminate MSP coverage nor can they transition an individual to lesser coverage. The example provided in the FAQ is that the state cannot move a beneficiary from the Qualified Medicare Beneficiary (QMB) group to the Specified Low Income Beneficiary (SLMB) group because the SLMB group provides less assistance than the QMB group. This requirement is regardless of a change in circumstance for the beneficiary.²⁴⁴

Oral Health

Traditional Medicare currently does not cover routine dental care.²⁴⁵ Some Medicare Advantage Plans include dental coverage, though the benefit is usually limited.²⁴⁶ A few notes on oral health during the pandemic:

- In March 2020, at the outset of the pandemic, the CDC recommended that dental practices prioritize treatment
 of urgent or emergency dental treatment, and delay elective treatments. Current openings and restrictions are
 based on local orders, generally based on number of cases in the area.²⁴⁷
- Some Medicare Advantage Plans have expanded teledentistry during the pandemic. The aim being to assist
 members experiencing an urgent dental condition and prevent them from seeking care in the Emergency
 Department during the COVID-19 pandemic, in order to limit potential exposure to coronavirus/COVID-19 and
 limit the use of scarce resources.
- CMS waived the requirement in 42 C.F.R. §483.30 for physicians and non-physician practitioners to perform

in-person visits for nursing facility residents, by allowing those visits to be conducted via telehealth when appropriate, and also allows physicians to delegate tasks to a PA, NP, and CNS, if not prohibited under State law or the facility's policy. It is the Center for Medicare Advocacy's view that this CMS waiver does not apply to the requirement at 42 C.F.R. §483.55 that skilled nursing facilities must assist residents in obtaining routine and 24-hour emergency dental care. Therefore, if a resident is having a dental emergency, the nursing facility is still required to assist them in making arrangements to have that addressed.

 CDC's COVID-19 guidelines place dental emergencies in the same category as strokes, heart attacks, acute abdominal pain, certain cancer treatment—and recommend treatment without delay because deferral of treatment is highly likely to result in patient harm.²⁴⁸

Disparities in COVID-19 Infections

Early COVID-19 research and data demonstrate the correlation between low incomes, communities of color, and risks of illness and severity of illness, for and following infection with COVID-19.

CMS, CDC, Kaiser Family Foundation data, as well as media reports of studies throughout the pandemic, have consistently shown that racial disparities in COVID infections were present throughout the country and across all age groups.

Disparities have continued as vaccines have become available. According to CDC data, over the course of the vaccination rollout Black and Hispanic people have been less likely than their White counterparts to have received a vaccine, but these disparities have narrowed over time, particularly for Hispanic people.

As of November 2, 2021, CDC reported that race/ethnicity was known for 62 percent of people who had received at least one dose of the vaccine. Among this group, 60 percent were White, 11 percent were Black, 17 percent were Hispanic, 6 percent were Asian, 1 percent were American Indian or Alaska Native, and <1 percent were Native Hawaiian or Other Pacific Islander, while 5 percent reported multiple or other race. To date, CDC is not publicly reporting state-level data on the racial/ethnic composition of people vaccinated.

The Center for Medicare Advocacy highlights these issues and related resources to help call attention to the ongoing, harmful health disparities exposed by the pandemic. The data regarding the disparate impact from the COVID crisis is striking and calls out for change.

Resources

Kaiser Family Foundation: Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus, https://www.kff.org/d7d708a/

Kaiser Family Foundation: Communities of Color at Higher Risk for Health and Economic Challenges due to COVID-19, https://www.kff.org/c99b5eb/

Kaiser Family Foundation: Double Jeopardy: Low Wage Workers at Risk for Health and Financial Implications of COVID-19, https://www.kff.org/74b5f96/

Kaiser Family Foundation: In Medicare, Black and Hispanic Individuals Account for Disproportionate Share of COVID-19 Cases and Hospitalizations, https://www.kff.org/coronavirus-covid-19/slide/in-medicare-black-and-hispanic-individuals-account-for-disproportionate-share-of-covid-19-cases-and-hospitalizations/

Kaiser Family Foundation: Growing COVID-19 Hotspots in the U.S. South and West will Likely Widen Disparities for People of Color, https://www.kff.org/?p=474996

Kaiser Family Foundation: Racial Disparities in COVID-19: Key Findings from Available Data and Analysis, https://www.kff.org/027a271/

Brookings Institution: Why are Blacks dying at higher rates from COVID-19?, https://www.brookings.edu/blog/fixgov/2020/04/09/why-are-blacks-dying-at-higher-rates-from-covid-19/

Brookings Institution: How to Reduce the Racial Gap in COVID-19 Deaths,

https://www.brookings.edu/blog/fixgov/2020/04/10/how-to-reduce-the-racial-gap-in-covid-19-deaths/

Urban Institute: COVID-19 Racial Health Disparities Highlight Why We Need to Address Structural Racism, https://www.urban.org/urban-wire/covid-19-racial-health-disparities-highlight-why-we-need-address-structural-racism

Center on Budget and Policy Priorities: More Relief Needed to Alleviate Hardship: Households Struggle to Afford Food, Pay Rent, Emerging Data Show, https://www.cbpp.org/research/poverty-and-inequality/more-relief-needed-to-alleviate-hardship

New York Times Report: https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latinos-african-americans-cdc-data.htmlKaiser Family Foundation: Latest Data on COVID-19 Vaccinations by Race/Ethnicity, https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-by-race-ethnicity/

Washington Post: Covid and cancer: A dangerous combination, especially for people of color, https://www.washingtonpost.com/health/2021/10/11/covid-cancer-delayed-diagnosis/

JAMA Network: Racial/Ethnic Differences in COVID-19 Vaccine Hesitancy Among Health Care Workers in 2 Large Academic Hospitals, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783615

The New York Times: Why the Tuskegee Study Slowed Vaccinations of Black Americans, https://www.nytimes.com/2021/10/13/us/black-americans-vaccine-tuskegee.html

The Center for Medicare Advocacy, established in 1986, is a national nonprofit, nonpartisan law organization that provides education, advocacy and legal assistance to help older people and people with disabilities obtain access to Medicare and quality health care. The Center is headquartered in Connecticut and Washington, DC with additional attorneys throughout the country.

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Endnotes:

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<sup>1</sup>https://www.congress.gov/bill/116th-congress/house-bill/6074.
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¹⁴See, e.g., CMS memo, "COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing" (updated Apr. 9, 2020), available at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.

¹⁵See CMS Press Release, "Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge" (Mar. 30, 2020), available at https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient.

¹⁶See CMS memo, "Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge" (Mar. 30, 2020), available at https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient; see also CMS memo, "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers," available at https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf—note that CMS states that "only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19."

¹⁷See CMS memo, "Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge" (Mar. 30, 2020), available at https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient; see also CMS memo, "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers," available at https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf—note that CMS states that "only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19."

¹⁸See CMS document: https://www.cms.gov/files/document/summary-covid-19-emergencydeclaration-waivers.pdf, info on page 3; see also CMS memo, "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers," available at https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

¹⁹IFR, p. 19278; *see also* CMS memo, "COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing" (updated Apr. 9, 2020), *available at* https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf. ²⁰IFR, p. 19280.

²¹COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, available at

https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

²²COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, *available at* https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

²³COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, available at

https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

²⁴COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, available at

https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf; IFR, p. 19262.

²⁵Sec. 3711 of Coronavirus Aid, Relief, and Economic Security (CARES) Act, H.R. 748 (COVID Bill #3).

²⁶COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, *available at* https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

²⁷COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, available at

https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

²⁸CMS, "COVID-19 Guidance and Updates for Nursing Homes during COVID-19" (Aug. 25, 2020), *available at* https://www.cms.gov/files/document/covid-guidance-and-updates-nursing-homes-during-covid-19.pdf.

²⁹See, e.g., CMS, "COVID-19 Emergency Declaration Health Care Providers Fact Sheet" (Mar. 13, 2020), available at https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf; note that the "waiver applies to all SNF-level beneficiaries under Medicare Part A, regardless of whether the care the beneficiary requires

²https://www.congress.gov/116/bills/hr6201/BILLS-116hr6201eh.pdf.

³https://www.congress.gov/bill/116th-congress/house-bill/748/text.

⁴https://www.congress.gov/bill/116th-congress/house-bill/266/text.

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provision of home health services at 85 Fed. Reg. 70,298 (Nov. 4, 2020).

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https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf. ¹⁶¹COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, *available at*

https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

¹⁶²Note that language in a CMS press release is fairly broad (*see* https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19), whereas the Interim Final Rule states that NPs, CNSs, PAs, and CNMs may order, furnish directly, and supervise the performance of diagnostic tests, subject to applicable state law, during the PHE. IFR 2, 85 Fed. Reg. 27,555.

¹⁶³IFR 2, 85 Fed. Reg. 27,558.

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¹⁶⁹Section 3713 of Coronavirus Aid, Relief, and Economic Security (CARES) Act, H.R. 748 (COVID Bill #3). Also *see*, *e.g.*, Medicare.gov website at: https://www.medicare.gov/coverage/coronavirus-disease-2019-covid-19-vaccine.

¹⁷⁰See CMS Press Release (June 9, 2021), available at https://www.cms.gov/newsroom/press-releases/biden-administration-continues-efforts-increase-vaccinations-bolstering-payments-home-covid-19.

¹⁷¹See CMS Press Release (Aug. 24, 2021), available at https://www.cms.gov/newsroom/press-releases/cms-expands-medicare-payments-home-covid-19-vaccinations.

¹⁷²See CMS website at: https://www.cms.gov/medicare/covid-19/medicare-billing-covid-19-vaccine-shot-administration.

¹⁷³See CMS News Alert (Oct. 22, 2021) available at https://www.cms.gov/newsroom/news-alert/cms-reminds-eligible-consumers-they-have-coverage-covid-19-booster-shots-no-cost; also see CMS Press Release (Sept. 24, 2021):

https://www.cms.gov/newsroom/press-releases/cms-will-pay-covid-19-booster-shots-eligible-consumers-can-receive-no-cost.

174 See CDC website at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-

shot.html?utm_campaign=20211029_cvd_prv_gal&utm_content=english&utm_medium=email&utm_source=govdelivery.

176See CMS Press Release (May 6, 2021), available at https://www.cms.gov/newsroom/press-releases/cms-increases-medicare-payment-covid-19-monoclonal-antibody-infusions.

¹⁷⁷See Medicare.gov website at: https://www.medicare.gov/coverage/coronavirus-disease-2019-covid-19-monoclonal-antibody-treatments.

¹⁷⁸https://www.cms.gov/newsroom/fact-sheets/fourth-covid-19-interim-final-rule-comment-period-ifc-4, page 7.

¹⁷⁹See, generally, CMS "Medicare Telemedicine Health Care Provider Fact Sheet" (Mar. 17, 2020), available at https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet; see also CMS memo,

¹⁴⁹IFR, pp. 19246–19247.

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¹⁵⁶https://www.cms.gov/files/document/hqrp-2020-quarter-23-newsletterjuly-2020.pdf, info on page 9.

¹⁵⁷https://www.cms.gov/files/document/hqrp-2020-quarter-23-newsletterjuly-2020.pdf, info on page 9.

¹⁶⁴IFR, p. 19258.

¹⁶⁵Section 6002, Families First Coronavirus Response Act, H.R. 6201 (COVID Bill #2).

- "COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing" (updated Apr. 9, 2020), available at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.
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- ¹⁹³IFR, p. 19265.
- ¹⁹⁴See, generally, IFR 2, Section II.F., starting at 85 Fed. Reg. 27,562.
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- ²⁰⁰See, e.g., CMS memo, "COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing" (updated Apr. 9, 2020), p. 24, available at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf. ²⁰¹IFR 2, 85 Fed. Reg. 27,556.
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- ²¹⁰IFR, p. 19266.
- ²¹¹IFR, p. 19267.

- ²¹²IFR 2, p. 27595.
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- ²¹⁵IRF 2, 85 Fed. Reg. 27,558.
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- ²³⁹ OPENING UP AMERICA AGAIN Centers for Medicare & Medicaid Services (CMS) Recommendations Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I" (Apr. 19, 2020), *available at* https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf.
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- A special Medicaid state plan amendment (SPA) template that lets states change their Medicaid state plans: https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/state-plan-flexibilities/index.html.
- A template states can use to make additional requests using section 1135 authority: https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/section-1135-waiver-flegibilities/index.html.

- CMS also has a webpage with approved waivers: https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/federal-disaster-resources/index.html.
- A template for emergency 1115 waivers that provides an expedited way for states to make their requests: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-application-process/index.html.
- CMS also has 1915(c) guidance: https://www.medicaid.gov/medicaid/home-community-based-services/downloads/1915c-appendix-k-instructions.pdf.
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- ²⁴²CMS FAQ (Apr. 13, 2020), *available at* https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf.
- ²⁴³CMS FAQ (Apr. 13, 2020) Number 27, *available at* https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-fags.pdf.
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- ²⁴⁸Center for Disease Control and Prevention, *available at* https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html.